

THE GEORGE WASHINGTON LAW REVIEW



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The George Washington Law Review, ISSN 0016-8076, is published in February, April, June, August, October, and December by students of The George Washington University Law School, 720 20th St., N.W., Washington, D.C. 20052. Email: gwlr@law.gwu.edu. Website: <http://www.gwlr.org>. Phone: (202) 994-4610. Fax: (202) 994-4609. Publication Office: Joe Christensen, Inc., P.O. Box 81269, Lincoln, Nebraska 68501. Please send address changes to the Editorial Office.

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Bibb Balancing: Regulatory Mismatches Under the Dormant Commerce Clause

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ABSTRACT

Courts and commentators have long understood dormant Commerce Clause doctrine to contain two types of cases: discrimination and undue burdens. This Article argues for a further distinction that divides cases into single-state burdens, which arise from the application of a single state's law alone, and mismatch burdens, which arise from legal diversity. Although the Supreme Court purports to apply Pike balancing in all undue-burden cases, we show that the Court's approach in mismatch cases differs substantially. Specifically, unlike in single-state cases, balancing in mismatch cases involves an implicit and potentially problematic comparison by the Court between the challenged state's regulation and those of other states. We label this analysis "Bibb balancing," after the famous mudflaps case, and we show that mismatch cases present the Court with a more challenging set of issues than do other types of dormant Commerce Clause cases. Despite the criticisms that attach to Bibb balancing, failing to restrain regulatory mismatches would threaten the smooth functioning of the national marketplace and undercut important federalism values. Thus, in addition to clarifying the doctrine and acknowledging the drawbacks of Bibb balancing, this Article provides advice for achieving more consistent and defensible results in mismatch cases.

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INTRODUCTION

Every law student learns that the dormant Commerce Clause has two major doctrinal strands—discrimination and undue burden. The doctrinal test for the latter involves balancing the burden a state imposes on interstate commerce against the state’s legitimate interest in the challenged regulation. This balancing test has become synony-

mous with *Pike v. Bruce Church, Inc.*,¹ although it is actually much older.² For decades, commentators and jurists have condemned *Pike* balancing. Justice Scalia likened it to “judging whether a particular line is longer than a particular rock is heavy.”³ He also declared balancing a “quagmire”⁴ that was “ill suited to the judicial function.”⁵ Justice Rehnquist complained that balancing “gives no guidance whatsoever to . . . [s]tates as to whether their laws are valid or how to defend them.”⁶

Those criticisms find expression in today’s Supreme Court. For example, Justice Thomas concluded that, because *Pike* balancing turns “solely on policy considerations,” it involves legislative, not judicial, decision-making.⁷ Lower courts have likewise remarked that such balancing is subjective and challenging to apply.⁸ Heaping scorn upon *Pike* balancing, commentators have called it “fundamentally wrong,”⁹

¹ 397 U.S. 137 (1970).

² See Brannon P. Denning, *Reconstructing the Dormant Commerce Clause Doctrine*, 50 WM. & MARY L. REV. 417, 445–46 (2008) [hereinafter Denning, *Reconstructing*] (describing *Southern Pacific Co. v. Ariz. ex rel. Sullivan*, 325 U.S. 761 (1945), as “the paradigmatic balancing opinion”). *Id.* at 445 n.150 (tracing balancing back to *Baldwin v. G. A. F. Seelig, Inc.*, 294 U.S. 511 (1935)).

³ *Bendix Autolite Corp. v. Midwesco Enters., Inc.*, 486 U.S. 888, 897 (1988) (Scalia, J., concurring).

⁴ *W. Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 210 (1994) (Scalia, J., concurring) (“[O]nce one gets beyond facial discrimination our negative-Commerce-Clause jurisprudence becomes (and long has been) a quagmire.”).

⁵ *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 95 (1987) (Scalia, J., concurring in part).

⁶ *Kassel v. Consol. Freightways Corp.*, 450 U.S. 662, 706 (1981) (Rehnquist, J., dissenting). *Id.* at 706 (calling the doctrine “hopelessly confused”).

⁷ *United Haulers Ass’n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 349 (2007) (Thomas, J., concurring in the judgment); see also *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 619 (1997) (Thomas, J., dissenting) (suggesting that such balancing “surely invites us, if not compels us, to function more as legislators than as judges”); *id.* at 610 (concluding that the doctrine “makes little sense, and has proved virtually unworkable in application”). In *Department of Revenue of Kentucky v. Davis*, 553 U.S. 328, 354 (2008), a majority of the Court questioned whether courts are capable of such balancing.

⁸ *Colon Health Ctrs. of Am., LLC v. Hazel*, 813 F.3d 145, 155 (4th Cir. 2016) (“highly subjective”); *Am. Beverage Ass’n v. Snyder*, 735 F.3d 362, 379 (6th Cir. 2013) (Sutton, J., concurring) (“ineffable test”); *Nat’l Ass’n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1149 (9th Cir. 2012) (balancing has “not turned out to be easy to apply”); *Wiesmueller v. Kosobucki*, 571 F.3d 699, 704 (7th Cir. 2009) (“The judiciary lacks the time and the knowledge to be able to strike a fine balance between the burden that a particular state regulation lays on interstate commerce and the benefit of that regulation to the state’s legitimate interests.”); *Pharm. Rsch. & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 84 (1st Cir. 2001) (finding the “balancing test more challenging to apply”).

⁹ Julian N. Eule, *Laying the Dormant Commerce Clause to Rest*, 91 YALE L.J. 425, 436 (1982). (“[T]he likelihood of judicial invalidation increases with the degree of burden imposed

a “historical vestige[],”¹⁰ plagued by “severe conceptual problems,”¹¹ incoherent and inconsistent,¹² “seriously flawed,”¹³ “illegitimate,”¹⁴ “reviled,”¹⁵ and “a disaster.”¹⁶

Whereas a solid majority of the current Supreme Court supports the *discrimination* strand of the dormant Commerce Clause,¹⁷ it is not clear where the Court stands on undue burdens.¹⁸ Although the Su-

by state law There is something fundamentally wrong with a judicial framework that prompts judicial intervention by the same trigger that induces political response.”).

¹⁰ *Id.* at 435.

¹¹ Earl M. Maltz, *How Much Regulation Is Too Much—An Examination of Commerce Clause Jurisprudence*, 50 GEO. WASH. L. REV. 47, 59 (1981).

¹² Denning, *Reconstructing*, *supra* note 2, at 417.

¹³ Jack L. Goldsmith & Alan O. Sykes, *The Internet and the Dormant Commerce Clause*, 110 YALE L.J. 785, 813 (2001).

¹⁴ Martin H. Redish & Shane V. Nugent, *The Dormant Commerce Clause and the Constitutional Balance of Federalism*, 1987 DUKE L.J. 569, 599 (1987).

¹⁵ Brannon P. Denning, *Justice Thomas, The Import-Export Clause, and Camps Newfound/Owatonna v. Harrison*, 70 U. COLO. L. REV. 155, 156–57 (1999) [hereinafter Denning, *Justice Thomas*] (“Almost universally reviled by academics and Justices on the Supreme Court as without solid foundation in text or intent, and altogether lacking a coherent application, it nevertheless endures and continues to be employed by the Court, when its members are not busy criticizing it.” (citations omitted)).

¹⁶ Richard B. Collins, *Economic Union as a Constitutional Value*, 63 N.Y.U. L. REV. 43, 45 n.14 (1988) (quoting DAVID P. CURRIE, *THE CONSTITUTION IN THE SUPREME COURT: THE FIRST HUNDRED YEARS 1789-1888*, at 342 (1985)); *id.* at 44 n.14 (skeptically noting arguments against the dormant Commerce Clause made by David Currie). For other leading critical accounts, see generally, Mark Tushnet, *Rethinking the Dormant Commerce Clause*, 1979 WIS. L. REV. 125 (1979); Saul Levmore, *Interstate Exploitation and Judicial Intervention*, 69 VA. L. REV. 563 (1983); Donald H. Regan, *The Supreme Court and State Protectionism: Making Sense of the Dormant Commerce Clause*, 84 MICH. L. REV. 1091 (1986); Michael E. Smith, *State Discriminations Against Interstate Commerce*, 74 CAL. L. REV. 1203 (1986); Paul E. McGreal, *The Flawed Economics of the Dormant Commerce Clause*, 39 WM. & MARY L. REV. 1191 (1998); Barry Cushman, *Formalism and Realism in Commerce Clause Jurisprudence*, 67 U. CHI. L. REV. 1089 (2000).

¹⁷ *See infra* note 51.

¹⁸ The paucity of undue-burden decisions makes it difficult to discern the views of the sitting Justices, which are discussed here in order of seniority, after describing the views of the Chief Justice. Chief Justice Roberts did not join the part of *United Haulers* that applied *Pike*. *See United Haulers Ass’n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 334 (2007). At the same time, however, the part of the decision he authored and signed involved balancing under the dormant Commerce Clause. *See id.* at 342 (weighing the state’s nonprotectionist interest in the challenged ordinance that required waste to be disposed only at a public facility). Justice Thomas’s opposition to all aspects of the dormant Commerce Clause is well-known and unlikely to change. *See, e.g.,* *Comptroller of the Treasury of Md. v. Wynne*, 575 U.S. 542, 578 (2015) (Thomas, J., dissenting). Justice Alito would adhere to dormant Commerce Clause precedent. *See Dep’t of Revenue of Ky. v. Davis*, 553 U.S. 328, 376 (2008) (Alito, J., dissenting) (“[T]he Court’s established dormant Commerce Clause precedents should be followed . . .”). Justice Alito joined Justice Kennedy’s dissent in *Davis* that argued that “[t]he undue burden rule . . . remains an essential safeguard against restrictive laws that might otherwise be in force for decades until Congress can act.” *Id.* at 365, 376 (Kennedy, J., dissenting). In 2018, the major-

preme Court referenced *Pike* favorably in 2018,¹⁹ it has not invalidated a state statute under *Pike* for “a generation,”²⁰ and Justice Thomas has even called for the termination of undue-burden analysis.²¹

At a time when important undue-burden cases are pending,²² we clarify the dormant Commerce Clause and *Pike* balancing. We also provide principled methods to cabin judicial discretion in undue-burden cases as an alternative to abandoning this vital constitutional doctrine. This Article thus constitutes a rare defense of a doctrinal area that has been excoriated as both illegitimate and unclear, including by members of the Court itself.

Courts and commentators divide dormant Commerce Clause doctrine into facial discrimination cases and undue-burden cases. Laws

ity in *South Dakota v. Wayfair* cited *Pike* as the applicable standard in dormant Commerce Clause cases. See *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2091 (2018). Although Justices Sotomayor and Kagan joined Chief Justice Roberts’ dissent in *Wayfair*, that dissent was grounded on the view that the Court should have hewed to precedent in *Wayfair* and not overturned a prior case. The dissenters therefore did not address *Pike* or the standard in undue-burdens cases at all. See *id.* at 2101–05 (Roberts, C.J., dissenting); see also Edward A. Zelinsky, *Comparing Wayfair and Wynne: Lessons for the Future of the Dormant Commerce Clause*, 22 CHAP. L. REV. 55, 58 (2019) (arguing that despite dissenting in *Wayfair*, none of Roberts, Breyer, Sotomayor, or Kagan “dispute[d] the fundamental legitimacy of the dormant Commerce Clause”). That all three of Roberts, Sotomayor, and Kagan joined the 2019 majority decision in *Tennessee Wine* to preclude a facially discriminatory state regulation for violating the dormant Commerce Clause confirms Professor Zelinsky’s claim that those Justices continue to respect the fundamental legitimacy of the dormant Commerce Clause, but it does not indicate those Justices’ views on the undue-burden doctrine specifically, as opposed to the nondiscrimination doctrine. See *Tenn. Wine & Spirits Retailers Ass’n v. Thomas*, 139 S. Ct. 2449, 2456 (2019). Justice Gorsuch concurred in *Wayfair*, but he emphasized that his “agreement with the Court’s discussion of the history of our dormant commerce clause jurisprudence . . . should not be mistaken for agreement with all aspects of the doctrine.” *Wayfair*, 138 S. Ct. at 2100 (Gorsuch, J., concurring). At the time this Article went to press, the views of Justices Kavanaugh, Barrett, and Jackson on *Pike* were unknown.

¹⁹ The majority in *Wayfair* cited *Pike* as the applicable standard in undue-burden cases. *Wayfair*, 138 S. Ct. at 2091. Justice Kennedy wrote the majority opinion, which Justices Thomas, Ginsburg, Alito, and Gorsuch joined. *Id.* at 2087. Perhaps reflecting a perception of the obsolescence of *Pike*, of the forty-seven amicus and party briefs filed in *Wayfair*, only five, including our amicus, discussed *Pike*. See Brief of Brill, Knoll, Mason & Viard in Support of Petitioner at 3, 17–20, *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080 (2018) (No. 17-494).

²⁰ BORIS I. BITTKER & BRANNON P. DENNING, BITTKER ON THE REGULATION OF INTER-STATE AND FOREIGN COMMERCE § 6.05 (Aspen Publishers 2022) (2d ed. 2013) (citing *Edgar v. MITE Corp.*, 457 U.S. 624 (1982) as the last time such preclusion occurred). Lower courts, however, regularly engage in such balancing and at times do invalidate state laws on such grounds. *Id.* (“*Pike* balancing is, however, alive and well in the lower courts.”).

²¹ See *Wynne*, 575 U.S. at 578.

²² See, e.g., *Nat’l Pork Producers Council v. Ross*, 6 F.4th 1021, 1025 (9th Cir. 2021), *cert. granted*, 142 S. Ct. 1413 (2022) (challenging, under the dormant Commerce Clause, California’s food product regulations that are stricter than those of other states).

that overtly treat cross-border commerce worse than in-state commerce are facially discriminatory and presumptively unconstitutional.²³ In contrast, courts examine facially neutral regulations for whether they impose undue burdens on cross-border commerce; that is, facially neutral regulations are ostensibly subject to *Pike* balancing. Although commentators have provided coherent explanations for the nondiscrimination strand of the dormant Commerce Clause, they have struggled to understand undue burdens. Rather than focusing on the discrimination cases, which are well understood and well justified, this Article focuses on the harder undue-burden cases.²⁴ Augmenting the traditional discrimination/undue-burden dichotomy, we offer a more nuanced account. Our account considers not only whether the challenged regulation explicitly discriminates, but also the *type* of burden the regulation imposes. We identify two types of burdens (or costs) on interstate commerce: (1) those arising from a single state's law, and (2) those arising from interactions—more specifically, mismatches—among two or more states' laws.

Single-state burdens arise when—*irrespective* of what other states do—a regulation impedes interstate commerce relative to in-state commerce. Thus, all facially discriminatory regulations impose single-state burdens; the excess burden on interstate commerce arises from the application of the challenged state's law *alone*.

Facially neutral regulations, in turn, can impose single-state or mismatch burdens. Consider the regulation challenged in *Pike*. In *Pike*, Arizona required cantaloupes grown in Arizona also to be packed there.²⁵ In our terms, this constituted a single-state burden because it did not depend on the packing regulations applicable in other states; instead, the burden arose from Arizona law *alone*. In balancing

²³ *Hughes v. Oklahoma*, 441 U.S. 322, 337 (1979) (“[F]acial discrimination invokes the strictest scrutiny.”).

²⁴ For example, in his leading account of the dormant Commerce Clause, which garners over 600 citations in Westlaw, Donald Regan argues that the Supreme Court decides dormant Commerce Clause cases by reference to a simple question: Was the state motivated to pass the challenged rule by intentional protectionism? If so, the Court strikes it down, and if not, the Court upholds it. *See Regan, supra* note 16. Regan noted, however, that many cases did not seem to fit into this paradigm, and so he excluded those cases from his analysis. *See id.* at 1104 (cabin-ing cases in which “genuine national interests other than the interest in avoiding state protectionism” are at stake). This Article argues that certain undue-burden cases, namely, those involving regulatory diversity, are not necessarily about protectionism, and so they cannot be explained by a paradigm that relies exclusively on the presence or absence of intentional protectionism. *See discussion infra* Section III.A.2.

²⁵ *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 138, 142 (1970) (noting that rule challenged was “even-handed[]”).

in *Pike*, the Supreme Court thus examined *only* Arizona law, an approach we refer to as using an internal benchmark.²⁶

Mismatch burdens, in contrast, arise from the interaction of *multiple* states' laws.²⁷ The defining feature of a mismatch burden is that the presence or absence of similar regulation by other states *does* affect the cost to comply with the first state's regulation. The paradigmatic mismatch case was *Bibb v. Navajo Freight Lines, Inc.*,²⁸ in which the Supreme Court precluded an Illinois law that required trucks on Illinois highways to have curved mudflaps at a time when other states permitted or required trucks to have straight mudflaps. As a result of the differences in the content of these regulations, trucks with straight mudflaps traveling interstate had to divert around Illinois or, if they wanted to enter Illinois, switch to curved mudflaps at the state border.²⁹ Although the Supreme Court purports to use *Pike* balancing in both single-state and mismatch cases—indeed, the Court does not expressly distinguish the two types of cases—this Article shows that the Supreme Court's approach to each type of case differs substantially. Specifically, in mismatch cases, the Court uses external benchmarks consisting of *other states' laws* to measure both the burden on interstate commerce and the challenged state's regulatory interest. In *Bibb*, for example, the Supreme Court understood the burden on interstate commerce to arise from Illinois's *departure* from the straight-mudflap rule applicable in other states.³⁰ Likewise, in defending its deviating rule, Illinois had to show that its curved-mudflap requirement produced a significant safety gain over and above that from the straight mudflaps permitted on roads in other states.³¹ As this Article explains, such a posture can place a heavy burden on innovating states.

One purpose of this Article is simply to recognize that the Supreme Court uses different baselines for evaluating single-state and mismatch cases; namely, it uses internal benchmarks in single-state cases, whereas it uses external benchmarks consisting of other states' laws in mismatch cases. Dividing cases into those imposing single-state or mismatch burdens helps to explain dormant Commerce Clause doctrine—it represents an improvement over the traditional discrimina-

²⁶ See *id.* at 142.

²⁷ The Supreme Court sometimes refers to “inconsistent” regulations. See *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 88 (1987). We refer to “mismatches” to convey neutrality about the constitutional status of such regulations.

²⁸ 359 U.S. 520 (1959).

²⁹ *Id.* at 527–28.

³⁰ *Id.* at 529–30.

³¹ *Id.* at 523–24.

tion/undue-burden dichotomy and allows us to better understand the hard cases.

Armed with our doctrinal reframing, this Article also offers criticisms of judicial review in mismatch cases. First, the Supreme Court has not taken a consistent approach in mismatch cases. For example, at times, the Supreme Court refuses to intervene *at all* in mismatch cases on the grounds that courts lack institutional competence to preclude regulatory diversity.³² Other times, the Court intervenes in mismatch cases on the theory that it is a duty of the Court to preclude state laws that otherwise would segment, or “Balkanize,” the national marketplace.³³ Such doctrinal inconsistency generates justified claims of arbitrariness, and it stands in stark contrast with the Supreme Court’s approach to single-state cases. The justices generally agree about *whether* and *how* to analyze single-state cases, although they sometimes disagree about the proper outcome of that analysis.

Second, in any case in which the Supreme Court decides to intervene to analyze a mismatch, it must then choose external benchmarks against which to measure both the burden on interstate commerce and the challenged state’s interest. But justices do not always agree on the proper external benchmarks. Benchmark selection thus also generates claims of arbitrariness.³⁴

Third, mismatch cases are more susceptible than are single-state cases to charges of “judicial legislation.” The reason for this has to do with how states cure constitutional violations. The remedy in any dormant Commerce Clause case is preclusion, but preclusion takes on special meaning in mismatch cases. Specifically, when the Supreme Court precludes a mismatch burden, that preclusion may implicitly endorse the regulation that the Court used as the external benchmark in the case. Thus, this Article argues that mismatch cases may have the practical effect of imposing harmonized substantive rules. Consider *Bibb*. Although the formal remedy in *Bibb* was preclusion of Illinois’s curved-mudflap rule, the implication of the Court’s decision was clear;

³² See, e.g., *S.C. State Highway Dep’t v. Barnwell Bros., Inc.*, 303 U.S. 177, 195–96 (1938).

³³ See, e.g., *Bibb*, 359 U.S. at 527 (emphasizing a need for national uniformity); see also *Tenn. Wine & Spirits Retailers Ass’n v. Thomas*, 139 S. Ct. 2449, 2461 (2019) (noting a “central concern of the Framers that was an immediate reason for calling the Constitutional Convention: the conviction that in order to succeed, the new Union would have to avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation.” (quoting *Hughes v. Oklahoma*, 441 U.S. 322, 325–26 (1979))).

³⁴ See *infra* Section III.A.2.a (discussing Justice Rehnquist’s criticism of the selection of the benchmark in *Kassel*).

Illinois had to conform to the mudflap rules of neighboring states, a phenomenon we refer to as harmonization by preclusion.³⁵ In contrast, in single-state cases, the typical remedy involves *desisting* application of the offending regulation—as in *Pike*—or *equalizing* the treatment of in-state and interstate economic actors—as in facial discrimination cases—but it need not lead to harmonization. This Article also gives reasons why judicial intervention in mismatch cases is more likely than judicial intervention in single-state cases to lead to deregulation.³⁶

Fourth, this Article demonstrates that because more constitutional values are at stake in mismatch cases than in single-state cases, mismatch cases are generally harder to resolve.

This Article proceeds as follows: Part I provides background on and criticisms of the dormant Commerce Clause. Part II reframes the dormant Commerce Clause by supplementing the discrimination-versus-undue-burden distinction with a distinction that looks to the type of burden—single-state or mismatch—imposed by the challenged regulation. Our framework augments, but does not supplant, the discrimination-versus-undue-burden dichotomy. Part III compares mismatch and single-state cases, explaining why certain well-known criticisms of the dormant Commerce Clause apply with more force to mismatch cases than to single-state cases. Part IV applies our new doctrinal framework to a pending case to illustrate that mismatch cases raise questions—such as *which state's rule prevails in cases of conflict?* and *who decides?*—that go to the core of federalism. Part IV also offers suggestions for how the Supreme Court could minimize the adverse impacts of mismatch cases, without completely refusing to consider them.

I. THE DORMANT COMMERCE CLAUSE AND ITS CRITICS

A. *The Dormant Commerce Clause*

The Commerce Clause of the Constitution grants Congress the power “[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.”³⁷ The Supreme Court has interpreted the Commerce Clause to express not only an affirmative

³⁵ *Bibb*, 359 U.S. at 530 (observing that “a new safety device—out of line with the requirements of the other States—may be so compelling that [Illinois] need not be the one to give way. . . . [T]he present showing—balanced against the clear burden on commerce—is far too inconclusive to make [Illinois’s] mudguard meet that test.”).

³⁶ See *infra* Section III.C.

³⁷ U.S. CONST. art. I, § 8, cl. 3.

grant of power to Congress, but also an implicit restraint on the states.³⁸ For two centuries, the Supreme Court has employed this “dormant” aspect of the Commerce Clause to strike a balance between state and federal interests.³⁹

The relevant state interest is regulatory autonomy. Autonomy enables states to govern flexibly, satisfy preferences, and act as laboratories of democracy.⁴⁰ The Court has identified various national and federal interests that limit state regulatory autonomy; for example, the Court often refers to free-trade values, such as “preserv[ing] ‘the free flow of interstate commerce.’”⁴¹ In the Court’s view, forbidding protectionism by states is union-preserving because it prevents “rivalries and dislocations and reprisals”⁴² that would “threaten at once the peace and safety of the Union.”⁴³ Moreover, the Supreme Court has interpreted the dormant Commerce Clause to protect out-of-state political interests that are not directly represented in the regulating state’s political process, a concept sometimes called representation reinforcement.⁴⁴ Importantly for this Article, the Court also has cited risks that state regulations might segment—or “Balkanize”⁴⁵—the na-

³⁸ *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 13–14 (1824).

³⁹ For a history of the dormant Commerce Clause, see Denning, *Reconstructing*, *supra* note 2, at 421, 427–48.

⁴⁰ *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991) (reciting federalism values); *Dep’t of Revenue of Ky. v. Davis*, 553 U.S. 328, 338 (2008) (“[T]he Framers’ distrust of economic Balkanization was limited by their federalism favoring a degree of local autonomy.”).

⁴¹ *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2090 (2018) (quoting *S. Pac. Co. v. Ariz. ex rel. Sullivan*, 325 U.S. 761, 770 (1945)).

⁴² *H. P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 539 (1949).

⁴³ *Id.* at 533. See generally Collins, *supra* note 16 (focusing on the dormant Commerce Clause’s role in forging economic union).

⁴⁴ See, e.g., *Southern Pacific*, 325 U.S. at 767–68, n.2 (“[T]he Court has often recognized that to the extent that the burden of state regulation falls on interests outside the state, it is unlikely to be alleviated by the operation of those political restraints normally exerted when interests within the state are affected.”); *Hood*, 336 U.S. at 539 (“[E]very consumer may look to the free competition from every producing area in the Nation to protect him from exploitation by any.”). For commentary, see, e.g., Eule, *supra* note 9, at 428, 435 (discussing representation reinforcement); see also JOHN HART ELY, *DEMOCRACY AND DISTRUST: A THEORY OF JUDICIAL REVIEW* 83 (1980) (describing the dormant Commerce Clause as needed “to protect the politically powerless”); Tushnet, *supra* note 16, at 133 (observing that, in addition to outsiders, “the general consumer interest is at a systematic disadvantage in legislative combat against organized groups”).

⁴⁵ The first reference to Balkanization by the Supreme Court was in a concurrence in *Duckworth v. Arkansas*, 314 U.S. 390, 400 (1941) (Jackson, J., concurring) (“The practical result is that in default of action by us [state regulations] will go on suffocating and retarding and Balkanizing American commerce, trade and industry.”). The first mention of Balkanization in the majority of a dormant Commerce Clause case was in 1979 in *Hughes v. Oklahoma*, 441 U.S. 322, 325–26 (1979) (noting the Framers’ “conviction that in order to succeed, the new Union

tional market. Emphasizing the need for “national uniformity” in regulation, the Court at times has interpreted the dormant Commerce Clause to preclude market-segmenting regulations.⁴⁶ At other times, the Court declared it inappropriate to intervene to prevent states from enacting market-segmenting laws.

Given the vital, but often opposing, interests at stake in dormant Commerce Clause cases, it is perhaps no surprise that judicial standards in them have evolved over time.⁴⁷ Modern doctrine sees two principal types of challenges: facial discrimination and undue burdens.⁴⁸ Facial discrimination involves explicit distinctions between in-state and out-of-state economic actors or between in-state and interstate commerce. When states expressly discriminate, their regulations receive strict scrutiny.⁴⁹ Although some commentators criticize facial discrimination doctrine,⁵⁰ nearly all accept it as either consistent with our overall federal structure and the vision of the Constitution’s founders, or applicable as a matter of precedent, or both.⁵¹

would have to avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation”). *Id.* at 326 (citing similar analysis, in *Hood*, 336 U.S. at 533–34, that did not employ the term “balkanization”). The Court’s most recent use of the term was in 2019 in *Tennessee Wine & Spirits Retailers Ass’n v. Thomas*, 139 S. Ct. 2449, 2461 (2019) (quoting *Hughes*, 441 U.S. at 325–26). The Court has employed the term in a number of other instances. *See* *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 577 (1997) (“Avoiding this sort of ‘economic balkanization,’ and the retaliatory acts of other States that may follow, is one of the central purposes of our negative Commerce Clause jurisprudence.” (citation omitted)); *Fulton Corp. v. Faulkner*, 516 U.S. 325, 333 n.3 (1996) (referring to “‘economic Balkanization’ that our dormant Commerce Clause jurisprudence has long sought to prevent”); *Bacchus Imports, Ltd. v. Dias*, 468 U.S. 263, 276 (1984) (“It is also beyond doubt that the Commerce Clause itself furthers strong federal interests in preventing economic Balkanization.”).

⁴⁶ *See, e.g.*, *Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520, 527 (1959) (quoting *Morgan v. Virginia*, 328 U.S. 373, 386 (1946)).

⁴⁷ *See* Denning, *Reconstructing*, *supra* note 2, at 427–48 (giving history of dormant Commerce Clause jurisprudence).

⁴⁸ *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2090–91 (2018) (“Modern precedents rest upon two primary principles that mark the boundaries of a State’s authority to regulate interstate commerce. First, state regulations may not discriminate against interstate commerce; and second, States may not impose undue burdens on interstate commerce. State laws that discriminate against interstate commerce face ‘a virtually *per se* rule of invalidity.’ State laws that ‘regulate[] even-handedly to effectuate a legitimate local public interest . . . will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.’” (citation omitted) (first quoting *Granholm v. Heald*, 544 U.S. 460, 476 (2005); then quoting *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970))). Other dormant Commerce Clause challenges involve nexus and extraterritoriality, doctrines this Article does not consider.

⁴⁹ *See, e.g., id.*

⁵⁰ *See generally* McGreal, *supra* note 16 (arguing that courts should not strike even facially discriminatory state laws in areas where in-state and out-of-state commerce do not compete).

⁵¹ *Direct Mktg. Ass’n v. Brohl*, 814 F.3d 1129, 1150 (10th Cir. 2016) (Gorsuch, J., concur-

A state law that does not facially discriminate may nevertheless violate the dormant Commerce Clause by imposing an “undue burden” on interstate commerce. For the better part of a century, undue-burdens analysis has involved judicial balancing.⁵² The modern description of this balancing derives from *Pike v. Bruce Church*:

Where the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.⁵³

Ultimately, judges have the same goals when they apply undue-burden analysis as when they apply nondiscrimination analysis, namely, to weigh national and federal interests against state interests. But whereas facially discriminatory regulations rarely survive dormant Commerce Clause analysis, courts regularly uphold statutes against claims that they unduly burden interstate commerce. The Supreme Court has not always been clear about why it permitted or precluded

ring) (“And to the extent that there’s anything that’s uncontroversial about dormant commerce clause jurisprudence it may be this anti-discrimination principle, for even critics of dormant commerce clause doctrine often endorse it even as they suggest it might find a more textually comfortable home in other constitutional provisions.”). In *Tennessee Wine*, Justices Alito, Breyer, Ginsburg, Kagan, Kavanaugh, Sotomayor, and Chief Justice Roberts joined in precluding a facially discriminatory state regulation for violating the dormant Commerce Clause. 139 S. Ct. 2449, 2456, 2476 (2019). Justices Gorsuch and Thomas dissented. Justice Gorsuch dissented because he concluded that the Twenty-first Amendment immunized the challenged regulation from dormant Commerce Clause review. *Id.* at 2484 (Gorsuch, J., dissenting). Even as he has concurred in judgments applying the dormant Commerce Clause, Justice Gorsuch has expressed skepticism about it. See *Wayfair*, 138 S. Ct. at 2100–01 (2018) (Gorsuch, J., concurring) (“Whether and how much of this can be squared with the text of the Commerce Clause, justified by *stare decisis*, or defended as misbranded products of federalism or antidiscrimination imperatives flowing from Article IV’s Privileges and Immunities Clause are questions for another day.”). Justice Thomas opposes all aspects of the dormant Commerce Clause on grounds of its atextuality. See, e.g., *Comptroller of the Treasury of Md. v. Wynne*, 575 U.S. 542, 578 (2015) (Thomas, J., dissenting) (“I continue to adhere to my view that the negative Commerce Clause . . . cannot serve as a basis for striking down a state statute.” (quoting *McBurney v. Young*, 569 U.S. 221, 237 (2013) (Thomas, J., concurring))). Since *Tennessee Wine*, Justice Barrett filled the seat of the late Justice Ginsburg, and Justice Jackson filled the seat of retired Justice Breyer. As discussed *supra* note 18, their views as justices on dormant Commerce Clause doctrine are not yet known.

⁵² See Denning, *Reconstructing*, *supra* note 2, at 443–45 (tracing balancing back to 1938).

⁵³ *Pike*, 397 U.S. at 142 (citation omitted).

particular “even-handed” regulations under its undue-burdens standard.⁵⁴ As the next Section explains, this lack of clarity has generated significant criticism.

B. *Criticisms of Dormant Commerce Clause Doctrine*

This Section reviews criticisms of the dormant Commerce Clause. Although some—including Justice Thomas—have argued that the dormant Commerce Clause is illegitimate because it lacks a sufficient textual basis,⁵⁵ this Article focuses on criticisms lodged by those who, although they accept dormant Commerce Clause doctrine in principle, argue that the Court’s approach to deciding cases is deficient. The main criticisms are that the doctrine is arbitrary and invites courts to act as legislatures.

Discrimination against interstate commerce has a clear intuitive meaning, but the idea of “undue burdens” does not. Critics—on and off the bench—complain that *Pike* balancing usurps the legislative role by encouraging judges to indulge their own preferences when deciding whether to uphold or to preclude a state regulation.⁵⁶ Justice Scalia, for instance, disparaged the analysis as “ad hocery.”⁵⁷ And a persistent frustration with undue-burdens doctrine is that seemingly similar cases garner sharply different outcomes. For example, in one case, the Supreme Court held that a state that imposed more stringent truck *length* limits than did neighboring states unduly burdened interstate commerce, but in another, it held that a state that imposed more stringent truck *weight* limits than did neighboring states did not violate the dormant Commerce Clause.⁵⁸

Despite criticisms of arbitrariness, there are some settled doctrines. As Donald Regan observed in his seminal 1986 article criticizing the dormant Commerce Clause, many cases boil down to the question of whether the state enacted a regulation with protectionist

⁵⁴ For examples, see *infra* Part II; see also BITTKER & DENNING, *supra* note 20.

⁵⁵ See Denning, *Justice Thomas*, *supra* note 15, at 157–59 (discussing views of Justice Thomas).

⁵⁶ See *supra* notes 4–16 (describing criticisms).

⁵⁷ *Comptroller of the Treasury of Md. v. Wynne*, 575 U.S. 542, 574 (2015) (Scalia, J., dissenting); see also Denning, *Reconstructing*, *supra* note 2, at 422 (describing “cases with similar facts being decided differently, and the different outcomes justified on the basis of tendentious distinctions.”).

⁵⁸ Compare *Kassel v. Consol. Freightways Corp.*, 450 U.S. 662, 677–79 (1981) (precluding a state from deviating from the truck-length rule implemented in contiguous states), with *S.C. State Highway Dep’t v. Barnwell Bros., Inc.*, 303 U.S. 177, 195–96 (1938) (upholding ability of state to maintain truck width and weight limits that differed from those of neighboring states).

intent.⁵⁹ Although an express consideration of protectionist intent does not always form part of the Supreme Court’s analysis, Regan argued that the outcome of most cases could be predicted based on the absence or presence of protectionist intent.⁶⁰ Specifically, where protectionist intent was present, the Court generally precluded the regulation; where such intent was absent, the Court generally sustained the regulation. A major problem with this account, as Regan readily acknowledged, was that it could not explain the decisions in a number of dormant Commerce Clause cases—involving, among other topics, cross-border transportation and tax—where the burden on interstate commerce did not arise from intentional protectionism.⁶¹ Regan therefore cabined these cases as exceptions to the general rule that the dormant Commerce Clause targets only intentional protectionism.⁶² This Article reveals what the cases excluded by Regan have in common—they are mismatch cases, which warrant, and receive, different doctrinal analysis.

II. REFRAMING THE DORMANT COMMERCE CLAUSE

This Part reframes undue-burdens doctrine.⁶³ The Supreme Court’s dormant Commerce Clause doctrine has long been understood to involve two principal types of cases: facial discrimination and

⁵⁹ Regan, *supra* note 16, at 1093.

⁶⁰ *Id.* Regan summarized the dormant Commerce Clause by the simple statement that “[l]aws with protectionist purpose are invalid . . . laws without protectionist purpose . . . are valid.” *Id.* at 1104. We think Regan overstates his claim, but it is important to note that he limited it to only what he called “movement-of-goods” cases. *Id.* at 1182. Regan readily acknowledged that interstate transportation, tax, and some other cases were not decided exclusively upon the absence or presence of intentional protectionism, but rather were based on other values, including “national interest.” *Id.* (describing cases in which “the Court appears to do more under the dormant commerce clause than merely suppress state protectionism”). What the cases Regan excluded from his category of movement-of-goods have in common is that they are mismatch cases. Although Regan referred to cases by topical area, there is nothing special about transportation, tax, or even goods. Mismatches can occur in *any* area, including regulation of goods. Indeed, Regan was forced to define his category of movement-of-goods cases as including only “those cases in which no national interest other than the anti-protectionism interest is implicated,” a definition he noted was “an interesting tautology.” *Id.* at 1191.

⁶¹ *Id.* at 1182. Another problem with Regan’s claim—which is that courts do *and should* decide dormant Commerce Clause cases based only on the absence or presence of protectionist intent—is that, except in cases of facial discrimination, it not only may be difficult to ascertain legislative intent, but disputes have arisen regarding what types of evidence legitimately can be used to ascertain legislative intent. See generally Caleb Nelson, *Judicial Review of Legislative Purpose*, 83 N.Y.U. L. REV. 1784, 1795–1858 (2008) (giving history of judicial practices in determining legislative intent).

⁶² See Regan, *supra* note 16, at 1184–86. These exceptions are important for our analysis, and for understanding the dormant Commerce Clause more generally. See *infra* Section II.B.

⁶³ Because it seeks to address the core of the dormant Commerce Clause, this Article does

undue burdens.⁶⁴ Jurists and commentators paired each type of case with a method of judicial review: strict scrutiny for facial discrimination, and *Pike* balancing for undue burdens.⁶⁵ But that framework does not accurately reflect the doctrine, which is more nuanced. The disconnect between the actual doctrine and its description by courts and commentators has bolstered claims that the doctrine is confusing and incoherent and therefore should be limited or even eliminated.

This Part advocates for a conception of undue-burden doctrine that is more faithful to the cases; one that takes into account the type of burden the challenged rule imposes: single-state or mismatch. Section II.A defines single-state and mismatch burdens. Section II.B shows how the Supreme Court analyzes single-state burdens. Section II.C shows how the Supreme Court analyzes mismatch burdens. Thinking of cases in terms of single-state burdens and mismatch burdens allows us to see consistent, but unstated, differences in the Supreme Court's approaches to deciding these cases. Although the Supreme Court has not formally acknowledged a distinction between single-state and mismatch burdens, and even though the Court claims to apply the same doctrinal test—*Pike* balancing—to all cases involving facially neutral rules, this Part shows that the Court as a practical matter treats the two types of cases differently. For example, unlike with single-state cases, justices often express reluctance to intervene in mismatch cases, reasoning that because resolving mismatch cases involves picking one state's rule to prevail over another, it is essentially legislative, not judicial. Likewise, this Part shows that, in those mismatch cases in which the Court decides to intervene, it uses what we call external benchmarks. Specifically, it compares the challenged state's regulation to *other states'* regulation. No such cross-state comparisons are needed in single-state cases because, by definition, the burden in a single-state case arises from the regulation of a single state acting alone. Thinking about the cases in the way we suggest here clarifies and simplifies the doctrine and lays the groundwork for our normative arguments in the rest of the Article.

not address several of its subdoctrines, including the market-participation exception, the government-function exception, the extraterritoriality doctrine, or dormant-Commerce-Clause nexus.

⁶⁴ See *supra* text accompanying note 48.

⁶⁵ See *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2090–91 (2018); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986).

A. *Defining Types of Burdens*

Before diving into our doctrinal analysis, this Section reviews the types of burdens that matter under the dormant Commerce Clause, and it defines single-state and mismatch burdens.

1. *Symmetrical Versus Asymmetrical Burdens*

Not all regulations impose burdens relevant to dormant Commerce Clause analysis. Consider regulations that impose what we call symmetrical burdens. Symmetrical burdens fall evenly on in-state and interstate commerce. For example, although they undoubtedly impact cross-border commerce, some local regulations—such as minimum wage laws and building codes—are symmetrical; compliance is no more burdensome for out-of-staters than for in-staters, and hence the rules do not discourage interstate commerce relative to in-state commerce. Accordingly, *any* legitimate state interest should be enough to sustain them against dormant Commerce Clause challenges.⁶⁶

Contrast *asymmetrical* burdens, which this Article defines as those that impose disproportionately greater costs on interstate commerce than on in-state commerce, hence discouraging interstate commerce *relative to* in-state commerce and potentially inspiring tit-for-tat retaliation among states. The dormant Commerce Clause restrains some, but not all, asymmetrical burdens. Specifically, it restrains only *unjustified* asymmetrical burdens. State autonomy interests—including states' need to protect residents, cater to local conditions, and achieve other legitimate ends—can justify asymmetrical burdens. Mediating between or balancing those interests is the heart of dormant Commerce Clause analysis.

2. *Single-State Versus Mismatch Burdens*

A principal insight of this Article is that to fully understand dormant Commerce Clause doctrine, we must first understand that regulations impose different *types* of asymmetrical burdens on interstate commerce. We can subdivide those burdens into two types: single-state burdens and mismatch burdens. Single-state burdens arise from the application of the challenged state's law alone. Mismatch burdens arise from the application of two or more states' laws.

A regulation imposes a *single-state burden* when it burdens interstate commerce more than in-state commerce *irrespective* of what

⁶⁶ See, e.g., *Huron Portland Cement Co. v. Detroit*, 362 U.S. 440, 448 (1960) (applying rational-basis review).

other states do. Specifically, regulation imposes a single-state burden when: (1) it would discourage cross-border commerce relative to in-state commerce if no other states regulated in the area, and (2) it would also do so if all other states were to adopt *regulation identical to* that of the challenged state. Thus, one can think of single-state burdens as being functionally equivalent, in compliance-cost terms, to an entry toll. If a state has a flat annual entry toll, that toll imposes an asymmetrical cost that is higher for cross-border commercial actors than for commercial actors operating wholly within the state. And the cost associated with that toll is independent of other states' tolls; it does not rise or fall depending on any other state's toll.

Facially discriminatory rules impose single-state burdens—the asymmetrical burden on interstate commerce arises from the law of the discriminating state alone. But facially neutral rules can impose single-state or mismatch burdens.⁶⁷ For example, *Pike v. Bruce Church* involved a facially neutral rule that imposed a single-state burden. In *Pike*, Arizona required farmers who grew cantaloupes in the state also to pack them there.⁶⁸ Because the burden arising from Arizona's rule did not depend on the actions or regulations of other states, it was a single-state burden. Specifically, adoption by other states of rules similar to (or different from) the Arizona rule would not affect the cost to comply with the Arizona rule.

But facially neutral rules also may impose mismatch burdens. A regulation imposes a mismatch burden if: (1) it would discourage cross-border commerce relative to in-state commerce if no other state regulated in the area, but (2) it would *not* discourage cross-border commerce relative to in-state commerce if all other states adopted the same regulation as the challenged state. Mismatch burdens are contingent on other states' regulations; they disappear when other states have the same rule.

Mismatches can consist of substantive differences in the content of regulations, as when one state allows sixty-five-foot trucks while another prohibits them. Mismatches also occur when one state has a regulation, and another state has no corresponding regulation, such that an interstate economic actor becomes subject to new rules when it expands across the border. Mismatches thus either increase costs for cross-border, but not in-state, economic actors or strip out-of-state economic actors of comparative advantages they otherwise would possess. When state regulations interact, the cost to comply with one

⁶⁷ A state law can also impose *both* single-state and mismatch burdens. See *infra* note 70.

⁶⁸ *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 143 (1970).

state's regulation can vary from zero (if the state's regulation is in no dimension stricter than or incompatible with other states' regulations)⁶⁹ to infinite (if the state's rule is mutually exclusive with other states' rules). In some cases, compliance will be cheap; in others it could be so high that it stops cross-border commerce in its tracks.⁷⁰

Consider the facially neutral mismatch in *Bibb*, in which cross-border truckers challenged an Illinois regulation that imposed a curved-mudflap requirement at a time when neighboring states permitted or required straight mudflaps.⁷¹ If all other states adopted Illinois's curved-mudflap rule, then interstate truckers would experience no greater costs to comply with Illinois's rule than would in-state truckers because truckers everywhere would use only curved mudflaps. But because Illinois's rule was different from those of other states, out-of-state truckers had to stop at the border to change mudflaps. Therefore, the burden in *Bibb*, which arose from regulatory diversity, is a mismatch burden. The most important feature of mismatches is that they are *conditional*—the burden one state's rule imposes depends on the existence and content of other states' rules. Even when protectionist intent does not motivate the adoption of a regulatory mismatch, a mismatch may severely curtail interstate commerce. Worse, states may create regulatory mismatches with protec-

⁶⁹ Consider the existence of different opening-hours requirements for retailers. While technically the regulations are mismatched, opening-hours diversity would have a negligible asymmetrical burden on interstate commerce. Other examples might include local safety regulations that impose costs on both in-state and out-of-state economic interests. *See, e.g., Ray v. Atl. Ritchfield Co.*, 435 U.S. 151, 173 (1978) (upholding a facially neutral requirement that tankers exceeding certain size limits be accompanied by a tug escort in Puget Sound).

⁷⁰ Regulations that impose mismatch burdens also can impose single-state burdens. The classic example of a regulation that imposes both single-state and mismatch burdens is the Illinois anti-takeover regulation struck down in *CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69 (1987). That regulation, which permitted Illinois to prevent a merger or acquisition if as little as ten percent of the target corporation's shares were held by Illinois residents, would potentially create a mismatch with anti-takeover laws of other states. *Id.* at 72–75. The Illinois law also imposed a single-state burden in that the law allowed the Illinois Secretary of State almost unfettered ability to block such an acquisition. *Id.* at 81. Underscoring these two different types of burdens, the Court several years later in *Edgar v. MITE Corp.*, 457 U.S. 624 (1982) upheld an Indiana anti-takeover law that only applied to target corporations chartered in Indiana, thus reducing the possibility of overlapping jurisdictional claims (and hence reducing potential mismatch burdens). *Id.* at 626–27, 646. In contrast, the dissent would have struck the law because it gave Indiana broad authority to prevent takeovers, and takeovers overwhelmingly involved out-of-state acquirers and in-state targets. In our terms, the dissent determined that the challenged regulation imposed a severe single-state burden on interstate commerce. *Id.* at 656. This Article does not consider the corporate law cases here because they implicate extraterritoriality more than undue burdens.

⁷¹ *Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520, 520 (1959).

tionist intent, as when North Carolina forbade apple growers from displaying quality-grading information from their state of origin in *Hunt v. Washington State Apple Advertising Commission*.⁷² Section II.C will discuss both *Bibb* and *Hunt*.

B. *Single-State Burdens and Pike Balancing*

This Section illustrates how the Supreme Court analyzes single-state cases that allege discrimination against or undue burdens on interstate commerce.⁷³ Whereas facial discrimination receives strict scrutiny, facially neutral single-state burdens are subject to *Pike* balancing.

1. *Facially Discriminatory Regulations*

The easiest type of single-state burden to identify and understand involves facial discrimination, that is, regulation that *expressly* distinguishes between state residents and nonresidents or between in-state and interstate commerce. Facial discrimination imposes single-state burdens because the burden does not depend on the content of any other state's rule. Facial discrimination cases have never been controversial or difficult for courts to resolve under the dormant Commerce Clause. Subjected to strict scrutiny, facially discriminatory regulations almost never survive.⁷⁴ For example, in *Hughes v. Oklahoma*,⁷⁵ the Supreme Court held that Oklahoma could not forbid the out-of-state sale of minnows caught within Oklahoma, while at the same time permitting the in-state sale of such minnows; in *Lewis v. BT Investment Managers, Inc.*,⁷⁶ the Court held that Florida could not prohibit out-of-state business entities from conducting certain financial activities in Florida that the state permitted equivalent Florida entities to conduct;

⁷² 432 U.S. 333, 335–36 (1977).

⁷³ The goal of this Article is to explain the most puzzling cases, namely facially neutral, but burdensome, regulations. Other types of single-state burdens, including facially discriminatory laws and taxes that fail the Court's internal-consistency test, are subject to strict scrutiny and are almost always precluded. The reason for strict scrutiny in cases of facial discrimination are obvious; reasons for strict scrutiny of internally inconsistent taxes less so. For explanation as to why internally inconsistent taxes properly receive strict scrutiny, see Michael S. Knoll & Ruth Mason, *The Economic Foundation of the Dormant Commerce Clause*, 103 VA. L. REV. 309, 329–33 (2017). Notwithstanding the technical nature of the explanation that underlies use of the internal consistency test, the actual application of that test is straightforward, and so it is easy to identify tax rules that are internally inconsistent and therefore discriminatory. See generally *id.*

⁷⁴ *Hughes v. Oklahoma*, 441 U.S. 322, 337 (1979) (“[F]acial discrimination invokes the strictest scrutiny . . .”).

⁷⁵ 441 U.S. 332, 337–38 (1979).

⁷⁶ 447 U.S. 27, 27, 44 (1980).

and in *Boston Stock Exchange v. State Tax Commission*,⁷⁷ the Court held that New York could not tax stock sales at a lower rate when they took place in New York than when they took place elsewhere. The Supreme Court likewise has struck down facially discriminatory regulations that banned in-state operations by nonresidents,⁷⁸ banned direct shipment of alcohol to state residents by out-of-state producers,⁷⁹ and more.⁸⁰ Rarely has the Supreme Court found a facially discriminatory regulation to be justified.⁸¹ Few commentators dispute that courts act properly when they preclude facially discriminatory rules.⁸²

2. *Facially Neutral Regulations*

The dormant Commerce Clause also precludes facially neutral rules that discriminate in effect. The Supreme Court has stated that “[t]he commerce clause forbids discrimination, whether forthright or ingenious.”⁸³ When evaluating a facially neutral rule, what matters to the Court is the rule’s impact on interstate commerce.⁸⁴ Each case discussed in this Section involves a facially neutral regulation that imposed a single-state burden on interstate commerce; these cases involve *Pike* balancing.

⁷⁷ 429 U.S. 318, 318–19, 336 (1977).

⁷⁸ *Tenn. Wine and Spirits Retailers Ass’n v. Thomas*, 139 S. Ct. 2449, 2476 (2019).

⁷⁹ *Granholt v. Heald*, 544 U.S. 460, 465–66 (2005) (precluding a Michigan law allowing in-state, but not out-of-state, wineries to ship directly to Michigan customers).

⁸⁰ *Great Atl. & Pac. Tea Co. v. Cottrell*, 424 U.S. 366, 367–68 (1976) (striking down a Mississippi statute prohibiting the sale of out-of-state milk in Mississippi unless its source state accepted the sale of Mississippi milk in its territory); *Sporhase v. Nebraska ex rel. Douglas*, 458 U.S. 941, 943, 960 (1982) (precluding a Nebraska statute prohibiting the withdrawal of Nebraska groundwater for transport across state lines unless the destination state granted reciprocal rights of withdrawal and transport into Nebraska); *see, e.g., New England Power Co. v. New Hampshire*, 455 U.S. 331, 333–34, 344 (1982) (precluding a New Hampshire law prohibiting the export of hydroelectric power).

⁸¹ *See Maine v. Taylor*, 477 U.S. 131, 132–33, 151–52 (1986) (finding complete ban on imported baitfish justified to prevent introduction of parasites and invasive species when no less restrictive preventative measures would be effective).

⁸² *But see Eule, supra* note 9, at 428 (arguing for a “radically diminished role” for the dormant Commerce Clause, even in discrimination cases).

⁸³ *W. Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 201 (1994); *see also Dean Milk Co. v. City of Madison*, 340 U.S. 349, 354 (1951) (reasoning that limiting dormant Commerce Clause scrutiny to facially discriminatory regulation “would mean that the Commerce Clause of itself imposes no limitations on state action . . . save for the rare instance where a state artlessly discloses an avowed purpose to discriminate against interstate goods”).

⁸⁴ *See W. Lynn Creamery*, 512 U.S. at 201 (referring to a rule’s “practical operation”).

a. *Pike v. Bruce Church* (1970)

In *Pike v. Bruce Church*, the challenged regulation involved tying, a requirement that forces a commercial actor that conducts some commercial activity in a state to also conduct additional commercial activity there.⁸⁵ A cantaloupe grower challenged Arizona's requirement that cantaloupes grown in Arizona also had to be packed there.⁸⁶ The asymmetrical burden in *Pike* arose because, by tying packing to growing, Arizona precluded multistate growers from obtaining economies of scale from using packing facilities that they may have already owned outside Arizona. For example, the challenger in *Pike* would have preferred to use a packing facility it already owned nearby, just across the border in California.⁸⁷ This asymmetrical burden was also a single-state burden. Specifically, the cost to comply with Arizona's regulation would not decrease if all other states adopted an identical rule. The Arizona rule, in effect, functioned as an entry toll.

To decide *Pike*, the Supreme Court invoked a preexisting doctrinal tool that has come to be known as *Pike* balancing. Under *Pike* balancing, the Court first compares the asymmetrical burden a state imposes on interstate commerce to the state's interest in the challenged regulation.⁸⁸ The Court then may engage in narrow tailoring by asking whether the state could have achieved its interest via a method that would burden interstate commerce less than does the challenged regulation.⁸⁹ In *Pike*, the Supreme Court compared the burden Arizona imposed on in-state growers to the burden Arizona imposed on interstate growers, and it concluded that only interstate growers had to relinquish economies of scale that derived from consolidating pack-

⁸⁵ *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 138, 145 (1970) (defining tying as "requiring business operations to be performed in the home State that could more efficiently be performed elsewhere"); cf. *S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 102, (1984) (Rehnquist, J., dissenting) (arguing that the majority should not have invalidated under the dormant Commerce Clause a state's "tying arrangement" that required timber harvested in a state also to be processed there).

⁸⁶ *Pike*, 397 U.S. at 138. The Court considered the Arizona packing rule to be facially neutral because it did not draw a de jure distinction between in-state and out-of-state growers in order to treat them differently. On the contrary, by its terms, the Arizona statute applied to all growers the same way—if they grew cantaloupes in Arizona, they had to pack them there. *Id.* at 140–42.

⁸⁷ *Id.* at 138. The parties in *Pike* stipulated that its practical effect was to "compel the company to build packing facilities in [Arizona]." *Id.* at 140.

⁸⁸ *Id.* at 142–43.

⁸⁹ The Supreme Court does not always engage in explicit narrow tailoring as part of *Pike* balancing, and in its most recent description of *Pike* balancing, it did not even mention it. See *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2091 (2018).

ing into a single plant.⁹⁰ The Supreme Court weighed this burden against Arizona’s justification for the regulation, which was to inform the market that the relevant cantaloupes had been grown in Arizona,⁹¹ and the Court concluded that the burden outweighed Arizona’s interest.⁹² The Court also noted the relevance of alternative, less burdensome, regulations—such as labeling—by which Arizona could achieve its local interest.⁹³ It is not uncommon for courts striking a law that imposes a single-state burden under *Pike* to find both that the law’s burden exceeds its benefit and that less burdensome means were available to achieve the state’s legitimate ends.

Not every reader will be convinced by the Court’s analysis in *Pike* that the asymmetric burden on interstate commerce outweighed the states’ regulatory interest. Balancing involves a judgment call. The Court’s decision in *Pike* rested in part on its long-held⁹⁴ attitude toward the practice of tying, which it saw as imposing a “straitjacket on the appellee company with respect to the allocation of its interstate resources.”⁹⁵ The Court declared tying worthy of “particular suspicion”⁹⁶ and declared it “virtually *per se* illegal.”⁹⁷

b. H. P. Hood & Sons, Inc. v. Du Mond (1949)

Dormant Commerce Clause challenges also arise when states use facially neutral rules to limit market access. In *H. P. Hood & Sons*,

⁹⁰ *Pike*, 397 U.S. at 145–46.

⁹¹ *Id.* at 142.

⁹² *Id.* at 143, 145 (distinguishing Arizona’s “tenuous” interest in the reputation of its produce from other types of interests that would have carried more weight, such as safety).

⁹³ *Id.* at 142.

⁹⁴ See *Toomer v. Witsell*, 334 U.S. 385, 403 (1948) (striking down a North Carolina statute that tied shrimp packing to shrimp fishing, concluding that “an inevitable concomitant of [this] statute . . . is to divert to South Carolina employment and business which might otherwise go to Georgia”).

⁹⁵ *Pike*, 397 U.S. at 146; *id.* at 145 (“The *nature* of that burden is, constitutionally, more significant than its extent” (emphasis added)); see also *Toomer*, 334 U.S. at 403–04 (disapproving South Carolina’s attempt to “impose an artificial rigidity on the economic pattern of the industry”); *id.* at 410 (Rutledge, J., concurring) (referring to the tying regulation as “aimed in terms directly at interstate commerce alone, and thus would seem to be discriminatory in intent and effect”). For other cases invalidating tying, see, e.g., *Minnesota v. Barber*, 136 U.S. 313, 329–30 (1890) (meat sold in-state had to be inspected there); *Foster-Fountain Packing Co. v. Haydel*, 278 U.S. 1, 13–14 (1928) (requiring shrimp caught in-state to be processed there); *Johnson v. Haydel*, 278 U.S. 16, 16–17 (1928) (requiring oysters caught in-state to be processed there); *S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 84–85 (1984) (requiring timber harvested in-state to be processed there).

⁹⁶ *Pike*, 397 U.S. at 145.

⁹⁷ *Id.*

Inc. v. Du Mond,⁹⁸ for example, the Supreme Court considered whether New York could deny an out-of-state milk buyer a license to operate an in-state milk depot because the state wanted to protect its in-state milk market from greater competition from *any* source, whether in-state or out-of-state. A majority of the Court held that New York violated the dormant Commerce Clause because, despite the absence of facial discrimination, the “avowed purpose” of the denial of the license was to “aid local economic interests”⁹⁹ and for the Court to permit such “prohibition of competition”¹⁰⁰ might spur “fantastic rivalries and dislocations and reprisals.”¹⁰¹ But the dissenters in the case would have struck a different balance.¹⁰² They regarded as legitimate New York’s interest in stabilizing the milk market by regulating *all* new entrants.¹⁰³ They viewed “the prevention of destructive competition [as] a permissible exercise of the police power,”¹⁰⁴ provided the state did not target out-of-state competition for special treatment.¹⁰⁵ Put differently, regulating to reduce competition was permissible, whereas regulating to reduce competition *specifically from out-of-staters* was impermissible. Thus, the dissenters would have remanded for more fact-finding on the state’s intentions and its interests.

c. *Dean Milk Co. v. City of Madison* (1951)

In 1951, the Supreme Court decided another milk case, *Dean Milk Co. v. City of Madison*.¹⁰⁶ In *Dean Milk*, the City of Madison banned the sale of milk in the city unless the milk was bottled within

⁹⁸ 336 U.S. 525, 526–27 (1949).

⁹⁹ *Id.* at 530–31, 538 (“[T]he state may not use its admitted powers to protect the health and safety of its people as a basis for suppressing competition.”).

¹⁰⁰ *Id.* at 538 (quoting *Buck v. Kuykendall*, 267 U.S. 307, 315 (1925)).

¹⁰¹ *Id.* at 539.

¹⁰² *Id.* at 564 (Frankfurter, J., dissenting) (refusing to join the majority because he could not “agree in treating what is essentially a problem of striking a balance between competing interests as an exercise in absolutes”). Joined by Justice Murphy, Justice Black separately dissented, concluding that there was no discrimination, and that, on balance, the state’s interest should have prevailed. *Id.* at 549 (Black, J., dissenting).

¹⁰³ Because a state’s interest in ensuring its residents a steady supply of wholesome milk is so strong, the Supreme Court has accepted stringent regulation of the milk industry, including price controls. *Id.* at 529.

¹⁰⁴ *Id.* at 566 (Frankfurter, J., dissenting) (distinguishing state regulation of “competition from whatever source,” which is permitted under the dormant Commerce Clause, from regulation of “out-of-state competition,” which is not).

¹⁰⁵ *Id.* at 570 (Frankfurter, J., dissenting).

¹⁰⁶ 340 U.S. 349 (1951).

five miles of Madison’s central square.¹⁰⁷ Although the ordinance did not explicitly target interstate commerce—and many Wisconsin dairy farmers were also disadvantaged—an Illinois milk distributor argued that the ordinance nevertheless violated the dormant Commerce Clause. Madison responded that the ordinance promoted a legitimate state interest, namely “convenient, economical and efficient plant inspection.”¹⁰⁸ But the Supreme Court held that the ordinance had the “practical effect” of “exclud[ing] from distribution in Madison wholesome milk produced and pasteurized in Illinois.”¹⁰⁹ In this case, physical distance to the Madison town square operated as a proxy to discriminate against interstate commerce.¹¹⁰ The Court concluded that by limiting milk sold in the city to only milk bottled at a short distance from the city center, Madison—and by extension Wisconsin—discriminated against milk from other states.¹¹¹ *Dean Milk* featured narrow tailoring: because the city had available to it “reasonable [and] nondiscriminatory alternatives” to satisfy “its unquestioned power to protect the health and safety of its people,” the Supreme Court held that the ordinance was not justified.¹¹² Such more narrowly tailored alternatives would have included a requirement that milk from points farther away be inspected to the same quality standards as those applicable in Madison.¹¹³

d. *Bendix Autolite Corp. v. Midwesco Enterprises, Inc.* (1988)

*Bendix Autolite Corp. v. Midwesco Enterprises, Inc.*¹¹⁴ involved a challenge to an Ohio statute that tolled the statute of limitations for claims against out-of-state corporations that had not designated an agent for service.¹¹⁵ The Supreme Court noted that the challenged statute imposed a heavy burden on interstate commerce.¹¹⁶ The Ohio

¹⁰⁷ *Id.* at 350–51, 355.

¹⁰⁸ *Id.* at 352.

¹⁰⁹ *Id.* at 354.

¹¹⁰ Although the Court did not describe the challenged regulation in terms of tying, the regulation conditioned one economic activity in the city (selling milk) upon the economic actor’s performance of additional economic activity in the city (inspection). *See id.* at 354–55.

¹¹¹ *Id.* at 354.

¹¹² *Id.*

¹¹³ *Id.* at 355 (noting that the city health inspector had suggested this option to the city based on a federal “Model Milk Ordinance”).

¹¹⁴ 486 U.S. 888 (1988).

¹¹⁵ *Id.* at 889–90.

¹¹⁶ *Id.* at 891 (the nature of the burden was that an out-of-state company had to either indefinitely toll the statute of limitations or indefinitely subject itself to suit in Ohio on any cause of action).

statute imposed a single-state burden—the adoption by other states of a tolling statute identical to Ohio’s would do nothing to reduce the burden Ohio imposed on interstate commerce.

Although it did not cite *Pike*, in deciding *Bendix*, a majority of the Supreme Court engaged in balancing.¹¹⁷ It compared the burden Ohio imposed on interstate commerce to Ohio’s interest in enabling its residents to serve process on foreign corporations. The Court held that the challenged statute added little to Ohio’s long-arm statute, and therefore the burden it imposed on interstate commerce could not be justified under the dormant Commerce Clause.¹¹⁸ One may agree or disagree with the outcome in *Bendix*; we review it here to emphasize that, even though it did not expressly cite *Pike*, the *Bendix* Court used balancing to decide the case.

e. C & A Carbone, Inc. v. Town of Clarkstown (1994)

Like milk, waste disposal has generated many dormant Commerce Clause challenges. In the 1994 case *C & A Carbone, Inc. v. Town of Clarkstown*,¹¹⁹ a majority of the Supreme Court held that a New York town violated the dormant Commerce Clause by requiring local companies to process solid waste at a particular commercial facility. The town had granted the commercial facility a monopoly to process local waste at above-market prices as part of a deal under which the monopolist would build the processing plant and later transfer it to the town for one dollar.¹²⁰ A majority of the Court held the arrangement violated the dormant Commerce Clause because it “deprive[d] out-of-state businesses of access to a local market”¹²¹ and “squelche[d] competition.”¹²² Although the town had a legitimate, nonprotectionist, reason for granting the monopoly, namely, it was a way to fund the construction of a processing plant that would be transferred to the town, the Court held that the town could have achieved its goal through less protectionist measures, such as taxation.¹²³ Three

¹¹⁷ See *id.* at 897 (Scalia, J., concurring) (citing *Pike* and describing the majority opinion as “[h]aving evaluated the interests on both sides as roughly as this, the Court then proceeds to judge which is more important. This process is ordinarily called ‘balancing.’”).

¹¹⁸ *Id.* at 893–94 (majority opinion).

¹¹⁹ 511 U.S. 383 (1994).

¹²⁰ *Id.* at 386–87.

¹²¹ *Id.* at 389.

¹²² *Id.* at 392.

¹²³ *Id.* at 393–94. The majority held the challenged ordinance to be discriminatory, but Justice O’Connor pointed out that it was not facially so, since all of the town’s waste had to be processed by the monopolist. See *id.* 405–06 (O’Connor, J., concurring) (concluding that the ordinance was invalid under *Pike*).

dissenting justices concluded that the ordinance should have been upheld because the processing facility was so closely related to the town's governing function.¹²⁴

f. Lloyd A. Fry Roofing Co. v. Wood (1952)

In contrast with the facially neutral cases just discussed, which involved obvious protectionist impacts, rules that impose only incidental single-state burdens and do not involve protectionist intent typically survive dormant Commerce Clause review. For example, in 1952 in *Lloyd A. Fry Roofing Co. v. Wood*,¹²⁵ the Supreme Court upheld a facially neutral state truck-licensing regime that required “driver-owners to do nothing except apply for a permit.”¹²⁶ Although the permitting regime involved what we would call an asymmetrical single-state burden on interstate commerce,¹²⁷ the Supreme Court held that the burden was justified because it enabled the state to “properly apply [its] valid police, welfare, and safety regulations to motor carriers using its highways.”¹²⁸ In other cases, the Supreme Court upheld regulations, despite the asymmetric burdens they imposed on interstate commerce, either because the asymmetric impact on interstate commerce was only incidental or because the burden was justified by the regulatory interest.

3. Understanding Single-State Cases

Balancing in some single-state cases is easy because one side of the scale—either adverse impact on interstate commerce or legitimate state interest—is essentially empty. For example, facially discriminatory rules almost never survive dormant Commerce Clause review for lack of a legitimate state interest in the discriminatory rule. Similarly, in *Hood*, a majority of the Court ultimately rejected the legitimacy of New York's proffered state interest, which was to reduce competition.¹²⁹ Such reasoning is equivalent to concluding that the state had no legitimate interest to weigh against the burden it imposed on inter-

¹²⁴ *Id.* at 419 (Souter, J., dissenting).

¹²⁵ 344 U.S. 157 (1952).

¹²⁶ *Id.* at 161; *id.* at 163 (upholding the regulation).

¹²⁷ That is, the cost to comply did not depend on the rules of any other state, and in particular, the cost to comply would not decrease if other states adopted the same rule.

¹²⁸ *Fry Roofing*, 344 U.S. at 161; *see also* *California v. Thompson*, 313 U.S. 109, 111, 116 (1941) (upholding a \$1 licensing fee and \$1000 bond requirement).

¹²⁹ *H. P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 542 (1949) (“[H]ere the challenge is only to a denial of facilities for interstate commerce upon the sole and specific grounds that it will subject others to competition and take supplies needed locally, an end, as we have shown, always held to be precluded by the Commerce Clause.”).

state commerce. Other *Pike* balancing cases are likewise easy to resolve because the burden side of the balancing scale is essentially empty, such that any legitimate state interest can outweigh it. This is true of de minimis asymmetrical burdens on interstate commerce, such as the registration requirement in *Fry Roofing*.¹³⁰

The remainder of cases involve more careful review. For example, regulations that impose significant asymmetrical burdens—such as the tying regulation in *Pike* or the statute of limitations in *Bendix*—can only be justified by legitimate state interests that cannot be satisfied via less burdensome regulation. Thus, it should come as no surprise when the Supreme Court strikes down regulations—such as those in *Dean Milk* and *Carbone*—that completely close the state’s market to out-of-state competition. The Court upholds such stringent rules only in rare cases, as when needed to prevent contagion that cannot be stopped by other means.¹³¹ Other cases involve close judgment calls. Although a majority of the Court in *Hood* thought that New York’s refusal to grant a milk-depot permit to an out-of-state milk buyer was motivated by an illegitimate state interest—namely protectionism that would inspire retaliation—three dissenters regarded the state as motivated by an intent to stabilize competition in a way that did not impermissibly target out-of-state interests. Cases like *Hood* frustrate observers because it is difficult to predict their outcomes.¹³² Likewise, in his concurrence in *Bendix*, Justice Scalia observed that the interests on each side of the *Pike* balancing scale were “incommensurate,” and “an opinion could as persuasively have been written coming out the opposite way.”¹³³ This Article will have more to say about *Pike* balancing in Part III, after we introduce the notion of mismatches.

¹³⁰ See *Fry Roofing*, 344 U.S. at 162 (citing precedent for the conclusion that “a state can regulate so long as no undue burden is imposed on interstate commerce, and that a mere requirement for a permit is not such a burden”).

¹³¹ Compare *Maine v. Taylor*, 477 U.S. 131, 151–52 (1986) (finding complete ban on imported baitfish was justified to prevent introduction of parasites and invasive species because no less restrictive means would be effective), with *R.R. Co. v. Husen*, 95 U.S. 465, 473–74 (1877) (precluding exclusion of out-of-state cattle to prevent contagion because less restrictive means, including quarantines and inspections, were available).

¹³² See, e.g., Regan, *supra* note 16, at 1262 (“I am not certain *Hood* was correctly decided or, if it was, what is the best analysis.”).

¹³³ *Bendix Autolite Corp. v. Midwesco Enters., Inc.*, 486 U.S. 888, 897 (Scalia, J., concurring).

C. *Mismatch Burdens and Bibb Balancing*

We now consider mismatches.¹³⁴ The defining feature of a mismatch is that the presence or absence of similar regulation by *other states* affects the cost to comply with the first state's rule. Put simply, mismatch burdens arise from *differences* among states' regulations, and they either increase costs for cross-border, but not in-state, economic actors or strip out-of-state economic actors of comparative advantages they otherwise would possess.

Some dormant Commerce Clause concerns are common to both single-state and mismatch cases, whereas others are unique to mismatch cases. As with single-state cases, mismatches may raise questions about intentional protectionism. That is, mismatches may be designed deliberately to exclude out-of-state products or services or to otherwise increase costs for out-of-staters, and concerns about intentional protectionism may be present even when states also seem to have good reasons (e.g., safety or consumer protection) for regulating. When mismatches display intentional protectionism, the Court resolves them on that basis alone. But the Court may also closely scrutinize mismatch cases *even when it finds no protectionist intent*. In such cases, the Court employs what we call *Bibb* balancing. Unlike *Pike* balancing, *Bibb* balancing employs external benchmarks consisting of *other states'* laws as a baseline for evaluating the challenged state's rule. This approach is inevitable; mismatch burdens must be measured against other states' laws because the nature of a mismatch burden is that it arises from regulatory diversity.

1. *Cases*

a. *Intentionally Protectionist Mismatches*

When states enact regulatory mismatches with protectionist intent, courts have precluded them for that reason.¹³⁵ In this respect, mismatch and single-state cases are similar. Such cases pose the problem of establishing intent, but this problem is common to both single-state and mismatch cases.

¹³⁴ In general, our selection of cases is meant to be representative, rather than comprehensive, of the problem of mismatches.

¹³⁵ See, e.g., *J. R. Brooks & Son, Inc. v. Reagan*, No. C-71-1311 SC, 1973 U.S. Dist. LEXIS 15732, at *8, *20 (N.D. Cal. Sept. 18, 1973) (precluding an intentionally protectionist mismatch).

i. *Florida Lime & Avocado Growers, Inc. v. Paul* (1963)

For example, in *Florida Lime & Avocado Growers, Inc. v. Paul*,¹³⁶ California prohibited the shipment within California of avocados that did not meet a minimum fat threshold.¹³⁷ Florida's use of federal ripeness standards, which relied on picking date and fruit size, created a mismatch with California's use of fat content.¹³⁸ California defended the fat-content rule as needed to ensure ripeness, but Florida avocado growers complained that Florida avocado varieties were unlikely to reach California's prescribed minimum fat content, even when fully ripe according to federal standards.¹³⁹ Although California did not facially discriminate against Florida avocados, there was a question of whether California used fat content as a discriminatory proxy.¹⁴⁰ The trial record in *Florida Lime* did not enable the Supreme Court to conclude that California had protectionist intent to exclude Florida avocados. This was not only because the trial record contained conflicts and questions regarding the admissibility of certain evidence,¹⁴¹ but also because the trial court assumed, apparently contrary to fact, that at the time California enacted the challenged regulation "California growers faced no meaningful competition from Florida growers."¹⁴²

To get clarity on this question, the Supreme Court remanded the case for further fact finding.¹⁴³ The Court also confirmed that even if the regulation was not adopted for protectionist motives, given its disproportionate effect on Florida avocados, "the continued application" of the regulation might discriminate against or unduly burden or interstate commerce,¹⁴⁴ in a manner that outweighed what the Court regarded as California's legitimate interest in ensuring the ripeness of

¹³⁶ 373 U.S. 132 (1963).

¹³⁷ *Id.* at 133–34.

¹³⁸ *Id.* at 139.

¹³⁹ *Id.* at 134–35 (federal standards were based on days of maturity).

¹⁴⁰ *Florida Lime* is a mismatch case because, if all states implemented California's fat-content rule, then farmers would adjust to that regulation, and farmers in Florida would grow either no avocados or only avocados that could meet California's standard, which would also be Florida's standard. Thus, under conditions of uniform rules, the asymmetrical burden on interstate commerce would disappear. *See id.* at 133–134.

¹⁴¹ *Id.* at 155.

¹⁴² *Id.* at 153 n.19 (noting that this assumption was questionable because there not only "appear[ed] to have been vigorous competition" between the two states, but also because Florida growers "immediately and vigorously protested" the passage of the fat-content rule, and a U.S. senator representing Florida filed a complaint with the Department of Agriculture).

¹⁴³ *Id.* at 136–37. *See id.* at 154 (noting that the district court's evidentiary rulings had created confusion in the record).

¹⁴⁴ *Id.* at 153–54.

avocados for California consumers.¹⁴⁵ Interestingly, four dissenting justices would have held that federal avocado ripeness standards preempted conflicting California rules, in part on the grounds that a goal of the Secretary of Agriculture in prescribing national standards was to avoid “[l]ack of uniformity [that] tends to obstruct commerce [and] to divide the nation into many markets.”¹⁴⁶ Although there is no published case on remand, in a subsequent case challenging the same regulation, a three-judge California district court precluded the fat-content rule on the grounds that it operated “as an embargo against Florida-grown avocados” that could not be justified by California’s consumer-protection interests.¹⁴⁷ In striking the law, the panel underscored extensive evidence of intentional protectionism on the part of the California legislature, and it pointed to—as a less discriminatory alternative—the federal picking-date and size rules that Florida used.¹⁴⁸

ii. *Hunt v. Washington State Apple Advertising Commission* (1977)

In 1977, the Supreme Court decided on the merits another case involving what the out-of-state challenger charged was an intentionally protectionist mismatch. In *Hunt v. Washington State Apple Advertising Commission*,¹⁴⁹ North Carolina had a rule that required apple shipping containers to bear only either federal quality gradings or no grades at all; such containers could not bear grades from other states’ regulatory regimes.¹⁵⁰ North Carolina’s requirement was “unique in

¹⁴⁵ *Id.* at 154 (noting that “[o]ther state regulations raising similar problems have been found to be discriminatory or burdensome notwithstanding a legitimate state interest in some form of regulation—either because they exceeded the limits necessary to vindicate that interest or because they unreasonably favored local producers at the expense of competitors from other States”) (citation omitted). Note, however, that the dissenters emphasized that there was no claim by California that the regulation advanced health or protected consumers against fraud or deceptive practices. *See id.* at 161 n.3 (White, J. dissenting).

¹⁴⁶ *Id.* at 169 (White, J., dissenting).

¹⁴⁷ *J. R. Brooks & Son, Inc. v. Reagan*, No. C-71-1311 SC, 1973 U.S. Dist. LEXIS 15732, at *8 (N.D. Cal. Sept. 18, 1973). The case involved a fourteen-day trial in which the court took evidence of asymmetrical effect and protectionist intent. Among other facts, the panel concluded that maintenance of the fat-content regulation was “the result of pressure from the California avocado industry, for the purpose, inter alia, of excluding competition from Florida avocados in California markets.” *Id.* at *14–15 (holding that California’s interest could be served by adopting the federal standards of ripeness, which were based on size and harvest date).

¹⁴⁸ *Id.* at *10–11.

¹⁴⁹ 432 U.S. 333 (1977).

¹⁵⁰ *Id.* at 352.

the 50 States,”¹⁵¹ and specifically, it was different from grading standards applicable in Washington. Because Washington quality grading standards were stricter, they conferred a marketplace advantage on Washington apples.¹⁵² Indeed, the Washington Apple Commission, which brought the case, suggested that North Carolina adopted its rule barring other states’ labels specifically to strip Washington apples of their competitive advantage in the North Carolina market. The Commission insisted that the impact on Washington apples was “not an unintended byproduct” of the North Carolina regulation.¹⁵³ Although the Supreme Court acknowledged “some indications in the record”¹⁵⁴ that North Carolina sought to exclude or disadvantage Washington apples, the Court concluded that it “need not ascribe an economic protection motive to the North Carolina Legislature to resolve this case.”¹⁵⁵

Instead, the Court noted that North Carolina’s rule would require Washington growers to either repack their apples or to “obliterate the printed labels on containers shipped to North Carolina.”¹⁵⁶ The Court thus took Washington law as a given, and framed North Carolina law as a deviation from it. Put differently, the Court used Washington’s regime as a baseline for measuring the burden that the North Carolina regime imposed on interstate commerce. The use of other states’ regimes as a baseline in measuring the burden on interstate commerce imposed by the challenged state’s regulation is what we mean when we characterize the Supreme Court as using an “external benchmark” in mismatch cases.

Citing *Pike*, the Court weighed against this burden North Carolina’s proffered interest, which was to protect consumers from confusion arising from a multiplicity of different apple grading standards.¹⁵⁷

¹⁵¹ *Id.* at 337.

¹⁵² *Id.* at 350–51 (noting that the market preferred Washington’s grading system to the federal grading system because Washington’s displayed “greater consistency, [due to] its emphasis on color, and its supporting mandatory inspections”).

¹⁵³ *Id.* at 352.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ North Carolina required labels on closed containers of apples to either have the applicable USDA grade or no grade shown at all. This meant that Washington growers could not display Washington’s own unique state grade on apple containers they shipped to North Carolina. Because Washington growers packed their apples into prelabeled containers before shipping to various states, North Carolina’s “unique regulation would have required Washington growers to obliterate the printed labels on containers shipped to North Carolina, thus giving their product a damaged appearance,” or face the significant logistical and financial cost of repacking apples specifically for sale in North Carolina. *Id.* at 337–38.

¹⁵⁷ *See id.* at 350. North Carolina cited the fact that seven states used their own unique

The Court did not think the North Carolina statute would advance North Carolina's legitimate¹⁵⁸ consumer-protection goal.¹⁵⁹ And moreover, the Court reasoned that North Carolina buyers would experience less confusion from Washington's more precise labeling regime than from North Carolina's preferred alternative.¹⁶⁰ Such reasoning weighs not only the burden, but also North Carolina's regulatory interest against a baseline generated by Washington's labeling regime. Finally, the Court pointed to less restrictive alternatives by which North Carolina could achieve its consumer-protection goals, such as allowing Washington growers to display both Washington and federal grades.¹⁶¹

Ultimately, the *Hunt* Court engendered doctrinal confusion by mixing the discrimination and undue burden strands of dormant Commerce Clause when it concluded that "the challenged statute has the practical effect of not only burdening interstate sales of Washington apples, but also discriminating against them."¹⁶² We may be able to attribute this mixed legal conclusion to evidence that North Carolina intentionally created the mismatch to exclude Washington apples.¹⁶³ A better way to understand *Hunt* under the balancing standard might be to say that the burden on interstate commerce arising from the mismatch easily outweighed North Carolina's dubious¹⁶⁴—or even impermissibly protectionist—interest in its labeling rule.

b. Nonprotectionist, or Arguably Nonprotectionist, Mismatches

When the Supreme Court cannot resolve a mismatch case based on intentional protectionism, it follows one of two major doctrinal approaches. Under the first, it summarily upholds the regulation. We call this approach *noninterventionist* because the Court justifies it by refer-

apple grading system and argued that lack of uniformity could confuse the consumer as to the apple's actual quality. *Id.* at 349.

¹⁵⁸ *Id.* at 350 (referring to "health and consumer protection" as legitimate goals).

¹⁵⁹ *Id.* at 353 (North Carolina's rule can "hardly be thought to eliminate the problems of deception and confusion").

¹⁶⁰ *Id.*

¹⁶¹ *Id.* at 354.

¹⁶² *Id.* at 350, 352 (noting the challenger's argument that the regulation's "discriminatory impact on interstate commerce was not an unintended byproduct").

¹⁶³ *Id.* at 352 (acknowledging "some indications in the record" to the effect that North Carolina intentionally discriminated against Washington apples).

¹⁶⁴ North Carolina's consumer protection interest was dubious both because the state sought to protect sophisticated bulk apple buyers who could be expected to know their business, and because there was no evidence of actual market confusion for the sixty years of operation of the Washington grading regime. *Id.* at 338.

ence to limits on its own institutional powers. The second approach, which is *interventionist*, involves *Bibb* balancing. Under *Bibb* balancing, the Court either precludes or sustains the challenged law after analysis. Both the interventionist and noninterventionist approaches appear to be alive and well, and which will prevail in a given case is unpredictable.

i. Nonintervention

1. State Highway Department v. Barnwell Bros., Inc. (1938)

In 1938, in *South Carolina State Highway Department v. Barnwell Bros., Inc.*,¹⁶⁵ South Carolina adopted truck weight and width limits that were stricter than those of neighboring states.¹⁶⁶ Challengers argued that South Carolina's rule unconstitutionally burdened interstate commerce. The South Carolina regulation imposed a mismatch burden; specifically, if all states had the same limits as South Carolina, truckers everywhere would comply with those limits, and so South Carolina's rule would not disproportionately burden (or exclude) out-of-state trucks.

South Carolina argued that it needed strict weight and width limits to protect its roads from wear.¹⁶⁷ Even though the district court found the limits were an unreasonable means to preserve highways and conferred no safety advantage,¹⁶⁸ and even though the Supreme Court acknowledged that the vast majority of interstate trucking exceeded the South Carolina limits and therefore would be shut out of South Carolina,¹⁶⁹ the Supreme Court nevertheless unanimously¹⁷⁰ upheld the regulation on the grounds that state highways were a particularly local concern.¹⁷¹ Expressly rejecting judicial balancing¹⁷² to resolve "non-discriminatory"¹⁷³ burdens, the Supreme Court applied rational-basis review.¹⁷⁴ Unlike in some other cases this Article discusses, a perceived need for national uniformity in highway regula-

¹⁶⁵ 303 U.S. 177 (1938).

¹⁶⁶ *Id.* at 179.

¹⁶⁷ *Id.* at 192–93.

¹⁶⁸ *Id.* at 183.

¹⁶⁹ *See id.* at 182.

¹⁷⁰ The decision was 7–0. Justices Cardozo and Reed did not take part. *Id.* at 196.

¹⁷¹ *Id.* at 190.

¹⁷² *Id.* at 191–92 (noting that the constitutionality of such highway regulation "is not to be determined by weighing in the judicial scales the merits of the legislative choice and rejecting it if the weight of evidence presented in court appears to favor a different standard").

¹⁷³ *Id.* at 190.

¹⁷⁴ *Id.* at 189 ("[S]o long as the state action does not discriminate, the burden is one which the Constitution permits because it is an inseparable incident of the exercise of a legislative

tions played no role in *Barnwell*; indeed, the Court observed that precluding South Carolina’s rule would be tantamount to “forc[ing] the states to conform to standards which Congress might, but has not adopted.”¹⁷⁵ Thus, if uniform regulation of highways were needed, Congress, not the Supreme Court, should impose them.¹⁷⁶

2. *Moorman Manufacturing Co. v. Bair* (1978)

*Moorman Manufacturing Co. v. Bair*¹⁷⁷ was a 1978 case involving a state income tax. Before examining *Moorman*, however, we offer a word of qualification. In 2015, in *Comptroller of the Treasury of Maryland v. Wynne*,¹⁷⁸ the Supreme Court confirmed that mismatches in tax bases (as opposed to mismatches in tax compliance rules), do not violate the dormant Commerce Clause as long as they are what the Court calls “internally consistent” because internally consistent taxes do not asymmetrically burden interstate commerce.¹⁷⁹ Forty years ago, however, when the Supreme Court decided *Moorman*, the *Wynne* view of tax mismatches had not yet been developed. Thus, when judges, litigants, and commentators thought about mismatched tax bases, particularly when such mismatches produced double taxation, they generally assumed that mismatches produced asymmetric effects—that is, that they imposed greater costs on interstate than in-

authority.”). *Id.* at 192 (applying rational-basis review in the absence of any finding of discrimination).

¹⁷⁵ *Id.* at 187.

¹⁷⁶ *Id.* at 190 (deciding that burdens arising from conflicts may require “legislation designed to secure uniformity or in other respects to protect the national interest in the commerce, [and] curtail to some extent the state’s regulatory power. But that is a legislative, not a judicial function, to be performed in the light of the Congressional judgment of what is appropriate regulation of interstate commerce . . .”).

¹⁷⁷ 437 U.S. 267, 283 (1978).

¹⁷⁸ 575 U.S. 542 (2014).

¹⁷⁹ An internally consistent rule is one that, if adopted by all the states, would not result in higher taxation for interstate than for in-state commerce. *Id.* at 560 (2015). The Court is correct, as an economic matter, that—even when they lead to double taxation—tax base mismatches do not asymmetrically burden interstate commerce as long they are internally consistent. The reasons are technical and explained in our earlier work. See Knoll & Mason, *supra* note 73.

The Court recently gave an example of a tax-base mismatch that would not violate the dormant Commerce Clause. The Court stated that if one state taxed solely on the basis of residence—that is, it taxed its residents on their income regardless of where they earned that income—and another state taxed solely on the basis of source—that is, it taxed all income earned in the state regardless of where the owner of the income resided—then the simultaneous application of those two regimes to a single person engaged in interstate commerce would not violate the dormant Commerce Clause, notwithstanding resulting double taxation (or nontaxation). See *Wynne*, 575 U.S. at 565–66. For more on why this result makes sense as an economic matter—namely, because it would impose no asymmetric burden on interstate commerce—see Knoll & Mason, *supra* note 73.

state commerce.¹⁸⁰ Although the Supreme Court ultimately adopted a more sophisticated view of tax mismatches in *Wynne*—one that is supported by economic analysis—this Article nevertheless discusses *Moorman* because it provides insights into how justices think about mismatches that they perceive as imposing asymmetrical burdens on interstate commerce.¹⁸¹

Understanding *Moorman* also requires a little background on state taxation. The definition of income for state tax purposes generally does not generate mismatches because the states use harmonized rules; specifically, they borrow the federal definition of income.¹⁸² But conflicts arise when states divide that income among themselves. For example, states use formulas to calculate the portion of a company's income that is taxable in each state; those formulas account for the relative presence in the state of the company's factors of production, such as payroll, property, and sales. In *Moorman*, a corporate taxpayer complained that it suffered unconstitutional double taxation when Iowa used a single-factor-sales formula at a time when all other states used a particular three-factor formula dubbed the Massachusetts formula.¹⁸³

In a 6–3 decision, the *Moorman* Court acknowledged that diversity in tax-apportionment formulas could lead to double taxation, but it concluded that responsibility for any resulting burden was not attributable solely to any one state.¹⁸⁴ Different states adopted different tax apportionment rules. Iowa used sales; all other states used the Massachusetts formula. As a result, the Court regarded multiple states to be responsible for the mismatch.¹⁸⁵ Because the overlap could have been cured by Iowa adopting the Massachusetts formula, or by other states “us[ing] the Iowa formula,”¹⁸⁶ the Court could not conclude that “the Iowa formula was at fault for whatever overlap may have ex-

¹⁸⁰ They did not yet understand that although internally inconsistent mismatches were protectionist, internally consistent mismatches are not. See Knoll & Mason, *supra* note 73, at 312 (explaining which types of tax mismatches are protectionist).

¹⁸¹ Incidentally, although it played no role in the decision in *Moorman*, the challenged regime in *Moorman* was internally consistent, and therefore also would be upheld under the Court's post-*Wynne* jurisprudence.

¹⁸² See Ruth Mason, *Delegating Up: State Conformity with the Federal Tax Base*, 62 DUKE L.J. 1267, 1269 (2013).

¹⁸³ *Moorman Mfg. Co. v. Bair*, 437 U.S. 267, 271–72 (1978); *id.* at 283 (Powell J., dissenting) (noting that forty-four out of forty-five states with income taxes used the three-factor formula).

¹⁸⁴ *Id.* at 270, 276 (majority opinion).

¹⁸⁵ *Id.* at 277 (“[W]e could not accept appellant's argument that Iowa, rather than Illinois, was necessarily at fault in a constitutional sense.”).

¹⁸⁶ *Id.*

isted.”¹⁸⁷ The Court specifically refused to use the dominant Massachusetts formula as a benchmark for evaluating Iowa’s rule, reasoning that doing so would require “the prevalent practice [to] be endorsed as the constitutional rule.”¹⁸⁸ The Court resisted such endorsement, even though it would have prevented double taxation, because the Constitution is “neutral with respect to the content of any uniform rule.”¹⁸⁹ Endorsing the Massachusetts formula as a nationwide rule would have involved “extensive judicial lawmaking.”¹⁹⁰ Although conceding that there may be “an overriding national interest in uniformity” in taxation, the majority disagreed that any uniform rule could be selected by the Supreme Court.¹⁹¹ Instead, it was to Congress, “and not this Court, that the Constitution has committed such policy decisions.”¹⁹²

Like the Court’s holding in *Barnwell*, the majority’s reasoning in *Moorman* was that any burden on interstate commerce arising from legal diversity was not cognizable under the dormant Commerce Clause. Although forty years separated *Moorman* and *Barnwell*, and although the *Moorman* Court did not rely on *Barnwell*, the reasoning in the two cases is similar in the sense that the Supreme Court would not attribute the burden arising from a regulatory mismatch to the challenged state alone—even when the challenged state had an outlier rule. The Court refused to use other states’ laws as a benchmark, and it refused to endorse a nationally uniform rule. In contrast, two dissenters in *Moorman* cited *Pike* and *Bibb* to argue that the Supreme Court should have eliminated the mismatch by precluding Iowa’s outlier tax rule.¹⁹³

ii. Intervention

When mismatch cases do not involve clear protectionism, the Court takes one of two approaches. Either it summarily upholds the mismatch on the grounds that doing otherwise would exceed its competence, as in *Barnwell* and *Moorman*, or it engages in more meaningful dormant Commerce Clause review—using *Bibb* balancing as distinct from *Pike* balancing—as in the cases discussed in this Section.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.* at 279.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.* at 278.

¹⁹¹ *Id.* at 280.

¹⁹² *Id.*

¹⁹³ *Id.* at 295–96 (Powell, J., dissenting) (citing *Bibb*); *id.* at 289 (Powell, J., dissenting) (citing *Pike*).

I. *Southern Pacific v. Arizona* (1945)

Our first interventionist case, *Southern Pacific Co. v. Arizona ex rel. Sullivan*,¹⁹⁴ sharply contrasts with *Barnwell*. In *Southern Pacific*, the Supreme Court considered Arizona's facially neutral regulation that, for safety reasons, placed upper bounds on the lengths of passenger and freight trains.¹⁹⁵ Neighboring states had no (or less restrictive) train-length standards, so challengers complained that the Arizona rule inhibited interstate commerce by requiring interstate train operators to remove cars at the border.¹⁹⁶ This is a mismatch burden because if all states adopted Arizona's train-length rules, then all train operators in all states would comply with the Arizona rule everywhere, and cross-border train operators would face no special costs that in-state operators did not.¹⁹⁷ For example, there would be no border stops to remove train cars.

The *Southern Pacific* Court specifically identified the relevant burden as one associated with state regulatory diversity, and the Court noted that such diversity "impair[ed]" the "uniformity of efficient railroad operation."¹⁹⁸ Moreover, the Court singled out Arizona's practice as restrictive compared to the rules of other states, because, at the time, many other states had no length limits at all, so it was "standard practice" to use more train cars than the Arizona law permitted.¹⁹⁹ *Southern Pacific* marks a sharp contrast with the view expressed by the *Barnwell* Court that the content of other states' rules did not matter.²⁰⁰

Although the *Southern Pacific* Court employed balancing, the way it measured the burden and benefits of the Arizona regulation was different than in the single-state cases, such as *Pike*.²⁰¹ Acknowl-

¹⁹⁴ 325 U.S. 761 (1945).

¹⁹⁵ *Id.* at 763.

¹⁹⁶ *Id.* at 774.

¹⁹⁷ The mismatch burdens arose from differences between Arizona's rule and other states' rules (or, in this case, the absence of rules in other states). If all other states had the same rule as Arizona, then trains everywhere would comply with it, and so trains crossing Arizona's border would face no burden that trains traveling exclusively within Arizona did not also face. Because the burden would disappear upon harmonization, it is a mismatch burden.

¹⁹⁸ *Southern Pacific*, 325 U.S. at 773.

¹⁹⁹ *Id.* at 771.

²⁰⁰ *S.C. State Highway Dep't v. Barnwell Bros., Inc.*, 303 U.S. 177, 195 (1938) ("The fact that many states have adopted a different standard is not persuasive.").

²⁰¹ *Southern Pacific*, 325 U.S. at 768–69 ("[R]egulation of local matters may also operate as a regulation of commerce, in which reconciliation of the conflicting claims of state and national power is to be attained only by some appraisal and accommodation of the competing demands of the state and national interests involved."). *Id.* at 783–84 (concluding the "state interest is out-

edging public safety as a compelling government interest, the Supreme Court concluded that Arizona attained only a “slight and dubious advantage”²⁰² in safety by implementing length limitations. And it concluded that the safety interest could not outweigh “the national interest in keeping interstate commerce free from interferences which seriously impede it and subject it to local regulation which does not have a uniform effect.”²⁰³ Thus, it was not the *absolute* effect of the Arizona rule on interstate commerce that mattered, but rather its effect *relative* to the rules—or lack thereof—of other states. In this way, the *Southern Pacific* Court weighed contingent interests on both sides of the balancing scale: it calculated the burden Arizona imposed on interstate commerce by reference to other states’ regulation (or lack thereof), and it evaluated Arizona’s improvement in safety relative to other states’ rules.²⁰⁴ Under this calculus, the Court concluded that the burden outweighed the state interest. The Court furthermore concluded that if safety concerns warranted train-length limits, only Congress could impose them.²⁰⁵ Justice Black dissented from the decision, arguing that it was improper for the Supreme Court to act as a “super-legislature”²⁰⁶ that second-guessed the safety judgments of the Arizona legislature.²⁰⁷

2. Bibb v. Navajo Freight Lines (1959)

Decided in 1959, *Bibb v. Navajo Freight Lines, Inc.*²⁰⁸ involved a challenge to an Illinois regulation requiring trucks to have curved

weighed by the interest of the nation in an adequate, economical and efficient railway transportation service, which must prevail”).

²⁰² *Id.* at 779.

²⁰³ *Id.* at 776.

²⁰⁴ *See, e.g., id.* at 778 (comparing Arizona’s accident record after it regulated train lengths to that of other states without regulation). *Id.* at 779 (contrasting other measures, such as headlight, caboose, and full-crew requirements, where the safety gains justified the burden on interstate commerce).

²⁰⁵ *Id.* at 781 (“[W]hen a state goes beyond safety measures which are permissible because only local in their effect upon interstate commerce, . . . the State will encounter the principle that such requirements, if imposed at all, must be [imposed] through the action of Congress which can establish a uniform rule.”). By contrast, in other cases in which the Supreme Court deemed train safety measures to be less burdensome, the Court permitted them. *See id.* at 782 (referencing prior cases in which the Court upheld train regulations requiring full crews, headlights, and more).

²⁰⁶ *Id.* at 788 (Black, J., dissenting).

²⁰⁷ *Id.* at 786 (noting also that Congress had considered imposing the same length limits that the Court now declared to confer inadequate safety benefits). Justice Douglas likewise dissented, on the grounds that “courts should intervene only where the state legislation discriminated against interstate commerce.” *Id.* at 795 (Douglas, J., dissenting).

²⁰⁸ 359 U.S. 520 (1959). The Court’s interventionist opinion in *Bibb* was drafted by Justice

mudflaps at a time when all other states either permitted or required straight mudflaps.²⁰⁹ The Supreme Court focused on the regulatory mismatch, identifying “the question [as] whether one State could prescribe standards for interstate carriers that would conflict with the standards of another State.”²¹⁰ As in *Southern Pacific*, the *Bibb* Court took those other states’ regulations as the benchmark in measuring the burden imposed by Illinois’s different rule. As a result, it attributed *exclusively to Illinois* the costs truckers incurred to stop at the border to weld on new mudflaps, even though those costs arose from regulatory diversity traceable to at least two states.²¹¹ The Supreme Court weighed this burden against Illinois’s proffered safety interest, but, citing findings by the district court, the Court held that the purported safety advantages of curved over straight mudflaps were insufficient to overcome the “need for national uniformity in the regulations for interstate travel.”²¹² The *Bibb* Court, like the *Southern Pacific* Court, thus weighed contingent interests on both sides of the balance scale; it calculated the burden imposed by the Illinois regulation against a baseline of other states’ regulations, and it weighed Illinois’s safety interest against a baseline of other states’ safety measures.²¹³

3. *Kassel v. Consolidated Freightways Corp. of Delaware* (1981)

In *Kassel v. Consolidated Freightways Corp. of Delaware*,²¹⁴ Iowa limited trucks on its highways to fifty-five or sixty feet in length, depending on the type of truck.²¹⁵ The rule faced a dormant Commerce Clause challenge because it was “out of step”²¹⁶ with those of many other states, which permitted sixty-five-foot trucks on their highways. In evaluating the challenge to the mismatched rule, the Supreme Court used external benchmarks. For example, in determining that the

Douglas, who fourteen years earlier dissented in *Southern Pacific*, arguing that the Court should not have intervened because the Arizona law was not discriminatory. *Id.* at 521.

²⁰⁹ *Id.* at 521–23.

²¹⁰ *Id.* at 526.

²¹¹ *Id.* at 524–25, 527.

²¹² *Id.* at 527 (quoting *Morgan v. Virginia*, 328 U.S. 373, 386 (1946)); *id.* at 530.

²¹³ The state relied on *Barnwell* to argue that “a federal court is precluded from weighing the relative merits of the contour mudguard against any other kind of mudguard.” *Id.* at 528. In rejecting this argument, the Supreme Court referred to the “equal footing” of the states, whose statutes “are of equal dignity when measured against the Commerce Clause.” *Id.* at 529.

²¹⁴ 450 U.S. 662 (1981).

²¹⁵ *Id.* at 665–66. Each limit applied to a different kind of truck. *Id.*

²¹⁶ *Id.* at 671.

burden on interstate commerce included the need to detour around Iowa or switch to smaller trucks, the Supreme Court implicitly used other states' preexisting regulations as a baseline.²¹⁷ The Court thus regarded Iowa alone as causing interstate truckers to incur switching and detour costs.²¹⁸ Iowa defended its rule on safety grounds, but in weighing the state's safety concerns, the Court again conducted a relative, not absolute, inquiry. Specifically, the Court used other states' regulations as a benchmark by comparing the safety of Iowa's rule to the safety of other states' rules.²¹⁹ Citing the trial court's findings, the Court concluded that the comparative safety benefit from Iowa's shorter length limits was "illusory."²²⁰ Moreover, the Court found that because the regulation would "bear[] disproportionately on out-of-state residents and businesses," it was not due the typical deference shown by courts to safety regulations.²²¹ In striking down the regulation, the Court also noted that exceptions to Iowa's truck length limits were "helpful to local interests," while burdening out-of-state interests, which raised suspicion that Iowa's regulation "may not have been designed to ban dangerous trucks, but rather to discourage interstate truck traffic."²²² Indeed, two concurring justices found the regulation protectionist. By contrast, citing *Barnwell*, three dissenters invoked the noninterventionist approach. They concluded that a court's role in dormant Commerce Clause cases was limited to determining whether the challenged regulation, "although rational, is merely a pretext for discrimination against interstate commerce."²²³

4. Minnesota v. Clover Leaf Creamery Co. (1981)

In 1981 in *Minnesota v. Clover Leaf Creamery Co.*,²²⁴ Minnesota banned the sale of milk in plastic containers because use of such containers "presents a solid waste management problem for the state, promotes energy waste, and depletes natural resources."²²⁵ On an evidentiary record it described as mixed, the trial court held that Minnesota adopted the regulation to advantage the Minnesota pulp wood

²¹⁷ See *id.* at 671, 674.

²¹⁸ See *id.* at 667, 671.

²¹⁹ *Id.* at 671; *id.* at 673 (citing studies and testimony comparing safety of fifty-five-foot to sixty-five-foot trucks).

²²⁰ *Id.* at 671.

²²¹ *Id.* at 676–77.

²²² *Id.* Iowa exempted from the regulation individuals and businesses in important border cities, which covered Iowa's ten largest cities. *Id.* at 676.

²²³ *Id.* at 692 (Rehnquist, J., dissenting).

²²⁴ 449 U.S. 456 (1981).

²²⁵ *Id.* at 457 (quoting MINN. STAT. § 116F.21 (1978) (repealed 1981)).

industry, which made materials used in paper milk cartons.²²⁶ The Minnesota Supreme Court, by contrast, found that although Minnesota passed the regulation for the legitimate purpose of “encouraging [] reuse and recycling of materials and reducing the amount and type of material entering the solid waste stream,” the regulation was not rationally related to achieving that purpose, and therefore the court struck the regulation under the Equal Protection Clause without reaching the dormant Commerce Clause.²²⁷

The Supreme Court reversed. On the equal protection claim, the Supreme Court concluded that the plastic container ban was rationally related to Minnesota’s environmental goals.²²⁸ The Supreme Court then turned to the dormant Commerce Clause and concluded, citing *Pike*, that “[e]ven granting that the out-of-state plastics industry is burdened relatively more heavily than the Minnesota pulpwood industry, we find that this burden is not ‘clearly excessive’ in light of the substantial state interest in promoting conservation of energy and other natural resources and easing solid waste disposal problems.”²²⁹ Interestingly, although the Supreme Court used external benchmarking to determine the burden of Minnesota’s rule—it compared Minnesota’s plastic-container ban to other states’ laws permitting plastic—it did not benchmark Minnesota’s environmental goals against the regulations of any other states. This choice may have been motivated by the difference in purposes animating Minnesota’s plastic ban as compared to other states’ packaging rules, which did not serve environmental goals. Ultimately, the Supreme Court held that the regulation was “nondiscriminatory” and that its burden on interstate commerce was small relative to Minnesota’s interest in protecting the environment by banning plastic jugs.²³⁰

Although he agreed that the statute survived equal protection challenge, Justice Powell dissented from the dormant Commerce Clause decision in *Clover Leaf*. He would have remanded the case to

²²⁶ *Id.* at 460.

²²⁷ *Clover Leaf Creamery Co. v. State*, 289 N.W.2d 79, 82 (Minn. 1979), *rev’d*, 449 U.S. 456 (1981); *see also Clover Leaf*, 449 U.S. at 463–64 (noting that the challengers had “produced impressive supporting evidence at trial to prove that the probable consequences of the ban on plastic nonreturnable milk containers will be to deplete natural resources, exacerbate solid waste disposal problems, and waste energy, because consumers unable to purchase milk in plastic containers will turn to paperboard milk cartons, allegedly a more environmentally harmful product”).

²²⁸ *Clover Leaf*, 449 U.S. at 459, 466.

²²⁹ *Id.* at 473; *see also Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970) (articulating “clearly excessive” standard for burdens on interstate commerce).

²³⁰ *Clover Leaf*, 449 U.S. at 472–74.

determine whether, as the trial court had found, the regulation was enacted with protectionist intent.²³¹ Also dissenting, Justice Stevens would have deferred to the factual findings of the lower courts, and therefore he concluded that the “the essential predicate for the majority’s conclusion that the ‘local benefits [are] ample to support Minnesota’s decision under the Commerce Clause,’ is absent.”²³²

2. *Understanding Mismatch Cases*

Recognizing the differences between single-state and mismatch cases does not enable us to explain the different outcomes across the mismatch cases in a satisfying way. In three out of four of the interstate transportation cases this Article discussed—all but *Barnwell*—the Court balanced, which led it to preclude outlier interstate transportation rules regarding train lengths, mudflaps, and truck lengths. In *Barnwell*, however, the Court upheld state regulations involving truck weight and widths without balancing their adverse effects on interstate commerce against the challenged states’ interests in enacting the regulations. Outcomes in the product-standards cases were also mixed. In *Hunt*, the Court held that the asymmetric burden on interstate commerce outweighed the state’s proffered consumer-protection interest; the *Hunt* Court did not take seriously the consumer-protection justification for North Carolina’s apple labeling rule, in part due to evidence that protectionism motivated the rule. Unsure of how to balance in *Florida Lime*, the Court remanded for a clearer determination of the state’s interest in the avocado fat-content rule, and specifically, whether the state adopted the rule for protectionist purposes. In contrast, where the Court, as with the plastic-container ban in *Clover Leaf*, was convinced of the state’s legitimate interests, it upheld deviating regulations notwithstanding their asymmetric burdens. In *Moorman*, the Court once again returned to the strong noninterventionist view it had expressed forty years earlier in *Barnwell* that it had no power to force a state to conform to the rules—here, the tax-apportionment rules—of other states.

Although separating out the mismatch cases from single-state cases does not enable us to explain the different outcomes across the mismatch cases in a satisfying way, it does enable us to draw several

²³¹ *Id.* at 476–77 (Powell, J., concurring in part and dissenting in part) (“[T]his Court has no basis for *inferring* a rejection of the quite specific factfindings by the trial court,” which included the trial court’s specific finding that the actual purpose of the regulation was to advantage the in-state pulpwood industry at the expense of nonresident commercial interests).

²³² *Id.* at 488 (Stevens, J., dissenting) (citation omitted) (quoting majority opinion).

clarifying conclusions. First, as with single-state cases, if protectionist legislative intent is evident in a mismatch case, then that intent, coupled with protectionist effect, is usually dispositive, notwithstanding the facial neutrality of the rule.²³³ This explains the ultimate preclusion by a California district court of the statute considered in *Florida Lime*. Arguably, the presence of protectionist intent also explains the result in *Hunt*. And even in cases like *Kassel* and *Clover Leaf*, where the Court went on to balance, some justices, having concluded that there was intentional protectionism, would have precluded the challenged regulation on that basis alone.²³⁴ Second, sometimes the Court intervenes to prevent mismatches, but other times, it does not. Depending upon your perspective, nonintervention in mismatch cases reflects judicial modesty or judicial abdication. This Article will have more to say on this topic later.²³⁵ Third, when it does balance in mismatch cases, to measure the extent of a mismatch burden, the Court has no choice but to look to the actual substantive laws applicable in other states. Mismatch burdens are *by definition* measured against other states' actual laws (or lack thereof) because the nature of a mismatch burden is that it arises from regulatory diversity.

III. THE SPECIAL PROBLEMS OF *BIBB* BALANCING

To highlight the differences between dormant Commerce Clause balancing in single-state cases and mismatch cases, we have used “*Pike* balancing” to refer only to balancing in single-state cases and “*Bibb* balancing” to refer to balancing in mismatch cases. Several critical insights emerge from our distinction between *Pike* and *Bibb* balancing. Specifically, single-state and mismatch cases are different and therefore should be—and are—treated differently by the Supreme Court. This Part explains how our new doctrinal gloss bears on old criticisms of dormant Commerce Clause analysis, namely that it is arbitrary and invites “judicial legislation.” To that end, this Part critically compares single-state and mismatch cases from four perspectives: (1) the initial decision whether or not the Court should intervene, (2) the selection of benchmarks against which to evaluate the burden on interstate commerce, (3) the tendency of preclusion in

²³³ This is the same reason that we did not find any mismatch cases that involved *facial* discrimination. If a case involved facial discrimination, it usually would be summarily precluded, and so the Court would not engage in fulsome balancing.

²³⁴ See *Kassel v. Consol. Freightways Corp.*, 450 U.S. 662, 685 (1981) (Brennan, J., concurring); *Clover Leaf*, 449 U.S. at 475–76 (Powell, J., concurring).

²³⁵ See *infra* Section III.A.

each type of case to result in judicial legislation, and (4) the number and complexity of interests that the Court must balance in each type of case. The goal of this Part is to acknowledge that, although both single-state and mismatch cases are open to criticism, the criticisms differ in each type of case. Most importantly, in several respects, mismatch cases are subject to additional and more significant criticisms than are single-state cases.

A. *Judicial Intervention or Nonintervention*

There appears to be broad—albeit not universal²³⁶—agreement that courts are entitled to intervene in single-state cases. This Section explains, however, that no such consensus exists regarding judicial intervention in mismatch cases. As a result, the approach to mismatches is unsettled, providing little guidance to lower courts as to how to resolve cases and little guidance to states regarding how to formulate their laws to survive dormant Commerce Clause review.

1. *Relative Consensus in Single-State Cases*

Compared to mismatch cases, there seems to be much less controversy surrounding judicial intervention in single-state cases. First, intervention in facial discrimination cases has deep support.²³⁷ Indeed, as a judge on the Tenth Circuit, now-Justice Gorsuch wrote “to the extent that there’s anything that’s uncontroversial about dormant commerce clause jurisprudence it may be this anti-discrimination principle, for even critics of dormant commerce clause doctrine often endorse it even as they suggest it might find a more textually comfortable home in other constitutional provisions.”²³⁸ Similarly, with respect to facially neutral single-state regulations, justices gener-

²³⁶ For example, Justice Thomas rejects the dormant Commerce Clause altogether, including in cases of facial discrimination. *See supra* note 18. Because he rejects the dormant Commerce Clause in its entirety, we cannot know whether Justice Thomas regards single-state cases differently from mismatch cases. In Justice Thomas’s view, the Court acts improperly when considering either type of case under the dormant Commerce Clause.

²³⁷ For discussion of the current Supreme Court justices’ views on discrimination doctrine, see *supra* note 51.

²³⁸ *See, e.g.,* *Direct Mktg. Ass’n v. Brohl*, 814 F.3d 1129, 1150 (10th Cir. 2016) (Gorsuch, J., concurring). Supreme Court justices use the terms “discrimination” and “protectionism” interchangeably. For discussion of this, see *supra* Section II.A. Justice Thomas is the most consistent dissenter from the view described by Justice Gorsuch. *United Haulers Ass’n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 352 (2007) (Thomas, J., concurring in the judgment) (referring to “the erroneous assumption that the Court must choose between economic protectionism and the free market. But the Constitution vests that fundamentally legislative choice in Congress.”).

ally seem to regard intervention as appropriate, and justices decide those cases from a steady normative perspective, one that promotes free trade.²³⁹ Consistent with the notion that the dormant Commerce Clause promotes free trade, analysis in cases involving facially neutral single-state regulation often reads as an attempt to “smoke out” protectionism.²⁴⁰

2. *Unsettled Approach to Mismatch Cases*

Although justices generally agree that “discriminatory” mismatches—mismatches that a state enacted to deliberately exclude or disadvantage interstate commerce compared to in-state commerce—should be struck down, no similar general agreement exists about other mismatch cases.²⁴¹ Specifically, justices disagree about whether the dormant Commerce Clause limits regulatory diversity when that diversity seems to be motivated by a legitimate state interest, rather than protectionism.

a. *Noninterventionist View*

Under the noninterventionist view, mismatches that do not involve intentional protectionism are subject to merely rational-basis review.²⁴² For noninterventionists, regulatory diversity is either normatively desirable—because, for instance, it promotes government efficiency, responsiveness, experimentation, and ultimately liberty²⁴³—or it is an inevitable concomitant of state autonomy that courts have no authority to curtail.²⁴⁴ As such, regulatory mismatches

²³⁹ See Regan, *supra* note 16, at 1097, 1269 (arguing that the Court is singularly focused on suppressing protectionist legislation, and highlighting that, although the suppression of protectionist legislation aids free trade, such suppression is not the same as supporting *laissez-faire* or free markets).

²⁴⁰ *Id.* (focusing on what Regan called free-movement-of-goods cases).

²⁴¹ See, e.g., *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 352–53 (1977) (writing, of a facially neutral statute, that it had the “effect of an embargo” and therefore constituted “discrimination against commerce”).

²⁴² See *supra* note 174.

²⁴³ Cf. *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991) (claiming that federalism “assures a decentralized government that will be more sensitive to the diverse needs of a heterogeneous society; it increases opportunity for citizen involvement in democratic processes; it allows for more innovation and experimentation in government; and it makes government more responsive by putting the States in competition for a mobile citizenry”).

²⁴⁴ *Eule*, *supra* note 9, at 442, 445 (arguing that “judicial invalidation of evenhanded state commercial legislation through the current weighing process is inconsistent with our constitutional system of representative democracy,” and the “rejection of unfettered trade as an appropriate goal of judicial scrutiny of local legislative efforts” would allow for salutary state experimentation); Regan, *supra* note 16, at 1187 (“The existence of [regulatory] diversity can

are a permanent feature of federalism. To illustrate the noninterventionist view, this Section considers *Barnwell* and *Moorman*, cases in which the noninterventionist view prevailed, as well as noninterventionist dissents in *Southern Pacific* and *Kassel*.

In 1938, the *Barnwell* Court unanimously held that the burden arising from mismatched truck width and weight rules “is one which the Constitution permits because it is an inseparable incident of the exercise of a legislative authority, which, under the Constitution, has been left to the states.”²⁴⁵ Even when they acknowledge that mismatches significantly burden interstate commerce,²⁴⁶ justices holding the noninterventionist view conclude that the Constitution provides no authority for courts to eliminate mismatches. The *Barnwell* Court expressed this view in typical fashion when it observed that “courts are not any the more entitled, because interstate commerce is affected, to substitute their own for the legislative judgment.”²⁴⁷ Rather, because the “[State] legislature, being free to exercise its own judgment, is not bound by that of other legislatures,”²⁴⁸ even the fact that “all [other] states had adopted a single standard” cannot force an outlier state to conform to that standard.²⁴⁹ If regulatory diversity becomes too burdensome, the noninterventionist view holds that the states could take it upon themselves to harmonize their rules, or Congress could enact nationwide rules.²⁵⁰

In 1978 in *Moorman*, a six-justice majority held that the Supreme Court could not force a state to use the same tax-allocation rule as other states, even if leaving the deviating state’s rule in place would lead to double taxation, which was presumed to burden interstate commerce. The *Moorman* Court emphasized that because mismatches arise from differences between different states’ rules, no one state

hardly be thought to create a constitutional problem. As I have argued previously, uniformity of commercial regulation is not a constitutional value.”).

²⁴⁵ S.C. State Highway Dep’t v. *Barnwell Bros., Inc.*, 303 U.S. 177, 189 (1938).

²⁴⁶ *Id.* at 183 (reciting lower court finding that the challenged regulations “would seriously impede motor truck traffic passing to and through the state”); *Moorman Mfg. Co. v. Bair*, 437 U.S. 267, 277 (1978) (acknowledging risk of burdens due to tax “duplication”).

²⁴⁷ *Barnwell*, 303 U.S. at 191.

²⁴⁸ *Id.* at 195.

²⁴⁹ *Id.* at 196.

²⁵⁰ *Id.* at 189–90 (“Congress . . . may determine whether the burdens . . . are too great, and may, by legislation designed to secure uniformity . . . curtail . . . the states’ regulatory power.”); *Moorman*, 437 U.S. at 280 (“It is to [Congress], and not this Court, that the Constitution has committed such policy decisions.”); *id.* at 279 (noting that any uniform rule “would require a policy decision based on political and economic considerations that vary from State to State”).

could be held responsible for them “in a constitutional sense.”²⁵¹ Moreover, the *Moorman* Court observed that harmonizing state rules was a legislative, not a judicial, function.²⁵²

Dissenting in *Southern Pacific*, Justice Black likewise argued that courts had no authority to second-guess the state legislature regarding nondiscriminatory commercial regulations—particularly when the challenged regulation was designed to promote public safety.²⁵³ In Justice Black’s view, if interstate commerce truly required uniform regulation of train lengths, then Congress had the power to affirmatively establish such uniform rules. Until then, the Supreme Court could not “den[y] to the state . . . power to protect life and property within its borders.”²⁵⁴ Moreover, Justice Black argued that the correct inference to draw from congressional inaction in the area was that Congress chose to leave the regulatory decision to the states.²⁵⁵ Likewise, in his view, the Supreme Court should “leave that choice to the elected legislative representatives of the people themselves, where it properly belongs both on democratic principles and the requirements of efficient government.”²⁵⁶

Dissenting for himself and two others in *Kassel*, Justice Rehnquist concluded that “a court is not called upon, as are state legislatures, to determine what, in its judgment, is the most suitable restriction to be applied of those that are possible, or to choose that one which in its opinion is best adapted to all the diverse interests affected.”²⁵⁷ In Rehnquist’s view, by striking down Iowa’s truck-length limits, the majority “oversteps our ‘limited authority to review state legislation

²⁵¹ *Moorman*, 437 U.S. at 277 (holding that the challenged state (Iowa) was no more at fault for the mismatch than was Illinois, the challenger’s home state).

²⁵² *Id.* at 280; *id.* at 279 (noting that the only way to prevent burdens arising from mismatches in apportionment formulas would be to “require national uniform rules. . . . The Constitution, however, is neutral with respect to the content of any uniform rule.”); *Barnwell*, 303 U.S. at 189–90 (“Congress . . . may determine whether the burdens imposed on [interstate commerce] by state regulation, otherwise permissible, are too great, and may, by legislation designed to secure uniformity or in other respects to protect the national interest in the commerce, curtail to some extent the state’s regulatory power. But that is a legislative, not a judicial, function . . .”).

²⁵³ *S. Pac. Co. v. Ariz. ex rel. Sullivan*, 325 U.S. 761, 789 (1945) (Black, J., dissenting).

²⁵⁴ *Id.* at 791.

²⁵⁵ *Id.* at 792 (“[T]o leave the state free in this field was a deliberate choice, which was taken with a full knowledge of the complexities of the problems and the probable need for diverse regulations in different localities.”).

²⁵⁶ *Id.* at 789; see also *Eule*, *supra* note 9, at 442 n.89 (“If democracy means anything, it is that the choice between competing substantive political values must be made by representatives of the people rather than by unelected judges.”).

²⁵⁷ *Kassel v. Consol. Freightways Corp.*, 450 U.S. 662, 691 (1981) (Rehnquist, J., dissenting) (quoting *Barnwell*, 303 U.S. at 190).

under the commerce clause’ and seriously intrudes upon the fundamental right of the States to pass laws to secure the safety of their citizens.”²⁵⁸ He emphasized that “[t]he Commerce Clause is, after all, a grant of authority to Congress, not to the courts.”²⁵⁹

In addition, noninterventionists underscore other problems with what we call *Bibb* balancing—including the problem of choosing a benchmark and the phenomenon that intervention in such cases typically involves choosing one state’s law over another. Sections III.B and III.C below discuss both of these issues. For all of these reasons, the noninterventionists would sustain state regulatory mismatches *regardless* of the magnitude of the burden they impose on interstate commerce, unless it was clear that a state devised a mismatch for protectionist purposes.²⁶⁰

b. Interventionist View

The interventionist view, by contrast, draws normative support from implicit and explicit limits the Constitution places on state power in the name of preserving the union. Justice Cardozo captured these themes in his frequently repeated line from *Baldwin v. G. A. F. Seelig, Inc.*²⁶¹ that “[t]he Constitution was framed . . . upon the theory that the peoples of the several states must sink or swim together, and that in the long run prosperity and salvation are in union and not division.”²⁶² This Cardozo quotation suggests that, more than merely preventing protectionism, a goal of our constitutional order is to actively forge the states into a federal union with a single national market, including by eliminating even non-tariff barriers to a free interstate market.²⁶³

²⁵⁸ *Id.* at 687 (citation omitted) (quoting *Locomotive Firemen v. Chi., Rock Island & Pac. R.R. Co.*, 393 U.S. 129, 136 (1968)).

²⁵⁹ *Id.* at 690.

²⁶⁰ For example, although Justice Rehnquist strongly backed the noninterventionist view in *Kassel*, he observed that intervention would be appropriate if the mismatch were a mere “pretext for discrimination against interstate commerce.” *Id.* at 692 (Rehnquist, J., dissenting).

²⁶¹ 294 U.S. 511 (1935). In *Baldwin*, the Court precluded a New York regulation that required out-of-state milk sold into the state to have been purchased at not less than the New York statutory minimum price for milk. *Id.* at 528.

²⁶² *Id.* at 523; *see also* *Am. Trucking Ass’n v. Mich. Pub. Serv. Comm’n*, 545 U.S. 429, 433 (2005); *W. Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 206 (1994); *Healy v. Beer Inst.*, 491 U.S. 324, 336 n.12 (1989); *H. P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 532 (1949); *Kassel*, 450 U.S. 662 at 687 (Brennan, J., concurring); *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 152 (1978) (Blackmun, J., concurring in part, dissenting in part).

²⁶³ *See* Daniel Halberstam, *Of Power and Responsibility: The Political Morality of Federal Systems*, 90 VA. L. REV. 731, 809–811 (2004). For more on the implications of structural federalism for state obligations under the dormant Commerce Clause, *see generally* Erin F. Delaney &

Justices propounding the interventionist view have concluded that taking the federalism limits on state power seriously requires preclusion of mismatched regulations that—while not intentionally protectionist—nevertheless unduly burden interstate commerce. Interventionist justices emphasize the perils of “economic Balkanization,”²⁶⁴ which refers to segmentation of the national marketplace into smaller markets delineated by state boundaries. Interventionists also emphasize the impropriety of leaving it to state legislatures to take adequate account of national and federal interests when enacting legislation. For instance, the Court in *Southern Pacific* wrote:

For a hundred years it has been accepted constitutional doctrine that the commerce clause, without the aid of Congressional legislation, thus affords some protection from state legislation inimical to the national commerce, and that in such cases, where Congress has not acted, this Court, and not the state legislature, is under the commerce clause the final arbiter of the competing demands of state and national interests.²⁶⁵

Jurists taking the interventionist view would not preclude *all* mismatches, no matter how slight their effects on interstate commerce nor how compelling their justifications.²⁶⁶ But interventionists do not see the dormant Commerce Clause as limited to protecting the national marketplace from only intentionally protectionist mismatches.

Ruth Mason, *Solidarity Federalism*, 98 NOTRE DAME L. REV. 617 (2022); Allan Erbsen, *Horizontal Federalism*, 93 MINN. L. REV. 493 (2008).

²⁶⁴ See, e.g., *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2089 (2018).

²⁶⁵ *S. Pac. Co. v. Ariz. ex rel. Sullivan*, 325 U.S. 761, 769 (1945) (citations omitted). Justice Kennedy, writing for the majority in 2018 in *Wayfair*, used almost the same language: “Of course, when Congress exercises its power to regulate commerce by enacting legislation, the legislation controls. But this Court has observed that ‘in general Congress has left it to the courts to formulate the rules’ to preserve ‘the free flow of interstate commerce.’” *Wayfair*, 138 S. Ct. at 2089–90 (quoting *Southern Pacific*, 325 U.S. at 769).

²⁶⁶ For example, the *Southern Pacific* Court also contrasted its decision to preclude the challenged train-length rule with its holdings in other train-safety cases in which it upheld the challenged laws, either because the burden was lower than in *Southern Pacific*, the safety interest more compelling, or both. Upheld safety regulations, governed, for example, full crews, headlights, heated cabins, and the like. *Southern Pacific*, 325 U.S. at 782 (“While the full train crew laws undoubtedly placed an added financial burden on the railroads in order to serve a local interest, they did not obstruct interstate transportation or seriously impede it. They had no effects outside the state beyond those of picking up and setting down the extra employees at the state boundaries; they involved no wasted use of facilities or serious impairment of transportation efficiency, which are among the factors of controlling weight here. In sustaining those laws the Court considered the restriction a minimal burden on the commerce comparable to the law requiring the licensing of engineers as a safeguard against those of reckless and intemperate habits . . .”).

Instead, as the *Southern Pacific* Court put it, when Congress has not acted, the Supreme Court must act as “the final arbiter of the competing demands of state and national interests.”²⁶⁷ The *Southern Pacific* Court also observed that “in general Congress has left it to the courts to formulate the rules thus interpreting the commerce clause in its application, doubtless because it has appreciated the destructive consequences to the commerce of the nation if [the courts’] protection were withdrawn.”²⁶⁸ And three dissenters in *Moorman* perceived it as the Court’s “duty . . . ‘to make the delicate adjustment between the national interest in free and open trade and the legitimate interest of the individual States.’”²⁶⁹ A majority of the modern Supreme Court endorsed the interventionist view taken in *Southern Pacific* as recently as 2018, noting that “‘in general Congress has left it to the courts to formulate the rules’ to preserve ‘the free flow of interstate commerce.’”²⁷⁰

The interventionist and noninterventionist camps thus diverge based on their answer to the following question: in the *absence* of congressional action, should courts intervene in mismatch cases? Noninterventionists see congressional inaction as an implicit grant of regulatory power to the states, which the courts should not obstruct. But interventionists view congressional inaction as an implicit charter for the courts to carefully review state actions that adversely impact interstate commerce.

3. *Comparing Intervention in Single-State and Mismatch Cases*

That strong normative arguments support both the interventionist and noninterventionist approaches may help explain why the Supreme Court has not steadily committed to one approach over the other in mismatch cases. Indeed, in the mismatch cases described above, *individual justices* were not even consistent in following either an interventionist or noninterventionist approach. Specifically, more than half of the justices in the mismatch cases considered above signed

²⁶⁷ *Id.* at 769.

²⁶⁸ *Id.* at 770; *see also* *Kassel v. Consol. Freightways Corp.*, 450 U.S. 662, 671 (1981) (“In the absence of congressional action to set uniform standards,” the Court will not tolerate state regulations for which the “safety interest has been found to be illusory” and that “impair significantly the federal interest in efficient and safe interstate transportation.”).

²⁶⁹ *Moorman Mfg. Co. v. Bair*, 437 U.S. 267, 283 (1978) (Powell, J., dissenting) (quoting *Bos. Stock Exch. v. State Tax Comm’n*, 429 U.S. 318, 329 (1977)).

²⁷⁰ *Wayfair*, 138 S. Ct. 2080, 2090 (2018) (quoting *Southern Pacific*, 325 U.S. at 770).

on to both decisions intervening and those not intervening.²⁷¹ There is no obvious partisan valence to the voting patterns in the mismatch cases described above; both views have been endorsed by justices appointed by Democrats and by Republicans.²⁷² Spread out over forty years, those cases reveal that individual members of the Court do not seem to regard the doctrinal approach in mismatch cases as a matter of stare decisis or settled law. This allows the Court—and even individual justices—to move back and forth between interventionist and noninterventionist approaches to mismatches.

In contrast, there seems to be much less normative disputation surrounding single-state cases, even though, for reasons we discuss presently, the outcome of single-state cases may not be easy to predict. Other than Justice Thomas, who rejects the dormant Commerce Clause outright, justices generally have accepted both that judicial intervention in single-state cases is appropriate and that the goal of such intervention is to prevent states from inhibiting free trade by enacting protectionist regulations. Hence the Court's focus in single-state cases on protectionist intent. A finding of protectionist intent, which the Court may feel comfortable ascribing to a state when the immediate effect of its regulation is to protect in-state economic actors from out-of-state competitors, enables the Court to resolve a single-state case easily under *Pike* balancing. Because protectionism is not a valid state interest, it supplies no counterweight to offset the challenged regulation's impact on interstate commerce, and so the Court can easily preclude the regulation. On the other hand, the absence of such immediately obvious protectionist intent forces the Court to engage in more robust *Pike* balancing. And because the justices' views may differ on how to evaluate the relevant considerations in the balance—including how much the challenged regulation burdens interstate commerce, whether and to what extent the regulation benefits the enacting state, and whether that benefit could be achieved with lesser impact on interstate commerce—the outcome of this more robust *Pike* balancing in single-state cases can be difficult to predict.²⁷³ This is the difficulty the late Justice Scalia identified when he wrote in his *Bendix* concurrence that *Pike* balancing involved weighing “incom-

²⁷¹ The seven cases, in chronological order, were: *Barnwell*, *Southern Pacific*, *Bibb*, *Hunt*, *Moorman*, *Clover Leaf*, and *Kassel*.

²⁷² See *infra* Table.

²⁷³ Adding to the uncertainty, before they get to balancing, justices may disagree over whether the state had protectionist intent (which would trigger analysis akin to strict scrutiny) or whether the state had no such protectionist intent (which would trigger less searching review).

mensurables” against each other.²⁷⁴ This criticism led Justice Scalia to urge the Court to abandon *Pike* balancing altogether as inappropriate for courts, as opposed to the legislature.²⁷⁵ Justice Thomas shares this view, but would go further. Whereas Justice Scalia agreed that courts should preclude discriminatory state regulations, Justice Thomas entirely rejects the dormant Commerce Clause at all. Despite the views of these two justices, and notwithstanding that the outcome in a *Pike* balancing case can be difficult to predict, there otherwise appears to be little disagreement about whether the Supreme Court is entitled to consider single-state cases, whether balancing is the right approach to those cases, and whether the normative goal in such analysis is maintaining and promoting a national market.²⁷⁶

Appreciating the differences between single-state and mismatch cases allows us to conclude that the most biting scholarly criticisms of dormant Commerce Clause doctrine—that it is arbitrary and that its rationale is unstated or variable—apply with more force to mismatch than single-state cases.²⁷⁷ The normative grounding of single-state cases has been consistent over time—the dormant Commerce Clause prevents states from interfering with free trade because such interference undermines the national market, erodes interstate unity, and inspires retaliation. Differences in outcomes and inability to predict outcomes reflect disagreement over how to apply the law to the facts of the particular case. Such differences generally do not reflect fundamental disagreement about whether courts are entitled to intervene in single-state cases.

In contrast, justices disagree over whether mismatch cases warrant judicial review at all. The clash between the interventionist and noninterventionist approaches in mismatch cases generates at least two problems. First, disagreement over how to resolve mismatch cases can lead (and has led) to diametrically opposed decisions in cases with similar facts. For example, the *Barnwell* Court, citing limits on its institutional authority, upheld South Carolina’s mismatch on truck widths and weights,²⁷⁸ whereas the *Kassel* Court, citing impediments to inter-

²⁷⁴ *Bendix Autolite Corp. v. Midwesco Enters., Inc.*, 486 U.S. 888, 897 (1988) (Scalia, J., concurring).

²⁷⁵ *Id.* at 898.

²⁷⁶ As noted previously, Justice Gorsuch raised concerns about undue-burden analysis, but we do not know whether, like Justice Thomas and the late Justice Scalia, he would eschew dormant Commerce Clause balancing, and if so, whether he would disapply it in both single-state and mismatch cases. *See supra* note 51.

²⁷⁷ *See supra* Section I.B.

²⁷⁸ *See S.C. State Highway Dep’t v. Barnwell Bros., Inc.*, 303 U.S. 177, 189 (1938).

state commerce arising from regulatory diversity, precluded Iowa's mismatch on truck lengths.²⁷⁹ Second, the failure to settle whether balancing is or is not appropriate in mismatch cases does a disservice to both courts and state legislatures. State courts and inferior federal courts are required to follow Supreme Court precedent, and state legislatures are expected to enact constitutional laws. If the Supreme Court cannot resolve such a basic and fundamental question as whether intervention is appropriate in mismatch cases, how can inferior courts and legislatures fulfill their obligations?

B. Benchmarking

At a high level of generality, the analysis in every dormant Commerce Clause case is the same, namely, the Court balances the burden on interstate commerce against the state's interest in the regulation.²⁸⁰ But significant differences characterize balancing in single-state and mismatch cases. This Section highlights that the Supreme Court uses internal benchmarking in single-state cases, but external benchmarking in mismatch cases. This Section also discusses special problems raised by external benchmarking.

²⁷⁹ See *Kassel v. Consol. Freightways Corp.*, 450 U.S. 662, 671 (1981); see also *Raymond Motor Transp., Inc. v. Rice*, 434 U.S. 429, 445–46 (1978) (striking down a truck-length limit using reasoning similar to that in *Kassel*).

²⁸⁰ The Court also sometimes, but not always, engages in narrow tailoring, although such narrow tailoring is not a major focus of this Article. See generally Jud Mathews & Alec Stone Sweet, *All Things in Proportion? American Rights Review and the Problem of Balancing*, 60 EMORY L.J. 797 (2011). “In constitutional systems across the globe, proportionality balancing today constitutes the dominant, ‘best practice’ judicial standard for resolving disputes that involve either a conflict between (a) two rights claims or (b) a rights provision and a legitimate government interest.” *Id.* at 802. Proportionality analysis, which can be traced to German law but has since spread widely, involves (1) *suitability*, or what Americans would call rational basis review, (2) *necessity*, including a least-restrictive-means test, which is equivalent to what Americans would call narrow tailoring, and lastly, (3) “balancing *stricto sensu*,” or proportionality in which “the judge weighs, in light of the facts, the benefits of the act (already found to have been narrowly tailored) against the costs incurred by infringement of the right, in order to decide which side shall prevail.” *Id.* at 802–03.

As with single-state cases, the Court uses narrow tailoring in some mismatch cases. Thus, the *Hunt* Court considered whether North Carolina could have fulfilled its interest in protecting consumers from confusion in a less restrictive manner than by forbidding the display of other states' apple grades. *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 354 (1977) (suggesting that North Carolina allow Washington growers to display the Washington *and* federal grades). Likewise, when the California District Court examined the avocado fat-content rule that had been challenged in *Florida Lime*, it considered whether California could achieve its goal to assure that California consumers bought ripe avocados by less restrictive means, including by using federal days-to-maturity and size standards. *Fla. Lime & Avocado Growers, Inc. v. Paul*, 197 F. Supp. 780, 787 (N.D. Cal. 1961).

1. *Single-State Cases*

As in any dormant Commerce Clause case, in single-state cases, the Supreme Court must determine the asymmetrical burden the challenged regulation imposes on interstate commerce. To do so, it employs what we call an “internal benchmark,” under which it compares the impact of the challenged state’s rule on in-state commerce with the impact of the *same state’s* rule on interstate commerce. For example, in a case involving facially discriminatory rules, the Court compares the state’s (worse) treatment of nonresidents or interstate commerce with the same state’s (better) treatment of residents or in-state commerce. The difference between the two constitutes the asymmetrical burden on interstate commerce. There is thus no need in a facial discrimination case for the Court to learn about or consider the laws of any state other than the challenged state.

Likewise, the Court need not use external benchmarks in single-state cases that involve facially neutral rules. For example, in *Pike*, the Supreme Court compared Arizona’s interest in ensuring that the market understood that the cantaloupes were grown in Arizona to the burden on interstate commerce arising from the requirement to pack cantaloupes in Arizona. One may agree or disagree with the Court’s judgment in *Pike* that the burden on interstate commerce outweighed the state’s interest, but the balancing exercise did not require the Court to examine, or know, the law of any state other than Arizona to determine either the burden on interstate commerce or the strength of the state’s proffered interest in the challenged regulation. By contrast, as the next Section discusses, balancing in mismatch cases *requires* the Court to refer to external benchmarks consisting of other states’ actual laws.

2. *Mismatch Cases*

In contrast with dormant Commerce Clause balancing in single-state cases, balancing in mismatch cases uses external benchmarks consisting of other states’ actual laws. By definition, the asymmetrical burden on interstate commerce in a mismatch case is conditional. It arises due to differences between two or more states’ law. Thus, to know what the mismatch consists of, the Supreme Court must examine the laws of another state or states. Consider *Southern Pacific*, in which the Court expressly compared Arizona’s regulation to that of other states, concluding that:

Enforcement of the law in Arizona, while train lengths remain unregulated or are regulated by varying standards in

other states, must inevitably result in an impairment of uniformity of efficient railroad operation because the railroads are subjected to regulation which is not uniform in its application. Compliance with a state statute limiting train lengths requires interstate trains of a length lawful in other states to be broken up and reconstituted as they enter each state according as it may impose varying limitations upon train lengths. The alternative is for the carrier to conform to the lowest train limit restriction of any of the states through which its trains pass.²⁸¹

In this way, the Court measured the burden that Arizona imposed on interstate commerce by reference to the content of other state's rules. Likewise in *Bibb*, the Court understood Illinois's curved-mudflap requirement to require trucks traveling interstate to weld on curved mudflaps at the Illinois border.²⁸² This view of the issue implicitly takes other states' laws as the benchmark for measuring the burden imposed by Illinois's curved mudflap rule. Similarly, in *Kassel*, the Supreme Court understood the burden Iowa imposed on interstate commerce with its more restrictive truck-length rule to include the need for interstate truckers to switch trucks or to divert around Iowa.²⁸³ Thus, the Court determined the burden Iowa imposed on interstate commerce against a background of other states' preexisting regulations. This kind of external benchmarking uses *other states' laws* as the standard for determining the burden the challenged rule imposes on interstate commerce.

Just as it uses external benchmarking to determine burdens, in mismatch cases the Supreme Court also uses external benchmarking to assess the state interest. Specifically, the Court considers whether a deviating regulation provides any benefit *over and above* the benefit conferred by other states' preexisting regulations. For example, the *Southern Pacific* Court measured Arizona's safety interest relative to other state's regimes before it concluded that Arizona's regulation "affords at most slight and dubious advantage, if any, over unregulated train lengths."²⁸⁴ The *Bibb* Court likewise conducted a relative state-interest analysis, comparing the safety of curved mudflaps to the

²⁸¹ *S. Pac. Co. v. Ariz. ex rel. Sullivan*, 325 U.S. 761, 773 (1945).

²⁸² *Bibb v. Navajo Freight Lines*, 359 U.S. 520, 527 (1959) (noting that the case raised the question "whether one State could prescribe standards for interstate carriers that would conflict with the standards of another State, making it necessary, say, for an interstate carrier to shift its cargo to differently designed vehicles once another state line was reached").

²⁸³ *Kassel*, 450 U.S. at 667.

²⁸⁴ *Southern Pacific*, 325 U.S. at 779.

safety of straight mudflaps,²⁸⁵ and it concluded that the advantage of curved mudflaps as “a new safety device—out of line with the requirements of the other States . . . [was] far too inconclusive” to justify its burden on interstate commerce.²⁸⁶ Likewise, in *Kassel*, the Court expected Iowa to show that the fifty-five-foot trucks it permitted were markedly safer than the sixty-five-foot trucks permitted in other states.²⁸⁷

3. Comparing Benchmarking in Single-State and Mismatch Cases

External benchmarking raises at least three issues. First, judges may not agree about which external benchmark to use, which injects uncertainty into *Bibb* balancing. Most of the time, the Court uses the nationally dominant practice as the benchmark. Although Justice Powell explained that “there can be no rule of 26 States, of 35, or of 45,”²⁸⁸ it is equally clear that consensus among the other states is important for choosing the external benchmark for *Bibb* balancing.²⁸⁹ But such consensus is not always present. For example, in *Kassel*, the dissent noted that there was no real consensus among other states in their truck-length rules, which called into question whether sixty-five feet was the appropriate baseline for evaluating Iowa’s rule.²⁹⁰ Moreover, even if all other states had identical rules, the question arises as to why the challenged state’s rule should have to be tested against the dominant rule. As Justice Rehnquist put it, “there is nothing in the laws of nature which make 65-foot doubles an obvious norm” for judging appropriate truck lengths.²⁹¹

Identifying the baseline also seems to be problematic when one state has a rule, but other states have no rule. For example, in *Southern Pacific*, the Court used the *absence* of regulation in other states as a baseline to attribute to Arizona all the costs associated with Arizona’s limits on train lengths. But in an interstate transportation case decided in 1960, *Huron Portland Cement Co. v. Detroit*,²⁹² the fact that other states had no regulation in the area covered by the challenged

²⁸⁵ *Bibb*, 359 U.S. at 523–30.

²⁸⁶ *Id.* at 530.

²⁸⁷ *Kassel*, 450 U.S. at 677.

²⁸⁸ *Moorman Mfg. Co. v. Bair*, 437 U.S. 267, 296 (1978) (Powell, J., dissenting) (arguing that the majority should have removed the mismatch burden generated by Illinois’s outlier tax apportionment formula).

²⁸⁹ See *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 337 (1977); *Bibb*, 359 U.S. at 523; *Kassel*, 450 U.S. at 671; *Southern Pacific*, 325 U.S. at 774.

²⁹⁰ *Kassel*, 450 U.S. at 688 (Rehnquist, J., dissenting).

²⁹¹ *Id.* at 699.

²⁹² 362 U.S. 440 (1960).

state's regulation meant that the Supreme Court failed to perceive that it was even dealing with a mismatch. In *Huron*, the Supreme Court considered whether Detroit violated the dormant Commerce Clause by forbidding ships docked in its ports from emitting more than a maximum amount of air pollution.²⁹³ Complying with the regulation required ship owners to install pollution-mitigation equipment. Distinguishing *Huron* from *Bibb*, the Court concluded that although the challenger complained that "local governments might impose differing requirements as to air pollution, [the challenger] has pointed to none. The record contains nothing to suggest the existence of any such competing or conflicting local regulations."²⁹⁴ Stating that the dormant Commerce Clause question "needs no extended discussion,"²⁹⁵ the Court easily upheld Detroit's "[e]venhanded"²⁹⁶ regulation, which had been "enacted for the manifest purpose of promoting the health and welfare of the city's inhabitants."²⁹⁷

Notwithstanding the Court's conclusion that *Huron* involved no regulatory conflict, under our definition, Detroit's regulation created a mismatch burden in the same way that Arizona's did in *Southern Pacific*. Specifically, if all ports had Detroit's rule, then all ships everywhere would comply with it and out-of-state shippers would face no additional costs to dock in Detroit that they did not face in their home ports. But because other ports had not adopted the same rule as Detroit, out-of-state shippers had to buy special equipment just to dock in Detroit. Because the Detroit regulation did not affirmatively conflict with laws adopted by other states or cities, however, the Supreme Court was unable to perceive a mismatch burden.²⁹⁸ In *Southern Pacific*, by contrast, the Court perceived the mismatch and employed an external reference base consisting of the absence of regulation to measure the burden Arizona imposed on interstate commerce. Because the choice of the benchmark often will be determinative under *Bibb*

²⁹³ *Id.* at 448.

²⁹⁴ *Id.* (providing a "compare," that is, "*cf.*," reference to *Bibb*); *id.* at 444 (citing *Southern Pacific* and *Bibb* for the proposition that "a state may not impose a burden which materially affects interstate commerce in an area where uniformity of regulation is necessary").

²⁹⁵ *Id.* at 448.

²⁹⁶ *Id.* at 443.

²⁹⁷ *Id.* at 442.

²⁹⁸ If the Court had perceived the mismatch in *Huron*, and had it engaged in *Bibb* balancing, it presumably would have weighed the burden, which it would have calculated against an external benchmark consisting of other states' nonregulation, against Detroit's interest in reducing pollution and against other states' interests in nonregulation, which might include the interest in keeping costs low for shippers.

balancing, if that choice is unpredictable or arbitrary, so may be the outcome of the case.

Second, external benchmarking in *Bibb* cases is *properly* dynamic and depends on factors outside the control of any one state. This is due to the conditional nature of regulatory mismatches. Mismatches arise from differences between the laws of the challenged state and the *actual present configuration* of the laws of other states. As laws change, the benchmark also changes. Moreover, this is not only the proper, but the only way to analyze a mismatch case; the crux of a mismatch case is the difference between the challenged state's laws and those of other states. Thus, the exact same law may be constitutional today, but unconstitutional at some point in the future, depending on intervening changes to other states' laws. The reverse is also true: a law deemed unconstitutional today because it conflicts with the laws of other states could become constitutional in the future if more states adopted it. This seeming paradox—that widespread adoption of an unconstitutional regulation could transform it into a constitutional regulation—is a straightforward implication of the Court's willingness to engage in balancing with external benchmarks in mismatch cases. As with the normative uncertainty regarding whether or not courts should intervene in mismatch cases, the additional variables and contingencies that arise from external benchmarking make mismatch cases more vulnerable than are single-state cases to charges of arbitrariness.

Third, as the next Section explains, external benchmarking leads to greater policy impacts than does internal benchmarking.

C. Judicial Legislation

This Section explains that eliminating a mismatch requires some form of regulatory harmonization across the states, whereas no such harmonization is needed to cure a single-state burden. Thus, preclusion in mismatch—but not single-state—cases drives not only changes in law, but substantive regulatory harmonization. Moreover, for reasons explained here, this harmonization has a deregulatory bias; conversely, allowing mismatches to remain will tend to have a pro-regulatory bias, as discussed later.²⁹⁹ These phenomena suggest that criticism that dormant Commerce Clause review leads to judicial law-

²⁹⁹ See *infra* text accompanying notes 303–04.

making applies with more force to mismatch than to single-state cases.³⁰⁰

On the surface, the remedy in single-state and mismatch cases is the same, namely, preclusion. Differences emerge after preclusion. In single-state cases, the state typically can cure the constitutional infirmity either by *equalizing* the treatment of insiders and outsiders—as in cases of facial discrimination—or by *reducing or eliminating* the offending state’s barrier to interstate commerce—as for regulations that function equivalently to tolls, like *Pike*.³⁰¹ Preclusion thus creates no implicit preference for adopting any particular substantive rule. Curing mismatch burdens, by contrast, requires removing regulatory diversity through forbearance, conformity, or coordination. Specifically, a state could practice *forbearance* by repealing the offending regulation and replacing it with nothing, or it could *conform* by adopting the same substantive regulation as that used by other states. Finally, the states acting together could *coordinate* their regulations, for example, by adopting a rule that would determine which state’s law should apply in cases of potential conflict.³⁰² As a practical matter, all three options involve some form of regulatory harmonization.

When the Court strikes a mismatched state law under the dormant Commerce Clause, in effect it forces the state to harmonize its rule with the rule of one or more sister states.³⁰³ In particular, preclusion tends to force the challenged state to adopt—or at least permit—the benchmark rule, a phenomenon that could be called harmonization by preclusion. Regulatory harmonization is thus an important outcome of mismatch, but not necessarily single-state, cases. As in any dormant Commerce Clause case, preclusion in mismatch cases implic-

³⁰⁰ For criticisms of dormant Commerce Clause cases for judicial lawmaking, see discussion *supra* Section I.B.

³⁰¹ Trade law calls this “national treatment;” the Supreme Court calls it “leveling.” See General Agreement on Tariffs and Trade art. III, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT] (“National Treatment on Internal Taxation and Regulation.”); *Comptroller of Treasury of Maryland v. Wynne*, 575 U.S. 542, 598 (2015) (Ginsburg, J., dissenting) (“Whenever government impermissibly treats like cases differently, it can cure the violation by either ‘leveling up’ or ‘leveling down.’ Whenever a State impermissibly taxes interstate commerce at a higher rate than intrastate commerce, that infirmity could be cured by lowering the higher rate, raising the lower rate, or a combination of the two.”).

³⁰² The corporate internal-affairs doctrine, under which other states defer to the charter state regarding certain corporate regulations, represents a coordination rule. See *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 89 (1987). For more on coordination rules, see discussion *infra* Section IV.B.2.

³⁰³ Halberstam, *supra* note 263, at 810 (criticizing undue-burden cases generally, without distinguishing between single-state and mismatch cases, because undue burden cases represent “a naked effort to contain democratic politics by harmoniz[ation]”).

itly, if not explicitly, rejects the tradeoffs that the offending state chose in its political process. But only in mismatch cases does judicial preclusion reject the challenged state's tradeoffs *in favor of different tradeoffs made by other states*. For example, in *Kassel*, Iowa's legislature at the margin would have traded less efficient trucking for safer roads. But other states at the margin chose commerce over safety. When the Supreme Court determined that Iowa's shorter maximum truck length impermissibly burdened interstate commerce as compared to an external benchmark consisting of other states' longer maximums, the Court implicitly chose other states' democratic tradeoffs over Iowa's. Some justices object to this type of harmonization by preclusion. For example, in his dissent in *Kassel*, Justice Rehnquist criticized the Court for "essentially . . . compelling Iowa to yield to the policy choices of neighboring States."³⁰⁴

Beyond forcing harmonization, this Article shows that preclusion in mismatch cases will tend to be deregulatory in ways that preclusion in single-state cases is not. On the surface, judicial preclusion in both single-state and interaction cases is deregulatory because after either, the state must eliminate or revise its regulation. However, because mismatch cases implicitly involve *selecting one regulation over another*, and because commercial actors will tend to challenge stricter and novel regulations, but not laxer and common regulations, when mismatch cases end in preclusion, they tend to preclude stricter and novel regulations. Again, *Kassel* serves as a good example. Private litigants challenged Iowa's stricter law, and the Court used other states' laxer laws as the benchmark for evaluating the benefit and burden of Iowa's law. In this way, stricter and newer laws face challenges that older and laxer laws do not; the role of private litigants in dormant Commerce Clause cases will thus tend to make preclusion on those cases deregulatory.

The most obvious deregulatory impact of preclusion in mismatch cases occurs when the challenged state simply repeals its own stricter rule and adopts the laxer benchmark rule. But deregulation following preclusion in a mismatch case can work through other mechanisms as well. Return to *Kassel*. After the Supreme Court precluded its short-truck rule, Iowa had to allow other states' sixty-five-foot trucks on its roads. Iowa could do this by repealing its own truck-length limit and conforming to the sixty-five-foot benchmark rule. But Iowa could try to advance its residents' preferred tradeoff between safety and com-

³⁰⁴ *Kassel v. Consol. Freightways Corp.*, 450 U.S. 662, 699 (1981) (Rehnquist, J., dissenting) (arguing that only Congress could prescribe a uniform national rule for truck lengths).

mercial efficiency while simultaneously satisfying its obligations under the dormant Commerce Clause by retaining its shorter limit for *Iowa-licensed trucks* while permitting longer trucks from other states to drive on its roads. If Iowa maintains its shorter limit for Iowa-licensed trucks, out-of-state truckers will have a competitive advantage over Iowa truckers whenever longer trucks are more efficient. This will tend to advantage out-of-state truckers and will likely lead to more non-Iowa-licensed trucks on Iowa highways. Thus, out-of-state truckers, who are subject to laxer regulations, can be expected to constitute a larger share of the Iowa market. In-state truckers, now disadvantaged in competition with out-of-state truckers, in turn, can be expected to lobby for the laxer rule to apply to themselves as well. In this way, even if it does not lead directly to adoption of the laxer rule by the precluded state, preclusion pursuant to *Bibb* balancing will tend over time to lead to deregulation and to encourage legal harmonization. Economists call this phenomenon—under which laxer regulations spill over to other jurisdictions—the “Delaware Effect” or a “race to the bottom.”³⁰⁵

In contrast with mismatch cases, state responses to preclusion in single-state cases are relatively straightforward. Preclusion of single-state burdens leads to “equalization” of the in-state and out-of-state case, or it leads to disapplication of the offending state’s rule in whole or part. What a state need not do to cure a single-state violation, however, is to examine—much less accept or adopt—the laws of other states. Thus, harmonization is not a necessary outcome of single-state cases.

D. Complexity of Balancing

A persistent criticism of dormant Commerce Clause review concerns the difficulty of conducting balancing analysis.³⁰⁶ Acknowledg-

³⁰⁵ See generally DAVID VOGEL, *TRADING UP: CONSUMER AND ENVIRONMENTAL REGULATION IN A GLOBAL ECONOMY* 5 (1995) (using the terms “Delaware Effect” and “race to the bottom”). Note that adopting a coordination rule will also tend towards deregulation, as multistate commercial actors respond to the coordination rule. See *infra* Section IV.B.2. Indeed, the term “Delaware Effect” refers to the *private* response to the internal-affairs doctrine, under which states defer to certain corporate regulation of a company’s charter state. The internal-affairs doctrine has led multistate companies to disproportionately incorporate in Delaware. See VOGEL, *supra*, at 5–6. Under the early view of this phenomenon, corporations favored Delaware because managers sought to take advantage of the state’s management-favorable corporate law. Under the more recent view, corporations choose Delaware because Delaware’s rules maximize the value of the firm, which benefits both shareholders and managers.

³⁰⁶ Justice Scalia famously compared balancing state interests and impacts on interstate commerce to comparing the length of a line to the heaviness of a rock. *Bendix Autolite Corp. v.*

ing these concerns, this Section considers whether there is any reason to expect that balancing would be easier or harder in mismatch cases than in single-state cases.

First, determining the burden in *Bibb* cases may be harder than in *Pike* cases because determining the magnitude of any disruptive effect on the national market of a mismatch—as opposed to a single-state rule that functions equivalently to a toll—requires knowledge of the law in multiple states and of the goods and services produced by different firms in different states. It also requires knowledge—possibly deep knowledge—of the marketplace, including competing products, production techniques, marketing practices, and consumer perceptions. These are not assessments that courts are well-equipped to make. Second, mismatch cases are dynamic—that is, the benchmark will change as states change their regulations, and as economic actors adjust their commercial practices. This, in turn, may necessitate *more frequent* judicial consideration in mismatch than single-state cases. Put differently, whereas a decision in a single-state case generally may be regarded as final, a decision in a mismatch case is only final as long as the benchmark remains unchanged.³⁰⁷ Third, mismatch cases are more

Midwesco Enters., Inc., 486 U.S. 888, 897 (1988) (Scalia, J., concurring). We have no special response to this impossibility or “incommensurability” argument, which applies not only to dormant Commerce Clause review, but to all areas in which courts use balancing to trade off constitutional rights, entitlements, and values. Instead, we merely observe, as have others before us, that if constitutional courts are the correct institution to make tradeoffs among such interests, then those courts inevitably will have to balance among them. *See generally* Mathews & Stone Sweet, *supra* note 280, at 803 (defending balancing, which they call by its European name, proportionality). We also observe that the types of comparisons called for in dormant Commerce Clause review are less problematic than Justice Scalia’s quip would suggest. As more cases are heard and more decisions are rendered, earlier decisions provide context for later decisions, so later decisions can more readily and reasonably be evaluated for their consistency with earlier decisions. *Id.* at 820 (“One of the virtues of proportionality balancing is that it allows a court to claim doctrinal consistency while retaining flexibility across time and cases.”).

³⁰⁷ The fifty-year battle over collection of state sales taxes by remote sellers, which required the Supreme Court to revisit substantively the same legal issue *three times* under changing market, legal, and technological conditions, provides a nice demonstration of the perils of dynamic baselines. *See* Ruth Mason, *Implications of Wayfair*, 46 INT’L TAX REV. 810, 810–14 (2018) (describing three Supreme Court cases dealing with tax-compliance mismatches, decided over fifty years, in which the outcome on the dormant Commerce Clause issue changed principally due to shifting technological and market conditions that altered both burdens and interests). Although these cases involved dormant Commerce Clause nexus, rather than dormant Commerce Clause undue burdens, the legal issues considered were so similar that in dicta in *South Dakota v. Wayfair*, the last of the three cases, the Supreme Court concluded by noting that the Court might have to take up analysis of the burdens and benefits of mismatched tax-compliance rules in the future under *Pike*. *See* *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2098 (2018). Specifically pointing to *Pike*, the Court stated that “other aspects of the Court’s Commerce Clause doctrine can protect against any undue burden on interstate commerce, taking into con-

difficult for courts to resolve than single-state cases for the simple reason that mismatch cases involve balancing among a larger number of competing interests than do single-state cases. Single-state cases involve weighing only two interests against each other—the burden on interstate commerce against one particular state’s regulatory interest. In this way, single-state cases represent a simple tug-of-war between the *national-market interests* and the *regulatory interest* of the challenged state. In contrast, mismatch cases involve *multifactor* analysis. In addition to implicating national-market interests and the regulatory interests of the challenged state, mismatch cases also effectively involve a *contest among two (or more) states* for regulatory control of a single commercial act that affects both states. In mismatch cases, unless the reviewing court sees a clear case of intentional protectionism (as with California’s fat-content rule for avocados), *Bibb*-balancing requires adjudicating disputes about whether, in the name of national market efficiency, one state’s regulations should prevail over another state’s regulations. When different states adopt different policies, resolving impediments to interstate commerce that result from those policy differences implicitly means choosing among the different regulations.³⁰⁸ Thus, balancing in mismatch cases is more complicated than in single-state cases. The next Part discusses these issues at greater length.

IV. THE FUTURE OF MISMATCH CASES UNDER THE DORMANT COMMERCE CLAUSE

So far, this Article has sought to reframe dormant Commerce Clause doctrine by emphasizing the differences between single-state and mismatch burdens that, in turn, motivate differences in *Pike* and *Bibb* balancing. This Article also explained how traditional criticisms of dormant Commerce Clause doctrine apply differently to single-state and mismatch cases. This Part uses an example from a recent case involving a challenge to California’s cage-free egg regulation to consider the most important disputes surrounding regulatory mismatches, namely, whether the Supreme Court should intervene in them, and if so, how it should decide which state’s law prevails. This

sideration the small businesses, startups, or others who engage in commerce across state lines.”
Id.

³⁰⁸ Reticence about refereeing between competing state regulations can be seen elsewhere in constitutional law. For example, the Supreme Court largely has withdrawn from active intervention in interstate conflicts-of-laws disputes. See *Allstate Ins. Co. v. Hague*, 449 U.S. 302, 310–13 (1981) (holding that state’s decision to apply its own law will conform to Constitution provided it is “neither arbitrary nor fundamentally unfair”).

Part also suggests ways that the Supreme Court could modify its analysis in mismatch cases to produce more predictable outcomes, or, in the alternative, it suggests different decision-making paradigms that the Court could use to resolve mismatch cases. These alternatives derive from EU law, trade law, and scholarship.

A. *A Current Example: Cage-Free Eggs*

There are several pending dormant Commerce Clause challenges to regulatory mismatches—on topics ranging from product standards³⁰⁹ to corporate-board composition³¹⁰—that will give courts, including the Supreme Court, the opportunity to formally recognize the distinction between single-state and mismatch cases. To make our arguments about the differences between *Pike* and *Bibb* balancing concrete, this Section considers one such dispute. In response to California recently banning the production or sale in California of non-cage-free eggs, six other states, led by Missouri, challenged the regulation, arguing that, as applied to eggs produced outside California, the regulation was discriminatory, or, in the alternative, that it imposed an undue burden on interstate commerce.³¹¹ The Ninth Circuit dismissed the challenge, holding that the six states lacked standing to challenge California’s rule. But injured farmers will have standing, and they presumably will bring their own challenges. If so, any court that hears the case would consider whether the California cage-free egg rule violates the dormant Commerce Clause. The law is not facially discriminatory; California treats in-state and out-of-state eggs the same; to be sold in California, they must be produced by cage-free chickens.³¹² Notwithstanding its facial neutrality, our analysis suggests that if the regulation had been enacted with protectionist intent, then

³⁰⁹ See *Nat’l Pork Producers Council v. Ross*, 6 F.4th 1021, 1025 (9th Cir. 2021), *cert. granted*, 142 S. Ct. 1413 (2022) (challenging as a mismatch a California law requiring sows to be kept in cages larger than those required by other states); see also Jessica Berch, *If You Don’t Have a Cow (or Chicken or Pig), You Can’t Call It Meat: Weaponizing the Dormant Commerce Clause to Strike Down Anti-Animal-Welfare Legislation*, 2021 UTAH L. REV. 73, 73 (2021) (tracking pending dormant Commerce Clause cases related to “the animal-protection movement,” such as labeling laws and laws related to the humane treatment of farm animals).

³¹⁰ See Joseph Grundfest, *Mandating Gender Diversity in the Corporate Boardroom: The Inevitable Failure of California’s SB 826*, at 3 (Stanford L. Sch. & Rock Ctr. for Corp. Governance, Working Paper Series 232, 2018) (arguing that recent legislation requiring companies headquartered in California, regardless of where incorporated, to appoint women and minorities to their boards violates the dormant Commerce Clause because it conflicts with regulations in the companies’ incorporation state).

³¹¹ *Missouri ex rel. Koster v. Harris*, 847 F.3d 646, 650–52 (9th Cir. 2017), *cert. denied sub. nom.* *Missouri v. Becerra*, 137 S. Ct. 2188 (2017) (dismissing the case for lack of standing).

³¹² See *id.* at 651–52.

courts typically would preclude it for that reason alone. Some judges would go no farther, concluding that, after exhausting the inquiry into intentional protectionism, further judicial intervention into mismatched cases is improper. Notice that the consequence of such a view is that the principal remaining limits on a state's ability to use mismatched rules to burden interstate commerce would be extraterritoriality principles developed under the dormant Commerce Clause, the possibility of federal preemption, and due process limits on the reach of a state regulatory authority.

Other judges, however, would go on to evaluate the California regulation as a mismatch burden—namely, a mismatch between California's regulation requiring eggs to be cage-free and other states', including Missouri's, laxer regulations. These judges would apply what we call *Bibb* balancing (but which courts typically describe as *Pike* balancing).³¹³ Such *Bibb* balancing involves choosing an external benchmark against which to measure the burden of the California rule. Although this Article noted earlier that there is no obvious, well-grounded method for selecting external benchmarks for evaluating mismatched regulations, past experience tells us that the reviewing court likely would pick an external benchmark consisting of the dominant egg regulation applicable in other states, if one exists, or perhaps the regulation of the complainant's state, such as Missouri. In either case, the reviewing court would judge the California rule against a baseline consisting of the regulation of another state or states.

Suppose the reviewing court identifies Missouri law as the relevant benchmark. It would then measure the burden that the California rule imposes on interstate commerce relative to that benchmark. The resulting burden, which would include the need for out-of-state egg producers to, for example, buy larger crates, would be attributed solely to California. Only then, to justify this burden on interstate commerce, would California be able to bring in its regulatory interests, such as preventing cruelty to animals and any human health benefits from cage-free over non-cage-free eggs. Assuming these are legitimate local interests,³¹⁴ they too would be judged by an external benchmark consisting of the laws of other states. California would

³¹³ Interventionist judges also might apply narrow tailoring in mismatch cases, either before or after balancing. Narrow tailoring is not our main focus.

³¹⁴ Determining California's interest could be contentious because California is protecting not only California chickens, but chickens outside of California as well. *Id.* at 650–51. Whether the welfare of egg-laying hens residing in other states is a legitimate state concern in our federal system is an unanswered question. One reason that an interest in the welfare of animals *outside* California might not be a legitimate interest of California is that, in a federation, such an interest

thus have to show that its regulation actually advanced California's legitimate local public interests—such as improving animal welfare or human health—compared to the benchmark rule, and that the regulation did so in a manner that did not unnecessarily burden interstate commerce. As we have explained, precluding the regulation would implicitly endorse the Delaware Effect, under which economic actors would arrange their affairs to take advantage of the laxest state regulation and in which states competing for economic activity would relax their regulatory standards. On the other hand, upholding the regulation would implicitly endorse the California Effect, under which strict state regulations would spill over to other states.³¹⁵ Mismatch cases thus involve not merely a narrow question of national market efficiency, but also the division of regulatory power among the states. That is, mismatch cases implicitly involve a contest among two or more states for regulatory control of a single commercial act that affects multiple states.

B. *Reforming Bibb Balancing*

As an initial matter, we advocate four minor steps to clarify the dormant Commerce Clause. First, and at a minimum, the Supreme Court and lower courts should acknowledge the differences between single-state and mismatch cases, especially the fact that balancing in single-state cases involves internal benchmarking, whereas balancing in mismatch cases involves external benchmarking. The second clarification involves deference to trial courts. In several mismatch cases, the Supreme Court essentially conducted a *de novo* review of the evidence presented at trial, overturning trial court findings regarding the presence of intentional protectionism.³¹⁶ Because the largest area of

might invade the policy prerogatives of other states (in this case, the states where the hens reside).

³¹⁵ S.C. *State Highway Dep't v. Barnwell Bros., Inc.*, 303 U.S. 177, 187 (1938) (“Congress not acting, state regulation of intrastate carriers has been upheld regardless of its effect upon interstate commerce.”); *Moorman Mfg. Co. v. Bair*, 437 U.S. 267, 277–78 (1978) (rejecting the argument that judicial invalidation of a nondiscriminatory state statute is required under the Commerce Clause to alleviate asymmetrical burdens on interstate commerce); *S. Pac. Co. v. Ariz. ex rel. Sullivan*, 325 U.S. 761, 795 (1945) (Douglas, J., dissenting) (“I have expressed my doubts whether the courts should intervene in situations like the present and strike down state legislation on the grounds that it burdens interstate commerce.”); *Kassel v. Consol. Freightways Corp.*, 450 U.S. 662, 705 (1981) (Rehnquist, J., dissenting) (acknowledging that “[w]henver a State enacts more stringent safety measures than its neighbors, in an area which affects commerce, the safety law will have the incidental effect of deflecting interstate commerce to the neighboring States,” but refusing to strike down the state law).

³¹⁶ See, e.g., *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 476 (1981) (Powell, J., concurring) (noting that “this Court has no basis for *inferring* a rejection of the quite specific

agreement under the dormant Commerce Clause is that it prevents intentional protectionism, it would seem particularly important for the Court to defer to trial court determinations regarding such findings, as long as such determinations are truly independent.³¹⁷ Third, to avoid dormant Commerce Clause challenges to mismatched regulations, the Supreme Court, where possible, could broadly construe federal laws that create uniform products standards so as to preempt inconsistent state standards.³¹⁸ Finally, the Court should confirm that because *Bibb* balancing is dynamic and depends on facts on the ground, *stare decisis* should not attach firmly to decisions in mismatch cases. Changing conditions on the ground—whether economic, regulatory, or commercial—properly affect *Bibb* balancing.

C. Alternatives to *Bibb* Balancing

1. Mutual Recognition and Harmonization

One potential alternative solution to mismatch cases would be for the Supreme Court to adopt (or endorse) coordination rules, which are rules for picking the prevailing rule. *CTS Corp. v. Dynamics Corp. of America*³¹⁹ is an example of the Supreme Court deferring to a pre-existing coordination rule in use by the states.³²⁰ Under the internal affairs doctrine, states defer to the state of incorporation regarding regulations that govern a corporation's "internal affairs." In *CTS*, the Supreme Court determined that, as a practical matter, a state that applied its antitakeover rules only to companies chartered in its own territory created no unconstitutional mismatch risk. The Court's reasoning depended on widespread adherence to the internal affairs

factfindings by the trial court"); *Barnwell*, 303 U.S. at 192–95 (ignoring the factual findings of the trial court).

³¹⁷ The concern with relying on lower courts' factual findings includes that state judges might be less willing than federal judges to make factual findings against the interests of state legislatures and in-state voters because in many states, state judges lack the independence of federal judges. See, e.g., Paul M. Friedman, *Threats to Judicial Independence and the Rule of Law*, ABA (Nov. 18, 2019), <https://www.americanbar.org/groups/litigation/initiatives/committee-on-american-judicial-system/in-the-news/threats-to-judicial-independence-and-rule-of-law/> [https://perma.cc/J69M-2TH5] ("In contrast to the institutional independence guaranteed to federal judges by the Constitution, most state court judges are not so insulated from outside pressures.").

³¹⁸ For example, four justices in *Florida Lime* would have held that California's fat-content rule was preempted by federal agricultural standards that determined the ripeness of avocados based on picking-date and size. *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 169 (1963) (White, J., dissenting).

³¹⁹ 481 U.S. 69 (1987).

³²⁰ *Id.* at 78.

doctrine, and the decision in *CTS* also had the effect of endorsing the internal-affairs doctrine as an appropriate coordination rule.³²¹

The Court of Justice of the European Union (“CJEU”) goes further by expressly adopting coordination rules of its own devising. The CJEU interprets a treaty regime that—like our Constitution—assures both state regulatory autonomy and free movement of goods, business establishments, and capital throughout the common market.³²² In 1979, in the famous *Cassis de Dijon* case, France required fruit liqueurs to contain at most twenty percent alcohol, whereas Germany required such liqueurs to contain at least twenty-five percent alcohol.³²³ As a result, products manufactured to French specifications could not be sold in Germany, and vice versa. Because the treaties of the European Union unsurprisingly provided no guidance as to the appropriate alcohol content of liqueur, it was not clear which state’s rule should prevail.

To resolve the case, the CJEU fashioned the celebrated “mutual recognition” requirement, under which products that comply with the regulation of their *state of manufacture* are putatively free to circulate in all other EU states.³²⁴ Mutual-recognition rules specify the jurisdictional basis—call it the jurisdictional hook³²⁵—that will govern a particular type of regulation for the whole European Union. The state that possesses that jurisdictional hook is called the *origin state*, while all other EU states are *destination states* for that type of regulation. Thus, rather than simply precluding mismatched regulations and leaving it to the challenged state to choose among forbearance, conformity, and coordination as a response, the CJEU itself specifies an EU-wide coordination rule—that is, it specifies the jurisdictional hook—for a given type of regulation. Again, the best-known example is *Cas-*

³²¹ It is uncertain whether the internal-affairs doctrine represents a constitutional requirement. See generally Richard M. Buxbaum, *The Threatened Constitutionalization of the Internal Affairs Doctrine in Corporation Law*, 75 CAL. L. REV. 29 (1987).

³²² For similarities between the dormant Commerce Clause and the EU fundamental freedoms, see generally Ruth Mason & Michael S. Knoll, *What is Tax Discrimination?*, 121 YALE L.J. 1014, 1106–15 (2012).

³²³ Case 120/78, *Rewe-Zentral v Bundesmonopolverwaltung für Branntwein* (*Cassis de Dijon*), 1979 E.C.R. 649, ¶ 1–3. Although the literature on mutual recognition is very substantial, especially in Europe, as far as we know, no one has argued that preclusion or affirmation under the dormant Commerce Clause doctrine may be understood to implicitly endorse mutual-recognition rules. Cf. Mathews & Stone Sweet, *supra* note 280, at 823–24.

³²⁴ *Cassis de Dijon*, 1979 E.C.R. at ¶ 14. See generally Jacques Pelkmans, *Mutual Recognition in Goods. On Promises and Disillusions*, 14 J. EUR. PUB. POL’Y 699, 703 (2007).

³²⁵ The term “jurisdictional hook” is ours; the CJEU does not use it. We use the term to avoid ambiguity between “origin state” in a mutual-recognition sense and “origin state” in the ordinary sense.

sis, in which the CJEU determined that the jurisdictional hook for consumer-protection regulation would be the state of manufacture, and all other states (as “destination states”) would have to accept products that complied with the rules of their state of manufacture.³²⁶ Mutual recognition combines a uniform jurisdictional hook with limited preclusion of destination states’ rules.

Mutual recognition relies on a crucial assumption, namely that there exists a fundamental consonance between different states’ policies that regulate the same subject matter.³²⁷ The notion of regulatory consonance works as follows: if the rules of both the origin and destination states are designed to protect consumers, then either state should be able to rely on the other’s rule. If this is so, then to promote market integration, rules that aim at the same outcome should be mutually recognized, even if they differ in specification. However, if the destination state can point to an important state interest that is not addressed by the origin state’s rule, then mutual recognition does not apply, and the destination state may apply its own rule.³²⁸ To avoid unravelling the benefits of mutual recognition, the CJEU construes this exception narrowly.³²⁹

Mutual recognition represents a bold intervention. Not only does the CJEU resolve the particular regulatory conflict before it, but it promulgates the functional equivalent of a conflict-of-law rule for the whole EU on the regulatory area subject to conflict. Such an approach is bold because of its broad applicability. But it also avoids what is, under the current doctrine of the Supreme Court, a stark choice: a reviewing court faced with a regulatory mismatch must either choose one state’s rule over another state’s or allow the conflict to remain.

The U.S. product-packaging cases discussed above, *Hunt* and *Clover Leaf*, can be placed into a mutual-recognition paradigm. In *Hunt*, the goal of both the North Carolina and Washington apple-labeling regimes were ostensibly to inform the consumer of the quality of the apples, thereby protecting consumers from fraud or confusion. Although North Carolina preferred the federal grading regime to the Washington grading regime, the Supreme Court essentially held that because the Washington regime was sufficient to meet North Carolina’s policy goal, North Carolina had to recognize that regime, rather

³²⁶ *Cassis de Dijon*, 1979 E.C.R. at ¶ 15.

³²⁷ Pelkmans, *supra* note 324, at 703.

³²⁸ See, e.g., *Cassis de Dijon*, 1979 E.C.R. at ¶ 8 (recognizing exceptions related to tax, fairness, public health, and consumer protection).

³²⁹ Pelkmans, *supra* note 324, at 711.

than displace it. This is tantamount to requiring mutual recognition. By contrast, Minnesota's environmental goals in *Clover Leaf* could not be fulfilled by the plastic milk containers that origin states permitted. Other states' more permissive container regulations were likely motivated by goals other than environmentalism. Under a European conception of mutual recognition, the failure of the origin state's regulation to meet the destination state's policy goals may entitle the destination state to displace the origin state's regulation. Notions of mutual recognition also may emerge in narrow tailoring analysis in dormant Commerce Clause cases. For instance, the Court's conclusion in *Dean Milk* that Madison could have relied on out-of-state inspectors to achieve its milk-safety goals takes a mutual-recognition approach.³³⁰

Although the parallels between the EU's fundamental freedoms and the dormant Commerce Clause are obvious, the Supreme Court never has adopted the concept of origin and destination states, nor expressly adopted mutual-recognition rules, even when seized with severe regulatory conflicts.³³¹ Arguably the closest the Supreme Court has come to mutual recognition was to approve a coordination rule—the internal-affairs doctrine—that the states had already adopted themselves.³³² Moreover, mutual recognition would require courts to develop an approach to decide which state would serve as the origin state for any particular situation. In some circumstances, such as the production of goods, the origin state may seem easy to select. However, in other circumstances, such as online activities, the issue is more complicated. Courts could choose the origin state by reference to national welfare,³³³ conflict-of-laws rules,³³⁴ general constitutional principles,³³⁵ or imagined interstate bargaining.³³⁶

³³⁰ *Dean Milk Co. v. City of Madison*, 340 U.S. 349, 356 (1951).

³³¹ Some might regard authorizing legislation as needed to propound mutual-recognition rules. One reason to doubt that the Supreme Court would seek to impose mutual-recognition rules in regulatory mismatch cases is the Court's virtual withdrawal from a constitutional jurisprudence of conflict of laws. Douglas Laycock, *Equal Citizens of Equal and Territorial States: The Constitutional Foundations of Choice of Law*, 92 COLUM. L. REV. 257–58 (1992) (citing *Allstate Insurance Co. v. Hague*, 449 U.S. 302 (1981), as part of a discussion concluding that “the modern Supreme Court has all but abandoned the field” of constitutional review of state conflict-of-laws rules).

³³² *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 78 (1987).

³³³ Harold W. Horowitz, *The Commerce Clause as a Limitation on State Choice-of-Law Doctrine*, 84 HARV. L. REV. 806, 814 (1971) (advocating that under the dormant Commerce Clause, the Supreme Court should select national regulations that “would best facilitate multistate commercial transactions”).

³³⁴ See generally Laycock, *supra* note 331, at 252–56 (discussing various approaches to conflicts-of-laws questions).

³³⁵ See generally *id.* at 250–51 (observing in the conflict-of-laws context that although the

2. Requiring “National Treatment” for “Like Products”

The European Union is not alone in constraining states’ abilities to enact and enforce mismatched regulations. The international rules that have underpinned the global economic system since the end of World War II do likewise. In 1948, the victorious allies, believing that a multilateral trade framework would both restrain the protectionist pressures that exacerbated the Great Depression and promote peace and security, established the General Agreement on Tariffs and Trade (“GATT”).³³⁷ The drafters’ goals were to create a framework that would reduce tariffs and establish a basic code of conduct for international trade. In a series of negotiations, the GATT members sharply reduced their tariff rates.³³⁸ In order to meaningfully hold the member countries to the tariff-reduction commitments they made, the GATT also included a requirement of “national treatment.”³³⁹ Under the national treatment provision, members cannot use internal laws, taxes, or nontax regulations to discriminate against imports from member states that are “like” domestic goods.³⁴⁰ An imported product is “like” a domestic product if it is “a directly competitive or substitutable product.”³⁴¹

Although it is widely recognized that it has been difficult to apply the concept of “like product” consistently and uniformly because its

Constitution does not “dictate[] a unique set of choice-of-law rules,” federal courts could use background constitutional principles to develop such rules, including the principles of (1) equal citizens, (2) equal states, and (3) territorial states, which Laycock defines, respectively, to mean that states “must treat the citizens of sister states equally with their own . . . must treat sister states as equal in authority to themselves . . . [and the idea that the] fundamental allocation of authority among states is territorial”); *see also* Erbsen, *supra* note 263, at 568–69 (“[C]ompeting state regulatory interests could lead a court to require one state to yield to another by inferring a [mandatory] comity principle from the structure of horizontal federalism. . . . A constitutional common law of comity, if applied with a light touch, could arguably help avoid interstate friction.”).

³³⁶ We are grateful to Dan Ortiz for suggesting Coasian bargaining to us.

³³⁷ *See* GATT, *supra* note 301; *see also* DOUGLAS A. IRWIN, PETROS C. MAVROIDIS & ALAN O. SYKES, *THE GENESIS OF THE GATT* 5–8 (2008).

³³⁸ *See* IRWIN ET AL., *supra* note 337, at 18–20.

³³⁹ GATT, *supra* note 301, art. III.

³⁴⁰ There are a few narrow exceptions permitted, such as for protecting health and exhaustible resources and for security. GATT, *supra* note 301, art. XX, XXI.

³⁴¹ *See The General Agreement on Tariffs and Trade (GATT 1947)*, WTO, https://www.wto.org/english/docs_e/legal_e/gatt47_03_e.htm#annexi [<https://perma.cc/YD3P-B7QQ>] (providing interpretative notes about provisions of the GATT); *see also* WTO, *GUIDE TO GATT LAW AND PRACTICE: VOLUME 1* 121, 124 (6th ed. 1995). In 1995, when the World Trade Organization (“WTO”), which updated the GATT, was created, the national treatment principle and the concept of “like products” were maintained.

boundaries are not well defined,³⁴² there is at least widespread agreement on what are the relevant factors: the products' physical characteristics, the end uses of the products, how the products are classified for tariff purposes, and how consumers view the products.³⁴³ Barring discrimination against foreign products that are "like" domestic products substantially curtails the ability of member states to enact protectionist policies that rely on small differences across products to justify differential treatment. It also prevents member states from treating products differently because of differences in the process or method of production.³⁴⁴ Thus, for example, the United States was challenged under the international trade framework when it banned imports of tuna that were caught using methods that killed more dolphins than U.S. standards allowed.³⁴⁵ The United States was found to have violated the national treatment standard because the tuna it banned was "like" the tuna that the United States allowed, namely both were canned yellowfin tuna (none of which contained dolphin meat).³⁴⁶

Notice, however, that under the logic of "like product" and "national treatment," the United States could have completely banned the sale of canned yellowfin tuna. Such a complete ban would not impact world trade less than did the U.S. ban on non-dolphin-safe tuna. But the multilateral trade rules do not aim at eliminating every impact on world trade that might arise from genuine policy differences. Instead, the rules aim to prevent invidious discrimination against foreign products. With a total ban, U.S. and non-U.S. producers would be equally affected. But when a country uses a process or method of production as a basis for differential treatment, the expectation is that domestic products will comply (and hence be allowed) whereas foreign products will not comply (and hence be excluded).

³⁴² See, e.g., Appellate Body Report, *Japan—Taxes on Alcoholic Beverages*, WTO Doc. WT/DS8/AB/R (adopted July 11, 1996) ("The concept of 'likeness' is a relative one that evokes the image of an accordion. The accordion of 'likeness' stretches and squeezes in different places as different provisions of the *WTO Agreement* are applied. The width of the accordion in any one of those places must be determined by the particular provision in which the term 'like' is encountered as well as by the context and the circumstances that prevail in any given case to which that provision may apply.").

³⁴³ Panel Report, *Japan—Customs, Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, L/6216 (Nov. 10, 1987), GATT B.I.S.D. (34th Supp.), at 93 (1988).

³⁴⁴ See Robert E. Hudec, "Like Product": *The Differences in Meaning in GATT Articles I and III*, in *REGULATORY BARRIERS AND THE PRINCIPLE OF NON-DISCRIMINATION IN WORLD TRADE LAW* 104 (Thomas Cottier & Petros C. Mavroidis eds., 2000).

³⁴⁵ See Panel Report, *United States—Restrictions on Imports of Tuna*, DS21/R (Sept. 3, 1991), GATT B.I.S.D. (39th Supp.), at 156–57 (1993).

³⁴⁶ *Id.* at 204–05.

If the U.S. Supreme Court were to interpret the dormant Commerce Clause to include a principle analogous to the multilateral trade system's national treatment principle for like products, states would be prohibited from using narrow distinctions to differentiate among products. Thus, for example, because caged eggs and cage-free eggs are like products different only with respect to production process—that is, they are the same in their physical characteristics, end uses, and are seen as close substitutes based on consumer tastes and habits—California would not be able to allow the sale of cage-free eggs while banning the sale of imported caged eggs. At the same time, however, California could ban the sale of eggs entirely. Although such a ban might have a larger impact on interstate commerce than would a ban of non-cage-free eggs, the logic underlying the multilateral trade rule is that states will not give in to protectionist pressures if the only way to do so is by enacting comprehensive bans because such bans would harm domestic producers (and consumers) as much as out-of-state producers. Thus, any comprehensive bans would likely reflect policy preferences other than protectionism. Notice also that if California did enact a complete ban on the sale of eggs, such a complete ban would not interfere with any other state's ability to prescribe regulations for egg production in their own territory. Thus, California's outright ban would not interfere with Minnesota's ability to regulate its own territory; mediating such interstate disputes is one of the horizontal federalism concerns addressed by dormant Commerce Clause review of mismatches.

3. *Focusing Exclusively on Legislative Intent*

Donald Regan's 1986 article, *The Supreme Court and State Protectionism: Making Sense of the Dormant Commerce Clause*, remains one of the most influential contributions on the dormant Commerce Clause. He argued that all the Supreme Court does, and all it should do, in dormant Commerce Clause cases is smoke out intentional protectionism.³⁴⁷ Although Regan limited this argument to what he called the free-movement-of-goods cases, and so did not include many of the mismatch cases this Article discussed, the same argument also could be made with respect to mismatch cases. That is, when faced with a regulatory mismatch, the Supreme Court could consider only whether the trial court record supports the conclusion that the mismatch was undertaken for protectionist reasons. Under this approach, if the in-

³⁴⁷ See generally Regan, *supra* note 16.

tent was protectionist, the regulation would be precluded; otherwise, the regulation would be upheld. Thus, trial courts would resolve the main issue in any mismatch case.

There is an obvious appeal to focusing on intent in mismatch cases; it would avoid balancing. But even setting aside concerns about whether a legislature can have a single intention,³⁴⁸ or concerns about whether trial courts would fail to uncover intentional protectionism,³⁴⁹ resolving mismatch cases solely by reference to intentional protectionism would seem to be insufficient. First, mismatched regulations segment the national marketplace even when such regulations are not motivated by protectionism. Second, limiting dormant Commerce Clause review to cases of intentional protectionism would seem to supply the states with a roadmap. To segment the market and to protect insiders from competition, all a state legislature would need to do

³⁴⁸ In *Kassel*, Justice Brennan pointed to the gubernatorial veto of a bill passed by the Iowa legislature that would have increased Iowa's limits to sixty-five feet. *Kassel v. Consol. Freightways Corp.*, 450 U.S. 662, 684 (Brennan, J., concurring). In vetoing the bill, the governor noted that the regulatory change would have increased traffic and accidents in Iowa. *Id.* Thus, concluded Justice Brennan, "Iowa's actual rationale" for the regulation had nothing to do with the difference in safety between trucks of different lengths; instead, "Iowa sought to discourage interstate truck traffic on Iowa's highways." *Id.* at 681–82 (Brennan, J., concurring). Brennan regarded the goal to deflect traffic to be an impermissible state interest because it was "*protectionist* in nature." *Id.* at 685 (emphasis in original). In response, Justice Rehnquist first questioned whether a legislature could even have "one discernible 'actual' purpose" capable of being discovered by a court. *Id.* at 702 (Rehnquist, J., dissenting). Next, he noted that "[s]triking down legislation . . . because of asserted impermissible motives for not enacting other legislation, motives which could not possibly have been present when the legislation under challenge here was considered and passed," was "unprecedented in this Court's history." *Id.* at 705 (emphasis omitted).

³⁴⁹ *Bibb* may be an example of failure to uncover intentional protectionism. The late Abner Mikva, congressman, circuit court judge, and White House counsel, noted that when he was in the Illinois legislature, he frequently voted "present," rather than "yea" or "nay," because a bill just smelled bad. Interview by Mark DePue with Judge Abner Mikva, former Congressman, D.C. Cir. Judge, and Clinton White House Couns., in Chicago, Ill. (Oct. 22, 2014), https://presidentlincoln.illinois.gov/Resources/c013a7b0-0931-4c38-83c4-2ff88a7abf12/Mikva_Abner_EXCPT_TRSCRPT.pdf [<https://perma.cc/VTC5-BXFP>]. The example Mikva gave was a 1955 bill requiring curved mudflaps on Illinois roads. *Id.* Paul Powell, a powerful Illinois legislator, who twice served as speaker, had introduced the bill. *Id.* Mikva was not sure what was going on, but to him the bill smelled bad. *Id.*

Although the courts that handled *Bibb* raised no concerns about improper motives, when Paul Powell died in 1970, it was clear that Mikva's nose was onto something. Among the many assets Powell had in his \$4.6 million estate when he died, were 17,000 shares in one Illinois company that produced curved mudflaps and a \$55,000 promissory note from another mudflap company. Dorothy Clune, *Powell Estate Inventory Filed*, MOUNT CARMEL DAILY REPUBLICAN REG., Jan. 29, 1971, at 1. A federal investigation determined that Powell acquired much of his wealth from bribes, and he had been bribed to introduce the bill that advanced the mudflap companies' interests. *Fender Guard Admits Writing Law*, CHI. DAILY TRIB., Feb. 9, 1957, at 7.

is adopt a mismatch that asymmetrically burdens interstate commerce without giving as the reason for doing so the desire to reduce or eliminate competition from outsiders. Savvy legislatures could thus impose intentionally protectionist mismatches with impunity. Third, limiting review to intentional protectionism would ignore the structural federalism concerns that mismatch cases raise, including questions regarding proper allocation of power among states. Thus, limiting judicial review of mismatched regulations only to those motivated by protectionist intent would do nothing to limit even severe *intentional* regulatory spillovers (provided such spillovers were not intentionally protectionist).³⁵⁰

CONCLUSION

Most commentators and, by our estimates, a majority of the newly constituted Supreme Court, support the nondiscrimination strand of dormant Commerce Clause doctrine, but much more controversy surrounds undue burdens. Views diverge about whether regulations that are facially neutral should be immune from scrutiny under the dormant Commerce Clause. That divergence is not surprising given the important values on both sides—the interest in preventing state enmities and protecting the national marketplace on the one hand, and the interests in preserving state autonomy and regulatory diversity on the other hand. Dormant Commerce Clause cases involve trading off these values against each other.

It is worth understanding, however, which cases pose the hardest problems under the dormant Commerce Clause, and which draw the most justified criticism. This Article sought to supplement the tradi-

³⁵⁰ An example is a California law that prohibits sales in California of pork from the offspring of breeding sows confined in a manner California considers cruel. CAL. HEALTH & SAFETY CODE § 25990(b) (West 2022). Such law probably cannot be reasonably said to have been intended to protect California hog farmers from outside competition because there are so few hog farmers in California. Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit at 17, *Nat'l Pork Producers Council v. Ross*, No. 21-468 (filed Sept. 27, 2021) (noting that 99.9 percent of pork sold in California is derived from sows outside of the state). However, the law can be understood as intended to impose California standards on hog farmers outside of California. Brief for the United States as Amicus Curiae Supporting Petitioners at 19, *Nat'l Pork Producers Council v. Ross*, No. 21-468 (filed Jun. 1, 2022) (“Proposition 12’s primary ‘purpose’—and according to the California Department of Food and Agriculture, its only substantial purpose—is ‘to prevent animal cruelty by phasing out’ what California voters deem to be ‘extreme methods of farm animal confinement.’” (citations omitted)). One of the issues in *Nat'l Pork Producers Council v. Ross*, set for argument in the Court’s 2022-23 term, is whether California has a constitutionally legitimate interest in housing conditions of *out-of-state* animals. The U.S. Solicitor General argues that California has no such interest. Brief for the United States, *supra*, at 19–24.

tional discrimination/undue-burden distinction in dormant Commerce Clause cases with a distinction that takes account of the type of burden imposed by the regulation: whether it is single-state or mismatch. Reframing the doctrine allowed us to show that (1) mismatch cases are meaningfully different than single-state cases, which is why they receive different treatment by the Supreme Court; (2) there are more sources of doctrinal uncertainty in mismatch cases than single-state cases, due to fundamental disagreements about whether and how to resolve such cases; (3) more so than single-state cases, decisions to preclude or uphold in mismatch cases tend to endorse particular rules and policy shifts; and (4) unlike single-state cases that principally raise concerns about the smooth functioning of the national market, mismatch cases raise fundamental horizontal federalism questions about the allocation of power between states. Thus, this Article sought to make clear what is really at stake in mismatch cases, how they differ from single-state cases, and why they generate so much controversy.

The goal of this Article was not to argue that the Supreme Court either should abandon undue-burden balancing in mismatch cases or engage in more balancing in such cases. Instead, the goal was to clarify what is actually happening in dormant Commerce Clause cases, including mismatch cases, to explain why it matters in terms of regulatory outcomes, the national economy, and federalism more generally, and to offer some rational ways of improving or curtailing balancing in mismatch cases.

TABLE. APPROACH OF JUSTICES IN MISMATCH CASES DISCUSSED IN PART II (AUTHOR CREATED)³⁵¹

Justice	Party of Appointing President	<i>Barnwell</i> 1938	<i>S. Pac.</i> 1945	<i>Bibb</i> 1959	<i>Hunt</i> 1977	<i>Moorman</i> 1978	<i>Kassel</i> 1981	<i>Clover Leaf</i> 1981
Black	D	N	N	I				
Blackmun	R				I	I	I	N
Brandeis	D	N						
Brennan	R			I	I	I	I	N
Burger	R				I	N	N	N
Butler	R	N						
Clark	D			I				
Douglas	D		N	I				
Frankfurter	D		I	I				
Harlan	R			I				
Hughes	R	N						
Jackson	D		I					
Marshall	D				I	N	I	N
McReynolds	D	N						
Murphy	D		I					
Powell	R				I	I	I	N/A
Reed	D		I					
Rehnquist	R					N	N	
Roberts	R	N	I					
Rutledge	D		I					
Stevens	R				I	N	I	I
Stewart	R			I	I	N	N	N
Stone	R	N	I					
Warren	R			I				
White	D				I	N	I	N
Whittaker	R			I				

³⁵¹ We are grateful to Lawrence Barker, UVA J.D. expected 2023, for this table. In this table, “N” indicates a noninterventionist approach, “I” indicates an interventionist approach, and “N/A” indicates that the justice did not reach the mismatch issue.

“Nutrition Facts Labels” for Artificial Intelligence/Machine Learning-Based Medical Devices—The Urgent Need for Labeling Standards

Sara Gerke*

ABSTRACT

Artificial Intelligence (“AI”), particularly its subset Machine Learning (“ML”), is quickly entering medical practice. The U.S. Food and Drug Administration (“FDA”) has already cleared or approved more than 520 AI/ML-based medical devices, and many more devices are in the research and development pipeline. AI/ML-based medical devices are not only used in clinics by health care providers but are also increasingly offered directly to consumers for use, such as apps and wearables. Despite their tremendous potential for improving health care, AI/ML-based medical devices also raise many regulatory issues. This Article focuses on one issue that has not received sustained attention in the legal or policy debate: labeling for AI/ML-based medical devices. Labeling is crucial to prevent harm to patients and consum-

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ers (e.g., by reducing the risk of bias) and ensure that users know how to properly use the device and assess its benefits, potential risks, and limitations. It can also support transparency to users and thus promote public trust in new digital health technologies.

This Article is the first to identify and thoroughly analyze the unique challenges of labeling for AI/ML-based medical devices and provide solutions to address them. It establishes that there are currently no standards of labeling for AI/ML-based medical devices. This is of particular concern as some of these devices are prone to biases, are opaque (“black boxes”), and have the ability to continuously learn. This Article argues that labeling standards for AI/ML-based medical devices are urgently needed, as the current labeling requirements for medical devices and the FDA’s case-by-case approach for a few AI/ML-based medical devices are insufficient. In particular, it proposes what such standards could look like, including eleven key types of information that should be included on the label, ranging from indications for use and details on the data sets to model limitations, warnings and precautions, and privacy and security. In addition, this Article argues that “nutrition facts labels,” known from food products, are a promising label design for AI/ML-based medical devices. Such labels should also be “dynamic” (rather than static) for adaptive algorithms that can continuously learn. Although this Article focuses on AI/ML-based medical devices, it also has implications for AI/ML-based products that are not subject to FDA regulation.

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INTRODUCTION

Alicia is a forty-six-year-old Black patient who sees her dermatologist for an annual skin exam. In earlier check-ups, the dermatologist inspected Alicia’s skin with a dermatoscope, a device that enhances the doctor’s view by visualizing the epidermis (the outer surface of the skin) and the layers beneath it, to diagnose cancerous and non-cancerous skin lesions.¹ This time, rather than using the dermatoscope, the dermatologist uses a new software program pow-

¹ For more information on annual skin exams and the dermatoscope, see *Annual Exams: Five Easy Steps to Prepare Yourself*, SKIN CANCER FOUND. (2022), <https://www.skincancer.org/early-detection/annual-exams> [<https://perma.cc/JM6B-2FBG>]; Jenna Fletcher, *What Is a Dermatoscope, and What Does It See?*, MEDICALNEWSTODAY (Mar. 18, 2021), <https://www.medicalnewstoday.com/articles/dermatoscope> [<https://perma.cc/Q6B6-6YF4>].

ered by Artificial Intelligence (“AI”)/Machine Learning (“ML”) that has just received marketing authorization. The new AI/ML dermatology tool is based on artificial neural networks (so-called “deep learning,” a subset of ML) to detect skin cancer in patients.²

The dermatologist takes several photos of Alicia’s skin and moles from different angles and uploads them to a cloud server. A few seconds later, the AI/ML dermatology tool answers: “No skin cancer detected. Reassess in twelve months.” Alicia is relieved that everything is alright and goes home satisfied. The AI/ML dermatology tool, however, missed that one of Alicia’s moles shows the first signs of melanoma, a serious type of skin cancer that usually requires surgery and can be fatal if left untreated.³

How could this happen? Why did the new AI/ML dermatology tool miss this diagnosis? It turns out that the algorithm was primarily trained on images of people with white skin. Therefore, it is not surprising that the AI/ML tool is likely to provide incorrect answers for people with brown and black skin. Moreover, the tool uses deep learning and is thus a noninterpretable AI/ML—a so-called “black-box” model—which means that it was impossible for the dermatologist—and humans in general—to understand the basis for its decision.⁴ In addition, the labeling of the AI/ML dermatology tool contains neither information about the training data set, such as race/ethnicity breakdown, nor warnings to dermatologists about the potential biases and risks related to the use of the tool.

This scenario is hypothetical, but it highlights a real-world issue. For example, Google has recently come under criticism for its AI-powered dermatology app because ninety percent of the training data set, consisting of a total of almost sixty-five thousand skin images, were images from people with light brown, darker white, or fair skin.⁵ Google’s AI-powered dermatology app is not yet available on the

² For more information on deep learning, see *infra* Section I.A.1.

³ See *Melanoma Overview: A Dangerous Skin Cancer*, SKIN CANCER FOUND. (Jan. 2022), <https://www.skincancer.org/skin-cancer-information/melanoma> [<https://perma.cc/5L4P-29B2>].

⁴ See *infra* Section I.A.2. (explaining black-box models).

⁵ See Yuan Lui et. al., *A Deep Learning System for Differential Diagnosis of Skin Diseases*, 26 NAT. MED. 900, 902 (2020); Todd Feathers, *Google’s New Dermatology App Wasn’t Designed for People with Darker Skin*, VICE (May 20, 2021, 9:40 AM), <https://www.vice.com/en/article/m7evmy/googles-new-dermatology-app-wasn-t-designed-for-people-with-darker-skin> [<https://perma.cc/67ZK-Q7H6>]; Peggy Bui & Yuan Liu, *Using AI to Help Find Answers to Common Skin Conditions*, GOOGLE HEALTH (May 18, 2021), <https://blog.google/technology/health/ai-dermatology-preview-io-2021> [<https://perma.cc/A572-ERGQ>] (describing Google’s announcement of the plan to launch a pilot study of the new AI-powered dermatology app).

U.S. market,⁶ but AI, especially its subset ML, is quickly entering medical practice. The U.S. Food and Drug Administration (“FDA”) has already cleared or approved over 520 AI/ML-based products classified as medical devices (“AI/ML-based medical devices”),⁷ and many more devices are in the research and development pipeline. The global health care AI market is forecasted to reach \$51.3 billion by 2027, a compound annual growth rate of 41.4% from 2020.⁸ AI/ML-based medical devices are not only used in clinics by health care providers but are also increasingly offered directly to consumers for use, such as apps and wearables.⁹

Despite their tremendous potential for improving health care, AI/ML-based medical devices also raise many regulatory issues.¹⁰ This au-

⁶ See *DermAssist*, GOOGLE HEALTH, <https://health.google/consumers/dermassist> [<https://perma.cc/5CTE-2ABS>].

⁷ *Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices*, U.S. FOOD & DRUG ADMIN. (Oct. 5, 2022), <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices> [<https://perma.cc/8F5F-9G9S>]. For other (non-FDA) literature, see, e.g., Stan Benjamens, Pranavsingh Dhunoo & Bertalan Meskó, *The State of Artificial Intelligence-Based FDA-Approved Medical Devices and Algorithms: An Online Database*, 3 NPJ DIGIT. MED. no.118, 2020, at 1, 2 (counting sixty-four AI/ML-based medical devices); Urs J. Muehlematter, Paola Daniore & Kerstin N. Vokinger, *Approval of Artificial Intelligence and Machine Learning-Based Medical Devices in the USA and Europe (2015–20): A Comparative Analysis*, 3 LANCET DIGIT. HEALTH e195 (2021) (counting 222 AI/ML-based medical devices); Casey Ross, *As the FDA Clears a Flood of AI Tools, Missing Data Raise Troubling Questions on Safety and Fairness*, STAT+ (Feb. 3, 2021), <https://www.statnews.com/2021/02/03/fda-clearances-artificial-intelligence-data> [<https://perma.cc/8QMR-NS9W>] (counting 161 medical AI tools). For two other online databases, see also *FDA-Approved A.I.-Based Algorithms*, MED. FUTURIST, <https://medicalfuturist.com/fda-approved-ai-based-algorithms> [<https://perma.cc/2SPA-BGW6>]; *AI Central*, AM. COLL. RADIOLOGY, DATA SCI. INST., <https://models.acrdsi.org> [<https://perma.cc/K73Z-NFC5>].

⁸ RSCH. & MKTS., HEALTHCARE ARTIFICIAL INTELLIGENCE MARKET (Dec. 2020), <https://www.researchandmarkets.com/reports/4753853> [<https://perma.cc/XL6J-X8PK>].

⁹ The term “consumers” is understood here broadly and can include not only healthy individuals but also patients. For more information on direct-to-consumer uses, see *infra* Section I.B.2.

¹⁰ See, e.g., W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 419, 457–62 (2015); W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 MICH. L. REV. 421 (2017); Barbara Evans & Pilar Ossorio, *The Challenge of Regulating Clinical Decision Support Software After 21st Century Cures*, 44 AM. J.L. & MED. 237 (2018); Charlotte A. Tschider, *Regulating the Internet of Things: Discrimination, Privacy, and Cybersecurity in the Artificial Intelligence Age*, 96 DENV. L. REV. 87 (2018); Boris Babic, Sara Gerke, Theodoros Evgeniou & I. Glenn Cohen, *Algorithms on Regulatory Lockdown in Medicine*, 366 SCIENCE 1202 (2019); W. Nicholson Price II, *Medical AI and Contextual Bias*, 33 HARV. J.L. & TECH. 65, 84–86, 100–15 (2019) [hereinafter Price, *Medical AI and Contextual Bias*]; Nicolas Terry, *Of Regulating Healthcare AI and Robots*, 21 YALE J.L. & TECH. 133 (2019); Nathan Cortez, *Digital Health and Regulatory Experimentation at the FDA*, 21 YALE J.L. & TECH. 4 (2019); Sara Gerke, Boris Babic, Theodoros Evgeniou & I. Glenn Cohen, *The Need for a System View to Regulate Artificial Intelligence/Machine Learning-Based Software as Medical Device*, 3 NPJ DIGIT. MED., no.53, 2020, at 1

thor has extensively written about the need for a new regulatory framework that ensures that AI/ML-based medical devices are reasonably safe and effective when brought to the U.S. market and will stay so throughout their life cycle and has made several suggestions as to what such a framework might entail.¹¹ This Article focuses on one issue that has not received sustained attention in the legal or policy debate¹² despite its importance: labeling for AI/ML-based medical devices. Labeling is crucial to prevent harm to patients and consumers (e.g., by reducing the risk of bias) and ensure that users know how to properly use the device and assess its benefits, potential risks, and limitations. It can also support transparency to users and thus promote public trust in new digital health technologies.

But what types of information should be included on the label of an AI/ML-based medical device? What are the limits of labeling? Or, in other words, when can disclosures on labels not be used as an excuse to introduce a poorly designed device into the market? This Article attempts to answer such questions and fill the existing literature gap. To the author's knowledge, it is the first to identify and thoroughly analyze the unique challenges of labeling for AI/ML-based medical devices while providing solutions to address them.

This Article establishes that the current labeling requirements in Title 21 of the Code of Federal Regulations ("C.F.R.") for medical devices are insufficient, and that there are currently no labeling standards for AI/ML-based medical devices.¹³ As seen in our hypothetical example, this is of particular concern because AI/ML-based medical devices differ in many ways from traditional medical devices such as contact lenses. For instance, they are prone to biases, can be black-box models, and can continuously learn.¹⁴ Many AI/ML-based medical devices available on the U.S. market do *not* provide users with important information, such as gender and race/ethnicity breakdowns of the data

[hereinafter Gerke et al., *The Need for a System View*]; Timo Minssen, Sara Gerke, Mateo Aboy, Nicholson Price & Glenn Cohen, *Regulatory Responses to Medical Machine Learning*, J.L. & BIOSCI., Jan.–June 2020, at 1; Nicolas P. Terry, *Assessing the Thin Regulation of Consumer-Facing Health Technologies*, 48 J.L., MED. & ETHICS 94 (2020); Sara Gerke, *Health AI for Good Rather Than Evil? The Need for a New Regulatory Framework for AI-Based Medical Devices*, 20 YALE J. HEALTH, POL'Y, L. & ETHICS 432 (2021) [hereinafter Gerke, *Health AI*].

¹¹ See, in particular, Gerke, *Health AI*, *supra* note 10.

¹² See Evans & Ossorio, *supra* note 10, at 248 (briefly mentioning the misuse of labeling in the context of clinical decision support software); Price, *Medical AI and Contextual Bias*, *supra* note 10, at 104–07 (briefly discussing the pros and cons of labeling for medical AI in relation to contextual bias).

¹³ See *infra* Section III.A.

¹⁴ See *infra* Section III.B.

sets used.¹⁵ This is the case even for the majority of the few AI/ML-based medical devices for which the FDA required specific labeling requirements on a case-by-case basis, and thus patient health may be at risk from unnecessary treatment or biased care.¹⁶

Consequently, this Article argues that there is an urgent need for labeling standards for AI/ML-based medical devices, in particular, to avoid harm to patients and consumers and to create certainty for manufacturers. It also makes suggestions as to what such standards could look like. Although this Article focuses on AI/ML-based medical devices, it also has implications for AI/ML-based products that are not subject to FDA regulation.

This Article proceeds in four Parts. Part I explains what AI/ML is and how it is applied in health care. It first looks at key concepts of AI, including its definition and relevant subsets and types. It then discusses different applications of AI, ranging from clinical care to workflow optimization.

Part II analyzes when an AI/ML-based product is classified as a medical device under Section 201(h)(1) of the U.S. Federal Food, Drug, and Cosmetic Act (“FDCA”).¹⁷ It first investigates the principle of when an AI/ML-based product is considered a medical device and then explores relevant exceptions and the FDA’s enforcement discretion. In particular, this Part argues that FDA’s new final guidance on clinical decision support (“CDS”) software (“CDS Guidance”) to clarify the agency’s regulatory approach to CDS software functions¹⁸ falls short of expectations. Not only does the CDS Guidance seem to violate the 21st Century Cures Act,¹⁹ but it also creates legal uncertainty for AI/ML manufacturers and safety concerns.

Part III focuses on the challenges of labeling for AI/ML-based medical devices. It first examines the relevant labeling requirements in Title 21 of the C.F.R. for medical devices and shows that none of them are specifically geared toward AI/ML-based medical devices. This is followed by an analysis of why AI/ML-based medical devices differ in many aspects from traditional medical devices. In particular, this Part argues that labeling standards for AI/ML-based medical de-

¹⁵ See Ross, *supra* note 7. For more information on this issue, see *infra* Section III.C.

¹⁶ For more information on the FDA’s case-by-case analysis, see *infra* Section III.C.

¹⁷ 21 U.S.C. § 321(h)(1).

¹⁸ U.S. FOOD & DRUG ADMIN., CLINICAL DECISION SUPPORT SOFTWARE: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 5 (2022), <https://www.fda.gov/media/109618/download> [<https://perma.cc/5DDT-DQKF>].

¹⁹ 21st Century Cures Act, Pub. L. No. 114–255, § 3060, 130 Stat. 1033, 1130–33 (2016) (codified at 21 U.S.C. §§ 321(h)(1), 360j(o)).

vices are urgently needed, as the current labeling requirements for medical devices and the FDA's case-by-case approach for a few AI/ML-based medical devices are insufficient. AI/ML-based medical devices are not only increasingly deployed in clinical care but are also offered directly to consumers.²⁰ Without enough information on their benefits, potential risks, and limitations, AI/ML-based medical devices may harm patients and consumers. Lastly, Part III also discusses practical challenges and methods for implementing such new labeling standards.

Part IV proposes eleven key types of information that should be included on the label of any AI/ML-based medical device, namely: (1) Model Identifiers; (2) Model Type; (3) Model Characteristics; (4) Indications for Use; (5) Validation and Model Performance; (6) Details on the Data Sets; (7) Preparation Before Use and Application; (8) Model Limitations, Warnings, and Precautions; (9) Alternative Choices; (10) Privacy and Security; and (11) Additional Information. This list should not be considered exhaustive but should serve as a helpful starting point for the FDA to begin the overdue development of labeling standards for AI/ML-based medical devices. Moreover, this Part argues that "nutrition facts labels," known from food products, are a promising label design for AI/ML-based medical devices. Through their eye-catching design, they encourage users to read them. In addition, the proposed labels should also be "dynamic" (rather than static) for adaptive algorithms that can continuously learn.

I. WHAT IS AI AND HOW IS IT APPLIED IN HEALTH CARE?

To understand the challenges of labeling for AI/ML-based medical devices, one first needs to understand what AI is and how it is applied in health care. Part I clarifies relevant terms and applications.

A. Key Concepts

1. Definition of AI and Relevant Subsets

The term "Artificial Intelligence" ("AI") was coined for the first time in 1955²¹ and has since been used with different meanings and in different contexts. Up to now, the term has not been universally de-

²⁰ See *infra* Section I.B.2.

²¹ See JOHN MCCARTHY, M.L. MINSKY, N. ROCHESTER & C.E. SHANNON, A PROPOSAL FOR THE DARTMOUTH SUMMER RESEARCH PROJECT ON ARTIFICIAL INTELLIGENCE (1955), <http://jmc.stanford.edu/articles/dartmouth/dartmouth.pdf> [<https://perma.cc/B2KU-LBZZ>].

defined.²² An often-cited definition is the one by John McCarthy, an American computer scientist renowned as the father of AI²³: “It is the science and engineering of making intelligent machines, especially intelligent computer programs. It is related to the similar task of using computers to understand human intelligence, but AI does not have to confine itself to methods that are biologically observable.”²⁴ Another definition that is frequently referred to is from the leading AI textbook *Artificial Intelligence: A Modern Approach* by Stuart Russell and Peter Norvig, in which the two computer scientists organized different definitions of AI into four categories: (1) Thinking Humanly, (2) Acting Humanly, (3) Thinking Rationally, and (4) Acting Rationally.²⁵

Regardless of its definition, there seems to be a consensus that AI has several subsets. The most popular subset is machine learning (see Figure 1 below), which is “a set of methods that can automatically detect patterns in data, and then use the uncovered patterns to predict future data, or to perform other kinds of decision making under uncertainty.”²⁶ Classical ML is categorized into supervised and unsupervised ML.²⁷ In supervised ML, the goal is to predict the desired output based on the input data.²⁸ The model is trained with input data and the desired output labels.²⁹ An example is pathology slides, some of which contain cancer cells and some of which do not.³⁰ The algorithm usually analyzes the patterns in the labeled input-output pairs and learns to predict the correct outputs for given inputs of new cases.³¹ In unsupervised ML, algorithms are tasked with detecting patterns in unlabeled data.³² For example, it can identify subclusters of

²² Gerke, *Health AI*, *supra* note 10, at 440.

²³ Martin Childs, *John McCarthy: Computer Scientist Known as the Father of AI*, INDEPENDENT (Nov. 1, 2011, 1:00 PM), <https://www.independent.co.uk/news/obituaries/john-mccarthy-computer-scientist-known-father-ai-6255307.html> [https://perma.cc/VCP8-AAFU].

²⁴ John McCarthy, *What Is Artificial Intelligence?* 2 (Nov. 12, 2007) (unpublished manuscript), <http://www-formal.stanford.edu/jmc/whatisai.pdf> [https://perma.cc/MD82-K38A].

²⁵ STUART RUSSELL & PETER NORVIG, *ARTIFICIAL INTELLIGENCE: A MODERN APPROACH* 1–5 (4th ed. 2020).

²⁶ KEVIN P. MURPHY, *MACHINE LEARNING: A PROBABILISTIC PERSPECTIVE* 1 (2012).

²⁷ See Kun-Hsing Yu, Andrew L. Beam & Isaac S. Kohane, *Artificial Intelligence in Healthcare*, 2 NATURE BIOMED. ENG’G 719, 720 (2018).

²⁸ *Id.*

²⁹ *Id.*

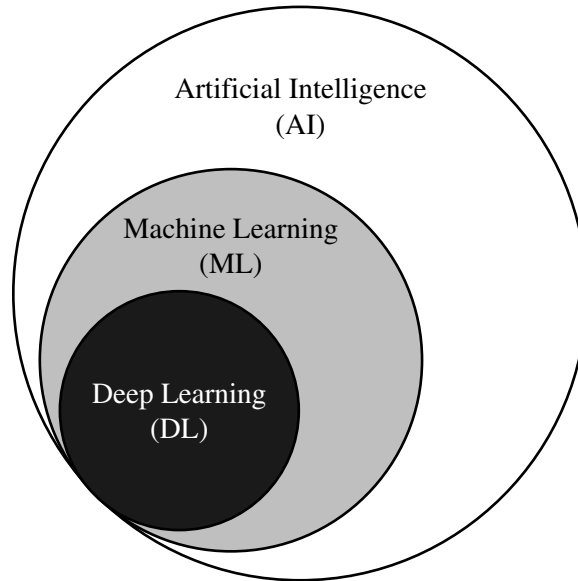
³⁰ AM. MED. ASS’N, *REPORT OF THE COUNCIL ON LONG RANGE PLANNING AND DEVELOPMENT* 254 (2018), <https://www.ama-assn.org/system/files/2018-11/a18-clrpd-reports.pdf> [https://perma.cc/SMC2-QVSL].

³¹ Yu et al., *supra* note 27, at 719.

³² *Id.* at 720; AM. MED. ASS’N, *supra* note 30, at 254.

the original data or create low-dimensional data representations.³³ A subset of ML is *deep learning* (see Figure 1 below), which has driven the rapid advances of AI in recent years and uses artificial neural networks to detect patterns in data.³⁴

FIGURE 1. AI AND RELEVANT SUBSETS



2. Types of AI

A distinction is also often made between *narrow or weak AI* and *general or strong AI*. Most AI-based products that currently surround us are narrow or weak AIs—AIs that perform specific tasks, such as playing Go, driving vehicles, or classifying skin cancer, just as well or occasionally better than humans.³⁵ In contrast, general or strong AI is a theoretical AI form that pertains to machines with an intelligence equal to humans, including self-aware consciousness.³⁶ Without a crystal ball, it is unclear what the future holds, but AI is expected to surpass human performance in complex tasks, such as performing surgeries.³⁷

³³ Yu et al., *supra* note 27, at 720.

³⁴ *Id.*; Gerke, *Health AI*, *supra* note 10, at 440.

³⁵ See IBM Cloud Educ., *Artificial Intelligence (AI)*, IBM (June 3, 2020), <https://www.ibm.com/cloud/learn/what-is-artificial-intelligence> [https://perma.cc/7P9Q-KEQJ]; Ahmed Hosny, Chintan Parmar, John Quakenbush, Lawrence H. Schwartz & Hugo J.W.L. Aerts, *Artificial Intelligence in Radiology*, 18 NATURE REV. CANCER 500, 502 (2018).

³⁶ IBM Cloud Educ., *supra* note 35.

³⁷ See Hosny et al., *supra* note 35, at 502.

Sometimes AI is also divided into three types based on its intelligence: *assisted*, *augmented*, and *autonomous*.³⁸ Assisted AI automates repetitive tasks, such as a universal robot that sorts blood samples.³⁹ This type of AI usually requires little or no human involvement.⁴⁰ In contrast, the term “augmented AI” emphasizes the idea that humans and machines work together collaboratively.⁴¹ AI enhances the physician’s intelligence instead of replacing it.⁴² An example is CDS software, such as an AI that gives individualized treatment recommendations.⁴³ And then there is autonomous AI that makes decisions with little or no human involvement.⁴⁴ An example is IDx-DR, an autonomous AI-based medical device used in more than twenty primary care practices across the U.S. to detect “more than mild diabetic retinopathy” in diabetic adult patients.⁴⁵ The uniqueness of IDx-DR is that it makes a medical decision—namely, to “rescreen in 12 months” or “refer [the patient] to an eye care professional”—without human supervision, meaning the primary care physician does *not* need to review its decision.⁴⁶

In recent times, a distinction has also been made between *interpretable AI/ML* and *explainable AI/ML*. Although there seems to be no universal definition or understanding of these terms, this Article interprets them as follows. Interpretable AI/ML refers to the use of “white-box” models, such as simple decision trees.⁴⁷ The use of inter-

³⁸ ANTHONY C. CHANG, INTELLIGENCE-BASED MEDICINE 12–13 (2020).

³⁹ *Id.*; Two UR5 Universal Robots Ensure Faster Delivery of Blood Sample Results, UNIVERSAL ROBOTS, <https://www.universal-robots.com/case-stories/gentofte-hospital> [https://perma.cc/2CVA-8PRT].

⁴⁰ CHANG, *supra* note 38, at 12–13.

⁴¹ *Id.* at 13.

⁴² AM. MED. ASS’N, *supra* note 30, at 254–55.

⁴³ See CHANG, *supra* note 38, at 12. An example of clinical decision support software is Watson for Oncology, developed by IBM. For more information on Watson for Oncology, see, e.g., Gerke, *Health AI*, *supra* note 10, at 456–57.

⁴⁴ CHANG, *supra* note 38, at 12.

⁴⁵ *Id.* at 13; Jack Carfagno, *IDx-DR, the First FDA-Approved AI System, Is Growing Rapidly*, DOCWIRE NEWS (Nov. 12, 2019), <https://www.docwirenews.com/docwire-pick/future-of-medicine-picks/idx-dr-the-first-fda-approved-ai-system-is-growing-rapidly> [https://perma.cc/C66X-Y5L6]; *IDx-DR*, DIGIT. DIAGNOSTICS, <https://dxs.ai/products/idx-dr/idx-dr-overview> [https://perma.cc/3FBK-B3H8]; U.S. FOOD & DRUG ADMIN., DE NOVO NO. DEN180001, CLASSIFICATION REQUEST FOR IDx-DR 1 (2018), https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180001.pdf [https://perma.cc/R4QY-RP93].

⁴⁶ Press Release, U.S. Food & Drug Admin., FDA Permits Marketing of Artificial Intelligence-Based Device to Detect Certain Diabetes-Related Eye Problems (Apr. 11, 2018), <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-artificial-intelligence-based-device-detect-certain-diabetes-related-eye> [https://perma.cc/4B7D-JHAE].

⁴⁷ Gerke, *Health AI*, *supra* note 10, at 490; see also Boris Babic, Sara Gerke, Theodoros

pretable algorithms has the advantage that they are transparent and can be understood by humans with reasonable effort.⁴⁸ Many AI/ML-based medical devices that are available on the U.S. market or in development, however, use deep learning.⁴⁹ For example, RhythmAnalytics is cloud-based software that uses deep neural network architecture to detect over fifteen cardiac arrhythmia types.⁵⁰ In such cases, where accuracy is critical, the use of *black-box AI/ML models*—algorithms typically labeled as deep learning—may often be superior to the use of white-box models.⁵¹ Black-box models, however, are frequently associated with a lack of trust and slow uptake in health care because the algorithms are very difficult, or even impossible, for human users to understand.⁵² Thus, a new research field—namely explainable AI/ML—is emerging to address these criticisms and concerns.⁵³ Explainable AI/ML refers to a black-box AI/ML model that is used to make diagnoses or predictions and a second explanatory algorithm—itself a white-box model—which approximates the outputs of the black box and provides post-hoc explanations.⁵⁴

Another important distinction is between *locked algorithms* and *adaptive algorithms*. The FDA defines a locked algorithm as “an algorithm that provides the same result each time the same input is applied to it and does not change with use.”⁵⁵ Examples include “static look-up tables, decision trees, and complex classifiers.”⁵⁶ Any AI/ML system that is fixed in advance can meet this definition.⁵⁷ As its name indicates, the term “adaptive algorithms” pertains to algorithms that

Evgeniou & I. Glenn Cohen, *Beware Explanations From AI in Health Care*, 373 SCIENCE 284, 284 (2021); Boris Babic & Sara Gerke, *Explaining Medical AI Is Easier Said Than Done*, STAT (July 21, 2021), <https://www.statnews.com/2021/07/21/explainable-medical-ai-easier-said-than-done> [<https://perma.cc/55Z4-YZ4J>].

⁴⁸ See sources cited *supra* note 47.

⁴⁹ See Benjamens et al., *supra* note 7, at 3–4.

⁵⁰ Biofourmis, *Biofourmis' RhythmAnalytics™ Platform Receives FDA Clearance for AI-Based Automated Interpretation of Cardiac Arrhythmias*, PR NEWswire (Apr. 30, 2019, 5:00 PM), <https://www.prnewswire.com/news-releases/biofourmis-rhythmanalytics-platform-receives-fda-clearance-for-ai-based-automated-interpretation-of-cardiac-arrhythmias-300841083.html> [<https://perma.cc/DDF3-QWZ5>].

⁵¹ See Babic et al., *supra* note 47, at 284; Babic & Gerke, *supra* note 47.

⁵² See sources cited *supra* note 47.

⁵³ *Id.*

⁵⁴ *Id.*; Gerke, *Health AI*, *supra* note 10, at 490.

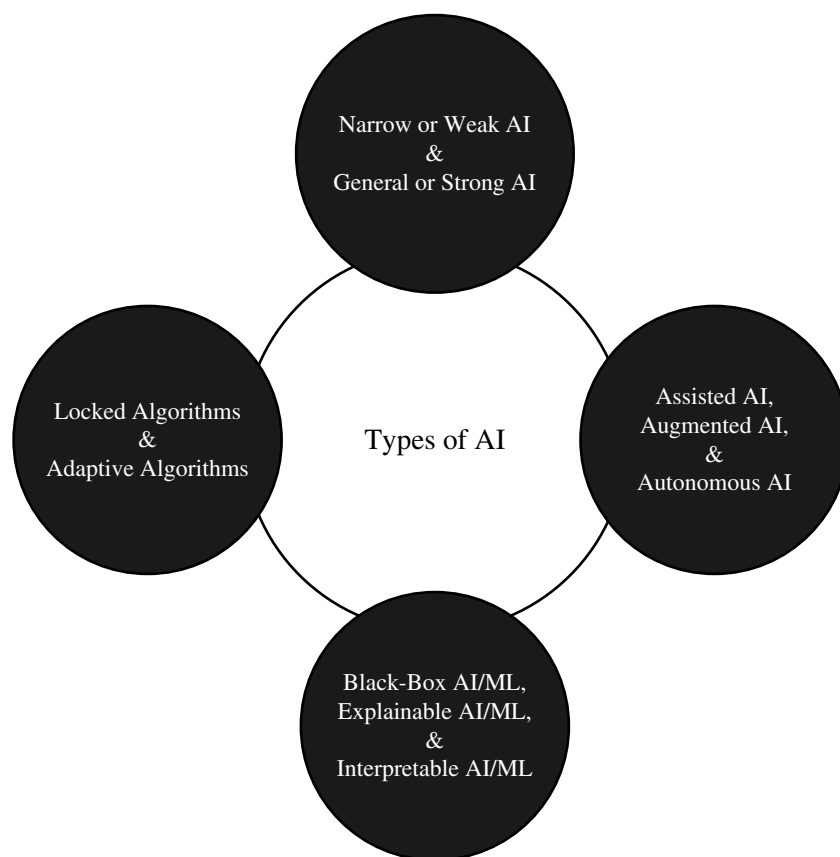
⁵⁵ U.S. FOOD & DRUG ADMIN., PROPOSED REGULATORY FRAMEWORK FOR MODIFICATIONS TO ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD) 3 n.7 (2019), <https://www.fda.gov/media/122535/download> [<https://perma.cc/67VX-NJTF>].

⁵⁶ *Id.*

⁵⁷ Babic et al., *supra* note 10, at 1203.

are adaptive. They have the ability to continuously learn from real-world experience and can change as they are applied to novel data.⁵⁸ The AI/ML-based medical devices that have received marketing authorization by the FDA thus far have typically included locked algorithms.⁵⁹ Figure 2 below depicts the different types of AI discussed in this Section.

FIGURE 2. TYPES OF AI



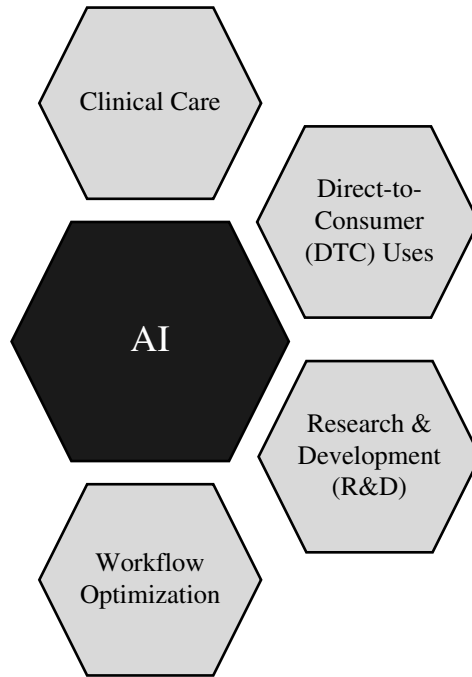
B. Different Applications and Different Users

AI can be applied in different contexts for different purposes and can be addressed to different users. In the health and research context, AI is expected to be increasingly used in four areas, as shown in Figure 3 and discussed below.

⁵⁸ U.S. FOOD & DRUG ADMIN., *supra* note 55, at 3; Gerke et al., *The Need for a System View*, *supra* note 10, at 4.

⁵⁹ U.S. FOOD & DRUG ADMIN., *supra* note 55, at 3.

FIGURE 3. KEY AREAS OF APPLICATIONS OF AI IN THE HEALTH AND RESEARCH CONTEXT



1. Clinical Care

AI is already applied in clinical care, especially in medical imaging and disease diagnostics.⁶⁰ For example, OsteoDetect is a software device used by clinicians to detect a common wrist fracture type, called distal radius fractures.⁶¹ OsteoDetect uses deep learning to analyze adult wrist radiographs for this type of fracture.⁶² Another example is Viz ICH, an AI/ML-based medical device that analyzes noncontrast computed tomography brain images.⁶³ If a suspected intracranial hemorrhage is identified, Viz ICH sends notifications to a

⁶⁰ Gerke, *Health AI*, *supra* note 10, at 442.

⁶¹ Press Release, U.S. Food & Drug Admin., FDA Permits Marketing of Artificial Intelligence Algorithm for Aiding Providers in Detecting Wrist Fractures (May 24, 2018), <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-artificial-intelligence-algorithm-aiding-providers-detecting-wrist-fractures> [<https://perma.cc/JP8Z-YZD6>]; U.S. FOOD & DRUG ADMIN., DE NOVO NO. DEN180005, EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR OSTEODETECT 2 (2018), https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180005.pdf [<https://perma.cc/4WWM-2VH2>].

⁶² See U.S. FOOD & DRUG ADMIN., *supra* note 61, at 1–2.

⁶³ Letter from Thalia T. Mills, Dir., Div. Radiological Health, Off. of In Vitro Diagnostics & Radiological Health, Off. of Prod. Eval. & Quality, Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., to Gregory Ramina, Dir. Regul. Affs., Viz.ai, Inc. (Mar. 23, 2021), https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210209.pdf [<https://perma.cc/PY2K-ZZGB>].

neurosurgical or neurovascular specialist and recommends checking the images, which can be previewed via a mobile app.⁶⁴ BrainScope is another AI/ML-based medical device used by emergency physicians to assess patients with head injuries for brain concussions and brain bleeds.⁶⁵

Most AI-based medical devices for clinical care are used by health professionals such as clinicians. Some AIs, however, are also intended for use by nonexperts. As seen, IDx-DR, for example, is an “autonomous” AI used by primary care physicians who are not eye specialists.⁶⁶ Another example is Caption Guidance: a cardiac ultrasound software device that can be used by nurses who are nonexperts in ultrasonography to capture cardiac ultrasound images.⁶⁷

2. DTC Uses

An increasing number of AI-based products are directly addressed to consumers. According to one estimate, there are over four hundred thousand health care apps available in app stores, some of which use AI.⁶⁸ Examples include Apple’s electrocardiogram

For more information on Viz.ai’s indications for use, see *Viz.ai Indications for Use*, VIZ.AI, <https://www.viz.ai/indications-for-use> [<https://perma.cc/YCA5-QQDN>].

⁶⁴ See Letter from Thalia T. Mills to Gregory Ramina, *supra* note 63.

⁶⁵ BRAINSCOPE, <https://www.brainscope.com> [<https://perma.cc/N4XG-3V7L>]. For the newest 510(k) clearance of BrainScope TBI (model: Ahead 500), see Letter from Jay Gupta, Assistant Dir., Div. Neurosurgical, Neurointerventional & Neurodiagnostic Devices, Off. Neurological & Physical Med. Devices, Off. Prod. Eval. & Quality, Ctr. Devices & Radiological Health, U.S. Food & Drug Admin., to Michael Singer, CEO, BrainScope Co., Inc. (Sept. 11, 2019), https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190815.pdf [<https://perma.cc/GAL8-FCR8>].

⁶⁶ See *supra* Section I.A.2.

⁶⁷ Press Release, U.S. Food & Drug Admin., FDA Authorizes Marketing of First Cardiac Ultrasound Software That Uses Artificial Intelligence to Guide User (Feb. 7, 2020), <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-first-cardiac-ultrasound-software-uses-artificial-intelligence-guide-user> [<https://perma.cc/M3W3-HHMJ>]; Letter from Robert Ochs, Ph.D., Deputy Dir. for Radiological Health, Off. of In Vitro Diagnostics & Radiological Health, Off. of Prod. Eval. & Quality, Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., to Sam Surette, RA/QA Manager, Caption Health, Inc. 1 (Feb. 7, 2020), https://www.accessdata.fda.gov/cdrh_docs/pdf19/DEN190040.pdf [<https://perma.cc/GE84-2UZK>].

⁶⁸ Michael Georgiou, *Developing a Healthcare App in 2022: What Do Patients Really Want?*, IMAGINATION (Feb. 9, 2022), <https://www.imagination.net/blog/developing-a-mobile-health-app-what-patients-really-want> [<https://perma.cc/B654-PN5T>]; see Monomita Chakraborty, *10 Best AI Based Healthcare Apps You Can Try in 2021*, ANALYTICS INSIGHT (Apr. 13, 2021), <https://www.analyticsinsight.net/10-best-ai-based-healthcare-apps-you-can-try-in-2021> [<https://perma.cc/NJX4-XH7U>]; Sara Gerke & Delaram Rezaeikhonakdar, *Privacy Aspects of Direct-to-Consumer Artificial Intelligence/Machine Learning Health Apps*, 6 INTEL-BASED MED., no. 100061, 2022, at 1.

(“ECG”) app⁶⁹ and Apple’s irregular rhythm notification feature⁷⁰—two apps directly addressed to consumers aged twenty-two and older and designed to be used with the Apple Watch. The first app is intended to create, store, record, transfer, and display a single-channel ECG.⁷¹ The second app notifies users of episodes of irregular rhythms suggestive of atrial fibrillation.⁷²

In May 2021, Google also announced its AI-powered dermatology app that is designed to help users identify issues such as skin conditions, but it is not yet available on the U.S. market.⁷³ Moreover, AI-assisted symptom checkers are emerging. An example is Ada, which aims to help consumers find answers about the causes of their symptoms, ranging from bellyaches to headaches.⁷⁴ Consumers need to respond to questions about their symptoms, and then Ada will offer advice.⁷⁵ AI is also revolutionizing consumer-facing fitness trackers and other wearables, such as via self-learning motion sensors.⁷⁶

3. R&D

AI shows great promise in research and development (“R&D”). Clinical trials of drugs and vaccines are costly (a median of \$41,117 per patient), and they usually take several years.⁷⁷ In addition, the success rate of clinical trials is low—only about fourteen percent of all

⁶⁹ Letter from Angela C. Krueger, Deputy Dir., Eng’g & Sci. Rev., Off. of Device Eval., Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., to Donna-Bea Tillman, Senior Consultant, Biologics Consulting Grp., Inc. (Sept. 11, 2018), https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180044.pdf [<https://perma.cc/5D62-VU8H>].

⁷⁰ Letter from Angela C. Krueger, Deputy Dir., Eng’g & Sci. Rev., Off. of Device Eval., Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., to Donna-Bea Tillman, Senior Consultant, Biologics Consulting Grp., Inc. (Sept. 11, 2018), https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180042.pdf [<https://perma.cc/S2FM-Y3CP>].

⁷¹ Letter from Angela C. Krueger to Donna-Bea Tillman, *supra* note 69, at 1; see Gerke, *Health AI*, *supra* note 10, at 444.

⁷² Letter from Angela C. Krueger to Donna-Bea Tillman, *supra* note 70, at 1; see Gerke, *Health AI*, *supra* note 10, at 444.

⁷³ Bui & Liu, *supra* note 5; *DermAssist*, *supra* note 6. As mentioned in the introduction, this app has been criticized because of its non-representative training data set. See, e.g., Feathers, *supra* note 5.

⁷⁴ Ada Health, *Ada—Check Your Health*, APPLE (2022), <https://apps.apple.com/app/id1099986434?mt=8> [<https://perma.cc/ND9H-2Q7W>]; see Gerke, *Health AI*, *supra* note 10, at 445.

⁷⁵ Ada Health, *supra* note 74.

⁷⁶ *Sensors Get Clever: AI Revolutionizes Fitness Tracking*, BOSCH, <https://www.bosch-sensortec.com/news/ai-revolutionizes-fitness-tracking.html> [<https://perma.cc/22RC-CWZB>].

⁷⁷ Amit Pratap Singh Rathore, *Getting a Handle on Clinical Trial Costs*, CLINICAL LEADER (Apr. 25, 2019), <https://www.clinicalleader.com/doc/getting-a-handle-on-clinical-trial-costs-0001> [<https://perma.cc/9Z7E-54VM>].

clinical trials of drugs and vaccines are successful.⁷⁸ AI has the potential to contribute to the higher efficiency of clinical trials by improving patient recruitment and clinical trial design.⁷⁹ For example, AI-powered virtual assistants can help engage patients enrolled in clinical trials, which improves protocol adherence, expedites clinical trials, and reduces costs.⁸⁰

Users of AI-based products designed to improve R&D can vary, ranging from researchers to study participants. For example, AI can also be deployed to accelerate the drug discovery process itself and cut costs. Relay Therapeutics developed an AI-based platform to enable a thorough understanding of protein motion and to help discover better medicines.⁸¹ MediKanren is another AI-driven system that discovers therapies for rare diseases.⁸² The system made headlines in August 2021 by pinpointing an unexpected drug, ketamine, as a potential treatment for ADNP syndrome, a neurodevelopmental genetic disorder.⁸³

4. Workflow Optimization

AI-based products are increasingly being used in medicine to optimize workflows. They can be designed for different users, including physicians, hospital administration, and leadership. For example, Beth Israel Deaconess Medical Center has managed to open thirty percent of operating capacity with the help of an ML algorithm.⁸⁴ While each surgical patient initially received one hour in the operating room, the

⁷⁸ Alex Berezow, *Clinical Trial Success Rates by Phase and Therapeutic Area*, AM. COUNCIL SCI. & HEALTH (June 11, 2020), <https://www.acsh.org/news/2020/06/11/clinical-trial-success-rates-phase-and-therapeutic-area-14845> [https://perma.cc/B5FF-QF6Z].

⁷⁹ See Wullianallur Raghupathi & Viju Raghupathi, *Big Data Analytics in Healthcare: Promise and Potential*, 2 HEALTH INFO. SCI. & SYS. 3 (2014); Arun Bhatt, *Artificial Intelligence in Managing Clinical Trial Design and Conduct: Man and Machine Still on the Learning Curve?*, 12 PERSP. CLINICAL RSCH. 1, 1–2 (2021).

⁸⁰ See, e.g., *Patient Engagement with Co-PRO®*, PATCHAI, <https://www.patchai.io> [https://perma.cc/6XNN-9FND].

⁸¹ *Dynamo Platform*, RELAY THERAPEUTICS, <https://relaytx.com/dynamo-platform> [https://perma.cc/4H84-DEMB].

⁸² Katie Palmer, *With a Nudge from AI, Ketamine Emerges as a Potential Rare Disease Treatment*, STAT (Aug. 5, 2021), <https://www.statnews.com/2021/08/05/artificial-intelligence-rare-disease-andp-medikanren> [https://perma.cc/ZQY7-7DJ5].

⁸³ See *id.*

⁸⁴ Jonah Comstock, *Beth Israel's Halamka on How Machine Learning Can Add Value for Hospitals Today*, MOBIHEALTHNEWS (Feb. 13, 2019, 4:38 PM), <https://www.mobihealthnews.com/content/beth-israels-halamka-how-machine-learning-can-add-value-hospitals-today> [https://perma.cc/D6MU-HQ5U].

now-used ML algorithm predicts how much time each patient actually needs and schedules surgery times more efficiently.⁸⁵

Voice-enabled virtual assistants can also help enable physicians to have more face time with their patients and spend less time on their computer for clinical documentation.⁸⁶ For example, the California-based company Suki developed an AI assistant called “Suki Assistant,” reducing about seventy-six percent of clinical documentation time.⁸⁷ Physicians speak their notes to Suki Assistant, which listens and documents.⁸⁸ Suki Assistant also learns the user’s preferences by tagging the data for ML.⁸⁹

The following focuses mainly on AI/ML-based medical devices that belong to the first two application areas, namely clinical care and DTC uses. The reason for this is that AI/ML-based medical devices belonging to such areas especially can endanger patient safety.

II. WHEN IS AN AI/ML-BASED PRODUCT A MEDICAL DEVICE?

Part II analyzes when an AI/ML-based product is considered a medical device under the FDCA. This information is essential to understand the issue of labeling for AI/ML-based medical devices. This Part first examines the principle of when an AI/ML-based product is classified as a medical device, and then explores relevant exceptions and the FDA’s enforcement discretion.

In particular, Part II argues that the FDA’s new final CDS guidance of September 28, 2022,⁹⁰ falls short of expectations. It creates legal uncertainty for AI/ML manufacturers, safety concerns, and seems to violate the 21st Century Cures Act.⁹¹ Especially the FDA’s new interpretation of criterion (4) of the CDS software exception in FDCA Section 520(o)(1)(E)⁹² no longer excludes a priori certain types of AI/ML. Thus, even CDS using black-box AI/ML can meet this medical device exception and fall outside FDA regulation. The agency’s current focus concerning criterion (4) appears to be primarily

⁸⁵ *Id.*

⁸⁶ Forbes Insights, *The Future of Voice AI in Patient Care*, FORBES (Feb. 11, 2019, 1:03 PM), <https://www.forbes.com/sites/insights-intelai/2019/02/11/the-future-of-voice-ai-in-patient-care/#726bcb6f309c> [<https://perma.cc/2BX3-6YNX>].

⁸⁷ *Suki Assistant: How It Works*, SUKI, <https://www.suki.ai/how-suki-works> [<https://perma.cc/QBX3-6HF4>].

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ U.S. FOOD & DRUG ADMIN., *supra* note 18.

⁹¹ 21st Century Cures Act, Pub. L. No. 114–255, § 3060, 130 Stat. 1033, 1130–33 (2016) (codified at 21 U.S.C. §§ 321(h)(1), 360j(o)).

⁹² *Id.* § 360j(o)(1)(E)(iii).

on improved labeling to circumvent regulation rather than safety and effectiveness. This Part argues that labeling is a crucial piece of the puzzle for successfully implementing AI/ML in health care but not to the detriment of patients’ health. It must be coupled with a robust regulatory framework for CDS software functions and should not be used as a loophole to escape regulatory oversight. The current burden of assessing the safety and effectiveness of CDS that do *not* fulfill the medical device definition in FDCA Section 201(h)(1) (“Non-Device CDS”)—which may even be an artificial deep neural network, according to the FDA’s newest interpretation—is borne primarily by health care professionals who use the Non-Device CDS in question. In general, the FDA’s final CDS Guidance creates confusion among stakeholders, and there is no clear, consistent line as to when a CDS software function is or is not considered a medical device. To be fair, the FDA is trying to fix a mistake that Congress made in the first place when enacting the CDS software exception as part of the 21st Century Cures Act. Now is the time for Congress to act and amend the FDCA by deleting FDCA Section 520(o)(1)(E).

A. *Principle*

If an AI/ML-based product is classified as a medical device, the FDA can regulate it. FDCA Section 201(h)(1) defines the term “medical device” as follows:

The term “device” . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

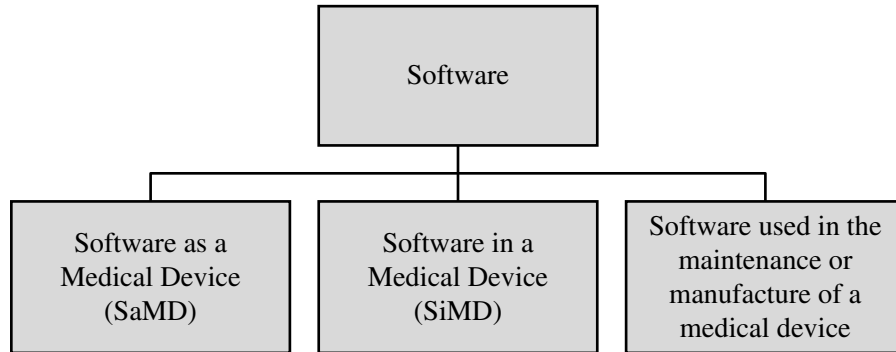
- (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (B) *intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or*
- (C) *intended to affect the structure or any function of the body of man or other animals, and*

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term “device” *does not include software functions excluded pursuant to section 520(o).*⁹³

⁹³ FDCA § 201(h)(1), 21 U.S.C. § 321(h)(1) (emphasis added).

In general, the term “medical device” also includes software functions (i.e., device software functions). This results from an *a contrario* reading of the second sentence of FDCA Section 201(h)(1).⁹⁴ Software can be divided into three types,⁹⁵ as shown in Figure 4 below.

FIGURE 4. SOFTWARE TYPES



In particular, the first two types, SaMD and SiMD, are relevant in the context of AI/ML-based medical devices. The International Medical Device Regulators Forum (“IMDRF”) is a forum of voluntary medical device regulators from across the world, such as the U.S., Canada, European Union, China, Japan, and Singapore, that drives international medical device regulatory harmonization forward.⁹⁶ In 2013, one of the IMDRF Working Groups published a document with key definitions on the topic of SaMD.⁹⁷ This document defines SaMD as “software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.”⁹⁸ The FDA endorses this definition and has made clear that the agency understands the term “medical purposes” to mean “those purposes that are intended to treat, diagnose, cure, mitigate, or prevent disease or other conditions.”⁹⁹ In other words, SaMD is

⁹⁴ See *id.*

⁹⁵ *Software as a Medical Device (SaMD)*, U.S. FOOD & DRUG ADMIN. (Dec. 4, 2018), <https://www.fda.gov/medical-devices/digital-health/software-medical-device-samd> [https://perma.cc/73P7-CEWY].

⁹⁶ INT’L MED. DEVICE REGULS. F., <http://www.imdrf.org> [https://perma.cc/48TQ-DSJ7]; Gerke, *Health AI*, *supra* note 10, at 446.

⁹⁷ IMDRF SaMD Working Grp., *Software as a Medical Device (SaMD): Key Definitions*, IMDRF Doc. IMDRF/SaMD WG/N10FINAL:2013 (Dec. 9, 2013), <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf> [https://perma.cc/Z2VV-B3F5].

⁹⁸ *Id.* at 6.

⁹⁹ U.S. FOOD & DRUG ADMIN., *supra* note 55, at 2; Gerke, *Health AI*, *supra* note 10, at 446–47.

“standalone software”;¹⁰⁰ the software is itself the medical device.¹⁰¹ SaMD is operated with familiar, everyday technology such as laptops, smartphones, and smartwatches.¹⁰² Examples of SaMD include Apple’s ECG app and irregular rhythm notification feature app, Viz ICH (analysis of noncontrast computed tomography brain images), and RhythmAnalytics (detection of over fifteen cardiac arrhythmia types).¹⁰³

The FDA defines “SiMD” as “software that is integral to a medical device.”¹⁰⁴ It thus has software and hardware components.¹⁰⁵ The software needs to help the function of the medical device in some way, such as controlling or powering the device or processing its information.¹⁰⁶ An example is software that helps run an insulin pump.¹⁰⁷ But the majority of AI/ML-based medical devices that are currently being developed or available on the U.S. market are SaMD.¹⁰⁸

B. *Exceptions, FDCA Section 520(o)*

Some software functions, however, are not considered to be medical devices (non-device software functions). The 21st Century Cures Act introduced exceptions in FDCA Section 520(o) and added clarifying language to FDCA Section 201(h)(1).¹⁰⁹ FDCA Section 520(o)¹¹⁰ lists *five categories* of software functions, as illustrated in Figure 5 below.

¹⁰⁰ U.S. FOOD & DRUG ADMIN., *supra* note 95; Gerke, *Health AI*, *supra* note 10, at 446.

¹⁰¹ See sources cited *supra* note 100; Codrin Arsene, *SaMD vs SiMD: What’s the Difference?*, HEALTHTECHZONE.COM (June 29, 2020), <https://www.healthtechzone.com/topics/health-care/articles/2020/06/29/445836-samd-vs-simd-whats-difference.htm> [https://perma.cc/9NNB-6V7G].

¹⁰² Arsene, *supra* note 101.

¹⁰³ For more information on these medical devices, see *supra* Section I.A.2., I.B.1.–2.

¹⁰⁴ U.S. FOOD & DRUG ADMIN., *supra* note 95.

¹⁰⁵ David Ritscher, *The New FDA?*, CAMBRIDGE CONSULTANTS (Feb. 4, 2018), <https://www.cambridgeconsultants.com/insights/opinion/new-fda> [https://perma.cc/R64K-GLKV].

¹⁰⁶ Arsene, *supra* note 101.

¹⁰⁷ *Id.*

¹⁰⁸ See, e.g., Simeng Zhu, Marissa Gilbert, Indrin Chetty & Farzan Siddiqui, *The 2021 Landscape of FDA-Approved Artificial Intelligence/Machine Learning-Enabled Medical Devices: An Analysis of the Characteristics and Intended Use*, 165 INT’L J. MED. INFORMATICS, no. 104828, 2022, at 1, 2.

¹⁰⁹ 21st Century Cures Act, Pub. L. No. 114–255, § 3060, 130 Stat. 1033, 1130–33 (2016) (codified at 21 U.S.C. §§ 321(h)(1), 360j(o)).

¹¹⁰ FDCA § 520(o), 21 U.S.C. § 360j(o).

FIGURE 5. CATEGORIES OF NON-DEVICE SOFTWARE FUNCTIONS

(1) Administrative Support of Health Care Facilities, FDCA Section 520(o)(1)(A);
(2) Maintenance or Encouragement of Healthy Lifestyles, FDCA Section 520(o)(1)(B);
(3) Serve as Electronic Patient Records, FDCA Section 520(o)(1)(C);
(4) Transfer, Store, Convert Formats, or Display Data and Results, FDCA Section 520(o)(1)(D); and
(5) Clinical Decision Support Software, FDCA Section 520(o)(1)(E).

If the specific requirements of one of these five categories are fulfilled, the software function in question is *not* classified as a medical device and thus is *not* subject to FDA regulation.¹¹¹ In the context of AI/ML-based medical devices for clinical care or DTC uses,¹¹² the second and fifth categories are especially pertinent.

1. *Maintenance or Encouragement of Healthy Lifestyles, FDCA Section 520(o)(1)(B)*

The second category laid down in FDCA Section 520(o)(1)(B) applies to a software function that is intended “*for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.*”¹¹³ The FDA has published two nonbinding guidance documents that are relevant to this category and express the agency’s current thinking:

(1) *Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act* (“Cures Act Guidance”)¹¹⁴ and

¹¹¹ See FDCA § 201(h)(1), 21 U.S.C. § 321(h)(1).

¹¹² For more information on AI/ML-based products for clinical care or DTC uses, see *supra* Section I.B.1.-2.

¹¹³ FDCA § 520(o)(1)(B), 21 U.S.C. § 360j(o)(1)(B) (emphasis added).

¹¹⁴ U.S. FOOD & DRUG ADMIN., CHANGES TO EXISTING MEDICAL SOFTWARE POLICIES RESULTING FROM SECTION 3060 OF THE 21ST CENTURY CURES ACT—GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2019), <https://www.fda.gov/media/109622/download> [<https://perma.cc/LZY5-LBL9>].

(2) *General Wellness: Policy for Low Risk Devices* (“General Wellness Guidance”).¹¹⁵

The Cures Act Guidance clarifies that software functions fall under the medical device exception in FDCA Section 520(o)(1)(B) if they are products that belong to the first category of general wellness intended uses, as described in the General Wellness Guidance.¹¹⁶ This is the case where software functions have “an intended use that relates to maintaining or encouraging a general state of health or a healthy activity,” such as “self-esteem,” “physical fitness,” or “stress management.”¹¹⁷ This category of general wellness intended uses exclusively involves claims that do *not* refer to diseases or conditions.¹¹⁸

The intended use—i.e., “the objective intent of the persons legally responsible for the labeling of” devices, usually of the manufacturers¹¹⁹—is decisive when assessing whether a software function falls under the medical device exception in FDCA Section 520(o)(1)(B). For example, the objective intent may be demonstrated by labeling claims, advertisement, and other written or oral statements by these persons or their representatives.¹²⁰

Many DTC AI/ML apps fall under FDCA Section 520(o)(1)(B) and thus are *not* considered to be medical devices and are *not* reviewed by the FDA. An example is a DTC AI/ML app that helps users manage weight, as its claims are “unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.”¹²¹ In fact, only a few DTC AI/ML apps are classified as medical devices (“DTC medical AI/ML apps”), such as Apple’s ECG app and Apple’s irregular rhythm notification feature app.¹²²

¹¹⁵ U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS: POLICY FOR LOW RISK DEVICES—GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2019), <https://www.fda.gov/media/90652/download> [<https://perma.cc/YF4L-S95Q>].

¹¹⁶ U.S. FOOD & DRUG ADMIN., *supra* note 114, at 4–5.

¹¹⁷ *Id.* at 5; U.S. FOOD & DRUG ADMIN., *supra* note 115, at 3.

¹¹⁸ U.S. FOOD & DRUG ADMIN., *supra* note 115, at 3. This is in contrast to the second category of general wellness intended uses that are considered medical devices. *See* Gerke, *Health AI*, *supra* note 10, at 450.

¹¹⁹ 21 C.F.R. § 801.4.

¹²⁰ *Id.*; Gerke, *Health AI*, *supra* note 10, at 450.

¹²¹ U.S. FOOD & DRUG ADMIN., *supra* note 114, at 5.

¹²² *See* Boris Babic, Sara Gerke, Theodoros Evgeniou & I. Glenn Cohen, *Direct-to-Consumer Medical Machine Learning and Artificial Intelligence Applications*, 3 NATURE MACH. INTEL. 283, 284 (2021). For more information on these apps, see *supra* Section I.B.2.

2. *Clinical Decision Support Software, FDCA Section 520(o)(1)(E)*

The fifth category of software functions laid down in FDCA Section 520(o)(1)(E) that are not classified as medical devices applies to software functions that are intended to support particular clinical decisions. On September 28, 2022, the FDA issued the long-awaited, final CDS Guidance to clarify the agency's regulatory approach to CDS software functions.¹²³ In its CDS Guidance, the FDA delineates *four criteria* that need to be fulfilled for a software function to fall under the medical device exception in FDCA Section 520(o)(1)(E):¹²⁴

- Criterion (1): The software function is *not* “intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system . . . ”;¹²⁵
- Criterion (2): The software function is intended for the purpose of “displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines) . . . ”;¹²⁶
- Criterion (3): The software function is intended for the purpose of “supporting or providing *recommendations to a health care professional* about prevention, diagnosis, or treatment of a disease or condition . . . ”;¹²⁷
- Criterion (4): The software function is intended for the purpose of “*enabling such health care professional to independently review the basis for such recommendations* that such software presents so that it is not the intent that such health care professional rely primarily on any of

¹²³ U.S. FOOD & DRUG ADMIN., *supra* note 18, at 5; see also *Your Clinical Decision Support Software: Is It a Medical Device?*, U.S. FOOD & DRUG ADMIN. (Sept. 27, 2022), <https://www.fda.gov/medical-devices/software-medical-device-samd/your-clinical-decision-support-software-it-medical-device> [<https://perma.cc/P899-53R6>] (providing an overview of the new CDS Guidance). There are many definitions of the term “CDS.” For example, the Office of the National Coordinator for Health Information Technology (“ONC”) defines “CDS” as a tool that “provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.” *Clinical Decision Support*, OFF. NAT’L COORDINATOR FOR HEALTH INFO. TECH. (Apr. 10, 2018), <https://www.healthit.gov/topic/safety/clinical-decision-support> [<https://perma.cc/5XDJ-HHLQ>].

¹²⁴ U.S. FOOD & DRUG ADMIN., *supra* note 18, at 6.

¹²⁵ FDCA § 520(o)(1)(E), 21 U.S.C. § 360j(o)(1)(E).

¹²⁶ FDCA § 520(o)(1)(E)(i), 21 U.S.C. § 360j(o)(1)(E)(i).

¹²⁷ FDCA § 520(o)(1)(E)(ii), 21 U.S.C. § 360j(o)(1)(E)(ii) (emphasis added).

such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.”¹²⁸

If all four of the above criteria are fulfilled, the software function is a “Non-Device CDS,” a CDS that is *not* a medical device under the FDCA and thus is *not* subject to FDA regulation.¹²⁹

Criterion (1) requires a software function that is *not* “intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system”¹³⁰ The FDA clarifies in its new CDS Guidance that the types of data inputs described in criterion (1) (i.e., medical images, signals from in vitro diagnostic devices, or patterns or signals from signal acquisition systems) are used in medical devices.¹³¹ For example, criterion (1) is *not* met when a software function uses image sets, such as magnetic resonance of a patient, to develop a personal treatment plan for review by a health care professional for patients undergoing external beam radiation therapy.¹³² Because such a software function is intended to analyze medical images, it is an example of a device software function subject to the FDA’s regulatory oversight.¹³³

In contrast to criterion (1), criterion (2) describes the types of data inputs (“medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines)”) ¹³⁴ utilized in Non-Device CDS.¹³⁵ In its final CDS Guidance, the FDA interprets the term “medical information about a patient” as

the type of information that normally is, and generally can be, communicated between HCPs [health care professionals] in a clinical conversation or between HCPs and patients in the context of a clinical decision, meaning that the relevance of the information to the clinical decision being made is well understood and accepted.¹³⁶

The FDA interprets the term “other medical information” as “information such as peer-reviewed clinical studies, clinical practice guidelines, and information that is similarly independently verified

¹²⁸ FDCA § 520(o)(1)(E)(iii), 21 U.S.C. § 360j(o)(1)(E)(iii) (emphasis added).

¹²⁹ U.S. FOOD & DRUG ADMIN., *supra* note 18, at 4, 7.

¹³⁰ FDCA § 520(o)(1)(E), 21 U.S.C. § 360j(o)(1)(E).

¹³¹ U.S. FOOD & DRUG ADMIN., *supra* note 18, at 7.

¹³² *Id.* at 21.

¹³³ *Id.* at 20–21.

¹³⁴ FDCA § 520(o)(1)(E)(i), 21 U.S.C. § 360j(o)(1)(E)(i).

¹³⁵ U.S. FOOD & DRUG ADMIN., *supra* note 18, at 7, 9.

¹³⁶ *Id.* at 9.

and validated as accurate, reliable, not omitting material information, and supported by evidence.”¹³⁷

According to the FDA’s current thinking, the above example of the software function that uses a patient’s medical images to develop a personal treatment plan for review by a health care professional for patients undergoing external beam radiation therapy also does not fulfill criterion (2) because such a software function is not intended for the purpose of “display[ing], analyz[ing], or print[ing] medical information.”¹³⁸

Criterion (3) requires a software function that is intended for the purpose of “supporting or providing *recommendations to a health care professional* about prevention, diagnosis, or treatment of a disease or condition.”¹³⁹ In contrast to the previous draft guidance on CDS software of September 27, 2019 (“CDS Draft Guidance”),¹⁴⁰ the new final CDS Guidance defines the term “health care professional” (albeit in a footnote) as

an individual who is licensed, registered, or certified by a State, territory, or other governing body, to administer health care, including but not limited to, nurse practitioner, registered nurse, licensed practical nurse, clinical social worker, dentist, occupational therapist, pharmacist, physical therapist, physician, physician assistant, psychologist, respiratory therapist, speech-language pathologist, technologist, or any other practitioner or allied health professional.¹⁴¹

According to the FDA, patients and caregivers do not fall within this definition.¹⁴² Thus, software functions that are intended for the purpose of supporting or providing recommendations to patients and caregivers are medical devices under the FDCA.¹⁴³

The FDA also clarifies in its CDS Guidance that criterion (3) is *not* satisfied in cases where software functions provide specific preventive, diagnostic, or treatment directives or outputs and in time-critical decision making.¹⁴⁴ The FDA states:

¹³⁷ *Id.*

¹³⁸ *Id.* at 21; FDCA § 520(o)(1)(E)(i), 21 U.S.C. § 360j(o)(1)(E)(i).

¹³⁹ FDCA § 520(o)(1)(E)(ii), 21 U.S.C. § 360j(o)(1)(E)(ii) (emphasis added).

¹⁴⁰ U.S. FOOD & DRUG ADMIN., CLINICAL DECISION SUPPORT SOFTWARE: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2019), <https://www.regulations.gov/document/FDA-2017-D-6569-0041> [<https://perma.cc/Y42F-8RG3>].

¹⁴¹ U.S. FOOD & DRUG ADMIN., *supra* note 18, at 4 n.1.

¹⁴² *Id.* at 13.

¹⁴³ *Id.*

¹⁴⁴ *Id.* at 10.

Two aspects of software functionality may affect whether a software function is being used to support or provide recommendations to an HCP [health care professional]: (1) the level of software automation, and (2) the time-critical nature of the HCP’s decision making. FDA considers both these aspects when determining whether a software function is being used to enhance, inform and/or influence an HCP’s decision-making (satisfying Criterion 3) or rather, to substitute, replace, or direct the HCP’s judgment (failing Criterion 3).¹⁴⁵

The FDA’s interpretation of criterion (3) (“support[ing] or provid[ing] recommendations”) is informed by the understanding of automation bias—i.e., “the propensity of humans to over-rely on a suggestion from an automated system.”¹⁴⁶ The agency explains in its CDS Guidance that automation bias is more probable to occur if a software function provides users with a specific output or solution instead of a list of options or comprehensive information for them to consider.¹⁴⁷ The risk of automation bias also increases in time-critical decision making because users do not have enough time to consider other information properly.¹⁴⁸

For example, based on the FDA’s interpretation of criterion (3), a software function that uses a patient’s medical images to develop a personal treatment plan for review by a health care professional for patients undergoing external beam radiation therapy meets neither criterion (1) nor (2) (as explained above) nor criterion (3).¹⁴⁹ Criterion (3) is not met because the software function generates the treatment plan that is intended to offer a specific treatment directive.¹⁵⁰ Similarly, a software function that detects patients with a likely diagnosis of opioid addiction also fails criterion (3) since it provides a specific treatment or diagnostic directive or output.¹⁵¹ Criterion (3) is also not satisfied when a software function provides time-critical alerts to prompt clinical intervention, such as for sepsis, or when a software function identifies a risk score or probability for a specific condition or disease.¹⁵² In contrast, a software function fulfills criteria (1) to (3) when it provides a health care professional with a list of treatment

¹⁴⁵ *Id.* at 11.

¹⁴⁶ *Id.* at 10–11.

¹⁴⁷ *Id.* at 11.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.* at 21.

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.* at 12, 13, 22.

order options based on clinical guidelines for the treatment of patients presenting with pneumonia symptoms.¹⁵³

In the context of AI/ML-based products, the interpretation of criterion (4) (“enabling such health care professional to independently review the basis for such recommendations”)¹⁵⁴ is especially relevant.

In order to fulfill criterion (4), the FDA recommends in its new CDS Guidance that:

- a) The software or labeling include the *purpose or intended use* of the product, including the *intended HCP [health care professional] user* and *intended patient population*. FDA does *not* consider software functions intended *for a critical, time-sensitive task or decision* to meet Criterion 4, because an HCP is unlikely to have sufficient time to independently review the basis of the recommendations
- b) The software or labeling identify the required *input medical information*, with plain language instructions on how the inputs should be obtained, their relevance, and data quality requirements.
- c) The software or labeling provide a plain language description of the *underlying algorithm development and validation that forms the basis for the CDS implementation*, including:
 - i. A *summary of the logic or methods relied upon to provide the recommendations* (e.g., meta-analysis of clinical studies, expert panel, statistical modeling, AI/ML techniques);
 - ii. A *description of the data relied upon so that an HCP can assess whether the data is representative of their patient population* (e.g., relevant sub-groups, disease conditions, collection sites, sex, gender, ethnicity) and *assess if best practices were followed* (e.g., independent development and validation datasets); and
 - iii. A *description of the results from clinical studies conducted to validate the algorithm/recommendations* so that an HCP can assess the *potential performance and limitations when applied to their patients* (e.g., sub-populations with untested or highly variable algorithm performance).
- d) The software output provides the HCP user with relevant *patient-specific information and other knowns/unknowns*

¹⁵³ *Id.* at 15–16.

¹⁵⁴ FDCA § 520(o)(1)(E)(iii), 21 U.S.C. § 360j(o)(1)(E)(iii).

for consideration (e.g., missing, corrupted, or unexpected input data values) that will enable the HCP to independently review the basis for the recommendations and apply their judgment when making the final decision.

In order to describe the *basis for the recommendations*, regardless of the complexity of the software and whether or not it is proprietary, the *software output or labeling should provide adequate background information in plain language on the input(s), algorithm logic or methods, datasets, and validation*. Relevant sources should be identified and available to the intended user (e.g., clinical practice guidelines with the date or version, published literature, or information that has been communicated by the CDS developer to the intended user) and understandable by the intended user (e.g., data points whose meaning is well understood by the intended user). In order to enable independent evaluation of its basis, the recommendation should be based on information whose meaning could be expected to be independently understood by the intended HCP user (e.g., the inputs used to generate the recommendations are identified, the recommendations are based on inputs that do not omit material information, and the quality and robustness of the datasets or clinical studies are described).¹⁵⁵

In addition to the final CDS Guidance, the FDA has also recently launched a new Digital Health Policy Navigator that should help developers determine whether their software function is possibly the focus of the agency’s oversight as a medical device.¹⁵⁶ This tool should also assist developers in identifying applicable legal requirements and FDA-specific recommendations.¹⁵⁷ It consists of seven steps with questions primarily based on the medical device definition in FDCA Section 201(h)(1), the categories of non-device software functions in FDCA Section 520(o)(E), and relevant FDA guidance documents.¹⁵⁸ Step 6 of this tool deals specifically with CDS software functions and, following the new CDS Guidance, asks the questions shown in Figure 6 to determine whether a developer’s software function may be considered a device under the FDCA.¹⁵⁹

¹⁵⁵ U.S. FOOD & DRUG ADMIN., *supra* note 18, at 14 (emphasis added).

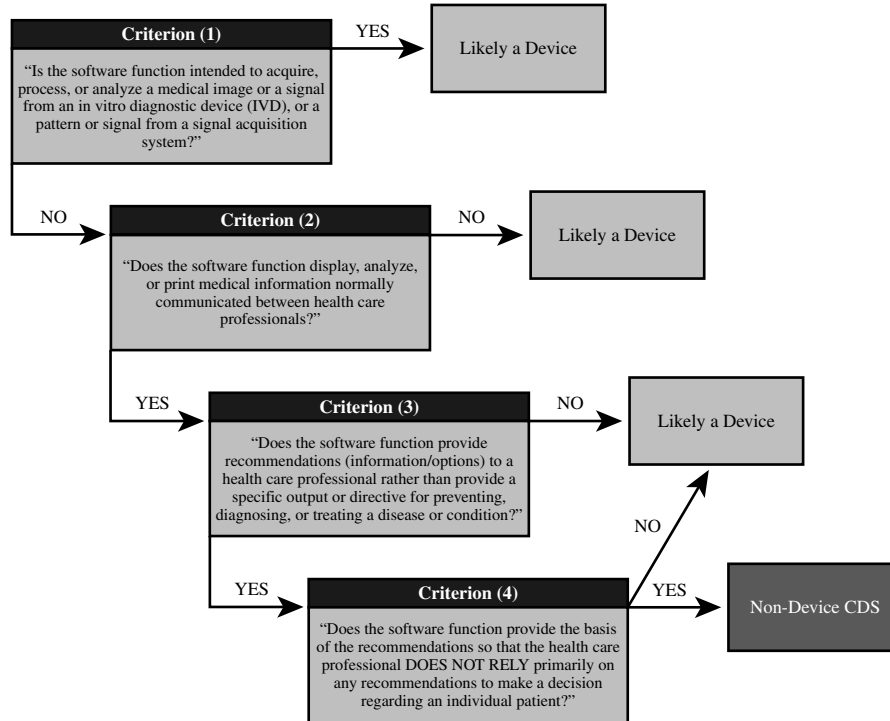
¹⁵⁶ *Digital Health Policy Navigator*, U.S. FOOD & DRUG ADMIN. (Dec. 14, 2022), <https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-policy-navigator> [<https://perma.cc/AP8F-7NWR>].

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* For the categories of non-device software functions, see *supra* Figure 5.

¹⁵⁹ *Step 6: Is the Software Function Intended to Provide Clinical Decision Support?*, U.S. FOOD & DRUG ADMIN. (Dec. 14, 2022), <https://www.fda.gov/medical-devices/digital-health->

FIGURE 6. CLASSIFICATION OF WHETHER A SOFTWARE FUNCTION FALLS UNDER THE MEDICAL DEVICE EXCEPTION IN FDCA SECTION 520(o)(1)(E) AND THUS IS A NON-DEVICE CDS BASED ON THE FDA'S CURRENT THINKING IN ITS NEW CDS GUIDANCE OF SEPTEMBER 28, 2022, AND DIGITAL HEALTH POLICY NAVIGATOR¹⁶⁰



3. Criticism of the New CDS Guidance of September 28, 2022

The new final CDS Guidance of September 28, 2022,¹⁶¹ differs significantly from the previous CDS Draft Guidance of September 27, 2019.¹⁶² Such a profound change without involving a reproposal was a massive surprise for stakeholders, such as CDS manufacturers and health care professionals.¹⁶³ Thus, it is not astonishing that the CDS Guidance has already been criticized significantly. For example, the final guidance has been called “truly a disaster” that “violates the law”

center-excellence/step-6-software-function-intended-provide-clinical-decision-support [https://perma.cc/4VW8-KMJC].

¹⁶⁰ See *id.*

¹⁶¹ U.S. FOOD & DRUG ADMIN., *supra* note 18.

¹⁶² See U.S. FOOD & DRUG ADMIN., *supra* note 140.

¹⁶³ The CDS Draft Guidance of September 27, 2019, was already a reproposal of the first CDS Draft Guidance *Clinical and Patient Decision Support Software* of December 8, 2017, likely because the revised 2019 draft guidance differed significantly from the first 2017 draft guidance.

(i.e., the 21st Century Cures Act).¹⁶⁴ It has been argued that, particularly with its interpretation of criteria (2) and (3) of FDCA Section 520(o)(1)(E), the FDA wants to “reclaim jurisdiction over software that Congress declared is unregulated.”¹⁶⁵

Indeed, the FDA appears to intend a significant shift from its previous regulatory approach to CDS software functions, expanding its oversight over at least some of them. For example, AI algorithms that analyze a patient’s medical information to detect sepsis and generate an alert to notify a health care professional have not been regulated by the FDA for years, despite their considerable safety and effectiveness concerns.¹⁶⁶ As seen above, the new CDS Guidance clearly articulates that this may change in the future because criterion (3) is not satisfied in cases where a software function is intended to provide a specific diagnostic directive or output, including an alert that supports time-critical decision making.¹⁶⁷

Although the FDA’s move to consider AI algorithms for sepsis alerts as medical devices seems commendable from a patient safety perspective, criticism of the new CDS Guidance cannot be dismissed easily. In particular, it has been argued that the FDA can interpret

¹⁶⁴ Bradley Merrill Thompson, *FDA’s Final Guidance on Clinical Decision Support Violates the Law*, LINKEDIN (Sept. 27, 2022), <https://www.linkedin.com/pulse/fdas-final-guidance-clinical-decision-support-law-thompson-rac> [https://perma.cc/TB54-TETF].

¹⁶⁵ *Id.*; FDCA § 520(o)(1)(E)(i)–(ii), 21 U.S.C. § 360j(o)(1)(E)(i)–(ii). For more information on criteria (2) and (3), see *supra* Section II.B.2.

¹⁶⁶ Casey Ross, *Epic’s AI Algorithms, Shielded from Scrutiny by a Corporate Firewall, Are Delivering Inaccurate Information on Seriously Ill Patients*, STAT+ (July 26, 2021), <https://www.statnews.com/2021/07/26/epic-hospital-algorithms-sepsis-investigation> [https://perma.cc/UUG3-TMED] (highlighting concerns that Epic’s algorithm for predicting sepsis “routinely fails to identify the condition in advance, and triggers frequent false alarms”); Andrew Wong, Erkin Otles; John P. Donnelly, Andrew Krumm, Jeffrey McCullough, Olivia DeTroyer-Cooley, Justin Pestrue, Marie Phillips, Judy Konye, Carleen Penzoza, Muhammad Ghous & Karandeep Singh, *External Validation of a Widely Implemented Proprietary Sepsis Prediction Model in Hospitalized Patients*, 181 JAMA INTERNAL MED. 1065 (2021); Casey Ross, *In New Guidance, FDA Says AI Tools to Warn of Sepsis Should Be Regulated as Devices*, STAT+ (Sept. 27, 2022), <https://www.statnews.com/2022/09/27/health-fda-artificial-intelligence-guidance-sepsis> [https://perma.cc/5B5X-5Z3Z]; Casey Ross, *A ‘Disaster’, or a ‘Clear Path’ Forward?: New FDA Guidance on AI in Medicine Sparks Strong Reactions*, STAT+ (Sept. 28, 2022) [hereinafter Ross, *A ‘Disaster’, or a ‘Clear Path’ Forward?*], <https://www.statnews.com/2022/09/28/fda-artificial-intelligence-tools-regulation-oversight> [https://perma.cc/BG9P-AVAC]; Casey Ross, *Epic Overhauls Popular Sepsis Algorithm Criticized for Faulty Alarms*, STAT+ (Oct. 3, 2022), <https://www.statnews.com/2022/10/03/epic-sepsis-algorithm-revamp-training> [https://perma.cc/LJQ7-HJW4] (revealing that Epic now has a new version of its sepsis prediction model, but it is still too early to say whether it will improve patient outcomes); Casey Ross, *Epic’s Overhaul of a Flawed Algorithm Shows Why AI Oversight Is a Life-Or-Death Issue*, STAT+ (Oct. 24, 2022), <https://www.statnews.com/2022/10/24/epic-overhaul-of-a-flawed-algorithm/> [https://perma.cc/4BS3-8RSC].

¹⁶⁷ See *supra* Section II.B.2.; U.S. FOOD & DRUG ADMIN., *supra* note 18, at 22.

ambiguous terms in the 21st Century Cures Act based on their typical meaning but cannot add novel concepts to the statutory language, which impacts what products are regulated as medical devices.¹⁶⁸ For example, it is questionable whether Congress limited criterion (2) (“*medical information about a patient*”) to “the type of information that *normally* is, and generally can be, communicated between HCPs in a clinical conversation or between HCPs and patients in the context of a clinical decision, meaning that the *relevance* of the information to the clinical decision being made is *well understood and accepted*.”¹⁶⁹ In addition, although the FDA’s concerns about the risks of automation bias are understandable and valid, that doesn’t change the issue that it is disputed whether Congress would agree with the FDA’s interpretation of criterion (3) (“supporting or providing recommendations”) to exclude software functions from the medical device exception in cases where they provide specific preventive, diagnostic, or treatment directives or outputs and in time-critical decision making.¹⁷⁰

But even with regard to criterion (4) of FDCA Section 520(o)(1)(E) (“enabling such health care professional to independently review the basis for such recommendations”),¹⁷¹ the final CDS Guidance falls short of expectations. Although it is positive that manufacturers are incentivized to improve their labels, particularly by listing information on the underlying algorithm development and validation, in order to be able to fall under the medical device exemption,¹⁷² the FDA’s latest interpretation of criterion (4) also brings with it many uncertainties for AI/ML manufacturers and safety concerns.

First of all, similar to the previous CDS Draft Guidance,¹⁷³ the final CDS Guidance does *not* distinguish between the different types of CDS using AI/ML (“AI/ML-based CDS”)—i.e., black-box AI/ML, explainable AI/ML, and interpretable AI/ML. In fact, the FDA only

¹⁶⁸ Thompson, *supra* note 164.

¹⁶⁹ U.S. FOOD & DRUG ADMIN., *supra* note 18, at 9 (second, third, and fourth emphasis added); FDCA § 520(o)(1)(E)(i), 21 U.S.C. § 360j(o)(1)(E)(i); Thompson, *supra* note 164 (arguing that “Congress did not so limit this exemption”).

¹⁷⁰ FDCA § 520(o)(1)(E)(ii), 21 U.S.C. § 360j(o)(1)(E)(ii); U.S. FOOD & DRUG ADMIN., *supra* note 18, at 10; Thompson, *supra* note 164 (arguing that “[n]one of this has any basis whatsoever in the statutory language” and “that language is nowhere found in the statute”).

¹⁷¹ FDCA § 520(o)(1)(E)(iii), 21 U.S.C. § 360j(o)(1)(E)(iii). For more information on criterion (4), see *supra* Section II.B.2.

¹⁷² See Ross, *A ‘Disaster’, or a ‘Clear Path’ Forward?*, *supra* note 166 (citing the clinical data scientist Mark Sendak who applauded this aspect of the new CDS Guidance).

¹⁷³ See U.S. FOOD & DRUG ADMIN., *supra* note 140.

uses the term “AI/ML” once in its new CDS Guidance,¹⁷⁴ although many CDS being developed use AI/ML.

Second, this omission of any differentiation between the different types of AI/ML-based CDS leads to uncertainties for AI/ML manufacturers as it is unclear whether their products can meet criterion (4) in the first place. The new language in the CDS Guidance makes it even more difficult for manufacturers to predict whether—according to the FDA’s interpretation—their AI/ML-based CDS is considered a medical device under FDCA Section 201(h)(1). The CDS Draft Guidance of September 27, 2019, still explained that “[i]n order to describe the basis for a recommendation . . . the software developer should describe the underlying data used to develop the algorithm and should include plain language descriptions of the logic or *rationale* used by an algorithm to render a recommendation.”¹⁷⁵

In contrast, the new final CDS Guidance no longer uses the term “rationale” for manufacturers to describe “the basis for the recommendations.”¹⁷⁶ Instead, the FDA now recommends that “the software output or labeling should provide adequate background information in plain language on the input(s), *algorithm logic or methods*, datasets, and validation.”¹⁷⁷

The previous CDS Draft Guidance suggested that *CDS using black-box AI/ML* were unlikely to fall under the medical device exception in FDCA Section 520(o)(1)(E).¹⁷⁸ In other words, according to the FDA’s previous interpretation, CDS using black-box AI/ML were likely considered a priori Device CDS (i.e., CDS that are medical devices under FDCA Section 201(h)(1)) and thus generally the focus of the FDA’s regulatory oversight). Many health AI/ML-based products that are available on the U.S. market use black-box AI/ML models—algorithms typically labeled as deep learning—such as the cloud-based software RhythmAnalytics, detecting over fifteen cardiac arrhythmias.¹⁷⁹ As mentioned previously, however, it is very difficult, if not impossible, for humans, such as software developers and users, to understand black-box AI/ML models.¹⁸⁰ Thus, applying the FDA’s previous interpretation of criterion (4) of FDCA Section 520(o)(1)(E) laid out in its CDS Draft Guidance, CDS using black-box AI/ML were

¹⁷⁴ U.S. FOOD & DRUG ADMIN., *supra* note 18, at 14.

¹⁷⁵ U.S. FOOD & DRUG ADMIN., *supra* note 140, at 12 (emphasis added).

¹⁷⁶ U.S. FOOD & DRUG ADMIN., *supra* note 18, at 14.

¹⁷⁷ *Id.* (emphasis added).

¹⁷⁸ See U.S. FOOD & DRUG ADMIN., *supra* note 140, at 12.

¹⁷⁹ For more information see *supra* Section I.A.2.

¹⁸⁰ See *supra* Section I.A.2.

likely considered Device CDS because, in most cases, manufacturers would not be able to describe the logic or rationale used by the algorithm to render a recommendation. In other words, users would likely not be able to “independently review the basis for such recommendations that such software presents” and thus would primarily rely on it.¹⁸¹

As explained earlier, to counter potential users’ skepticism about noninterpretable black-box models, the new research field *explainable AI/ML* is emerging.¹⁸² It is questionable, however, whether explainable AI/ML could help to describe the basis for rendering a recommendation under the FDA’s previous interpretation in its CDS Draft Guidance and thus could fall under the medical device exception in FDCA Section 520(o)(1)(E). Explainable AI/ML uses a second explanatory algorithm, but this algorithm only approximates the outputs of the black box.¹⁸³ These post-hoc explanations may, in fact, provide a false truth. They give manufacturers and users as much information as if a group of prospective male customers was told that they would not be allowed into an iconic nightclub because they wore sneakers. In reality, however, the bouncer would not let them in because the club was looking for more female customers. Explainable AI/ML provides manufacturers and users with a false sense that they understand the logic or rationale of the black-box model better. But the provided explanation is only an “ersatz understanding” and should be used with caution against all the current enthusiasm for explainability in health care.¹⁸⁴ Hence, explainable AI/ML does not guarantee to give manufacturers and users the *correct* rationale used by the algorithm to render a recommendation. Under the CDS Draft Guidance, it was therefore likely that CDS using explainable AI/ML would *not* fulfill criterion (4) of FDCA Section 520(o)(1)(E) and would thus be considered Device CDS.

In contrast, according to the FDA’s previous interpretation in its CDS Draft Guidance, CDS using *interpretable AI/ML* (i.e., white-box models)¹⁸⁵ were likely able to fulfill criterion (4). These models create ex ante transparency, whereby they can generally be understood by humans with reasonable efforts and give clear reasons for how deci-

¹⁸¹ FDCA § 520(o)(1)(E)(iii), 21 U.S.C. § 360j(o)(1)(E)(iii).

¹⁸² See *supra* Section I.A.2.

¹⁸³ *Id.*

¹⁸⁴ *Id.*; Babic et al., *supra* note 47, at 285.

¹⁸⁵ For more information on interpretable AI/ML, see *supra* Section I.A.2.

sions are made.¹⁸⁶ According to the CDS Draft Guidance, CDS using interpretable AI/ML for the purpose of “supporting or providing recommendations to a health care professional” could thus fall under the medical device exception in FDCA Section 520(o)(1)(E).¹⁸⁷ In cases where the intended user is a caregiver or patient rather than a health care professional—similar to the current CDS Guidance—however, CDS using interpretable AI/ML were considered Device CDS under the CDS Draft Guidance even if the user could “independently review the basis for such recommendations that such software presents.”¹⁸⁸

Figure 7 below illustrates the likely interpretation of the “independently review the basis” part of criterion (4) according to the FDA’s previous CDS Draft Guidance on FDCA Section 520(o)(1)(E) related to different types of CDS using AI/ML and classification as Device CDS/Non-Device CDS.

¹⁸⁶ Babic et al., *supra* note 47, at 284, 286.

¹⁸⁷ U.S. FOOD & DRUG ADMIN., *supra* note 140, at 12; FDCA § 520(o)(1)(E)(ii), 21 U.S.C. § 360j(o)(1)(E)(ii).

¹⁸⁸ U.S. FOOD & DRUG ADMIN., *supra* note 140, at 8; FDCA § 520(o)(1)(E)(ii)–(iii), 21 U.S.C. § 360j(o)(1)(E)(ii)–(iii).

FIGURE 7. LIKELY INTERPRETATION OF THE “INDEPENDENTLY REVIEW THE BASIS” PART OF CRITERION (4) OF FDCA SECTION 520(o)(1)(E) ACCORDING TO THE FDA’S PREVIOUS CDS DRAFT GUIDANCE OF SEPTEMBER 27, 2019, RELATED TO DIFFERENT TYPES OF CDS USING AI/ML AND CLASSIFICATION AS DEVICE CDS/NON-DEVICE CDS¹⁸⁹

Types of CDS	Can the User “Independently Review the Basis”? Part of Criterion (4) of FDCA Section 520(o)(1)(E)	Classification
Black-Box AI/ML	No	Device CDS
Explainable AI/ML	No	Device CDS
Interpretable AI/ML	Yes	Non-Device CDS (Intended User is a Health Care Professional)
		Device CDS (Intended User is a Caregiver or Patient)

In contrast, the new CDS Guidance of September 28, 2022,¹⁹⁰ suggests that the FDA has moved away from its previous thinking in its CDS Draft Guidance and the likely interpretation illustrated above in Figure 7. It appears that the FDA’s new interpretation of criterion (4) no longer a priori excludes certain types of AI/ML from being able to fulfill the medical device exception in FDCA Section 520(o)(1)(E). In other words, according to the final CDS Guidance, it seems that all types of AI/ML—i.e., black-box AI/ML, explainable AI/ML, and interpretable AI/ML—can fulfill criterion (4) in principle, and thus potentially can fall under the medical device exception. It is likely that the FDA deliberately dropped the term “rationale” from its new CDS Guidance and replaced it with the word “methods.”¹⁹¹ In particular, as already seen, in order to fulfill criterion (4), the FDA recommends in its new CDS Guidance, among other things, that:

- c) The software or labeling provide a plain language description of the underlying algorithm development and valida-

¹⁸⁹ See U.S. FOOD & DRUG ADMIN., *supra* note 140.

¹⁹⁰ U.S. FOOD & DRUG ADMIN., *supra* note 18.

¹⁹¹ *Id.* at 14.

tion that forms the basis for the CDS implementation, including:

- i. *A summary of the logic or methods* relied upon to provide the recommendations (e.g., meta-analysis of clinical studies, expert panel, statistical modeling, *AI/ML techniques*) ¹⁹²

The FDA explicitly lists “AI/ML techniques” as an example of the “summary of the logic or methods relied upon to provide the recommendations.”¹⁹³ The FDA does not distinguish between the different types of AI/ML here, suggesting that even black-box AI/ML could potentially meet this FDA recommendation. Unfortunately, the FDA does not clarify further its current view on this point in its final CDS Guidance, which leads to considerable uncertainties for AI/ML manufacturers. In fact, the above quote is the only time the FDA uses the term “AI/ML” in its CDS Guidance.¹⁹⁴ This is surprising considering that more and more CDS currently available or under development in the U.S. market utilize AI/ML.

A recent interview with the new acting director of the FDA’s Digital Health Center of Excellence, Brendan O’Leary, in *STAT* also supports the above analysis that the FDA has expanded its interpretation of criterion (4) in its new CDS Guidance and currently thinks that all types of AI/ML can potentially fall under the medical device exception in FDCA Section 520(o)(1)(E).¹⁹⁵ Speaking with *STAT* about the FDA’s new CDS Guidance, Brendan O’Leary said that “one thing that’s happened with this document through that notice and comment process is that we have gotten to that place where it is possible for certain artificial deep neural networks, artificial intelligence, and machine learning algorithms to meet the statutory criteria for exclusion from the device definition.”¹⁹⁶ O’Leary also made a similar statement during an FDA webinar on the new CDS Guidance held on October 18, 2022, emphasizing that even the most complex algorithms, such as deep learning, can fulfill the medical device exception.¹⁹⁷

¹⁹² *Id.* (emphasis added).

¹⁹³ *Id.*

¹⁹⁴ The FDA also does not use the terms “artificial intelligence” or “machine learning” in its CDS Guidance. The FDA does not clarify this topic in its new Digital Health Policy Navigator. See *Digital Health Policy Navigator*, *supra* note 156; *supra* Section II.B.2.

¹⁹⁵ Ross, *A ‘Disaster’, or a ‘Clear Path’ Forward*, *supra* note 166.

¹⁹⁶ *Id.*

¹⁹⁷ Brendan O’Leary, Acting Dir., Digit. Health Ctr. of Excellence, U.S. Food & Drug Admin., Remarks at FDA’s Center for Devices and Radiological Health Webinar on Clinical Decision Support Software—Final Guidance 11 (Oct. 18, 2022), <https://www.fda.gov/media/162880/download> [<https://perma.cc/9WHF-HNU4>]; Ctr. for Devices & Radiological Health, U.S.

Consequently, this means that even a software function using deep learning that provides a health care professional with a list of treatment order options based on clinical guidelines for the treatment of patients presenting with pneumonia symptoms can be considered a Non-Device CDS according to the FDA's current thinking as long as the developer follows the agency's recommendations on criterion (4) in its CDS Guidance.¹⁹⁸ The FDA's new interpretation is highly questionable and problematic, however, because it is more than unclear, as discussed above, how black-box AI/ML (and even explainable AI/ML) can fulfill the statutory requirement of "enabling such health care professional to independently review the basis for such recommendations that such software presents."¹⁹⁹

Third, the FDA's new approach is particularly concerning from a risk-based approach. The CDS Draft Guidance contained an entire section called "Application of IMDRF Risk Categorization," in which the FDA clarified its intention to leverage the IMDRF SaMD Framework²⁰⁰ to apply a risk-based policy to its regulation of Device CDS software functions.²⁰¹ This section, however, no longer exists in the FDA's final CDS Guidance. The FDA only mentions briefly in its interpretation of criterion (3) of FDCA Section 520(o)(1)(E) that developers should read the IMDRF document *Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations* "[f]or additional information regarding risk categorization and considerations that may apply to certain software functions."²⁰²

Even though the FDA's application of the IMDRF SaMD Framework to its regulation of Device CDS in its CDS Draft Guidance was far from perfect,²⁰³ the FDA at least placed a large focus on risks asso-

Food & Drug Admin., Webinar Presentation, Final Guidance on Clinical Decision Support Software (Oct. 18, 2022), <https://www.fda.gov/media/162345/download> [<https://perma.cc/Z4XN-J9XT>].

¹⁹⁸ See U.S. FOOD & DRUG ADMIN., *supra* note 18, at 14, 16.

¹⁹⁹ FDCA § 520(o)(1)(E)(iii), 21 U.S.C. § 360j(o)(1)(E)(iii).

²⁰⁰ IMDRF SaMD Working Grp., "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations, IMDRF Doc. IMDRF/SaMD WG/N12FINAL:2014 (Sept. 18, 2014), <https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf> [<https://perma.cc/9L4A-JKH4>].

²⁰¹ U.S. FOOD & DRUG ADMIN., *supra* note 140, at 13–18.

²⁰² U.S. FOOD & DRUG ADMIN., *supra* note 18, at 13. For the IMDRF Framework, see *supra* note 200.

²⁰³ See Gerke, *Health AI*, *supra* note 10, at 453–60 (revealing the issues and inconsistencies with applying this approach and criterion (4)).

ciated with CDS software functions. This still appears to be the case for the agency’s reinterpretation of criterion (3) of FDCA Section 520(o)(1)(E), but for criterion (4), this is highly questionable, especially considering that the FDA no longer excludes a priori certain types of AI/ML from being able to fulfill the medical device exception. The FDA’s job is to ensure, among other things, that medical devices are reasonably safe and effective when placed on the market.²⁰⁴ The agency’s current thinking concerning criterion (4), however, focuses mainly on improved labeling to circumvent regulation rather than safety and effectiveness. Although improved labeling is great and imperative, it alone is not enough to protect patient safety. Labeling must be coupled with a robust regulatory pre- and postmarket framework for CDS software functions.²⁰⁵

At the moment, it appears that the FDA puts the burden mainly on health care professionals who should “assess whether the data is representative of their patient population . . . and assess if best practices were followed” and “assess the potential performance and limitations when applied to their patients” and “independently review the basis for the recommendations and apply their judgment when making the final decision.”²⁰⁶ Do we really want certain CDS using black-box AI/ML (and even explainable AI/ML) to be released on the market without being reviewed by the FDA for their safety and effectiveness? In other words, do we want to put the responsibility for assessing those CDS software functions, including the associated liability risks,²⁰⁷ primarily on health care professionals who are already overburdened in their daily clinical practice? It is also not surprising that during the FDA webinar on the new CDS Guidance one stakeholder asked where health care professionals could obtain the training needed to assess these complex systems.²⁰⁸ O’Leary simply clarified that the FDA does not regulate the practice of medicine and thus could not answer that question.²⁰⁹

²⁰⁴ *FDA’s Role in Regulating Medical Devices*, U.S. FOOD & DRUG ADMIN. (Aug. 31, 2018), <https://www.fda.gov/medical-devices/home-use-devices/fdas-role-regulating-medical-devices> [<https://perma.cc/RGV3-FSN2>].

²⁰⁵ For more information, see *infra* Section III.C.

²⁰⁶ U.S. FOOD & DRUG ADMIN., *supra* note 18, at 14.

²⁰⁷ See, e.g., W. Nicholson Price II, Sara Gerke & I. Glenn Cohen, *Potential Liability for Physicians Using Artificial Intelligence*, 322 JAMA 1765 (2019).

²⁰⁸ Orest Boyko, Remarks at FDA’s Center for Devices and Radiological Health Webinar on Clinical Decision Support Software—Final Guidance, *supra* note 197, at 15.

²⁰⁹ Brendan O’Leary, Acting Dir., Digit. Health Ctr. of Excellence, U.S. Food & Drug Admin., Remarks at FDA’s Center for Devices and Radiological Health Webinar on Clinical Decision Support Software—Final Guidance, *supra* note 197, at 16.

The final CDS Guidance is not binding, but it does have a considerable impact in practice because it represents the FDA's current thinking on this topic.²¹⁰ AI/ML manufacturers should comply with the CDS Guidance to protect themselves from warning letters or other enforcement actions by the FDA. On the one hand, the many ambiguities in the new CDS Guidance make it even more difficult for AI/ML manufacturers to comply with the agency's recommendations. On the other hand, these uncertainties in the interpretation of the CDS Guidance also open doors for misuse of labeling to bypass regulation. Manufacturers likely have an interest in their AI/ML-based CDS being considered Non-Device CDS and thus not being reviewed by the FDA. To achieve this goal, manufacturers solely need to *intend* that their CDS is "for the purpose of enabling such health care professional to independently review the basis for such recommendations that such software presents."²¹¹ Even if the FDA makes specific suggestions in its CDS Guidance on how the labeling of a Non-Device CDS should look, there is still a lot of leeway for manufacturers that they can use to their advantage.

Thus, although the FDA goes further in its new CDS Guidance than in its previous CDS Draft Guidance and now considers that all types of AI/ML-based CDS can generally fulfill the medical device exception in FDCA Section 520(o)(1)(E), including deep learning, the FDA simultaneously seems to expand its regulatory oversight over certain CDS software functions, such as sepsis tools, with its new interpretation of criteria (2) and (3). In general, the new CDS Guidance does not offer the long-awaited hope of clarity, but rather creates confusion among stakeholders, especially AI/ML manufacturers. This puzzlement of stakeholders could also be seen during the question and answer session of the FDA webinar on the new CDS Guidance.²¹² In particular, there is no clear, consistent line apparent as to when a CDS software function is considered a Non-Device CDS or a device software function,²¹³ and frankly speaking, it seems to be an insurmountable task.

²¹⁰ U.S. FOOD & DRUG ADMIN., *supra* note 18, at 4.

²¹¹ See FDCA § 520(o)(1)(E)(iii), 21 U.S.C. § 360j(o)(1)(E)(iii). For more information on the term "intended use," see *supra* Section II.B.1; see also Evans & Ossorio, *supra* note 10, at 243 (arguing that "[t]he software manufacturer merely needs to *intend* for the software to explain its recommendations transparently").

²¹² See sources cited *supra* note 197.

²¹³ Leo Celi, a biostatistician at Harvard, told STAT+, "They come up with this (guidance) and it's not very clear where the line is between software as a medical device and a non-device."

To be fair, the FDA appears to be trying to fix a mistake Congress made in the first place when enacting the CDS software exception as part of the 21st Century Cures Act.²¹⁴ This decision reportedly was likely driven by lobbyists pushing relentlessly for proposals to vitiate regulatory hurdles facing health software.²¹⁵ This author has thus already argued in one of her other works in depth that Congress should amend the FDCA by deleting Section 520(o)(1)(E).²¹⁶ In other words, all CDS should be considered a priori device software functions.²¹⁷ This suggestion would be beneficial in three ways. First, it would eliminate the current blurry line between device software functions and Non-Device CDS and thus would contribute to greater clarity and legal certainty for AI/ML manufacturers.²¹⁸ Second, it would effectively prevent products from slipping off the FDA’s radar because they are considered Non-Device CDS, although their functionality could bear a risk to patient safety if they were *not* to operate as intended.²¹⁹ Third, it could offer a safeguard against automation bias.²²⁰ This suggestion would also entail that the FDA would still be free to exercise enforcement discretion over some device software functions that are lower risk.²²¹ With the release of the new CDS Guidance, calls are growing for “Congress to investigate what FDA is doing here to override the statute.”²²² Consequently, now is the perfect time for Congress to act and use the CDS Guidance as an opportunity to correct its mistake in enacting the CDS software exception as part of the 21st Century Cures Act in the first place and thereby giving the FDA the statutory authority it needs to regulate CDS safely and effectively.

Ross, *In New Guidance, FDA Says AI Tools to Warn of Sepsis Should Be Regulated as Devices*, *supra* note 166.

²¹⁴ 21st Century Cures Act, Pub. L. No. 114–255, § 3060, 130 Stat. 1033, 1130–31 (2016) (codified at 21 U.S.C. §§ 321(h)(1), 360j(o)).

²¹⁵ See Casey Ross & Ike Swetlitz, *IBM to Congress: Watson Will Transform Health Care, So Keep Your Hands off Our Supercomputer*, STAT+ (Oct. 4, 2017), <https://www.statnews.com/2017/10/04/ibm-watson-regulation-fda-congress> [<https://perma.cc/U8TX-P2YS>]; see also Gerke, *Health AI*, *supra* note 10, at 456–57 (discussing this scandal).

²¹⁶ Gerke, *Health AI*, *supra* note 10, at 453–63.

²¹⁷ *Id.* at 460.

²¹⁸ *Id.* at 461.

²¹⁹ *Id.* at 457–58, 463; see U.S. FOOD & DRUG ADMIN., POLICY FOR DEVICE SOFTWARE FUNCTIONS AND MOBILE MEDICAL APPLICATIONS—GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 2 (2022), <https://www.fda.gov/media/80958/download> [<https://perma.cc/B9MM-6WMZ>].

²²⁰ Gerke, *Health AI*, *supra* note 10, at 461.

²²¹ *Id.*; see also *infra* Section II.C. (discussing the FDA’s enforcement discretion).

²²² Thompson, *supra* note 164.

C. *The FDA's Enforcement Discretion*

The FDA clarifies in its *Policy for Device Software Functions and Mobile Medical Applications* that the agency follows a risk-based approach, meaning that the agency focuses its *regulatory oversight* entirely on device software functions “whose functionality could pose a risk to a patient’s safety if the device were to not function as intended.”²²³ An example of an AI/ML-based medical device subject to FDA’s regulatory oversight is a software function that calculates dosage for radiation therapy based on patient-specific parameters.²²⁴

The FDA, however, also clarifies in this policy that the agency intends to exercise *enforcement discretion* if the software function is or may be a medical device under the FDCA and poses a *lower risk* to the public.²²⁵ For instance, the FDA likely does not intend to enforce requirements under the FDCA in the case of an AI/ML-based software function that coaches patients with cardiovascular disease how to obtain optimal nutrition or maintain a healthy weight.²²⁶

The CDS Draft Guidance of September 27, 2019, still contained a comprehensive section explaining the policy for Device CDS functions and when the FDA intends to practice enforcement discretion.²²⁷ The final CDS Guidance of September 28, 2022, no longer includes this enforcement discretion policy.²²⁸ Instead, the CDS Guidance only states:

some decision support software functions may be identified in other guidance documents as software functions for which, based on our current understanding of the risks of these software functions, FDA does not intend at this time to enforce compliance with applicable device requirements of the FD&C Act, including, but not limited to, premarket clearance and approval requirements.²²⁹

Thus, it is even less clear to developers than before when the FDA intends to exercise enforcement discretion over specific Device CDS functions. The FDA’s new Digital Health Policy Navigator, however, contains at least some information on the agency’s enforcement

²²³ U.S. FOOD & DRUG ADMIN., *supra* note 219, at 2, 11.

²²⁴ *See id.* at 13.

²²⁵ *Id.* at 2, 13–15.

²²⁶ *See id.* at 14.

²²⁷ U.S. FOOD & DRUG ADMIN., *supra* note 140, at 16–18.

²²⁸ U.S. FOOD & DRUG ADMIN., *supra* note 18.

²²⁹ *Id.* at 5.

discretion policies.²³⁰ In particular, steps (3) and (7) of the Digital Health Policy Navigator, based on the FDA’s General Wellness Guidance²³¹ and Policy for Device Software Functions and Mobile Medical Applications,²³² may help developers determine whether the FDA intends to exercise enforcement discretion over their device software functions or at least identify the relevant FDA policies. For example, according to the General Wellness Guidance, the FDA intends to exercise enforcement discretion over software functions that remind users to avoid direct sunlight exposure on their skin when the UV index is high to help decrease skin cancer risk.²³³

III. WHAT ARE THE CHALLENGES OF LABELING FOR AI/ML-BASED MEDICAL DEVICES?

Part III examines the challenges of labeling for AI/ML-based medical devices. It first provides an overview of labeling for medical devices, including relevant definitions, information on misbranding, labeling regulations for medical devices in Title 21 of the C.F.R., and IMDRF documents. This knowledge helps to better illustrate why the current labeling requirements are insufficient for AI/ML-based medical devices. Furthermore, this Part shows why AI/ML-based medical devices differ from traditional medical devices such as contact lenses. In particular, Part III argues that there is an urgent need for labeling standards for AI/ML-based medical devices, as such devices are increasingly used by a wide range of users, such as health care professionals and consumers. And many users are *not* sufficiently informed about the device’s benefits, risks, and limitations. This even applies in the few cases in which the FDA has so far demanded specific labeling requirements on a case-by-case basis. This lack of knowledge can endanger patient health and lead to unnecessary treatment and biased care. Labeling standards would reduce these risks and help create certainty for manufacturers.

Part III also explores practical challenges and methods for implementing labeling standards for AI/ML-based medical devices. In particular, it suggests that the FDA could implement such new labeling standards either in the form of regulations or nonbinding recommendations through a guidance document. It would also be desirable from

²³⁰ *Digital Health Policy Navigator*, *supra* note 156. For more information on this Navigator, see *supra* Section II.B.2.

²³¹ U.S. FOOD & DRUG ADMIN., *supra* note 115.

²³² U.S. FOOD & DRUG ADMIN., *supra* note 219.

²³³ U.S. FOOD & DRUG ADMIN., *supra* note 115, at 7.

a global harmonization standpoint if the IMDRF additionally dealt with this topic. Moreover, this Part argues that labeling for AI/ML-based medical devices must go hand in hand with other needed regulatory reforms.²³⁴ A new regulatory framework for AI/ML-based medical devices, among other things, needs to ensure that labeling cannot be misused as an excuse to bring poorly designed devices—such as the one in the introductory example that missed Alicia’s melanoma because it was trained only on images of people with white skin—to market.

A. *Labeling for Medical Devices*

Currently, manufacturers of those AI/ML-based medical devices that are the focus of FDA’s regulatory oversight²³⁵ need to comply with the labeling requirements for medical devices. This Section first explains the difference between the terms “label” and “labeling.” It then briefly examines the issue of misbranding and the importance for manufacturers of knowing and complying with labeling requirements to shield themselves from civil enforcement proceedings and liability claims. Lastly, this Section discusses relevant labeling regulations for medical devices in Title 21 of the C.F.R. and pertinent IMDRF documents for medical device labeling, which demonstrate that there are currently no labeling standards for AI/ML-based medical devices.

1. *Difference Between Label and Labeling*

There are two essential terms that need to be distinguished from each other, namely “label” and “labeling.”²³⁶ FDCA Section 201(k) defines the term “label” as “a display of written, printed, or graphic matter upon the immediate container of any article.”²³⁷ An immediate container “does not include package liners.”²³⁸ The label usually consists of that portion of the display limited to the medical device itself.²³⁹ Any statement, word, or other information that appears on the label must also appear on the outside wrapper or container (if there is

²³⁴ See Gerke, *Health AI*, *supra* note 10.

²³⁵ See *supra* Part II.

²³⁶ Compare FDCA § 201(k), 21 U.S.C. § 321(k), with FDCA § 201(m), 21 U.S.C. § 321(m).

²³⁷ FDCA § 201(k), 21 U.S.C. § 321(k).

²³⁸ FDCA § 201(l), 21 U.S.C. § 321(l).

²³⁹ U.S. FOOD & DRUG ADMIN., LABELING: REGULATORY REQUIREMENTS FOR MEDICAL DEVICES 2 (1989), <https://www.fda.gov/media/74034/download> [<https://perma.cc/BWN5-GCN5>].

one) of its retail package or must be easily readable through the outside wrapper or container.²⁴⁰

What does this mean for AI/ML-based medical devices? What kind of label do such devices have? The answer to these questions likely depends on whether the AI/ML-based medical device is SaMD or SiMD. As we have seen,²⁴¹ most AI/ML-based medical devices that are currently being developed or available on the U.S. market are SaMD and thus are stand-alone software. Consequently, in the absence of a physical form, SaMD typically has no physical label.²⁴² The label of an AI/ML-based SaMD is instead available electronically via the software itself or other easily accessible means such as the inclusion of a web address.²⁴³ For example, the electronic label can be shown to clinicians when logging into a cloud-based software platform powered by AI. In contrast, SiMD has software and hardware components.²⁴⁴ SiMD is integral to a medical device, which typically has a physical label.

FDCA Section 201(m) defines the term “labeling” as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”²⁴⁵ The term “accompanying” is understood broadly.²⁴⁶ It does not only mean the physical association with the product, but it also includes, for example, tags, circulars, pamphlets, posters, brochures, direction sheets, booklets, and instruction books.²⁴⁷ The term also extends to labeling that is united with the medical device after (delivery for) shipment in interstate commerce.²⁴⁸ Consequently, labeling is an umbrella term that encompasses all labels as well as informational and descriptive literature, such as instructions for use, accompanying the AI/ML-

²⁴⁰ FDCA § 201(k), 21 U.S.C. § 321(k).

²⁴¹ See *supra* Section II.A.

²⁴² For example, SaMD could also be delivered on a physical medium, such as a CD or DVD, but in the modern world of technology, these media are “are dying out.” For more information on physical media and unique device identification, see *infra* Section III.A.4.

²⁴³ See IMDRF Good Regul. Rev. Pracs., *Principles of Labelling for Medical Devices and IVD Medical Devices*, IMDRF Doc. IMDRF/GRRP WG/N52FINAL:2019, at 26 (Mar. 21, 2019), <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-pl-md-ivd.pdf> [<https://perma.cc/6A72-3MT5>].

²⁴⁴ For more information on SiMD, see *supra* Section II.A.

²⁴⁵ FDCA § 201(m), 21 U.S.C. § 321(m).

²⁴⁶ U.S. FOOD & DRUG ADMIN., *supra* note 239, at 2; *Device Labeling*, U.S. FOOD & DRUG ADMIN. (Oct. 23, 2020) [hereinafter *Device Labeling*], <https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling> [<https://perma.cc/3M77-F22Q>].

²⁴⁷ See sources cited *supra* note 246.

²⁴⁸ See *id.*

based medical device.²⁴⁹ Some promotion is also considered labeling.²⁵⁰

2. *Misbranding, FDCA Section 502*

FDCA Section 502 lists when a medical device is considered misbranded. For example, a “device shall be deemed to be misbranded . . . [i]f its *labeling is false or misleading in any particular*.”²⁵¹ The terms “false or misleading” are interpreted broadly.²⁵² The labeling is “misleading” if it is deceptive—i.e., it leads or creates a false impression in the reader’s mind.²⁵³ A “false impression” can arise not only from literally false statements, but also from statements that create ambiguities, misdirections, and those that fail to include relevant information for the reader and thus act deceptively.²⁵⁴ Another example of a misbranded medical device that FDCA Section 502 lists is generally a device whose labeling does *not* bear adequate directions for use.²⁵⁵

It is important that manufacturers of AI/ML-based medical devices know and adhere to the labeling requirements for medical devices to shield themselves from civil enforcement proceedings for misbranding, including warning letters, recalls, or injunctions.²⁵⁶ Moreover, manufacturers who create the AI/ML-based medical device’s label may also face liability claims under tort law (products liability) as well as criminal penalties in severe cases.²⁵⁷

3. *Labeling Regulations for Medical Devices, Title 21 of the C.F.R.*

Six parts of Title 21 of the C.F.R. contain labeling requirements for medical devices, namely:

(1) General Device Labeling (Part 801),

²⁴⁹ See U.S. FOOD & DRUG ADMIN., *supra* note 239, at 2.

²⁵⁰ See *id.*; see also *Device Labeling*, *supra* note 246 (explaining that labeling often includes advertising). For more information on the distinction between the terms “label,” “labeling,” and “advertising,” and the FDA’s outer limits of jurisdiction over “labeling,” see, for example, PETER BARTON HUTT, RICHARD A. MERRILL, LEWIS A. GROSSMAN, NATHAN CORTEZ, ERIKA FISHER LIETZAN & PATRICIA J. ZETTLER, *FOOD AND DRUG LAW* 225–32 (5th ed. 2022).

²⁵¹ FDCA § 502(a), 21 U.S.C. § 352(a) (emphasis added).

²⁵² U.S. FOOD & DRUG ADMIN., *supra* note 239, at 4.

²⁵³ *Id.*

²⁵⁴ *Id.* at 4–5.

²⁵⁵ FDCA § 502(f), 21 U.S.C. § 352(f).

²⁵⁶ *Misbranding Defense*, OBERHEIDEN P.C., <https://federal-lawyer.com/criminal-law/misbranding-defense> [<https://perma.cc/Q2RN-CWJC>].

²⁵⁷ *Id.*

- (2) In Vitro Diagnostic Products for Human Use (Part 809),
- (3) Investigational Device Exemptions (Part 812),
- (4) Good Manufacturing Practices (Part 820),
- (5) Unique Device Identification (Part 830), and
- (6) General Electronic Products (Part 1010).²⁵⁸

AI-based medical devices are categorized into three classes based on their risk (low, moderate, or high).²⁵⁹ The regulatory controls increase the higher the classification of the device.²⁶⁰ Class I devices are subject to general controls, Class II devices are subject to general and special controls (if available), and Class III devices are subject to general controls and premarket approval (“PMA”).²⁶¹

The General Device Labeling requirements laid down in 21 C.F.R. Part 801 (*see* Box 1 below) are an example of general controls and thus usually apply to all medical devices, including AI/ML-based ones.

²⁵⁸ See 21 C.F.R. §§ 801, 809, 812, 820, 830, 1010; *Device Labeling*, *supra* note 246.

²⁵⁹ *How to Study and Market Your Device*, U.S. FOOD & DRUG ADMIN. (June 7, 2022), <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device> [<https://perma.cc/SD8C-C7PC>].

²⁶⁰ *Id.*

²⁶¹ FDCA § 513(a)(1), 21 U.S.C. § 360c(a)(1). For more information on regulatory controls, see *Regulatory Controls*, U.S. FOOD & DRUG ADMIN. (Mar. 27, 2018), <https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls> [<https://perma.cc/BC2V-MWR4>].

**Box 1: Overview of Relevant General Device
Labeling Requirements (21 C.F.R. Part 801)**

21 C.F.R. Part 801 consists of different Subparts (A–H).

▪ **Subpart A: General Labeling Provisions**

- 21 C.F.R. § 801.1—Name and Place of Business
 - The name of business of the manufacturer, distributor, or packer shall be specified conspicuously on the label of a medical device in package form.²⁶² This also applies to the place of business, which includes the city, state, zip code, and usually the street address.²⁶³
- 21 C.F.R. § 801.5—Adequate Directions for Use
 - “[D]irections under which the layman can use a device safely and for the purposes for which it is intended.”²⁶⁴ This includes statements of all conditions, uses, or purposes for which the device is intended, quantity of dose, preparation for use, as well as frequency, duration, time, and route or method of application or administration.²⁶⁵
- 21 C.F.R. § 801.15—Use of Symbols in Labeling
 - This Section contains, among other things, labeling requirements for the use of symbols,²⁶⁶ which were introduced by the FDA’s final rule, “Use of Symbols in Labeling,” and became effective on September 13, 2016.²⁶⁷ The requirements only apply to those symbols utilized to convey information under the authority of or required by the FDCA to appear on the device’s label or labeling.²⁶⁸

²⁶² 21 C.F.R. § 801.1(a).

²⁶³ *Id.* § 801.1(d).

²⁶⁴ *Id.* § 801.5.

²⁶⁵ *Id.* § 801.5(a)–(g).

²⁶⁶ *Id.* § 801.15.

²⁶⁷ Use of Symbols in Labeling, 81 Fed. Reg. 38911 (June 15, 2016). For more information on the final rule, see, for example, Antoinette (Tosia) Hazlett & Scott Colburn, *Using Symbols to Convey Information in Medical Device Labeling*, U.S. FOOD & DRUG ADMIN. (July 19, 2018), <https://www.fda.gov/news-events/fda-voices/using-symbols-convey-information-medical-device-labeling> [https://perma.cc/B6FB-D98B].

²⁶⁸ *Use of Symbols in Labeling: Frequently Asked Questions*, U.S. FOOD & DRUG ADMIN. (Mar. 22, 2018), <https://www.fda.gov/medical-devices/device-labeling/use-symbols-labeling-frequently-asked-questions> [https://perma.cc/A4A3-VTE8].

- Manufacturers have the choice of whether to use symbols on the label or labeling for a device.²⁶⁹ If they decide to use symbols, they can use them with adjacent explanatory text or stand-alone symbols.²⁷⁰ If they choose the latter, they need to make sure, among other things, that the symbols are established in a standard created by a standards development organization (“SDO”) and explained in a symbols glossary.²⁷¹
- 21 C.F.R. § 801.18—Standard Date Format
 - In general, dates provided on a medical device label (e.g., date of manufacturer, printed expiration date, etc.) must be presented in a specific format.²⁷² For example, February 23, 2021, must be presented as 2021-02-23.²⁷³
- **Subpart B: Unique Device Identification (“UDI”) Labeling Requirements**
 - 21 C.F.R. § 801.20—Label to Bear a UDI
 - In general, the label and package of “every medical device shall bear a unique device identifier (UDI) that

²⁶⁹ See 21 C.F.R. § 801.15(c)(1)(i).

²⁷⁰ *Id.*

²⁷¹ *Id.*; U.S. FOOD & DRUG ADMIN., *supra* note 268; see also Int’l Org. for Standardization [ISO], *Medical Devices—Symbols to Be Used With Information to be Supplied by the Manufacturer—Part 1: General Requirements*, ISO 15223-1:2021 (identifying requirements for symbols used in device labeling). The term “SDO” is defined as

an organization that is nationally or internationally recognized and that follows a process for standard development that is transparent, (*i.e.*, open to public scrutiny), where the participation is balanced, where an appeals process is included, where the standard is not in conflict with any statute, regulation, or policy under which FDA operates, and where the standard is national or international in scope.

21 C.F.R. § 801.15(c)(1)(iii)(A). A symbols glossary is “a compiled listing of”:

- (1) Each SDO-established symbol used in the labeling for the device;
- (2) The title and designation number of the SDO-developed standard containing the symbol;
- (3) The title of the symbol and its reference number, if any, in the standard; and
- (4) The meaning or explanatory text for the symbol as provided in the FDA recognition or, if FDA has not recognized the standard or portion of the standard in which the symbol is located or the symbol is not used according to the specifications for use of the symbol set forth in FDA’s section 514(c) recognition, the explanatory text as provided in the standard.

Id. § 801.15(c)(1)(iii)(B).

²⁷² 21 C.F.R. § 801.18(a).

²⁷³ See *id.*

meets the requirements of this subpart and part 830 of this chapter.”²⁷⁴

- A UDI helps to identify medical devices through use and distribution. It usually consists of two components:
 1. A *device identifier* (“DI”)—i.e., “a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device”; and
 2. A *production identifier* (“PI”)—i.e., “a conditional, variable portion of a UDI.” When included on the device label, it identifies different information (e.g., serial number, expiration date, manufacturing date, lot, or batch).²⁷⁵
- 21 C.F.R. § 801.40—Form of a UDI
 - The UDI needs to comply with the technical requirements of 21 C.F.R. § 830.20 and be presented in two forms:
 1. “Easily readable plain-text,” and
 2. “Automatic identification and data capture (AIDC) technology.”²⁷⁶
- 21 C.F.R. § 801.50—Labeling Requirements for Stand-Alone Software
 - Special labeling requirements apply for “[s]tand-alone software that is not distributed in packaged form (e.g., when downloaded from a Web site).”²⁷⁷ Such software “is deemed to meet the UDI labeling requirements . . . if it complies with the requirements of paragraph (b) of this

²⁷⁴ *Id.* § 801.20(a). Exceptions to the general rule are listed in 21 C.F.R. § 801.20(b). For example, in general, a medical device required to bear a UDI “on its label must also bear a permanent marking providing the UDI on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use.” *Id.* § 801.45(a). There is also the possibility to request an alternative to or exception from a UDI. *Id.* § 801.55. If requesting an alternative to a UDI, one would need to show why such alternative “would provide for more accurate, precise, or rapid device identification than the requirements of this subpart or how the alternative would better ensure the safety or effectiveness of the device that would be subject to the alternative.” *Id.* § 801.55(a)(4). If one requested an exception from a UDI, one would need to explain why the requirements “are not technologically feasible.” *Id.* § 801.55(a)(3).

²⁷⁵ *Id.* § 801.3. The UDI of Class I medical devices is not required to contain a PI; for this exception, see *id.* § 801.30(d). Moreover, the Universal Product Code (“UPC”) on the label and packages of Class I medical devices can serve as the UDI. *Id.* § 801.40(d). The UPC is “the product identifier used to identify an item sold at retail in the United States.” *Id.* § 801.3.

²⁷⁶ *Id.* § 801.40(a). The term “AIDC” is defined in 21 C.F.R. § 801.3 as “any technology that conveys the unique device identifier or the device identifier of a device in a form that can be entered into an electronic patient record or other computer system via an automated process.”

²⁷⁷ *Id.* § 801.50(a).

section and conveys the version number in its production identifier.”²⁷⁸

- According to paragraph (b) of this Section, there are two ways in which stand-alone software classified as a medical device must provide its UDI:

1. “An easily readable plain-text statement displayed whenever the software is started;” or
2. “An easily readable plain-text statement displayed through a menu command (e.g., an ‘About * * *’ command).”²⁷⁹

This requirement applies regardless of whether such software is distributed in packaged form.²⁸⁰

- Stand-alone software may be identified with the same DI when it is distributed in both forms (i.e., packaged and not packaged).²⁸¹

- Enforcement Discretion

- The FDA has faced some policy and technical challenges to ensure the utility and quality of UDI data.²⁸² The agency recently published its final Guidance for UDI, in which the FDA clarifies, among other things, its compliance policy concerning the Global Unique Device Identification Database (“GUDID”) submission requirements (21 C.F.R. § 830.300) for particular Class I medical devices.²⁸³

- **Subpart C: Over-the-Counter Device Labeling Requirements**

²⁷⁸ *Id.*

²⁷⁹ *Id.* § 801.50(b).

²⁸⁰ *Id.*

²⁸¹ *Id.* § 801.50(c).

²⁸² See U.S. FOOD & DRUG ADMIN., UNIQUE DEVICE IDENTIFICATION: POLICY REGARDING COMPLIANCE DATES FOR CLASS I AND UNCLASSIFIED DEVICES, DIRECT MARKING, AND GLOBAL UNIQUE DEVICE IDENTIFICATION DATABASE REQUIREMENTS FOR CERTAIN DEVICES 4 (2022), <https://www.fda.gov/media/110564/download> [<https://perma.cc/8BLE-97KA>].

²⁸³ *Id.* at 2, 6–8. According to 21 C.F.R. § 830.300, the labeler must usually submit key information concerning the medical device required to bear a UDI to the GUDID. See *Unique Device Identification System (UDI System)*, U.S. FOOD & DRUG ADMIN. (July 22, 2022), <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system> [<https://perma.cc/3HPC-W6MA>]. GUDID contains basic identifying elements for medical devices, including the DI (but not the PI). See *UDI Basics*, U.S. FOOD & DRUG ADMIN. (Aug. 17, 2022), <https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/udi-basics> [<https://perma.cc/X3LL-5Z3C>].

- **Subpart D: Exemptions from Adequate Directions for Use**
- 21 C.F.R. § 801.109—Prescription Device
 - A prescription device is “[a] device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device.”²⁸⁴
 - Such a device shall thus be exempt from “adequate directions for use” if certain conditions are fulfilled.²⁸⁵ For example, the device must be in the possession of a licensed practitioner, or another lawfully engaged person, who prescribes the device’s use in the course of her professional practice.²⁸⁶ The label must bear the “Rx only” or “℞ only” statement and the methods of its use or application.²⁸⁷ The labeling within or on the package must usually bear information for use, including routes, duration and frequency of administration, methods, effects, and indications, and any contraindications, side effects, relevant hazards, and precautions under which the licensed practitioner can safely use the device for the intended purpose.²⁸⁸ All labeling bearing information for device use (except cartons and labels) must also bear the issuance date or the date of the newest revision of the labeling.²⁸⁹
- **Subpart E: Other Exemptions**
- **Subpart H: Special Requirements for Certain Medical Devices** (e.g., hearing aid devices²⁹⁰)

Title 21 of the C.F.R. does not contain specific labeling requirements for AI/ML-based medical devices. As shown in Box 1, only with regard to the bearing of a UDI, there are special requirements for stand-alone software that are relevant for AI/ML-based SaMD.²⁹¹

Manufacturers of AI/ML-based medical devices need to ensure that their premarket submission contains all required information, in-

²⁸⁴ *Id.* 21 C.F.R. § 801.109.

²⁸⁵ *Id.*

²⁸⁶ *Id.* § 801.109(a).

²⁸⁷ *Id.* § 801.109(b).

²⁸⁸ *Id.* § 801.109(c).

²⁸⁹ *Id.* § 801.109(e).

²⁹⁰ *Id.* § 801.420.

²⁹¹ *Id.* § 801.50.

cluding proposed labels and labeling.²⁹² There are four relevant types of premarket submissions:

- (1) 510(k) Premarket Notification (for Class I or Class II devices, unless they are exempt),
- (2) PMA (for Class III devices),
- (3) Humanitarian Device Exemption (for Class III devices for rare conditions or diseases), and
- (4) De Novo Classification Request (for novel low- to moderate-risk devices).²⁹³

So far, most AI-based medical devices have been cleared via the 510(k) pathway.²⁹⁴ Eighteen of 521 AI-based medical devices have received marketing authorization via the De Novo pathway and only three devices via PMA.²⁹⁵ A 510(k) requires the sponsor to demonstrate that its medical device is “substantially equivalent” to a predicate device (i.e., a legally marketed device) concerning the intended use and technological characteristics or performance testing.²⁹⁶ In particular, the 510(k) submission must contain, among other information, “[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.”²⁹⁷

The FDA can require special label requirements through special controls.²⁹⁸ The agency, however, typically only requests those for Class II medical devices in the De Novo process, a pathway focusing on particular novel medical devices with no predicate device.²⁹⁹ As seen, however, only a tiny fraction of AI/ML-based medical devices have actually been reviewed via the De Novo process.³⁰⁰

²⁹² See, e.g., U.S. FOOD & DRUG ADMIN., *supra* note 259.

²⁹³ *Id.*

²⁹⁴ See U.S. FOOD & DRUG ADMIN., *supra* note 7.

²⁹⁵ *Id.*

²⁹⁶ FDCA § 513(i)(1)(A), 21 U.S.C. § 360c(i)(1)(A); U.S. FOOD & DRUG ADMIN., *supra* note 259. For more information on the 510(k) process, see, for example, *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN. (Mar. 13, 2020), <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k> [<https://perma.cc/9LQ9-9YTN>].

²⁹⁷ 21 C.F.R. § 807.87(e).

²⁹⁸ U.S. FOOD & DRUG ADMIN., *supra* note 261.

²⁹⁹ U.S. FOOD & DRUG ADMIN., *supra* note 259. For more information on the De Novo process, see, for example, Gerke, *Health AI*, *supra* note 10, at 470–71.

³⁰⁰ See *Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices*, *supra* note 7.

4. IMDRF Documents

The IMDRF has published four documents that are particularly relevant for medical device labeling, including labeling for AI/ML-based medical devices:

- (1) *Principles of Labelling for Medical Devices and IVD Medical Devices*,³⁰¹
- (2) *UDI Guidance*,³⁰²
- (3) *Unique Device Identification system (UDI system) Application Guide*,³⁰³ and
- (4) *Software as a Medical Device (SaMD): Clinical Evaluation*.³⁰⁴

The purpose of the first IMDRF document, *Principles of Labelling for Medical Devices and IVD Medical Devices*, published on March 21, 2019, is “to provide globally harmonized labelling principles for medical devices, including in vitro diagnostic (IVD) medical devices.”³⁰⁵ The IMDRF document provides guidance on three elements of medical device labeling:

- (1) the label,
- (2) the instructions for use (“package insert”), and
- (3) the information intended for patients.³⁰⁶

This document only gives an overview of the general labeling principles, which are globally harmonized; regulatory authorities may demand additional labeling requirements.³⁰⁷ It does contain, however, three labeling principles for SaMD and medical devices containing software.³⁰⁸ First, such devices should have a unique identifier (e.g., version, date of build release/issue, revision level) that should usually

³⁰¹ IMDRF Good Regul. Rev. Pracs., *supra* note 243.

³⁰² IMDRF UDI Working Grp., *UDI Guidance*, IMDRF Doc. IMDRF/UDI WG/N7FINAL:2013 (Dec. 9, 2013), <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf> [<https://perma.cc/PC27-GPVT>].

³⁰³ IMDRF UDI Working Grp., *Unique Device Identification system (UDI system) Application Guide*, IMDRF Doc. IMDRF/UDI WG/N48FINAL:2019 (Mar. 21, 2019), <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-udi-sag.pdf> [<https://perma.cc/NTB2-2LH2>].

³⁰⁴ Software as Med. Device Working Grp., *Software as a Medical Device (SaMD): Clinical Evaluation*, IMDRF Doc. IMDRF/SaMD WG/N41FINAL:2017 (Sept. 21, 2017), http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170921-samd-n41-clinical-evaluation_1.pdf [<https://perma.cc/9JWU-GQY3>].

³⁰⁵ IMDRF Good Regul. Rev. Pracs., *supra* note 243, at 4.

³⁰⁶ *Id.*

³⁰⁷ *See id.* at 5.

³⁰⁸ *See id.* § 8.

be accessible to the intended user.³⁰⁹ Second, the identifier does not have to be on the outside of the device in cases where software is incorporated into a medical device.³¹⁰ Third, the label may be presented electronically for SaMD without a packaging or physical form.³¹¹ Manufacturers need to make sure that users have easy access to the electronic label via the inclusion of a web address, via the software itself, or by other means.³¹²

The second relevant IMDRF document is the *UDI Guidance*, which was published on December 9, 2013, to provide a nonbinding framework for those regulatory authorities that aim to develop their UDI Systems.³¹³ It provides a high-level overview of how a globally harmonized UDI System intended for the identification of medical devices should work.³¹⁴

This IMDRF Guidance also contains nonbinding rules for specific medical device types, including SaMD.³¹⁵ For example, it specifies when a SaMD would require a new UDI-DI or UDI-PI.³¹⁶ A new UDI-DI would be needed in cases of complex or significant changes affecting the effectiveness and original performance or the intended use or safety of the SaMD.³¹⁷ Such changes may include database structures, new or modified algorithms, operating platforms, new channels for interoperability, or new user interfaces.³¹⁸ A new UDI-PI would be needed in cases of minor SaMD revisions, such as those associated with usability enhancements (not for safety purposes), bug fixes, operating efficiency, or security patches.³¹⁹ The IMDRF *UDI Guidance* also contains UDI placement criteria for SaMD.³²⁰ For example, the UDI applied to the physical medium, such as a DVD or CD, (if any) and its packaging (if existing) must be identical to the

³⁰⁹ *Id.* § 8.1.

³¹⁰ *Id.* § 8.2.

³¹¹ *Id.* § 8.3.

³¹² *Id.*

³¹³ IMDRF UDI Working Grp., *supra* note 302, at 3.

³¹⁴ *Id.*

³¹⁵ *Id.* § 10.

³¹⁶ *Id.* § 10.6.1.

³¹⁷ *Id.*

³¹⁸ *Id.*

³¹⁹ *Id.*

³²⁰ *Id.* § 10.6.2.

UDI given to the system level SaMD.³²¹ SaMD without a physical medium does not need to carry an AIDC representation of the UDI.³²²

The IMDRF also published on March 21, 2019, the *Unique Device Identification system (UDI system) Application Guide*, which is a supplement to the IMDRF *UDI Guidance*.³²³ It aims to provide the specifications and details to ensure consistency for facilitating a harmonized UDI system application.³²⁴ This Guide contains additional information on the UDI placement criteria for SaMD.³²⁵ For example, it clarifies that SaMD without a physical data carrier, such as a CD or DVD, will not be required to carry an AIDC.³²⁶ Appendix I of this Guide also contains examples of UDI assignment for software.³²⁷

Finally, the IMDRF document *Software as a Medical Device (SaMD): Clinical Evaluation*, published on September 21, 2017, provides a path for regulators to make SaMD clinically meaningful for users.³²⁸ It also contains a few considerations on labeling for SaMD.³²⁹ First, this document recommends that manufacturers properly review the collected postmarket information of their SaMD to assess whether any labeling changes are needed concerning warnings, contraindications, precautions, or instructions for use.³³⁰ Second, it points out that the labeling of the SaMD should identify, in end-user-friendly language, device limitations relevant to the interpretation of its output and its clinical performance.³³¹

In summary, the IMDRF documents do not contain specific labeling standards for AI/ML-based medical devices. They do, however, contain some information on SaMD that is relevant for AI/ML-based SaMD. Such information, however, is mainly limited to topics such as the format of labeling, labeling changes, and the UDI assignment and placement criteria. General information on the content or type of information that should be included in the labeling for SaMD is almost entirely missing.

³²¹ *Id.*

³²² *Id.* For more information on AIDC, see Box 1 *supra* Section III.A.3.; *see also supra* note 276.

³²³ IMDRF UDI Working Grp., *supra* note 303, at 5.

³²⁴ *Id.*

³²⁵ *Id.* at 34–35.

³²⁶ *Id.* at 35.

³²⁷ *Id.* at 58–68.

³²⁸ Software as Med. Device Working Grp., *supra* note 304, at 4.

³²⁹ *Id.* at 20.

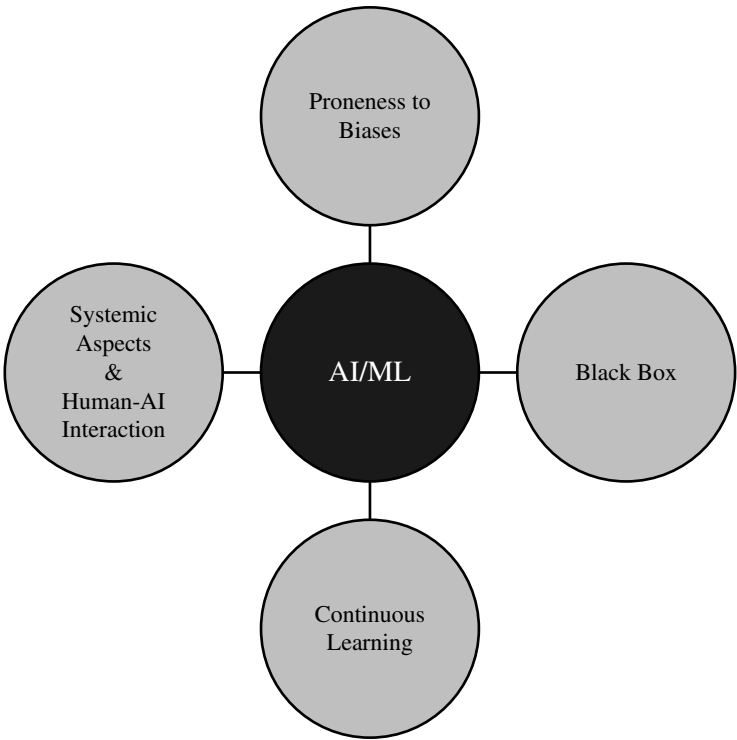
³³⁰ *Id.*

³³¹ *Id.*

B. *Why Do AI/ML-Based Medical Devices Differ from Traditional Medical Devices?*

There are several reasons why AI/ML-based medical devices differ from traditional medical devices, such as contact lenses. Figure 8 illustrates four of them, which will also be discussed below.

FIGURE 8. CHALLENGES OF AI/ML-BASED MEDICAL DEVICES



1. *Proneness to Biases*

In contrast to typical medical devices, such as surgical gloves or crutches, many, if not all, AI/ML-based medical devices are prone to biases. The term “bias” is often used differently in various fields.³³² For example, according to a technical definition, bias means “systematic difference in treatment of certain objects, people, or groups in comparison to others.”³³³ In contrast, in law, the term is frequently

³³² A.I. Med. Devices Working Grp., *Machine Learning-Enabled Medical Devices: Key Terms and Definitions*, IMDRF Doc. IMDRF/AIMD WG/N67, at 10 (May 6, 2022), <https://www.imdrf.org/sites/default/files/2022-05/IMDRF%20AIMD%20WG%20Final%20Document%20N67.pdf> [https://perma.cc/Z8YV-5XNJ].

³³³ Int’l Org. for Standardization, *Information Technology—Artificial Intelligence (AI)—Bias in AI Systems and AI Aided Decision Making*, ISO/IEC TR 24027:2021. The term “treat-

associated with the meaning “unfair or unfairly prejudiced/partial.”³³⁴ There are different types of biases, including the following four:

- (1) bias in the training data,
- (2) label choice bias,
- (3) contextual bias, and
- (4) unconscious bias.

First, in general, algorithms should learn from diverse data sets to ensure that they will perform well for all patient communities, including racial and ethnic minorities, thus promoting equity and inclusion. According to the motto “garbage in, garbage out,” the use of training data sets that lack diversity, such as in terms of gender, race/ethnicity, (dis)ability, etc., may result in biased AI/ML-based medical devices.³³⁵ This, in turn, can lead to two undesirable scenarios. In the first scenario, the most vulnerable patient communities in our society, in particular, would be excluded from benefiting from such innovative technologies in their care from the outset. In the second scenario, AI/ML-based medical devices would be used in the care of patients who were underrepresented in the training data set, and the devices’ recommendations or decisions could put their health at risk. As the introductory example shows, an AI/ML dermatology tool designed to diagnose specific skin diseases, including cancer, will be biased when predominantly trained on white skin images. Such a tool would likely make improper recommendations for people of color. For instance, if the AI/ML dermatology tool missed serious skin cancer in a Black patient, as was the case with Alicia’s melanoma, late cancer treatment would potentially have severe consequences for that patient, including death. Thus, it is essential that manufacturers have access to and utilize diverse training data sets that were developed in compliance with ethical principles.³³⁶ Regulators like the FDA should require AI/ML manufacturers to disclose detailed information on the used data sets, such as gender and race/ethnicity breakdowns. In general, they should

ment” is defined in ISO/IEC TR 24027 broadly as “any kind of action, including perception, observation, representation, prediction or decision.” *Id.* § 3.2.2.

³³⁴ A.I. Med. Devices Working Grp., *supra* note 332, at 10.

³³⁵ See Sascha Eder, *How Can We Eliminate Bias in Our Algorithms?*, FORBES (June 27, 2018, 8:00 AM), <https://www.forbes.com/sites/theyec/2018/06/27/how-can-we-eliminate-bias-in-our-algorithms/?sh=cba7198337eb> [<https://perma.cc/93KA-3AJR>].

³³⁶ For more information on health AI ethics and ethical principles, see, for example, Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, 26 ADVANCES HEALTH SCI. EDUC. 1447 (2021); Craig M. Klugman & Sara Gerke, *Rise of the Bioethics AI: Curse or Blessing?*, 22 AM. J. BIOETHICS 35 (2022). For the FAIR (Findable, Accessible, Interoperable, Reusable) principles, see Mark D. Wilkinson et al., Comment, *The FAIR Guiding Principles for Scientific Data Management and Stewardship*, 3 SCI. DATA 160018 (2016).

focus on promoting diversity, equity, and inclusion by ensuring that AI/ML-based medical devices that receive marketing authorization benefit everyone in our society, especially the most vulnerable ones.

Second, another major concern is label choice bias. A famous example is a widely used algorithm in the U.S. to guide health decisions.³³⁷ Ziad Obermeyer, Brian Powers, Christine Vogeli, and Sendhil Mullainathan found that the algorithm exhibited a significant racial bias against Black patients.³³⁸ The issue with this algorithm was that it predicted health care costs instead of illness.³³⁹ As a consequence, because fewer Black patients have access to health care, the algorithm falsely assumed that white patients are much sicker than similarly ill Black patients.³⁴⁰ The outcome was that many Black patients were denied extra care despite their needs.³⁴¹ Unfortunately, this is not an isolated incident. Biased algorithms are used throughout the health care system, guiding not only operational workflows and policy decisions but also clinical care.³⁴² Thus, it is important that C-suite leaders, technical teams working in health care, policymakers, and regulators critically define, measure, and reduce racial bias in live algorithms.³⁴³ Obermeyer and others have recently published an algorithmic bias playbook that describes four steps—(1) Inventory Algorithms, (2) Screen for Bias, (3) Retrain Biased Algorithms, and (4) Prevent Future Bias—that can be taken to promote this goal.³⁴⁴

Third, there is the risk of contextual bias.³⁴⁵ An example is an AI/ML-based medical device that is deployed in a specialist clinic in the U.S. and then used at a rural hospital in Africa.³⁴⁶ This transfer from one context to another may potentially harm patients because the recommendations made by the AI/ML-based medical device—even if the device is trained on a diverse data set—may not be suitable for a rural

³³⁷ See Ziad Obermeyer, Brian Powers, Christine Vogeli & Sendhil Mullainathan, *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations*, 366 *SCIENCE* 447, 447 (2019).

³³⁸ *Id.*

³³⁹ *Id.*

³⁴⁰ *Id.*

³⁴¹ *Id.*

³⁴² ZIAD OBERMEYER, REBECCA NISSAN, MICHAEL STERN, STEPHANIE EANEFF, EMILY JOY BEMBENECK & SENDHIL MULLAINATHAN, CHI. BOOTH CTR. FOR APPLIED A.I., *ALGORITHMIC BIAS PLAYBOOK 1* (June 2021), <https://www.chicagobooth.edu/-/media/project/chicago-booth/centers/caai/docs/algorithmic-bias-playbook-june-2021.pdf> [<https://perma.cc/4CCQ-AYPH>].

³⁴³ *Id.*

³⁴⁴ *Id.* at 4.

³⁴⁵ Price, *Medical AI and Contextual Bias*, *supra* note 10, at 67–68.

³⁴⁶ See Minssen et al., *supra* note 10, at 17.

hospital in Africa. For instance, the AI/ML-based medical device may recommend a high-risk surgery that requires a team of experts, a resource that is likely not available in the rural hospital, and therefore, in the worst-case scenario, may kill the patient when performed.³⁴⁷ Consequently, it will be essential to incentivize stakeholders and policymakers to build an infrastructure in low- and middle-income countries that promotes both data collection and use in health care.³⁴⁸ AI manufacturers also need to be incentivized to develop AI/ML-based medical devices that are specifically designed to address respective countries' needs with the regional context in mind.³⁴⁹ The importance of context has also been demonstrated in a recent study that showed a significant drop-off in model performance when a model was evaluated at only one U.S. clinical site and then evaluated at another location.³⁵⁰ This issue again highlights the imperative need for algorithms to perform well across representative patient populations and to conduct assessments at multiple clinical sites.

Lastly, developing reasonably safe and effective AI/ML-based medical devices is even more complicated because there are unconscious or hidden biases. For instance, computer scientists may unconsciously introduce bias through their engineering decisions, such as during feature engineering or when selecting the algorithm.³⁵¹ Consequently, bias is a real and significant risk associated with AI/ML-based medical devices which may harm patients and generally is not present in traditional medical devices such as contact lenses.

2. *Black-Box AI/ML Models*

Another complexity is that many high-performing AI/ML-based medical devices are opaque (so-called "black boxes").³⁵² An example is the cloud-based software RhythmAnalytics, designed to detect over fifteen cardiac arrhythmia types with the use of deep learning.³⁵³ Using black-box models instead of white-box models (interpretable AI/

³⁴⁷ *Id.*

³⁴⁸ See, e.g., Oluyemi E. Adetoyi & Olayanju A. Raji, *Electronic Health Record Design for Inclusion in Sub-Saharan Africa Medical Record Informatics*, 7 *SCI. AFR.*, no. e00304, 2020, at 1.

³⁴⁹ *Id.*

³⁵⁰ Eric Wu, Kevin Wu, Roxana Denshjou, David Ouyang, Daniel E. Ho & James Zou, *How Medical AI Devices Are Evaluated: Limitations and Recommendations from an Analysis of FDA Approvals*, 27 *NATURE MED.* 582, 583 (2021).

³⁵¹ A.I. Med. Devices Working Grp., *supra* note 332, at 10.

³⁵² For more information on black boxes, see *supra* Sections I.A.2., II.B.3.

³⁵³ See Biofourmis' *RhythmAnalytics™ Platform Receives FDA Clearance for AI-Based Automated Interpretation of Cardiac Arrhythmias*, *supra* note 50.

ML)³⁵⁴ can be especially beneficial to health care in cases where accuracy is critical. At the same time, black-box AI/ML models also raise considerable concerns among users because it is very difficult, or even impossible, for humans to understand them.³⁵⁵ Humans are usually in the dark concerning the logic or rationale used by the algorithm to render its recommendation or decision.³⁵⁶

Black boxes are not unique to AI/ML. They sometimes exist in drugs when their mechanisms of action are unknown, such as in the case of acetaminophen.³⁵⁷ Black boxes typically do not exist in traditional medical devices such as syringes, tongue depressors, and catheters, but they are prevalent in AI/ML-based medical devices.³⁵⁸

As analyzed earlier, explainable AI/ML is unlikely to help address the black box’s criticisms and concerns.³⁵⁹ Explainable AI/ML only provides an ersatz understanding and does not ensure that users are given the correct rationale used by the algorithm to render a recommendation or decision.³⁶⁰

User trust in black-box AI/ML models will be essential to promote their uptake in health care. Fostering this trust requires, among other things, that black-box AI/ML models be shown to be reasonably safe and effective in representative populations before their launch on the market. For example, clinical trials—unfortunately still rare in the health AI/ML field—are one tool that could be used more often to achieve this goal.³⁶¹ As seen in the pharmaceutical field, even though the mechanisms of action for some drugs like acetaminophen are still unclear, patients use such drugs all the time because they have been proven to be reasonably safe and effective.³⁶²

³⁵⁴ For more information on interpretable AI/ML, see *supra* Sections I.A.2., II.B.3.

³⁵⁵ See *supra* Section I.A.2.

³⁵⁶ See *supra* Section II.B.3.

³⁵⁷ See Gerke, *Health AI*, *supra* note 10, at 493; K. Toussaint, X.C. Yang, M.A. Zielinski, K.L. Reigle, S.D. Sacavage, S. Nagar & R.B. Raffa, *What Do We (Not) Know About How Paracetamol (Acetaminophen) Works?*, 35 J. CLINICAL PHARMACY & THERAPEUTICS 617, 617 (2010); Grzegorz W. Przybyła, Konrad A. Szychowski & Jan Gmiński, *Paracetamol—An Old Drug with New Mechanisms of Action*, 48 CLINICAL & EXPERIMENTAL PHARMACOLOGY & PHYSIOLOGY 3 (2021).

³⁵⁸ See Benjamens et al., *supra* note 7, at 3–4.

³⁵⁹ See *supra* Section II.B.3. For more information on explainable AI/ML, see also *supra* Section I.A.2.

³⁶⁰ See *supra* Section II.B.3.

³⁶¹ Gerke, *Health AI*, *supra* note 10, at 491–96.

³⁶² *Id.* at 493.

3. *Ability to Continuously Learn*

AI/ML-based medical devices currently marketed in the U.S. typically include so-called “locked” algorithms.³⁶³ The FDA defines a “locked” algorithm as “an algorithm that provides the same result each time the same input is applied to it and does not change with use,” such as decision trees, complex classifiers, or static look-up tables.³⁶⁴ Most AI/ML algorithms, however, have the ability to continuously learn from real-world experience,³⁶⁵ which makes them completely different from typical medical devices. In particular, such “adaptive” algorithms may provide different outputs compared to the ones initially cleared or approved for a given set of inputs.³⁶⁶ The term “continuous learning” can also be defined as “[t]raining that leads to change of an [AI/ML-based medical device] with each exposure to data that takes place on an ongoing basis during the operation phase of the [AI/ML-based medical device] life cycle.”³⁶⁷

Currently, manufacturers must submit a new 510(k) premarket notification in cases where the legally marketed device “is about to be significantly changed or modified in design, components, method of manufacture, or intended use.”³⁶⁸ Under 21 C.F.R. § 807.81(a)(3), significant changes or modifications that require a 510(k) premarket notification constitute:

- (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.
- (ii) A major change or modification in the intended use of the device.³⁶⁹

For example, another 510(k) is required when the modification introduces a significant change to the algorithm of a legally marketed AI/ML-based medical device.³⁷⁰ With a new 510(k) also comes the

³⁶³ U.S. FOOD & DRUG ADMIN., *supra* note 55, at 3.

³⁶⁴ *Id.* at 3 n.7.

³⁶⁵ *Id.* at 3.

³⁶⁶ *Id.*

³⁶⁷ A.I. Med. Devices Working Grp., *supra* note 332, at 11.

³⁶⁸ 21 C.F.R. § 807.81(a)(3).

³⁶⁹ *Id.*; see also U.S. FOOD & DRUG ADMIN., DECIDING WHEN TO SUBMIT A 510(K) FOR A SOFTWARE CHANGE TO AN EXISTING DEVICE—GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 2 (2017), <https://www.fda.gov/media/99785/download> [<https://perma.cc/9M4T-5XEM>].

³⁷⁰ See U.S. FOOD & DRUG ADMIN., *supra* note 55, at 3.

need for manufacturers to adjust their labeling.³⁷¹ Because it is time-consuming and expensive to undergo another or multiple premarket reviews, however, manufacturers may *not* carry out significant updates, and this failure to do so can jeopardize patient safety.³⁷²

To address this update problem, the FDA is currently exploring a new total product lifecycle (“TPLC”) approach for modifications to AI/ML-based SaMD that aims to allow such devices to continuously learn and optimize their performance in real-time while providing effective safeguards.³⁷³ In particular, during the initial premarket review of their device, manufacturers could voluntarily submit a modification plan (a so-called “predetermined change control plan”), composed of the anticipated modification types and the methodology being used to implement such modifications.³⁷⁴ Such a new approach would require manufacturers to ensure accurate labeling changes.³⁷⁵ In the FDA’s new action plan on AI/ML-based SaMD, the agency announced that the cardiac ultrasound software device Caption Guidance, which received marketing authorization via the De Novo pathway on February 7, 2020, is pioneering because the manufacturer uses a predetermined change control plan for future changes.³⁷⁶ The issue with using a predetermined change control plan, however, is that manufacturers often do not know in advance what updates are needed.³⁷⁷ Thus, the FDA should focus particularly on implementing a continuous risk monitoring approach to ensure that AI/ML-based SaMD with adaptive algorithms remain safe and effective while continuously learning and adapting to new conditions.³⁷⁸

4. Systemic Aspects and Human-AI Interaction

AI/ML-based medical devices come with different types of intelligence (assisted, augmented, or autonomous) and different levels of

³⁷¹ For more information, see *supra* Section III.A.3.

³⁷² See Babic et al., *supra* note 10, at 1202; Gerke, *Health AI*, *supra* note 10, at 496.

³⁷³ U.S. FOOD & DRUG ADMIN., *supra* note 55, at 3.

³⁷⁴ *Id.* at 10. For more information on the TPLC approach and predetermined change control plan, see Gerke, *Health AI*, *supra* note 10, at 498–500.

³⁷⁵ See U.S. FOOD & DRUG ADMIN., *supra* note 55, at 14. For more information on the need for a “dynamic” label, see also *infra* Section IV.A.

³⁷⁶ U.S. FOOD & DRUG ADMIN., ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SaMD) ACTION PLAN 2 (Jan. 2021), <https://www.fda.gov/media/145022/download> [<https://perma.cc/2ZQS-YLNF>]. For more information on Caption Guidance, see *supra* Section I.B.1.

³⁷⁷ See Babic et al., *supra* note 10, at 1204; Gerke, *Health AI*, *supra* note 10, at 500–01.

³⁷⁸ See Babic et al., *supra* note 10, at 1204; Gerke, *Health AI*, *supra* note 10, at 500–03.

human involvement (none, little, some, or high).³⁷⁹ For example, they can be CDS software, make autonomous decisions, such as IDx-DR for detecting more than mild diabetic retinopathy in diabetic adult patients, and may even begin to interact with health care professionals dynamically in the future.³⁸⁰

Human factors and how AI/ML-based medical devices interact with their environment may increase variance.³⁸¹ Therefore, AI/ML-based medical devices can perform differently in an actual practice setting versus the artificial testing environment, where there is less variance.³⁸² Thus, once marketed, the performance of many AI/ML-based medical devices is likely less predictable than that of typical medical devices. Consequently, regulators like the FDA need to adopt a system view considering the environment in which these devices are used.³⁸³

C. *The Urgent Need for Labeling Standards for AI/ML-Based Medical Devices*

This Article argues that there is an urgent need for labeling standards for AI/ML-based medical devices. As seen above, AI/ML-based medical devices differ in many ways from traditional medical devices such as crutches or contact lenses.³⁸⁴ Still, Title 21 of the C.F.R. does not contain specific labeling requirements for AI/ML-based medical devices.³⁸⁵

There are several further arguments pertaining to why labeling for AI/ML-based medical devices is important, as represented in Figure 9 and discussed below.

³⁷⁹ See *supra* Section I.A.2.

³⁸⁰ See *id.*; Gerke et al., *The Need for a System View*, *supra* note 10, at 2.

³⁸¹ Gerke et al., *The Need for a System View*, *supra* note 10, at 2.

³⁸² *Id.*

³⁸³ For more information on the system view, see *id.* at 1 and Gerke, *Health AI*, *supra* note 10, at 503–10. For example, the FDA could require more often that manufacturers conduct rigorous human factors testing to show that intended users can use their AI/ML-based medical device correctly based exclusively on reading its label. See *infra* Section IV.B.

³⁸⁴ See *supra* Section III.B.

³⁸⁵ See *supra* Section III.A.

FIGURE 9: BENEFITS OF LABELING FOR AI/ML-BASED MEDICAL DEVICE

- | |
|---|
| (1) Avoiding Harm to Patients & Consumers (e.g., by Reducing the Risk of Bias), |
| (2) Promoting Autonomous Decisions Regarding the Use of an AI/ML-Based Medical Device, |
| (3) Creating Legal Clarity for Labelers, & |
| (4) Creating Transparency & Facilitating Public Trust. |

First, labeling is helpful as it can ensure that users know how to use AI/ML-based medical devices correctly, thus avoiding harm to patients and consumers. It can contribute to the safety of patients and consumers by preventing device-related user errors that may result in severe injury or even death. Labeling can also help reduce the risk of bias. For example, suppose the labeling provides physicians with demographic information on the training data set. In that case, they could better assess whether the AI/ML-based medical device should be used in a specific patient’s care, thus reducing bias risk and preventing harm.

A recent study showed that out of a total of 161 legally marketed AI-based medical devices in the U.S., only seven provided publicly available race/ethnicity information, and only thirteen disclosed gender information.³⁸⁶ In addition, most manufacturers did not report information on the amount of data used to validate the device’s performance or the geographic breakdown.³⁸⁷ Thus, this study clearly confirms that the current labeling requirements for medical devices in Title 21 of the C.F.R. are insufficient. Without labeling standards for AI/ML-based medical devices, many users are left in the dark about important information, such as gender, race/ethnicity, and geographic breakdowns of the data sets used. Without this information, patients’ health may be jeopardized by unnecessary treatment or biased care.³⁸⁸

³⁸⁶ Ross, *supra* note 7; Casey Ross, *Explore STAT’s Database of FDA-Cleared AI Tools*, STAT+ (Feb. 3, 2021), <https://www.statnews.com/2021/02/03/fda-artificial-intelligence-clearance-products> [https://perma.cc/65X6-DFC3].

³⁸⁷ See sources cited *supra* note 386.

³⁸⁸ *Id.*

Even in the few cases in which the FDA has required special labeling requirements through special controls,³⁸⁹ those are not enough. As mentioned earlier,³⁹⁰ the FDA typically requests special controls for Class II medical devices in the De Novo process, but only eighteen marketed AI/ML-based medical devices out of 521 have undergone such a process.³⁹¹ Moreover, the majority of AI/ML-based medical devices that went through the De Novo process did *not* report gender and race/ethnicity breakdowns.³⁹² An example of such a device is BrainScope, which is used by emergency physicians to assess patients with head injuries for concussions.³⁹³ The FDA required the following special labeling requirements through special controls:

The labeling and training information must include:

- a. A warning that the device is not to be used as a stand-alone diagnostic.
- b. A detailed summary of the clinical performance testing, including any adverse events and complications.
- c. The intended use population and the intended use environment.
- d. Any instructions technicians should convey to patients regarding the collection of EEG data.
- e. Information allowing clinicians to gauge clinical risk associated with integrating the EEG interpretive assessment aid into their diagnostic pathway.
- f. Information allowing clinicians to understand how to integrate the device output into their diagnostic pathway when the device is unable to provide a classification or final result.³⁹⁴

These requirements are something, but it unfortunately appears that BrainScope did *not* provide gender and race/ethnicity breakdowns and there is no public data available on such information.³⁹⁵

³⁸⁹ For more information on special labeling requirements through special controls, see *supra* Section III.A.3.

³⁹⁰ See *supra* Section III.A.3.

³⁹¹ *Id.*

³⁹² See Ross, *supra* note 386 (download XLS file; then filter for “De Novo” under “Approval Type”) (showing data of fourteen AI/ML-based medical devices that went through the De Novo process).

³⁹³ BRAINSCOPE, *supra* note 65.

³⁹⁴ Letter from Jonette Foy, Deputy Dir. Eng’g & Sci. Rev., Off. Device Eval., Ctr. Devices & Radiological Health, U.S. Food & Drug Admin., to Michael Singer, President & CEO, BrainScope Co., Inc. 5 (Nov. 17, 2014), https://www.accessdata.fda.gov/cdrh_docs/pdf14/DEN140025.pdf [<https://perma.cc/QN63-YML5>].

³⁹⁵ See Ross, *supra* note 386 (download XLS file; then filter for “Ahead 100” under “Product”).

Consequently, the FDA’s case-by-case approach for particular AI/ML-based medical devices through special controls is also insufficient. Even if the FDA were to always require such a disclosure through the De Novo special controls, almost all AI/ML-based medical devices would be cleared through the 510(k) process and thus usually only would have to comply with the labeling requirements in Title 21 of the C.F.R.³⁹⁶

This brings us to the second benefit of labeling for AI/ML-based medical devices: because adequate labeling can inform users, among other things, about the benefits, potential risks, and limitations of the AI/ML-based medical device, it can promote autonomous decisions on whether to use the device. For instance, physicians need to know what the AI/ML-based medical device does, for whom its use is intended, and when and how to use it. In the case of DTC medical AI/ML apps, consumers should receive this information in a user-friendly manner (e.g., in plain language). This is crucial for them to properly understand the device’s benefits, risks, and limitations, including when to seek medical care.³⁹⁷

Third, standards of labeling for AI/ML-based medical devices also can create legal clarity for labelers (i.e., in most cases, manufacturers). In particular, these standards will help avoid misbranding, such as misleading or false labeling, thereby protecting manufacturers from FDA enforcement actions.³⁹⁸

Fourth, proper labeling creates transparency to users and thus can help facilitate public trust in new digital health technology. In its action plan on AI/ML-based SaMD, the FDA announced it would organize a public workshop on how labeling fosters transparency to users.³⁹⁹ In October 2021, the agency fulfilled this plan and virtually discussed how transparency through labeling might improve the safety and effectiveness of AI/ML-based medical devices.⁴⁰⁰ This workshop

³⁹⁶ For more information on Title 21 of the C.F.R., see *supra* Section III.A.3.

³⁹⁷ For more information on DTC medical AI/ML apps, see *supra* Section II.B.1.

³⁹⁸ See FDCA § 502, 21 U.S.C. § 352. For more information on misbranding, see *supra* Section III.A.2.

³⁹⁹ U.S. FOOD & DRUG ADMIN., *supra* note 376, at 4–5.

⁴⁰⁰ *Virtual Public Workshop—Transparency of Artificial Intelligence/Machine Learning-Enabled Medical Devices*, U.S. FOOD & DRUG ADMIN. (Nov. 26, 2021), <https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-public-workshop-transparency-artificial-intelligencemachine-learning-enabled-medical-devices> [https://perma.cc/4B7D-QYA7]; U.S. Food & Drug Admin., *Transcript of Virtual Public Workshop—Transparency of Artificial Intelligence/Machine Learning-Enabled Medical Devices* (Oct. 14, 2021), <https://www.fda.gov/media/154423/download> [https://perma.cc/G9MH-V39B].

was a welcomed attempt to gather stakeholder input and promote public trust in AI/ML-based medical devices.

In summary, labeling standards are urgently needed because the current labeling requirements for medical devices and the FDA's case-by-case approach for a few AI/ML-based medical devices are insufficient. Labeling for AI/ML-based medical devices is a valuable tool to avoid harm to patients and consumers, such as reducing the risk of bias in AI/ML-based medical devices. It fosters autonomous decisions regarding the use of AI/ML-based medical devices, creates transparency, and enhances public trust in innovative technology. Labeling standards for AI/ML-based medical devices will also create legal clarity for labelers.

D. Practical Challenges and Methods for Implementation

This Article argues that criticism such as “why do you care; no one reads labeling anyway” should be rejected.⁴⁰¹ Even if it is true that not a single person—which is doubtful—reads drug or device labeling, one still has the choice—i.e., to read or not read the label, instructions for use, etc. From a libertarian perspective, especially considering the new challenges raised by AI/ML-based medical devices, it is important to make users at least aware of the peculiarities, especially the potential risks and limitations of the device. What matters is that if users want to read this information, they can. Without labeling standards, some of the information about AI/ML-based medical devices would otherwise not be publicly available or would only be available to users with considerable effort and difficulty.

Nicholson Price expresses some skepticism about the usefulness of medical AI labeling, but such skepticism is limited to solving contextual bias issues and deterring off-label uses.⁴⁰² Labeling is not the panacea that solves all issues raised by AI/ML-based medical devices. In particular, labeling must be coupled with other needed regulatory reforms for AI/ML-based medical devices.⁴⁰³ A new regulatory frame-

⁴⁰¹ See, e.g., Dr. Jack Resneck, Remarks, in U.S. Food & Drug Admin., *supra* note 400, at 49 (for AI/ML-based medical devices); Mari Serebrov, *If No One Reads It, What's the Purpose of a Drug Label?*, BioWorld™ (Mar. 29, 2018), <https://www.bioworld.com/blogs/1-bioworld-perspectives/post/247-if-no-one-reads-it-what-s-the-purpose-of-a-drug-label-> [https://perma.cc/Z2J7-GA3B].

⁴⁰² See Price, *Medical AI and Contextual Bias*, *supra* note 10, at 104, 106–07.

⁴⁰³ This author has written extensively about the need for a new regulatory framework for AI/ML-based medical devices. She suggests what such a framework could look like to better ensure that these devices are reasonably safe and effective when brought to the U.S. market and stay so throughout their life cycle. See Gerke, *Health AI*, *supra* note 10; see also Kristin M.

work for AI/ML-based medical devices, among other things, needs to ensure that devices, like the AI dermatology tool that failed to detect Alicia’s melanoma because it was primarily trained on images of people with white skin, do not receive market authorization in the first place. Labeling has limits and must not be used as an excuse to bring a poorly designed device into the market.

Nonetheless, labeling is a necessary piece of the puzzle for successfully implementing AI/ML in health care. As noted above, there are several arguments in favor of labeling, including patient and consumer safety/prevention of harm, promoting autonomous decisions, creating legal clarity and transparency, and facilitating trust.⁴⁰⁴ It also serves as an obvious tool for regulators like the FDA to leverage risk mitigation. Moreover, the design of the label is crucial and may influence whether users read the label and thus may prevent at least some off-label uses. Even if labeling failed to solve the contextual bias issues in their entirety, as correctly pointed out by Price—and AI developers need to be better incentivized to build AI/ML tools for low- and middle-income countries—labeling could inform and motivate some developers to show cross-context efficacy.⁴⁰⁵

Regulators, like the FDA, should take up the challenge—with the help of stakeholders—and develop labeling standards as soon as possible, even if such standards would certainly need to be updated on a regular basis as new information about AI/ML in health care emerges. More than 520 AI/ML-based medical devices have already been cleared or approved by the FDA and many more devices are being developed.⁴⁰⁶ Without labeling standards for AI/ML-based medical devices, there is a high likelihood that such devices are deployed without providing users with the full package of information they should have to make informed decisions. This lack of knowledge can harm patients and consumers. Moreover, those standards will give labelers, especially AI/ML manufacturers, certainty about what will be expected from them.

Kostick-Quenet, I. Glenn Cohen, Sara Gerke, Bernard Lo, James Antaki, Faezah Movahedi, Hasna Njah, Lauren Schoen, Jerry E. Estep & J.S. Blumenthal-Barby, *Mitigating Racial Bias in Machine Learning*, 50 J. L. MED. & ETHICS 92, 98 (2022) (arguing for a robust regulatory framework to AI/ML).

⁴⁰⁴ See *supra* Section III.C.

⁴⁰⁵ See Price, *Medical AI and Contextual Bias*, *supra* note 10, at 107 (admitting that “[l]abeling may still have *some* benefit”). For more information on the contextual bias issues and the need for incentives, see *supra* Section III.B.1.

⁴⁰⁶ *Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices*, *supra* note 7.

Consequently, it will be essential for the FDA to develop adequate labeling standards for AI/ML-based medical devices that are easily accessible to users and designed in a manner that helps promote the benefits mentioned above. In particular, different audiences (e.g., health professionals, patients, consumers) need to be considered when developing labeling standards for AI/ML-based medical devices.

There are two options for the FDA to execute the new labeling standards. The first option is that the agency could implement the new standards in the form of regulations, such as through an amendment to Title 21 of the C.F.R., after receiving public feedback. The second option is that the FDA could publish nonbinding recommendations as a guidance document. On the one hand, regulations have the advantage of being published in the Federal Register and are legally binding. On the other hand, releasing guidance documents is less time-consuming than regulations, and guidance documents are more flexible; they can be changed easily and can be adapted to new technological developments. Regardless of which option the FDA ultimately chooses, it is crucial that the agency develop and implement specific labeling standards for AI/ML-based medical devices as quickly as possible to prevent harm to patients and consumers, promote autonomous decisions, create clarity and transparency, and promote trust. The FDA's virtual public workshop on transparency of AI/ML-based medical devices, focusing on labeling,⁴⁰⁷ is certainly a step in the right direction, but more needs to be done promptly.

In addition to developing national labeling standards, from a global harmonization perspective, it would be desirable for the IMDRF to become an active participant on this topic. For example, the IMDRF could either update its *Principles of Labelling for Medical Devices and IVD Medical Devices*⁴⁰⁸ to include specific standards for AI/ML-based medical devices or develop a separate guidance document.

IV. SUGGESTIONS

Part IV contains suggestions on how to move forward in developing labeling standards for AI/ML-based medical devices. It first focuses on the types of information that should be included on the label of all AI/ML-based medical devices, namely: (1) Model Identifiers; (2) Model Type; (3) Model Characteristics; (4) Indications for Use;

⁴⁰⁷ Virtual Public Workshop—Transparency of Artificial Intelligence/Machine Learning-Enabled Medical Devices, *supra* note 400.

⁴⁰⁸ IMDRF Good Regul. Rev. Pracs., *supra* note 243.

(5) Validation and Model Performance; (6) Details on the Data Sets; (7) Preparation Before Use and Application; (8) Model Limitations, Warnings, and Precautions; (9) Alternative Choices; (10) Privacy and Security; and (11) Additional Information. This list is intended to serve as a useful starting point for the FDA to develop the urgently needed labeling standards for AI/ML-based medical devices. During the development process, the FDA should maintain an ongoing dialogue with all stakeholders, including patient and consumer representatives. In addition to developing *general* labeling standards for AI/ML-based medical devices, the FDA should also investigate, with input from all stakeholders, whether additional labeling standards are needed for *specific types of AI* and/or *intended users*. Moreover, this Part argues that the suggested labels should be “dynamic” and not static for adaptive algorithms, meaning they should be continuously updated.

After exploring the label content, Part IV discusses design questions of the label and argues that “nutrition facts labels” known from food products, with their eye-catching design, are a promising label design for AI/ML-based medical devices. With the help of such labels, users should be able to quickly get an overview of all important information about AI/ML-based medical devices. Education campaigns will also be essential to ensure users can properly read the AI/ML-based medical device labeling. Lastly, this Part also discusses other labeling questions, namely instructions for use for health professionals and laypersons.

A. *Key Types of Information to Be Included on the Label*

What are the essential components of a label for AI/ML-based medical devices? The answer to this question is not easy but is key for developing labeling standards for AI/ML-based medical devices. This Section carves out some essential types of information that should be included on the label of an AI/ML-based medical device. These suggestions are not exhaustive. Rather, they are a helpful tool to initiate this important discussion and the overdue development of labeling standards. It will be crucial for the FDA to have an ongoing dialogue with all stakeholders, including patient and consumer representatives, to ultimately determine the essential ingredients to be included on the label of an AI/ML-based medical device.

To identify the standard content of the label, another factor that will be important to consider is the audience of the label. As already

stated,⁴⁰⁹ AI/ML-based medical devices are utilized by different users. For example, users include health professionals, nonexperts in a particular medical specialty,⁴¹⁰ and patients and consumers. Moreover, hospitals that buy and implement AI/ML-based medical devices and insurance companies will likely be interested in the label. It may be unrealistic, however, to expect labelers to develop a separate label for each potential audience. Rather, the label is addressed to the primary users—target audience or intended users—of the AI/ML-based medical device. For example, the intended users of the prescription device OsteoDetect, used to detect distal radius fractures, are clinicians, and the intended users of Apple’s over-the-counter ECG app are consumers aged twenty-two and older.⁴¹¹

Consequently, when developing labeling standards for AI/ML-based medical devices, the FDA could follow three steps with input from all stakeholders. As a first step, the FDA could develop *general* labeling standards for AI/ML-based medical devices—i.e., identify the essential ingredients of the label that are needed for all AI/ML-based medical devices regardless of the type of AI/ML or target audience. In a second step, the FDA could assess whether additional information would need to be included on the label depending on the *type of AI* in question, such as whether it is a black-box model versus an interpretable model or an AI/ML-based SaMD versus SiMD.⁴¹² In a third step, the FDA could analyze whether further additional information needs to be included on a label depending on the *intended users* in question, such as health professionals versus laypersons. The additional labeling standards related to specific types of AI or intended users could then be included as additional sections in the guidance or regulations, depending on how the FDA ultimately decided to implement the labeling standards for AI/ML-based medical devices.⁴¹³

As discussed previously, modifications to a legally marketed AI/ML-based medical device require a new 510(k) premarket notification if they introduce, for example, a significant change to the algorithm.⁴¹⁴ A new 510(k) also would require manufacturers to adjust their label-

⁴⁰⁹ See *supra* Section I.B.

⁴¹⁰ For example, the cardiac ultrasound software device, Caption Guidance, can also be used by nurses as nonexperts in ultrasonography. See *supra* Section I.B.1.

⁴¹¹ U.S. FOOD & DRUG ADMIN., *supra* note 61, at 2; Letter from Angela C. Krueger to Donna-Bea Tillman, *supra* note 69, at 1. For more information on both devices, see *supra* Section I.B.1.–2.

⁴¹² For more information on the types of AI, see *supra* Section I.A.2.–II.A.

⁴¹³ For FDA’s implementation options, see *supra* Section III.D.

⁴¹⁴ See *supra* Section III.B.3.

ing.⁴¹⁵ As mentioned, however, the long-term plan of the FDA is to routinely implement a TPLC approach for modifications to AI/ML-based SaMD that particularly aims to allow these devices to continuously learn and optimize their performance.⁴¹⁶ This would provide manufacturers with the option of submitting a predetermined change control plan.⁴¹⁷ Consequently, the FDA will need to ensure that when manufacturers use a predetermined change control plan for these adaptive algorithms, the label is “dynamic” and not static, meaning it is continuously updated. The continuous update of the label will be crucial to ensure a clear line between on- and off-label uses of the AI/ML-based medical device. In this context, it will also be of paramount importance that the intended users are made aware of the label update, such as through a notification by phone or email.

With the help of the label, the intended users should be able to quickly get an overview of the AI/ML-based medical device, its indications for use, as well as its benefits, risks, and limitations. The label should be eye-catching and no more than one page to prevent information overload.⁴¹⁸ The details can be included in the instructions for use.⁴¹⁹ Furthermore, once labeling standards are established for AI/ML-based medical devices, education will be crucial to ensure intended users can read the label and understand the basics of AI/ML, especially the potential risks such as bias.⁴²⁰

Box 2 below lists the types of information that should be included on the label of all AI/ML-based medical devices.

⁴¹⁵ See *supra* Section III.B.3.

⁴¹⁶ See *supra* Section III.B.3.

⁴¹⁷ See *supra* Section III.B.3.

⁴¹⁸ For more information on the design, see *infra* Section IV.B.

⁴¹⁹ For more information on the instructions for use, see *infra* Section IV.C.

⁴²⁰ For more information on the importance of education, see *infra* Section IV.C. For information on bias risks, see *supra* Section III.B.1.

**Box 2: Key Types of Information that Should be Included
on the Label of AI/ML-Based Medical Devices**

- (1) MODEL IDENTIFIERS
- (2) MODEL TYPE
- (3) MODEL CHARACTERISTICS
- (4) INDICATIONS FOR USE
- (5) VALIDATION & MODEL PERFORMANCE
- (6) DETAILS ON THE DATA SETS
- (7) PREPARATION BEFORE USE & APPLICATION
- (8) MODEL LIMITATIONS, WARNINGS & PRECAUTIONS
- (9) ALTERNATIVE CHOICES
- (10) PRIVACY & SECURITY
- (11) ADDITIONAL INFORMATION

The first key type of information that should be included on the label is the *Model Identifiers*. These should generally include the brand name, name and place of business, model version, clearance/approval date of the AI/ML-based medical device, the FDA premarket submission number, and the UDI. This information will provide the intended users with an overview of all essential model identifiers.

The second essential component of the label is the *Model Type*. This includes, for example, information on whether the model is an interpretable model or a recurrent neural network.⁴²¹ This knowledge can help intended users understand whether they are dealing with a white- or black-box model and whether they can independently review the basis for its recommendations.⁴²² In the case of an adaptive algorithm, for instance, the intended users would also be informed that the algorithm is continuously learning and adapting to novel situations, or in the case of autonomous AI, that there is no human supervision of the device's decision.

The third key type of information on the label of an AI/ML-based medical device is the *Model Characteristics*. This information should help clarify whether this device is, for example, a prescription device or an over-the-counter device.

The fourth essential ingredient is the *Indications for Use*. This includes a description of what disease or condition the AI/ML-based

⁴²¹ For the different types of AI, see *supra* Section I.A.2.

⁴²² For more information on white-box and black-box models and whether one can independently review the basis of their recommendations, see *supra* Sections I.A.2., II.B.2.– II.B.3.

medical device will diagnose, cure, mitigate, treat, or prevent.⁴²³ The label should include information on the benefits of the device and a description of the target population, as well as information relating to race/ethnicity and gender.⁴²⁴ As previously mentioned, however, the label should not be an excuse to market AI/ML-based medical devices that have not been trained on a diverse data set, and regulators like the FDA should generally deny their marketing authorization in the first place.⁴²⁵ Moreover, the label should clearly describe the role intended to be fulfilled by the algorithm’s output.⁴²⁶ This information is important so that the intended users know in which situations and for which target populations the AI/ML-based medical device should be used. It also helps identify potential off-label uses.

The fifth information type is *Validation and Model Performance*. The label should provide an overview of the validation and performance results.⁴²⁷ In particular, it should list all of the model’s cross-site performances to enable users to appraise its reliability. Recent research has shown that deep learning models that were evaluated at only a single clinical site can have weaknesses and may perform worse across clinical sites.⁴²⁸ Moreover, the label should clearly articulate whether the AI/ML-based medical device underwent retrospective or prospective studies. Unfortunately, until now, almost all AI/ML-based medical devices available on the U.S. market have undergone retrospective studies.⁴²⁹ Prospective studies are needed to fully assess the impact of such devices on clinical practice, especially whether they improve patient outcomes.⁴³⁰ Consequently, in addition to establishing

⁴²³ See *PMA Labeling*, U.S. FOOD & DRUG ADMIN. (Sept. 27, 2018), <https://www.fda.gov/medical-devices/premarket-approval-pma/pma-labeling> [<https://perma.cc/AT4E-M8TB>]. For the definition of the term “device,” see FDCA § 201(h)(1), 21 U.S.C. § 321(h)(1); *supra* Section II.A.

⁴²⁴ See *PMA Labeling*, *supra* note 423.

⁴²⁵ See *supra* Section III.D.

⁴²⁶ U.S. FOOD & DRUG ADMIN., *supra* note 376, at 5 (mentioning stakeholder’s express wishes on labeling needs).

⁴²⁷ See Mark P. Sendak, Michael Gao, Nathan Brajer & Suresh Balu, *Presenting Machine Learning Model Information to Clinical End Users with Model Facts Labels*, 3 NPJ DIGIT. MED., no. 41, 2020, at 1, 3 (for a sepsis ML model).

⁴²⁸ See Wu et al., *supra* note 350, at 582. For more information on this study, see *supra* Section III.B.1.

⁴²⁹ Wu et al., *supra* note 350, at 582.

⁴³⁰ *Id.* at 583; Xiaoxuan Liu, Samantha Cruz Rivera, Livia Faes, Lavinia Ferrante di Ruffano, Christopher Yau, Pearse A. Keane, Hutan Ashrafian, Ara Darzi, Sebastian J. Vollmer, Jonathan Deeks, Lucas Bachmann, Christopher Holmes, An Wen Chan, David Moher, Melanie J. Calvert & Alastair K. Denniston, *Reporting Guidelines for Clinical Trials Evaluating Artificial Intelligence Interventions Are Needed*, 25 NATURE MED. 1467, 1467 (2019).

labeling standards for AI/ML-based medical devices, the FDA should consider two things: first, requiring the evaluation of such models at multiple sites before permitting their marketing; and second, requiring prospective studies, at least for high-risk AI/ML-based medical devices, as a premarket requirement.

Details on the Data Sets comprise the sixth essential label component for an AI/ML-based medical device. Where possible, this includes information about the training data, validation data, and test data. Although training data is used to train the model, test data is used to assess the generalization error of the final selected model, and validation data is used to estimate the prediction error for model selection.⁴³¹ For example, where does the training data come from? Electronic health records, wearables, etc.? In particular, information should be provided on the diversity of the data sets and the input data type.⁴³²

In addition to developing labeling standards, with input from stakeholders, the FDA could create a checklist for AI/ML developers that lists what is minimally required to show during premarket review in terms of identifying, assessing, and mitigating risks of bias.⁴³³ For example, the default should be to establish that the AI/ML-based medical device works well across representative populations.⁴³⁴ As discussed earlier, many AI/ML-based medical devices that have received marketing authorization from the FDA have not reported gender breakdown, race/ethnicity breakdown, and geographic breakdown, and also have not provided information on the validation data.⁴³⁵ Manufacturers should not only report such data, but also have a reasonable justification when they cannot show a demographic representation of the data sets. An example of such a justification could be that the training data set does not include data from women because the AI/ML-based medical device is intended for diagnosing a disease that only exists in men, such as prostate cancer.⁴³⁶

The seventh key ingredient of the label is *Preparation Before Use and Application*. All things should be listed here that need to be done

⁴³¹ CHANG, *supra* note 38, at 70.

⁴³² See Sendak et al., *supra* note 427, at 3 (for a sepsis ML model).

⁴³³ For more information on bias, see *supra* Section III.B.1.

⁴³⁴ See Wu et al., *supra* note 350, at 583.

⁴³⁵ See Ross, *supra* note 7; Ross, *supra* note 386. For more information, see *supra* Section III.C.

⁴³⁶ For more information on prostate cancer, see, e.g., *Prostate Cancer*, MAYO CLINIC (Oct. 1, 2022), <https://www.mayoclinic.org/diseases-conditions/prostate-cancer/symptoms-causes/syc-20353087> [<https://perma.cc/LBT8-C8CS>].

by the intended users—who should also be clearly named⁴³⁷—before using the AI/ML-based medical device. For example, this could include a note that the validity of the AI/ML-based model must be confirmed first within the local setting before use or that user training is recommended.⁴³⁸ Moreover, the label should contain information about the general application of the device. For example, it should say in a few words where to attach a patch that comes with the software on the patient’s body or how to interact with the device. The details can then be explained in the instructions for use supplied by the manufacturer.

The eighth type of essential information that must be included on the label is *Model Limitations, Warnings, and Precautions*. Everything about the AI/ML-based medical device that should be brought to users’ immediate attention must be listed. For example, the label needs to list all known risks and potential biases associated with using the AI/ML-based medical device. In the case of a DTC device, for instance, it would be essential to inform consumers about the potential risk of false positives and negatives and when to seek medical care.⁴³⁹ If the algorithm is adaptive, users should be warned that it needs to be continuously assessed for its safety and effectiveness.⁴⁴⁰ Depending on the AI/ML-based medical device, a warning should be added that variance may increase through human factors.⁴⁴¹ Contraindications must also be clearly listed, for example, in cases where the AI/ML-based medical device is *not* intended to provide a diagnosis or is *not* generalizable across application sites.⁴⁴² Using clear symbols may also be an option, with more detailed information included in the instructions for use.⁴⁴³

⁴³⁷ See U.S. FOOD & DRUG ADMIN., COMPUTER-ASSISTED DETECTION DEVICES APPLIED TO RADIOLOGY IMAGES AND RADIOLOGY DEVICE DATA—PREMARKET NOTIFICATION [510(k)] SUBMISSIONS—GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 23 (2022), <https://www.fda.gov/media/77635/download> [<https://perma.cc/7MKN-JFZ6>].

⁴³⁸ See Sendak et al., *supra* note 427, at 2 (for a sepsis ML model); Letter from Robert Ochs to Sam Surette, *supra* note 67, at 3 (for Caption Guidance); Gerke, *Health AI*, *supra* note 10, at 505.

⁴³⁹ See, e.g., Sara Gerke, Carmel Shachar, Peter R. Chai & I. Glenn Cohen, *Regulatory, Safety, and Privacy Concerns of Home Monitoring Technologies During COVID-19*, 26 NATURE MED. 1176, 1178 (2020).

⁴⁴⁰ See Babic et al., *supra* note 10, at 1202.

⁴⁴¹ See Gerke et al., *The Need for a System View*, *supra* note 10, at 2.

⁴⁴² See Sendak et al., *supra* note 427, at 3 (for a sepsis ML model).

⁴⁴³ See IMDRF Good Regul. Rev. Pracs., *supra* note 243, at 18; see also *supra* Section III.A.3.

The ninth key ingredient of the label is *Alternative Choices*. It would be helpful for users to learn about alternative choices—if any—that they can consider instead of using the AI/ML-based medical device in question (e.g., an alternative treatment option). Given that AI/ML developers are likely to be hesitant to list alternative choices on the label as this can create a competitive disadvantage, a compromise could be to state on the label that alternative choices can be found on the FDA’s website. For example, the 510(k) summary of an AI/ML-based medical device always lists the predicate device used to demonstrate substantial equivalence and is published on the FDA’s website.⁴⁴⁴ Indeed, while it would be much easier for the consumer to have a list of alternative options—if any—right on the label, a link to the FDA’s website could balance the competing interests. It would still allow users to access this information and promote innovation in new AI/ML-based medical devices.

Privacy and Security is the tenth essential component of the label. It should contain essential information, such as whether the AI/ML-based medical device complies with the applicable privacy laws. The label should also say whether a privacy policy is publicly available, and if so, where to find it and when it was last updated.⁴⁴⁵ It should also state security safeguards, such as encryption, and other practices, such as whether there is a publicly available “Coordinated Vulnerability Disclosure” policy.⁴⁴⁶ This information could help potential users assess whether the privacy of individuals is adequately protected.

In the digital age, the FDA is increasingly finding itself in this relatively new situation of evaluating data-driven technologies for their safety and effectiveness, including AI/ML-based medical devices. The FDA enforces the FDCA, but it is the U.S. Department of Health and Human Services’s (“HHS”) Office for Civil Rights (“OCR”), for example, that is responsible for enforcing the Privacy and Security Rules of the Health Insurance Portability and Accountability Act (“HIPAA”).⁴⁴⁷ Both the HIPAA Privacy Rule and the HIPAA Secur-

⁴⁴⁴ See *Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices*, *supra* note 7 (listing the submission numbers of AI/ML-based medical devices marketed in the U.S. with hyperlinks to further information about the specific device, including usually a link to its summary).

⁴⁴⁵ See Andrea Coravos, Megan Doerr, Jennifer Goldsack, Christine Manta, Mark Shervey, Beau Woods & William A. Wood, *Modernizing and Designing Evaluation Frameworks for Connected Sensor Technologies in Medicine*, 3 NPJ DIGIT. MED., no. 37, 2020, at 1, 8 (for connected sensor technologies in medicine).

⁴⁴⁶ See *id.* at 6.

⁴⁴⁷ See *HIPAA Enforcement*, U.S. DEP’T HEALTH AND HUM. SERVS. (July 25, 2017), <https://www.hhs.gov/hipaa/enforcement/>

ity Rule aim to protect certain individually identifiable health information.⁴⁴⁸ In addition, privacy laws at the state level may help protect health information that falls outside of HIPAA’s scope.⁴⁴⁹ In addition, the Federal Trade Commission (“FTC”) is the key federal agency on privacy policy and enforcement, with the FTC Act as its primary statute.⁴⁵⁰ The Office of the National Coordinator for Health Information Technology (“ONC”), based within the Office of the Secretary for HHS, is the principal federal entity responsible for coordinating nationwide efforts to use and implement advanced health information technology, with a focus on establishing expectations on data sharing.⁴⁵¹

Consequently, there would be an urgent need for the FDA, OCR, FTC, ONC, and possibly other entities, such as the U.S. Department of Commerce’s National Institute of Standards and Technology (“NIST”),⁴⁵² to come together and discuss, in the context of AI/ML-based medical devices, how one can best ensure data protection and compliance with the applicable laws. It would be desirable to check compliance with privacy and security provisions upfront (i.e., premarket) rather than only intervening once the breach has already occurred. In this context, the agencies would need to decide what content should appear on the label of an AI/ML-based medical device in terms of privacy and security. An alternative option could also be for this information to be outsourced and included on an extra label dedicated solely to privacy and security, the development of which would be spearheaded by one of the other federal agencies in consultation with the FDA. In any case, this important discussion about labeling standards for AI/ML-based medical devices concerning privacy and

[/www.hhs.gov/hipaa/for-professionals/compliance-enforcement/index.html](https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/index.html) [https://perma.cc/8PH4-5S6M].

⁴⁴⁸ See, e.g., U.S. DEP’T HEALTH AND HUM. SERV.’S, SUMMARY OF THE HIPAA PRIVACY RULE 1 (2003), <https://www.hhs.gov/sites/default/files/privacysummary.pdf> [https://perma.cc/2EA9-NABP]. For more information on the HIPAA Security Rule, see, for example, *The Security Rule*, U.S. DEP’T HEALTH AND HUM. SERVS. (Oct. 20, 2022), <https://www.hhs.gov/hipaa/for-professionals/security/index.html> [https://perma.cc/V4SB-3LYX].

⁴⁴⁹ For more information on new state privacy laws, such as in California, Virginia, and Colorado, see, for example, Gerke & Rezaeikhonakdar, *supra* note 68, at 3.

⁴⁵⁰ *Protecting Consumer Privacy and Security*, U.S. FED. TRADE COMM’N, <https://www.ftc.gov/news-events/topics/protecting-consumer-privacy-security> [https://perma.cc/44BX-Q5BW]; Gerke & Rezaeikhonakdar, *supra* note 68, at 2.

⁴⁵¹ *About ONC*, OFF. NAT’L COORDINATOR FOR HEALTH INFO. TECH. (Sept. 8, 2022), <https://www.healthit.gov/topic/about-onc> [https://perma.cc/VWF7-PEWQ].

⁴⁵² See NAT’L INST. STANDARDS & TECH., U.S. DEP’T COM., <https://www.nist.gov> [https://perma.cc/DS6N-VP2M].

security between the federal agencies needs to occur as soon as possible.

The last key ingredient on the label is *Additional Information*. For example, this can include contact information and website addresses. The label should also contain the information regarding when it was last updated.

B. “Nutrition Facts Labels”

The design of the label will be important to ensure that the content of the label is presented in a way that is accessible and easy to understand for the intended users. The FDA should work closely with design experts to create an optimal design for a label for AI/ML-based medical devices that encourages reading. “Nutrition facts labels,” known from food products,⁴⁵³ are a promising label design for AI/ML-based medical devices. The key types of information—which should be included on the label of all AI/ML-based medical devices⁴⁵⁴—could be presented similar to nutrition facts labels on food products. Several scholarly groups have shown the design advantages of, for example, a “model card,” a “nutrition label,” a “nutrition-label-type visualization,” and a “model facts” label in different contexts, such as for trained machine learning models,⁴⁵⁵ for connected sensor technologies in medicine,⁴⁵⁶ and for a sepsis machine learning model.⁴⁵⁷ Such labels have the benefit of creating a visual (“eye-popping”) representation for users that should help them easily understand essential facts about

⁴⁵³ See 21 C.F.R. § 101.9. The FDA has also recently updated the nutrition facts label; for more information on the new label design, see, for example, *The New Nutrition Facts Label: What's in It for You?*, U.S. FOOD & DRUG ADMIN. (Apr. 13, 2022), <https://www.fda.gov/food/nutrition-education-resources-materials/new-nutrition-facts-label> [<https://perma.cc/GR5U-9DRJ>].

⁴⁵⁴ See *supra* Section IV.A.

⁴⁵⁵ Margaret Mitchell Simone Wu, Andrew Zaldivar, Parker Barnes, Lucy Vasserman, Ben Hutchinson, Elena Spitzer, Inioluwa Deborah Raji & Timnit Gebru, *Model Cards for Model Reporting* (2019) (unpublished manuscript presented at 2019 ACM Conference on Fairness, Accountability and Transparency) (available at <https://arxiv.org/pdf/1810.03993.pdf>) [<https://perma.cc/M7N7-9ARG>].

⁴⁵⁶ Coravos et al., *supra* note 445.

⁴⁵⁷ Sendak et al., *supra* note 427; see Erin Brodwin, *With ‘Nutrition Labels’ and an Anthropologist’s Eye, Duke Pioneers a New Approach to AI in Medicine*, STAT (Oct. 5, 2020), <https://www.statnews.com/2020/10/05/duke-artificial-intelligence-hospital-medicine> [<https://perma.cc/ALA3-W4PR>]. A few scholars have also suggested prescription drug labels as a possible design option, but most scholars are trending toward nutrition facts labels. See Barbara Barry, Collaborative Scientist, Robert D. & Patricia E. Kern, Ctr. for the Sci. of Health Care Delivery, Presentation at the Virtual Public Workshop, in U.S. FOOD & DRUG ADMIN., *supra* note 400, at 44.

the AI/ML-based medical device.⁴⁵⁸ A “nutrition facts label” also has the advantage that its design is familiar to users.

To improve the visibility of such labels, they could be shown to users immediately as the first thing they see when opening the software (typically in the case of SaMD) or be placed on the front and center of the physical device (typically in the case of SiMD).⁴⁵⁹ Studies also suggest that putting the most important information up at the top (rather than at the bottom) will increase users’ likelihood of reading them.⁴⁶⁰ Ultimately, it would be valuable if extensive research (e.g., from a social science perspective) were conducted on how the label could effectively communicate the key types of information suggested above.⁴⁶¹ To increase transparency, the FDA could additionally make the labels available on its website. For example, the agency could easily link them to its publicly available list of AI/ML-based medical devices marketed in the United States and update such a list at regular intervals.⁴⁶²

It will also be important that the intended users, such as health care professionals, patients, and consumers, of the AI/ML-based medical devices know how to read the label. Thus, education campaigns across multiple channels, including videos, social media, advertising, and user-friendly educational materials, similar to current nutrition facts label campaigns, will be imperative.⁴⁶³ Moreover, the FDA could require manufacturers of all AI/ML-based medical devices subject to premarket submission to show that intended users know its benefits, risks, and limitations and how to use it solely by reading its label.⁴⁶⁴ Indeed, the FDA required a similar demonstration for Apple’s ECG app; the agency asked for usability and human factors testing to demonstrate that users know how to use the app correctly based exclusively on reading the labeling.⁴⁶⁵ But the FDA could standardize

⁴⁵⁸ See Coravos et al., *supra* note 445, at 7.

⁴⁵⁹ It has been shown for nutrition labels that consumers would be more likely to read them if they were put on the front and center of the box. See Meredith Melnick, *Study: Why People Don’t Read Nutrition Labels*, TIME (Oct. 24, 2011), <https://healthland.time.com/2011/10/24/study-why-people-dont-read-nutrition-labels> [<https://perma.cc/5TYX-DCJG>]. For more information on SaMD and SiMD and their labels, see *supra* Sections II.A., III.A.1.

⁴⁶⁰ See, e.g., Melnick, *supra* note 459.

⁴⁶¹ See *supra* Section IV.A.

⁴⁶² For this list, see *Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices*, *supra* note 7.

⁴⁶³ See U.S. FOOD & DRUG ADMIN., *supra* note 453.

⁴⁶⁴ Gerke, *Health AI*, *supra* note 10, at 504.

⁴⁶⁵ Letter from Angela C. Krueger to Donna-Bea Tillman, *supra* note 69, at 2, 3. For more information on the app, see *supra* Section I.B.2.

the request for performing such tests to mitigate risks such as device-related user errors.⁴⁶⁶ Awareness campaigns and human factors testing are particularly important for DTC medical AI/ML apps like Apple's ECG app, which many consumers see as "diagnostic apps" but are actually just informational tools that are "not intended to replace traditional methods of diagnosis or treatment."⁴⁶⁷

C. *Instructions for Use*

With the consultation of all stakeholders, including patient and consumer representatives, the FDA should also develop standards for what should be or must be included in the additional information (besides the label) provided by the labeler, who is usually the manufacturer of the AI/ML-based medical device. An important element is the instructions for use, which should be supplied to users in an easily accessible form (e.g., electronic form, paper, or both).⁴⁶⁸

The target audience must be given special consideration when creating the instructions for use. For example, in the case of a DTC medical device, the instructions for use should be written in plain language to maximize consumers' understanding and the likelihood of reading the instructions. Sentences should be short and concise.⁴⁶⁹ Some AI/ML-based medical devices may also provide different information for different users, such as health care professionals and laypersons.⁴⁷⁰

In general, it will be crucial that the instructions for use contain an in-depth explanation of all the above-suggested information on the label.⁴⁷¹ This enables users to read more about a specific topic of their choice and learn more about the pros and cons of the particular AI/ML-based medical device. Moreover, the instructions for use may help users better understand when and how to correctly use the AI/ML-based medical device and thus mitigate risks.

⁴⁶⁶ See Gerke, *Health AI*, *supra* note 10, at 504.

⁴⁶⁷ Letter from Angela C. Krueger to Donna-Bea Tillman, *supra* note 69, at 1; Ashley N.D. Meyer, Traber D. Giardina, Christiane Spitzmueller, Umber Shahid, Taylor M.T. Scott & Hardeep Singh, *Patient Perspectives on the Usefulness of an Artificial Intelligence-Assisted Symptom Checker: Cross-Sectional Survey Study*, 22 J. MED. INTERNET RSCH. e14679 (2020).

⁴⁶⁸ See IMDRF Good Regul. Rev. Pracs., *supra* note 243, § 5.3.4.

⁴⁶⁹ U.S. FOOD & DRUG ADMIN., *supra* note 239, at 40–41.

⁴⁷⁰ See IMDRF Good Regul. Rev. Pracs., *supra* note 243, § 5.3.1.

⁴⁷¹ See *supra* Section IV.A.

CONCLUSION

Although AI/ML-based medical devices are increasingly used in clinical care and offered directly to consumers, very little has been written on labeling for AI/ML-based medical devices. This is surprising given how important labeling is to avoid harm to patients and consumers. This Article is the first to identify and thoroughly analyze the significant challenges of labeling for AI/ML-based medical devices and provides solutions to address them. Although this Article focuses on devices, it also holds lessons for AI/ML-based products that are not subject to FDA regulation. What follows are the author’s central findings and claims.

First, the long-awaited final CDS Guidance falls short of expectations. It seems to violate the 21st Century Cures Act, creates significant uncertainty for AI/ML manufacturers regarding whether their product is considered a medical device, and raises safety concerns. In particular, the FDA has expanded its interpretation of criterion (4) of FDCA Section 520(o)(1)(E) and currently thinks that all types of AI/ML—i.e., black-box AI/ML, explainable AI/ML, and interpretable AI/ML—can generally fall under the medical device exception and thus outside of FDA regulation. This is concerning because it is more than unclear how black-box AI/ML (and even explainable AI/ML) can fulfill the statutory requirement of “enabling such health care professional to independently review the basis for such recommendations that such software presents.”⁴⁷²

Second, regarding criterion (4) of FDCA Section 520(o)(1)(E), the FDA currently appears to be primarily focused on improved labeling to circumvent regulation rather than safety and effectiveness. While improved labeling is key, it alone is not enough to adequately ensure patient safety. Labeling must go hand in hand with a robust regulatory framework for CDS software functions. Currently, the responsibility for assessing the safety and effectiveness of Non-Device CDS—which the FDA thinks can even be an artificial deep neural network—rests mainly with health care professionals who use the CDS in question, including the associated liability risks for patient injury. In addition, the many ambiguities in the final CDS Guidance create confusion among stakeholders. To its credit, the FDA attempts to accomplish the impossible task of finding a clear, consistent, and even line between Non-Device CDS and device software functions. Congress needs to act and fix its mistake in enacting the CDS software

⁴⁷² FDCA § 520(o)(1)(E)(iii), 21 U.S.C. § 360j(o)(1)(E)(iii).

exception as part of the 21st Century Cures Act in the first place. The deletion of FDCA Section 520(o)(1)(E) would contribute to greater clarity and legal certainty by considering all CDS software functions *a priori* as medical devices. It would also effectively prevent products whose functionality could bear a risk to patient safety from absconding from the FDA's oversight and could serve as a safeguard against automation bias. This suggestion would also entail that the FDA would still be free to exercise enforcement discretion over some device software functions that are lower risk.

Third, there are currently no standards of labeling for AI/ML-based medical devices. This Article has shown, among other things, that Title 21 of the C.F.R. does not contain specific labeling requirements for AI/ML-based medical devices. This is concerning because AI/ML-based medical devices differ in many aspects from traditional medical devices such as contact lenses. For example, AI/ML-based medical devices can be biased. There are different types of biases, including bias in the training data, label choice bias, contextual bias, or unconscious bias. Some AI/ML-based medical devices also rely on black-box algorithms, which are usually impossible for humans to understand, and/or are adaptive and can continuously learn from novel data. Furthermore, the more human-AI interaction takes place, the more difficult it is to predict how AI/ML-based medical devices will perform in the real world once launched on the market.

Fourth, labeling standards for AI/ML-based medical devices are urgently needed because the current labeling requirements for medical devices and the FDA's case-by-case approach for a few AI/ML-based medical devices are insufficient. The FDA has already permitted marketing of more than 520 AI/ML-based medical devices, and many of them do *not* provide users with important information, such as gender, race/ethnicity, and geographic breakdowns of the data sets used. This lack of knowledge can ultimately harm patients and consumers. Labeling is crucial for users to understand, *inter alia*, the benefits, risks, and limitations of the specific AI/ML-based medical device and to empower them to assess when to use the device and how to use it correctly. It creates legal clarity for manufacturers, transparency to users, and can help facilitate public trust in new digital health technologies. The FDA could implement these new labeling standards either in the form of regulations, such as via an amendment to Title 21 of the C.F.R., or nonbinding recommendations through a guidance document. From a global harmonization perspective, it would also be desirable if the IMDRF dealt with this topic as well and either updated its

Principles of Labelling for Medical Devices and IVD Medical Devices or developed a separate guidance document on labeling for AI/ML-based medical devices.

Fifth, regulators like the FDA need to figure out what such labeling standards for AI/ML-based medical devices could look like, with input from all stakeholders, as soon as possible. This author suggested eleven key types of information that should be included on the label of all AI/ML-based medical devices, namely: (1) Model Identifiers; (2) Model Type; (3) Model Characteristics; (4) Indications for Use; (5) Validation and Model Performance; (6) Details on the Data Sets; (7) Preparation Before Use and Application; (8) Model Limitations, Warnings, and Precautions; (9) Alternative Choices; (10) Privacy and Security; and (11) Additional Information. In addition to creating general labeling standards for AI/ML-based medical devices as a first step, the FDA should also consider, in a second and third step, whether additional labeling standards are needed in the regulations or guidance document for specific types of AI and/or intended users.

Sixth, “nutrition facts labels,” known from food products, are a promising label design for AI/ML-based medical devices. The design is familiar to users and allows them to get a quick overview of all key information. If the user needs more information on a specific topic, the instructions for use can be consulted for this purpose. For adaptive algorithms, the label should also be “dynamic” (rather than static), meaning it needs to be continuously updated. This is important to maintain a clear line between on- and off-label use.

Finally, labeling for AI/ML-based medical devices must be coupled with educational campaigns and other needed regulatory reforms for AI/ML-based medical devices. A new regulatory framework for AI/ML-based medical devices is essential to ensure, for instance, that devices such as the one in the introductory example—which likely missed Alicia’s melanoma because it was primarily trained on images of people with white skin—do not receive marketing authorization in the first place. Labeling has limits and must not be misused as an excuse to launch poorly designed AI/ML-based medical devices that have not been trained on diverse data sets. For example, the FDA should require AI/ML manufacturers to disclose the gender, race/ethnicity, and geographic breakdowns of the used data sets. In general, the agency should have a special focus on promoting equity, diversity, and inclusion and ensuring that AI/ML-based medical devices benefit us all.

The Monetary Executive

Christina Parajon Skinner*

ABSTRACT

Contemporary presidents possess a significant array of powers to intervene in the economy unilaterally, via executive order or the Treasury Department's tools. But the Constitution does not vest the Executive Branch with monetary or fiscal power. Rather, the President has accumulated vast monetary power gradually, over time, through successive delegations from Congress. This Article traces the development of a constitutional oxymoron—the “Monetary Executive”—through the lens of statutory delegations. Ultimately, the Article urges that the consequence of this migration of monetary power from Congress to the Executive will be corrosive to our democratic institutions and contribute to inflation—undermining the central bank's independence, eroding fiscal discipline, and perpetuating policy error.

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INTRODUCTION

Presidents today possess significant power to influence federal spending and increase the public deficit. Consider a few recent examples: in August 2022, President Biden announced via executive order a “promise to cancel \$10,000 of student debt for low- to middle-income borrowers,”¹ which analysts estimate will add \$379 billion to the federal budget over the next three decades.² In a similar effort to “provide more breathing room to America’s working families,”³ the President also, in 2022, attempted to declare a “gas tax holiday.”⁴ And at various points in the past fifteen years, presidents have flirted with the idea of using the U.S. Treasury’s authority to create commemorative—“numismatic”—coins to mint a “trillion-dollar coin” in order to bypass Congress and finance spending programs.⁵ In each of these

¹ Press Release, White House, FACT SHEET: President Biden Announces Student Loan Relief for Borrowers Who Need It Most (Aug. 24, 2022), <https://www.whitehouse.gov/briefing-room/statements-releases/2022/08/24/fact-sheet-president-biden-announces-student-loan-relief-for-borrowers-who-need-it-most/> [https://perma.cc/7JT6-XBQU]. The plan would offer up to \$20,000 in cancellation for those that had received a Pell Grant. *Id.*

² See Amara Omeokwe, *Student Loan Forgiveness Plan’s Cost Likely to Widen 2022 Federal Deficit*, WALL ST. J. (Oct. 4, 2022, 10:29 PM), <https://www.wsj.com/articles/student-loan-forgiveness-plans-cost-likely-to-widen-2022-federal-deficit-11664924638> [https://perma.cc/FW45-X82G]. Other estimates suggest the student loan forgiveness program could cost between \$600 billion and more than \$1 trillion over the next decade. See Shankar Parameshwaran, *How Student Loan Forgiveness Will Transform College Financing*, KNOWLEDGE AT WHARTON (Sept. 13, 2022), <https://knowledge.wharton.upenn.edu/article/how-student-loan-forgiveness-will-transform-college-financing/> [https://perma.cc/TKU6-7YNQ].

³ Press Release, White House *supra* note 1.

⁴ See Press Release, White House, FACT SHEET: President Biden Calls for a Three-Month Federal Gas Tax Holiday (June 22, 2022), <https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/22/fact-sheet-president-biden-calls-for-a-three-month-federal-gas-tax-holiday/> [https://perma.cc/65M5-DP37].

⁵ 31 U.S.C. § 5112(k). In some cases, the idea of the trillion-dollar coin has been floated as a way of bypassing Congress’s decisions about limiting the debt ceiling. See Paul Krugman, Opinion, *Working Out: Biden Should Ignore the Debt Limit and Mint a \$1 Trillion Coin*, N.Y. TIMES (Oct. 1, 2021), <https://www.nytimes.com/2021/10/01/opinion/biden-coin-democrat-republican-debt-limit.html> [https://perma.cc/3F7Y-9H2K]; see also Jacob Bogage, *The Trillion-Dollar Coin: Is It a Solution to the Debt Ceiling Drama—Or a Gimmick?*, WASH. POST (Oct. 5, 2021, 4:53 PM), <https://www.washingtonpost.com/business/2021/10/05/trillion-dollar-coin-faq/> [https://perma.cc/RS9V-X4UN]; Ted Barrett et al., *Debt Ceiling: Timeline of Deal’s Development*, CNN

cases, the President referred to statutory authority that could be argued to justify the spending programs.⁶

The Framers of the Constitution were worried about accumulating monetary and fiscal power in the Executive in this manner.⁷ They were, after all, tasked with designing a new form of government that would be accepted by the People as legitimate.⁸ With fresh memories of the colonial experience with arbitrary taxation, and the popular resistance to government it fomented, the Framers believed it critical that the “power of the purse” be lodged firmly within the most representative body, the legislature.⁹ They therefore gave Congress the power to raise money to pay for government expenditure in the “general welfare” by taxing and borrowing, as well as power to decide how these public monies, once raised, would be spent through the allocative act of appropriation.¹⁰

POL. (Aug. 2, 2011, 5:55 PM), <http://www.cnn.com/2011/POLITICS/07/25/debt.talks.timeline/index.html> [https://perma.cc/6Q7H-KL2A]; Felix Salmon, *Trillion-Dollar Platinum Coin Could Be Minted at the Last Minute*, AXIOS (Oct. 5, 2021), <https://www.axios.com/trillion-dollar-platinum-coin-mint-janet-yellen-223e7722-d7ba-47c9-b5f6-49a841d181de.html> [https://perma.cc/9B9X-HTR6]. In other cases, the trillion-dollar coin would have been used to position the Treasury as a monetary authority, by giving it the power to force the Federal Reserve to monetize the coin and engage in a “Treasury-initiated version of helicopter money.” See George Selgin, *That Darn Coin*, ALT-M, Mar. 4, 2020.

⁶ See 20 U.S.C. § 1082(a)(6) (giving the Secretary of Education power to cancel or modify debt under any federal student loan program); 26 U.S.C. § 7508A(a) (giving the President power to direct IRS to suspend tax collection in connection with a “federally declared disaster”); see also Use of the HEROES Act of 2003 to Cancel the Principal Amounts of Student Loans, 46 Op. O.L.C. — (2022), <https://www.justice.gov/olc/file/1528451/download> [https://perma.cc/6WYQ-N9ZA].

⁷ MICHAEL W. MCCONNELL, *THE PRESIDENT WHO WOULD NOT BE KING* 101, 103–04 (Stephen Macedo ed., 2020).

⁸ See JERRY L. MASHAW, *CREATING THE ADMINISTRATIVE CONSTITUTION: THE LOST ONE HUNDRED YEARS OF AMERICAN ADMINISTRATIVE LAW* 35 (2012) (noting that Framers were concerned that if the structure and power of the new government “violated deep-seated principles of Republican governance . . . its authority would be rejected”).

⁹ See MCCONNELL, *supra* note 7, at 103–04; Kevin R. Kosar, Philip Wallach, John C. Fortier & Zachary Courser, *Does Congress Still Control the Power of the Purse?*, AEI (Apr. 1, 2021), <https://www.aei.org/podcast/does-congress-still-control-the-power-of-the-purse/> [https://perma.cc/VJ5S-XME3]. Further, the Origination Clause confirms this intent, that questions and decisions about raising funds and allocating them, would be made by the body closest to the people. See Erik M. Jensen, *Hands Off My Purse! Why Money Bills Originate in the House*, HERITAGE FOUND. (Jan. 27, 2011), <https://www.heritage.org/the-constitution/report/hands-my-purse-why-money-bills-originate-the-house> [https://perma.cc/VF3E-EU8H]; Abner J. Mikva, *Congress: The Purse, the Purpose, and the Power*, 21 GA. L. REV. 1, 1 (1986).

¹⁰ U.S. CONST. art. I, § 8, cl. 1 (covering the taxing power); *id.* art. I, § 7, cl. 1 (covering the Origination Clause); *id.* art. I, § 8, cl. 2 (covering borrowing); *id.* art. I, § 8, cl. 5 (covering the coinage power).

Keeping power over public money away from the President was also especially important. Understandably, the Framers were intent on protecting our new democracy against slippage into a monarchy.¹¹ Because monarchs cannot accomplish tyranny without money, the power to decide what would qualify as money, and which governmental organs could create it, was intentionally given to Congress—to guard against any future presidential propensity for profligacy or altering money’s value in ways hallmark of a despot.¹²

Not only were monetary and fiscal powers vested in Article I, but they were also enmeshed in an overall structure of government that divided, in order to constrain, power among the branches.¹³ It was thus unconscionable to the Framers that Congress would not jealously guard its monetary and fiscal powers, as James Madison expressed when writing *Federalist No. 51*.¹⁴

But Congress in the twentieth century began the practice of delegation with the rise in the administrative state. And so too it began to experiment with delegating pieces of its Article I monetary and fiscal powers directly to the President. Specifically, starting in the 1930s, Congress began to chip away at this separation of Article I monetary power from the President with serial emergency delegations.

In the 1930s, Congress gave emergency powers to President Roosevelt to alter the value of money and increase its supply.¹⁵ In the 1950s, Congress deferred to the President on the international monetary regime, setting the conditions for President Nixon to declare the dollar as a fiat currency for the first time since the Civil War.¹⁶ As an ongoing source of power, the Treasury has at its disposal the Exchange Stabilization Fund to fluctuate the global money supply and engage in quasi-monetary policy actions in tandem with the Fed.¹⁷ As

¹¹ See MASHAW, *supra* note 8, at 35.

¹² U.S. CONST. art. I, § 8, cl. 5; *see infra* Section I.B (discussing the original and founding discussions around the monetary powers).

¹³ See Ilan Wurman, *Nondelegation at the Founding*, 130 YALE L.J. 1490, 1531 (2021).

¹⁴ See THE FEDERALIST NO. 51 (James Madison) (Clinton Rossiter ed., 1961). Further, as Madison wrote in *Federalist No. 47*, “The accumulation of all powers, legislative, executive, and judiciary, in the same hands, whether of one, a few, or many, and whether hereditary, self-appointed, or elective, may justly be pronounced the very definition of tyranny.” THE FEDERALIST NO. 47, *supra*, at 301 (James Madison).

¹⁵ See, e.g., Stephen Greene, *Emergency Banking Act of 1933*, FED. RSRV. HIST. (Nov. 22, 2013), <https://www.federalreservehistory.org/essays/emergency-banking-act-of-1933> [https://perma.cc/98U7-CBXG].

¹⁶ See Sandra Kollen Ghizoni, *Nixon Ends Convertibility of U.S. Dollars to Gold and Announces Wage/Price Controls*, FED. RSRV. HIST. (Nov. 22, 2013), <https://www.federalreservehistory.org/essays/gold-convertibility-ends> [https://perma.cc/YJ3H-KTNH].

¹⁷ See *Exchange Stabilization Fund History*, U.S. DEP’T TREASURY, <https://>

a result of these successive yet ad hoc delegations, presidents today have a host of tools at their disposal to affect the size of the deficit and the supply of money—through executive order and the Treasury Department’s tools.

This Article argues that contemporary presidents’ cache of economic power was not consistent with the original constitutional design. Rather, it has built up over time as a result of statutory delegations from Congress.¹⁸ These delegations have thus created a constitutional oxymoron: a “Monetary Executive.” Inasmuch as our system of government was designed to guard against a Monetary Executive, this aspect of separated powers has become eroded in the past ninety years. This Article thus aims to shed light on key legal moments in U.S. history when statutory delegations contributed to the formation of a Monetary Executive.

It also highlights the contemporary policy implications of the Monetary Executive. One implication concerns the independence of the central bank, the Federal Reserve (“the Fed”).¹⁹ Large government deficits tend to create pressure on the central bank to “monetize” the deficit by creating money to pay for the new spending.²⁰ The

home.treasury.gov/policy-issues/international/exchange-stabilization-fund/exchange-stabilization-fund-history [https://perma.cc/VYE9-WST9].

¹⁸ To date, the formal mechanism of fiscal dominance has remained relatively mysterious—often discussed in soft law terms—for scholars of central banking. In the U.S. system, channels of fiscal dominance seem unclear, as there are few obvious legal mechanisms—written into the text of the Federal Reserve Act—for the President or the Treasury to influence the Fed. See Michael Salib & Christina Parajon Skinner, *Executive Override of Central Banks: A Comparison of the Legal Frameworks in the United States and the United Kingdom*, 108 GEO. L.J. 905, 953, 969–71 (2020) (comparing the U.K. Treasury’s power to direct the Bank of England with the lack of such formal override powers in the United States).

¹⁹ The Federal Reserve Reform Act of 1977, Pub. L. No. 95-188, 91 Stat. 1387, added section 2A to the Federal Reserve Act, thereby giving the Fed a formal mandate for price stability for the first time since its creation in 1913. For a history of the origins of section 2A and the “dual mandate,” see, for example, Christina Parajon Skinner, *Capture the Fed*, in *POPULISM AND THE FUTURE OF THE FED* 65–69 (James A. Dorn ed., 2022).

²⁰ See Daniel L. Thornton, *Monetizing the Debt*, FED. RESRV. BANK ST. LOUIS REV., Dec. 1984, at 30, 30–31 (defining the phrase “monetizing the debt”); see, e.g., Jeff Spross, *How World War II Reveals the Actual Limits of Deficit Spending*, THE WEEK (May 16, 2016), <https://theweek.com/articles/624334/how-world-war-ii-reveals-actual-limits-deficit-spending> [https://perma.cc/THG5-YMBC] (“During the [deficit] crisis of WWII, the Fed agreed to print as much money as needed to buy up enough U.S. debt and keep interest rates low.”). The United States experienced a period of fiscal dominance between and around the World Wars, whereby the Fed was pressured to keep rates artificially low to support the government’s wartime bond buying programs. This policy hamstrung the Fed’s ability to control the inflation that ensued from these periods of significant government spending. The famed Treasury-Fed Accord of 1951 established an informal détente between the Fed and Treasury, whereby the Treasury committed to abandoning the pressure of fiscal dominance in this respect. See Owen F. Humpage, *Fiscal Domi-*

years 2020–2021 may have been a case in point. The COVID-19 era fiscal stimulus was the largest in U.S. history and increased the federal debt by thirty percent.²¹ Importantly, it relied on monetary policy for support.²² The Fed engaged in an equally unprecedented bond-buying program, adding \$4.5 trillion of government debt to its balance sheet between March 2020 and March 2022, nearly doubling its balance sheet.²³ This “coordinated” work of the Treasury and the Fed prompted renewed attention to the possible influence of fiscal programs on monetary policy decisions and, in turn, inflation.²⁴ Experts are thus increasingly worried about the return of “fiscal dominance,” whereby the fiscal prerogatives of government influence a central bank’s decisions.²⁵ There is a fine line between the “coordination” of

nance and US Monetary: 1940–1975, at 2–3 (Fed. Rsr. Bank of Cleveland, Working Paper No. 16-32, 2016); Jessie Romero, *The Treasury-Fed Accord*, FED. RSRV. HIST. (Nov. 22, 2013), <https://www.federalreservehistory.org/essays/treasury-fed-accord> [<https://perma.cc/3VJF-7M2H>].

²¹ See John H. Cochrane, *Fiscal Inflation*, in *POPULISM AND THE FUTURE OF THE FED* 119, 119, 125 (James A. Dorn ed., 2022) (noting that, because of the size of the debt financed stimulus, “constraints on monetary policy are four times larger today [than in 1980]—and counting”).

²² See Christopher J. Waller, Governor, Fed. Rsr. Bd., Speech at the Peterson Institute for International Economics: Treasury-Federal Reserve Cooperation and the Importance of Central Bank Independence (Mar. 29, 2021), <https://www.federalreserve.gov/newsevents/speech/waller20210329a.htm> [<https://perma.cc/7HXU-DLUN>].

²³ See William B. English & Donald Kohn, *What If the Federal Reserve Books Losses Because of Its Quantitative Easing?*, BROOKINGS (June 1, 2022), <https://www.brookings.edu/blog/up-front/2022/06/01/what-if-the-federal-reserve-books-losses-because-of-its-quantitative-easing/> [<https://perma.cc/9VFT-DPP6?type=standard>]; Konstantinos Tsatsaronis, Michael Chui, Tirupam Goel & Aaron Mehrotra, *The Monetary-Fiscal Policy Nexus in the Wake of the Pandemic* 4 (Bank for Int’l Settlements, Working Paper No. 122, 2022), <https://www.bis.org/publ/bppdf/bispap122.pdf> [<https://perma.cc/JBB5-32FM>] (“By preventing fire sale dynamics and increasing liquidity in the longer part of the yield curve, interventions de facto eased governments’ borrowing costs and supported the fiscal expansion and the economy more generally.”).

²⁴ See Waller, *supra* note 22; see, e.g., ECONOMIC AFFAIRS COMMITTEE, QUANTITATIVE EASING: A DANGEROUS ADDICTION?, 2021–2, HL 42, at 3 (UK) [hereinafter HOUSE OF LORDS REPORT], <https://publications.parliament.uk/pa/ld5802/ldselect/ldconaf/42/4202.htm> [<https://perma.cc/WFV6-C78T>] (demonstrating, through a study by the U.K. Parliament on the effectiveness of quantitative easing and its impact on inflation, the increased attention worldwide towards the successes and limitations of quantitative easing as a monetary and fiscal policy strategy).

²⁵ See James Dorn, *The Menace of Fiscal Inflation*, ALT-M (June 16, 2022) [hereinafter Dorn, *Menace of Fiscal Inflation*], <https://www.alt-m.org/2022/06/16/the-menace-of-fiscal-inflation/> [<https://perma.cc/HGZ8-6WBX>] (noting data from the St. Louis Fed shows that monetary aggregates and deficits series “track each other well, suggesting that the expansion of money in the economy has a fiscal origin”); Fernando M. Martin, *What Are the Risks for Future Inflation?*, FED. RSRV. BANK OF ST. LOUIS (Oct. 7, 2021) [hereinafter Martin, *Risks for Future Inflation*], <https://www.stlouisfed.org/on-the-economy/2021/october/what-risks-future-inflation> [<https://perma.cc/4A3E-28FB>] (empirically suggesting a fiscal component to inflation); Fernando M. Martin, *Fiscal Dominance* 1 (Fed. Rsr. Bank of St. Louis, Working Paper No. 2020-040B, 2021), <https://research.stlouisfed.org/wp/more/2020-040> [<https://perma.cc/D6ED-82JC>] (“When the fiscal authority sets debt as its main policy instrument it achieves fiscal dominance, rendering the

monetary and fiscal policy and fiscal “dominance”—and the latter is a well-known recipe for inflation.²⁶

This shift toward a Monetary Executive also may belie a broader democratic ill. The President today possesses the power to spend public money on fiscal programs that Congress has not authorized or condoned. The congressional “end-run” possibilities that these powers pose threaten the liberal democratic order in ways that sweep broader than price levels.²⁷ Related, there is some danger in entrenching presidential monetary power through emergency. There is a rich legal literature that justifies a strong (“unitary”) President, either so that they may better control the administrative state generally or ensure decisive action in an emergency.²⁸ But as the concept of emergency continues to be stretched—particularly in economic contexts—it risks

preferences of the central bank, and thus its independence, irrelevant.”); James A. Dorn, *Fiscal Dominance and Fed Complacency*, CATO INST. (Apr. 8, 2021, 10:25 AM) [hereinafter Dorn, *Fiscal Dominance*], <https://www.cato.org/blog/fiscal-dominance-fed-complacency> [https://perma.cc/RK9E-X2FF] (“Fiscal dominance occurs when central banks use their monetary powers to support the prices of government securities and to peg interest rates at low levels to reduce the costs of servicing sovereign debt.”); Isabel Schnabel, *The Shadow of Fiscal Dominance: Misconceptions, Perceptions and Perspectives*, EUR. CENT. BANK (Sept. 11, 2020), <https://www.ecb.europa.eu/press/key/date/2020/html/ecb.sp200911~ea32bd8bb3.en.html> [https://perma.cc/SY4Z-L2UE] (noting that at the time of the formation of the European Central Bank, “high government debt was seen as a major threat to central bank independence, and it was feared that *fiscal dominance* could induce a central bank to deviate from its monetary policy objectives, endangering price stability”).

²⁶ In nearly all experiments with “cheap money polic[ies]” to finance government spending, tried in “country after country,” all cases “led to inflation and had to be abandoned.” MILTON FRIEDMAN, *THE COUNTER-REVOLUTION IN MONETARY THEORY* 15 (1970); see Michael U. Krause, Thomas A. Lubik & Karl Rhodes, *MMT and Government Finance: You Can’t Always Get What You Want*, FED. RSRV. BANK OF RICHMOND (Apr. 2021), https://www.richmondfed.org/publications/research/economic_brief/2021/eb_21-12 [https://perma.cc/973W-WDA2] (arguing that coordinated efforts between the Treasury and the Fed to print money to finance government spending may lead to inflation in the long run, despite short term projections that are skewed by other market factors); see also John Hooley & Mika Saito, *Inflation and ‘Fiscal Dominance’: Evidence From Sub-Saharan Africa*, VOXEU (Dec. 6, 2021), <https://voxeu.org/article/inflation-and-fiscal-dominance#:~:text=IN%20summary%2C%20our%20findings%20suggest,still%20generate%20significant%20inflation%20pressure> [https://perma.cc/3R2Y-RUD3] (“The dangers of fiscal dominance . . . have long been warned against by economists and policymakers and history provides no shortage of cautionary tales.”).

²⁷ As one former Fed Chairman, William McChesney Martin, powerfully stated in a 1955 speech, “The history of despotic rule, of authoritarian rule” over the economy is that illiberal policies take “a frightful toll in human misery and degradation.” In contrast, in a liberal economic order—in which the “[p]owers of decision are dispersed among the millions affected”—there is a more efficient use of society’s resources and “vast gains in terms of personal liberty.” James A. Dorn, *Myopic Monetary Policy and Presidential Power: Why Rules Matter*, 39 CATO J. 577, 582 (2019).

²⁸ See ERIC A. POSNER & ADRIAN VERMEULE, *THE EXECUTIVE UNBOUND* 7–8 (2010); Cass R. Sunstein & Adrian Vermeule, *The Unitary Executive: Past, Present, Future*, 2020 SUP.

empowering the President in permanent but unintended ways.²⁹ With standing monetary powers, the President can have outsized influence in the economy which, over time, could undermine established democratic values.

As such, this Article aims at three distinct literatures. The first is the literature on inflation, urging a place for legal scholarship in this conversation. Not only does this Article pinpoint the legal precedents to a President's power to promote fiscal spending and, in turn, fiscal dominance, and ergo inflation, but it also sheds new light on how shifts in economic theories around inflation also coincided with legal changes in the President's power, providing tailwinds to an economic theory. So, for example, in the 1930s, just as Congress gave Roosevelt more power to inflate the economy directly, academic economists were moving away from the classic quantity theory of money and embracing Keynesian economics.³⁰ This paradigm shift would have created the political-economy atmosphere in which fiscal spending programs would not necessarily be seen as problematically inflationary to Congress. Similar legal-economic paradigm shifts occurred in the 1970s and now again around the 2020s.³¹

This Article also advances the literature on central bank independence, which spans the fields of law, politics, history, and economics.³² As critics now question whether the Fed should, in fact, be independent from the President, this Article presents a new layer in the defense of central bank independence—namely, as a key institution for pushing back against the growth of a Monetary Executive.

Lastly, the arguments herein engage the literature on delegation generally. Although much of the delegation literature is focused on delegations to the administrative state,³³ this Article looks at the

CT. REV. 83, 90–91, 96 (discussing unitary theory more generally); Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2331–32, 2339 (2001).

²⁹ See Yeva Nersisyan & L. Randall Wray, *How to Pay for the Green New Deal* 3–4 (Levy Econ. Inst., Working Paper No. 931, 2019) (relying on the idea first proposed by William James in 1906, the “moral equivalent of war,” to define climate change as an emergency).

³⁰ See generally *infra* Section II.A.1.

³¹ For discussion, see *infra* Section II.A.2.

³² See, e.g., PETER CONTI-BROWN, *THE POWER AND INDEPENDENCE OF THE FEDERAL RESERVE* (2016); Charles Goodhart & Rosa Lastra, *Populism and Central Bank Independence*, 29 OPEN ECON. REV. 49 (2018); Kathryn Judge, *The Federal Reserve: A Study in Soft Constraints*, 78 L. & CONTEMP. PROBS. 65 (2015).

³³ See, e.g., MASHAW, *supra* note 8, at 7; Wurman, *supra* note 13, at 1490; see also Christine Desan & Nadav Orian Peer, *The Constitution and the Fed After the COVID-19 Crisis*, JUST MONEY: POL'Y SPOTLIGHT (June 10, 2020), <https://justmoney.org/the-constitution-and-the-fed-after-the-covid-19-crisis-2/> [<https://perma.cc/H8J9-RN88>] (discussing the specific situation of the Treasury and financial crisis guarantees). While there is notable literature discussing how the

unique kind of delegation directly to the President in the specific arena of monetary affairs.³⁴ More broadly, as most members of the Supreme Court narrow in on originalism as the primary statutory lens for interpreting the Constitution, an original understanding of the metes and bounds of the President's authority in monetary affairs should also be of value to the growing legal literature on central banking in—or alongside—the administrative state.

This Article proceeds in three parts. Part I discusses the original understanding of the monetary and fiscal powers in Article I of the Constitution—the power to “coin” money and regulate its value, and also the power to decide how money would be spent through the so-called power of the purse. It further explains why it would have been firmly understood that these powers could not or would not be delegated to the President.

Part II develops the descriptive argument—that Congress has delegated significant monetary and fiscal power to the President, thereby shifting the constitutional baseline balance of power. These delegations were done in an ad hoc way and often intended to be temporary. But when taken in full view, these delegated powers have amassed significantly and outlasted any exigency.

Part III offers some suggestions for regaining constitutional balance over public money. In particular, it suggests operational changes to Fed policy—for Congress to enforce limits on the Fed's ability to pay interest on excess reserves as a bulwark against future presidential pressure to monetize deficit spending. It also suggests that the Fed move back to a quasi-rules-based regime as another defense against a Monetary Executive and the threats it presents to Fed independence. Lastly, the Article makes suggestions to Congress for checking the presidential use of delegation grounded in an economic emergency.

Now, more than in any other period in U.S. history, there appears to be a willingness to entertain fundamental breaches to the constitutionally prescribed separation of powers, and nowhere is such experi-

President increasingly exercises Congress's appropriation power—see Gillian E. Metzger, *Taking Appropriations Seriously*, 121 COLUM. L. REV. 1075, 1075 (2021); Kate Stith, *Congress' Power of the Purse*, 97 YALE L.J. 1343, 1377 (1988) (discussing executive access to public funds); Zachary Courser & Kevin R. Kosar, *RESTORING THE POWER OF THE PURSE* (Am. Enter. Inst. 2021) (discussing earmarking and agency fines)—this Article focuses distinctly on the President's powers to affect the value of money. While appropriations certainly feature in this story, they do not star in it.

³⁴ See generally Kagan, *supra* note 28, at 2248. This Article also engages literature on the President and emergency. See POSNER & VERMEULE, *supra* note 28, at 7–8; Sunstein & Vermeule, *supra* note 28 (discussing unitary theory more generally).

mentation as enticing as where money and public finance are concerned.³⁵ It is crucial for the public, policymakers, and the legal academy to pause and reflect on whether we are satisfied with our new silent monetary constitution, where the President looms larger than Congress, and whether this mode of governance can be sustained as legitimate over time.

I. (NON)DELEGATION OF MONETARY MATTERS AT THE FOUNDING

The Framers of the Constitution gave Congress plenary power over money to ensure that it would remain the “first among equals”—the most powerful of the three branches.³⁶ As Alexander Hamilton made clear in *Federalist No. 30*, the founding generation astutely surmised that “[m]oney is, with propriety, considered as the vital principle of the body politic; as that which sustains its life and motion and enables it to perform its most essential functions.”³⁷ The Framers expected that control over money and spending would be the fount of the government’s power. Accordingly, the power to create money, set its value, and the power to spend money were kept separate from the presidency.

A. *The Original Monetary Power*

The question of what is “money” was an important part of the constitutional conversation. The Framers’ views on money and government were influenced by two distinct sets of history. The first was the history of Europe and its monarchs, which illustrated that Executives could use their power to create money, or alter its value, as a tool for denigrating the property interests of the People.³⁸ Such an outcome would be anathema to the ethos of the new republic, which was built on a theory of liberty that viewed private rights of property and contract, alongside life and liberty, as rights that, once vested, should never be “dependent upon the will of the government.”³⁹

³⁵ As former Chief Justice of the Supreme Court Warren Burger once said, “No one can doubt that Congress and the President are confronted with fiscal and economic problems of unprecedented magnitude, but ‘the fact that a given law or procedure is efficient, convenient, and useful in facilitating functions of government, standing alone, will not save it if it is contrary to the Constitution.’” *Bowsher v. Synar*, 478 U.S. 714, 736 (1986) (quoting *INS v. Chadha*, 462 U.S. 919, 944 (1983)).

³⁶ THE FEDERALIST NO. 30, *supra* note 14 (Alexander Hamilton).

³⁷ *Id.* at 188.

³⁸ See McCONNELL, *supra* note 7, at 100–04.

³⁹ *Wellness Int’l Network, Ltd. v. Sharif*, 575 U.S. 665, 713 (2015) (Thomas, J., dissenting) (citing 1 WILLIAM BLACKSTONE, COMMENTARIES ON THE LAWS OF ENGLAND 119 (1765)).

The second, more recent history the Framers had to bear in mind was the experience of money in England and the colonies before the Revolution. English experience suggested to the Framers, as Professor McConnell explains, that “[m]inting more money and debasing its value is a time-honored and usually pernicious way for debtor nations to get out from under their sovereign debt. Henry VIII had used this power to devastating effect, creating economic havoc.”⁴⁰ As a consequence, the Framers intentionally allocated this royal prerogative to Congress, even though it was possessed by King George at the time of the Constitutional Convention, and the President would have been the republic’s closest analog to a King.⁴¹

Colonial experience, meanwhile, made the Framers wary about the nature of money itself.⁴² At the time, Colony-issued paper money—referred to as “bills of credit”—had circulated widely alongside gold and silver—so-called “hard money.”⁴³ Although this paper money was used as currency, it was not always legal tender, which led to a host of problems in the Colonies ranging from tax avoidance to fraud and speculation.⁴⁴ During the actual Revolution, the Continental Congress also relied on bills of credit—without any power of taxation, printing money was the only means of financing the war.⁴⁵ The flood of paper money during the Revolution, with no real indication of a means to honor it, led to massive inflation after the war had ended.⁴⁶

⁴⁰ McCONNELL, *supra* note 7, at 103.

⁴¹ *Id.*

⁴² See HORACE WHITE, *MONEY AND BANKING* 44–49 (6th ed. 1935).

⁴³ A bill of credit, when issued by the government, was then usually understood as “a promise to pay coined money.” *Id.* at iv, 44; see Adam Hayes, *Hard Money*, INVESTOPEDIA (Apr. 25, 2022), <https://www.investopedia.com/terms/h/hardmoney.asp> [<https://perma.cc/T4XK-2M63>] (defining “hard money”); see generally Farley Grubb, *The U.S. Constitution and Monetary Powers: An Analysis of the 1787 Constitutional Convention and How a Constitutional Transformation of the Nation’s Monetary System Emerged* (Nat’l Bureau of Econ. Rsch., Working Paper No. 11783, 2005).

⁴⁴ A 1743 pamphlet, styled “A Letter from a Gentleman in Boston to his Friend in Connecticut,” articulated a warning about paper money:

[T]o themselves, Members of the Legislature, and to other Borrowers, their Friends, at easy and fallacious Lays, to be repaid at very long Periods; and by their provincial Laws made a Tender in all Contracts, Trade and Business, whereby Currencies, various and illegal, have been introduced which from their continued and depreciated nature in the Course of many Years have much oppressed Widows and Orphans and all other Creditors.

WHITE, *supra* note 42, at 46.

⁴⁵ See JOHN JAY KNOX, *A HISTORY OF BANKING IN THE UNITED STATES* 19–20 (Bradford Rhodes & Elmer H. Youngman eds., 1900).

⁴⁶ By 1779, twenty continental dollars were worth one in silver; and by 1780, that ratio was

Given these histories, the Framers viewed paper money with great skepticism. Historians believe that Robert Morris was the most influential in framing the monetary powers as eventually written in the Constitution.⁴⁷ In his view, paper money was not only capable of manipulation and inflation, it was often effective for popular movements in pressing the government to spend more. To Morris:

Emissions of paper money, largesses to the people—a remission of debts and similar measures, will at sometimes be popular, and will be pushed for that reason. . . . The press is indeed a great means of diminishing the evil, yet it is found to be unable to prevent it altogether.⁴⁸

Populist pressure for inflationary spending was never more acute, Morris observed, than in times of emergency.⁴⁹ In exigent circumstances, Morris knew the incentives for the government to print money—to, for instance, pay for a war—were inevitably high.⁵⁰ The printing press led to inflation and in turn necessitated drastic measures to control it. Given that predictable cycle, Morris condemned paper money as a “ruinous expedient.”⁵¹

The Framers thus opted to eliminate the possibility by reducing discretion as much as possible within the text of the Constitution’s so-called coinage power. That power, in Article I, section 8, gives Congress the power to “coin Money, regulate the Value thereof, and of foreign Coin, and fix the Standard of Weights and Measures.”⁵² “Coin” referred to hard-money specie—gold or silver—commodities of which there was a fixed quantity in circulation.⁵³ Further, the Con-

seventy-five to one. *Id.* Northern states soon thereafter abandoned continentals and started using French paper as currency, which had trickled in through the French army, and Southern states dropped continentals altogether. *Id.*; see *From Alexander Hamilton To—, [December–March 1779–1780]*, NAT’L ARCHIVES: FOUNDERS ONLINE, <https://founders.archives.gov/?q=ancestor%3AAARHN-01-02-02-0559&s=1511311111&r=2> [https://perma.cc/9VT3-8KPW]. This history informed the expression “not worth a continental.” See Clifford F. Thies, *Not Worth a Continental*, AM. INST. ECON. RSCH. (Nov. 3, 2021), <https://www.aier.org/article/not-worth-a-continental/> [https://perma.cc/437Y-D734].

⁴⁷ See KNOX, *supra* note 45, at 27–28.

⁴⁸ Grubb, *supra* note 43, at 31.

⁴⁹ *Id.* at 31–40.

⁵⁰ *Id.*

⁵¹ *Id.* at 31, 39.

⁵² U.S. CONST. art. I, § 8, cl. 5.

⁵³ See Grubb, *supra* note 43, at 42–45. The Framers’ choice not to refer to the emission of bills of credit (i.e., making paper money) was intentional. The original draft of the Constitution provided to the Convention by the Committee of Detail would have empowered Congress to borrow money and emit bills of credit of the United States. But when that section moved to debates, Governor Morris moved to strike the clause “and emit bills on the credit of the United

stitution specifies that “[n]o State shall . . . coin Money; emit Bills of Credit; make any Thing but gold and silver Coin a Tender in Payment of Debts.”⁵⁴ So, creating the actual material that would be used in the United States as “money” was a power the Constitution reserved to the federal government, and Congress in particular. The power to create paper money was thus the “only congressional power under the Articles that was deliberately denied to the federal government under the Constitution.”⁵⁵

The real value of money was taken at the Founding as a given. At the Founding, the United States, like Western Europe, adhered to a bimetallic standard by which the value of coin was set in reference to weights and fineness of gold and silver, so that gold and silver were valued at a ratio of fifteen and a half to one.⁵⁶ In the context of a bimetallic standard, world markets would establish the value of the coin, not government fiat, so discretion as to the “value” of American “coin” would have been meaningless.⁵⁷ Accordingly, the power to “regulate the value thereof” referred Congress to the administrative task of adjusting the metallic content of the metals in each coin minted to ensure the coins would more or less track their respective market values, domestically and abroad.⁵⁸ Eventually, the United States would adopt a classic gold standard at the end of the nineteenth century, reinforcing this constitutional commitment.⁵⁹

States.” *Id.* Thus, the States could not make paper money either. Notably, this left open the possibility that private institutions—banks—could emit bills of credit. *See id.*; *see also* 2 THE RECORDS OF THE FEDERAL CONVENTION OF 1787, at 144, 308–09 (Max Farrand ed., 1937) (discussing the limit on Congress’s power to the minting of the actual coin).

⁵⁴ U.S. CONST. art. I, § 10, cl. 1.

⁵⁵ McCONNELL, *supra* note 7, at 103.

⁵⁶ CRAIG K. ELWELL, CONG. RSCH. SERV., R41887, BRIEF HISTORY OF THE GOLD STANDARD IN THE UNITED STATES 1–2 (2011), <https://sgp.fas.org/crs/misc/R41887.pdf> [<https://perma.cc/3MHE-DJHX>]. Technically, because the world markets valued gold to silver at a ratio of 15 ½ to 1, this meant that the US was on a de facto silver standard. In 1834, Congress reduced the gold content of the dollar to make the ratio 16 to 1. *Id.* at 3.

⁵⁷ *Id.* at 1–2.

⁵⁸ *See* RICHARD H. TIMBERLAKE, CONSTITUTIONAL MONEY 35 (2013).

⁵⁹ A gold standard was unofficially adopted in 1834, when Congress fixed the price of gold at \$20.67 per ounce and, officially, in 1900, when Congress declared the gold dollar the standard and official unit of account—all money issued by the government would maintain parity with gold. *See* Michael D. Bordo, *Gold Standard*, ECONLIB, <https://www.econlib.org/library/Enc/Gold-Standard.html> [<https://perma.cc/5K4T-DSK2>]. A few historical facts regarding the gold standard may be instructive. Other major countries joined the gold standard in the 1870s. *Id.* The period from 1880 to 1914 is known as the classic gold standard; a majority of countries adhered to the standard. *Id.* The gold standard briefly broke down during World War I but was reinstated from 1925 to 1931. *See id.*; *see also* Gary Richardson, Alejandro Komai & Michael Gou, *Roosevelt’s*

For the first 120 years of the republic, Congress would follow the original intent of the Constitution's coinage power, and when deviations happened, in times of emergency, Congress eventually reverted to the mean. For example, during the Civil War, Congress authorized the U.S. government to issue paper money with legal tender status—and like the continentals, these “greenbacks” were not convertible for hard coin.⁶⁰ When the Civil War ended, the United States returned to its constitutional baseline. The government stopped issuing greenbacks and even retired some; eventually, it fixed the amount of greenbacks in circulation at whatever level was outstanding and returned to the Gold Standard.⁶¹

B. *The Original Fiscal Power*

Today, we often refer to Congress's fiscal powers colloquially as the “purse” and its “strings.” The “power of the purse” in fact consists of a constellation of constitutional powers. One refers to Congress's power to amass the funds necessary to run government: these are the taxing and spending powers from Article I, which grants Congress the “Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States.”⁶² Additionally, the borrowing power permits Congress “[t]o borrow Money on the credit of the United States.”⁶³ These powers were exclusively for Congress: the Framers intended that “the legislative department alone has access to the pockets of the people.”⁶⁴

The text of the appropriation clause established that Congress would decide how money raised for the government would be spent, that is, allocated to various projects, groups, or programs. Specifically, that clause provides that “[n]o Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law.”⁶⁵ Unlike the raising, spending, and borrowing powers—which are positive

Gold Program, FED. RESRV. HIST. (Nov. 22, 2013), <https://www.federalreservehistory.org/essays/roosevelts-gold-program> [<https://perma.cc/X658-MDY5>].

⁶⁰ See ELWELL, *supra* note 56, at 5. Congress was in the driver's seat; it authorized three separate issuances of greenbacks with the Legal Tender Acts in February 1862, July 1862, and March 1863. See TIMBERLAKE, *supra* note 58, at 56.

⁶¹ See ELWELL, *supra* note 56, at 6. As will be discussed, the United States remained on the Gold Standard, with brief exceptions during the World Wars, until 1971. See *infra* Section II.A.2.

⁶² U.S. CONST. art. I, § 8, cl. 1.

⁶³ *Id.* art. I, § 8, cl. 2.

⁶⁴ THE FEDERALIST NO. 48, *supra* note 14, at 310 (James Madison).

⁶⁵ U.S. CONST. art. I, § 9, cl. 7.

grants of authority—the Appropriations Clause supplies a limitation: only Congress can provide for the withdrawal of funds from the Treasury and only by virtue of an enacted law.⁶⁶

As with the coinage power, the Framers were informed by fear of antidemocratic outcomes. They had observed that monarchs could rule without a parliament if they controlled the purse.⁶⁷ Protecting the purse from executive control was therefore first order to protecting the new republic.⁶⁸ The Delegations thus strongly held the view that the President should not have control over the purse.⁶⁹ James Madison elaborated in *Federalist No. 58*:

They, in a word, hold the purse—that powerful instrument by which we behold, in the history of the British Constitution, an infant and humble representation of the people gradually enlarging the sphere of its activity and importance, and finally reducing, as far as it seems to have wished, all the overgrown prerogatives of the other branches of the government. This power over the purse may, in fact, be regarded as the most complete and effectual weapon with which any constitution can arm the immediate representatives of the people, for obtaining a redress of every grievance, and for carrying into effect every just and salutary measure.⁷⁰

Separating “the sword from the purse”—i.e., the Executive, who “take[s] Care” to enforce the laws—was integral to a theory of government that hinged on the notion of separating power between branches.⁷¹ Lodging the fiscal power with Congress became the key

⁶⁶ See *id.* For an example of how Congress utilizes this power in the form of earmarks, and arguments for and against such use, see generally Kosar, *supra* note 33.

⁶⁷ See JOSH CHAFETZ, CONGRESS’S CONSTITUTION: LEGISLATIVE AUTHORITY AND THE SEPARATION OF POWERS 51 (2017) (referring to the founding generation’s recent memory of monarchs ruling without parliamentary asset, resulting in the 1689 Revolution Settlement that took aim at “monarchical authority . . . royal revenues and royal control over a standing army”).

⁶⁸ See Grubb, *supra* note 43, at 45; CHAFETZ, *supra* note 67, at 56 (“The desire to control how money is spent, which we saw growing during the late Stuart period, coming to maturity in the eighteenth century, and asserted emphatically in colonial and early republican America, found its expression in the requirement—wholly uncontroversial at the Constitutional Convention—that ‘[n]o Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law.’” (quoting U.S. CONST. art. I, § 9, cl. 7)).

⁶⁹ See *Power of the Purse*, U.S.H.R.: HIST., ART & ARCHIVES, <https://history.house.gov/institution/origins-development/power-of-the-purse/> [<https://perma.cc/8FYC-FPP4>] (“The framers were unanimous that Congress, as the representatives of the people, should be in control of public funds—not the President or executive branch agencies. This strongly-held belief was rooted in the framers’ experiences with England, where the king had wide latitude over spending once the money had been raised.”).

⁷⁰ THE FEDERALIST NO. 58, *supra* note 14, at 359 (James Madison).

⁷¹ James Madison on the Necessity of Separating the Power of “The Sword From the Purse”

point of comfort to anti-Federalists, concerned about a strong President.⁷² So, for instance, when Patrick Henry worried that “[y]our President may easily become king,” Madison rejoindered that “the purse is in the hands of the representatives of the people. They have the appropriation of all moneys.”⁷³

The early congresses upheld the Framers’ vision that the powers of the purse and strings be tightly controlled by the legislature.⁷⁴ These powers were closely guarded, and, as Professor Jerry Mashaw explains, the first volume of the *United States Statutes at Large* supplies “evidence . . . [of] an overriding concern with money—with appropriations and taxes to finance a government that began its life already deeply in debt.”⁷⁵ Notably, even as Congress began a fledgling practice of delegating to the President in other areas of public administration,⁷⁶ it continued to keep its fiscal power close by micromanaging the details of the early revenue statutes with painstaking specificity and detail.⁷⁷

C. Early Public Finance Institutions

One caveat to the evidence of nondelegation at and shortly after the Founding concerns the institutions that developed to effectuate monetary and fiscal policy—the First and Second Banks of the United States, the U.S. Treasury, and eventually the Federal Reserve.⁷⁸ The

(1793), OLL, <https://oll.libertyfund.org/quote/james-madison-on-the-necessity-of-separating-the-power-of-the-sword-from-the-purse-1793> [https://perma.cc/8TUD-FEYX]; U.S. CONST. art. II, § 3.

⁷² See CHAFETZ, *supra* note 67, at 57.

⁷³ *Id.*

⁷⁴ See U.S.H.R.: HIST., ART & ARCHIVES, *supra* note 69.

⁷⁵ MASHAW, *supra* note 8, at 34.

⁷⁶ *Id.* at 46 (“Congress made broad delegations of authority in a host of other statutes, often to the President, but with full knowledge that his discretion would of necessity be subdelegated to others.”).

⁷⁷ *Id.* at 44 (The 1791 revenue statute was fifteen pages long specifying “everything from the brand of hydrometer to be used in testing proof to the exact lettering to be used on casks that have been inspected and the wording of signs to be used to identify revenue offices.”); *see also id.* at 36–38 (discussing the “complex administrative system” for collecting taxes on certain imported goods and distilled spirits in 1789 and 1791, respectively).

⁷⁸ See PAUL KAHAN, *THE BANK WAR* 7–9 (2016) (noting the first and second central banks “act[ed] as the Treasury Department’s fiscal agent” and “receiv[ed] taxes, disburs[ed] government payments, circulat[ed] currency, and discount[ed] bills of exchange”); RICHARD SYLLA & DAVID J. COWEN, *ALEXANDER HAMILTON ON FINANCE, CREDIT, AND DEBT* 53 (2018) (noting the need for delegation because “[i]t was impossible that the business of finance could be ably conducted by a body of men, however well composed or well intentioned”); FED. RSRV. BANK OF PHILA., *THE FIRST BANK OF THE UNITED STATES: A CHAPTER IN THE HISTORY OF CENTRAL BANKING* 2–3 (2021), <https://www.philadelphiafed.org/-/media/frbp/assets/institutional/>

First and Second Banks were meant to be public finance institutions but had distinctly private elements.⁷⁹ Because these institutions effectively would control the supply of money, they inherently exercised some delegated power.⁸⁰ It is noteworthy, however, that this delegation flowed to what were in truth privately owned institutions, not an Executive Branch authority. Regardless, these institutions suffered a lack of public legitimacy and did not survive over time. The First Bank was chartered in 1791 and had a twenty-year charter.⁸¹ Congress voted not to renew its charter in 1811, and the First Bank closed.⁸² Likewise, Congress also declined to renew the charter of the Second Bank of the United States, which was even more powerful than the first, in 1836.⁸³

Congress established the Federal Reserve—a true central bank—in 1913.⁸⁴ In part, the Federal Reserve Act was motivated by economic emergency. The period following the Civil War, the “Gilded Age,” was beset by banking panics.⁸⁵ Between 1863 and 1913, eight separate

education/publications/the-first-bank-of-the-united-states.pdf [https://perma.cc/FHL5-ZAUV] (discussing Hamilton’s desire to charter a national bank to act as Congress’s “fiscal agent,” and the opposition’s argument “that the Constitution did not grant the government the authority to establish banks”).

⁷⁹ See KAHAN, *supra* note 78, at 8–9 (discussing how the First Bank of the United States would largely be owned by private shareholders and would be governed by a board of directors, but would be limited in what it could trade in, thereby distinguishing it from a commercial bank). The First Bank of the United States was Alexander Hamilton’s key initiative for the new republic, which, in his view, was a “necessary auxiliary . . . [and] an indispensable engine in the administration of the finances.” SYLLA & COWEN, *supra* note 78, at 116.

⁸⁰ See KAHAN, *supra* note 78, at 7 (noting the central bank had the power “to regulate the nation’s money supply and credit”).

⁸¹ See JOHN THOM HOLDSWORTH & DAVIS R. DEWEY, *THE FIRST AND SECOND BANKS OF THE UNITED STATES*, S. DOC. NO. 571, at 19–20 (2d Sess. 1910).

⁸² See *id.* at 97.

⁸³ See *id.* at 157. After the charter expired, the bank became a private corporation, until it underwent liquidation starting in 1841. See Bray Hammond, *Jackson, Biddle, and the Bank of the United States*, 7 J. ECON. HIST. 1, 11 (1947). Among other difficulties, the Second Bank was challenged as unconstitutional, but the Supreme Court held that Congress did have authority to charter a bank. *McCulloch v. Maryland*, 17 U.S. 316, 421 (1819). President Jackson maintained that the bank was unconstitutional and his dispute with the Bank’s President, Nicholas Biddle, led to an infamous “Bank War.” See *Bank War*, HISTORY (Oct. 4, 2022), <https://www.history.com/topics/19th-century/bank-war> [https://perma.cc/F8T8-V2KD]. However, the First and Second Banks were quasi-public rather than purely public institutions, and therefore do not neatly fit into the discussion of delegations to other branches. For literature on these institutions, see, for example, JAY COST, *THE PRICE OF GREATNESS* (2018).

⁸⁴ Federal Reserve Act, Pub. L. No. 63-43, 38 Stat. 251 (1913) (codified as amended in scattered sections of 21 U.S.C.).

⁸⁵ See Gary Richardson & Tim Sablik, *Banking Panics of the Gilded Age*, FED. RSRV. HIST. (Dec. 4, 2015), <https://www.federalreservehistory.org/essays/banking-panics-of-the-gilded-age> [https://perma.cc/8KHT-C5ER]; Jon R. Moen & Ellis W. Tallman, *The Panic of 1907*, FED. RSRV. HIST. (Dec. 4, 2015), <https://www.federalreservehistory.org/essays/panic-of-1907> [https://

banking panics struck regionally and nationally, wreaking havoc on the economy.⁸⁶ The problem, it would seem, was a monetary one that overlays the business cycle—namely, that the supply of currency could not modulate across the seasons and with needs for liquidity to engage in harvests.⁸⁷ The Fed was created to use its tools to improve the elasticity of currency.⁸⁸

To be sure, Congress delegated some modicum of its Article I, section 8 power to this new central banking institution.⁸⁹ But the monetary delegation was a mild one at that. Thanks to the Gold Standard, the Fed would not, for some time, confront the task of making judgments about how to in fact determine the supply of money or what its value ought to be.⁹⁰ Rather, the supply of money would adjust automatically pursuant to the supply and demand for gold, alongside the international flows of the stock of gold.⁹¹ As such, Congress designed

perma.cc/95FC-X3AW] (explaining the panic of 1907, which tipped Congress over the edge into agreeing to form the Federal Reserve System).

⁸⁶ See Richardson & Sablik, *supra* note 85.

⁸⁷ See *id.* (“Panics tended to occur in the fall, when the banking system was under the greatest strain. Farmers needed currency to bring their crops to market, and the holiday season increased demands for currency and credit. Under the National Banking System, the supply of currency could not respond quickly to an increase in demand, so the price of currency rose instead. That price is known as the interest rate. Increasing interest rates lowered the value of banks’ assets, making it more difficult for them to repay depositors and pushing them toward insolvency. At these times, uncertainty about banks’ health and fear that other depositors might withdraw first sometimes triggered panics, when large numbers of depositors simultaneously ran to their banks and withdrew their deposits.”).

⁸⁸ Federal Reserve Act, Pub. L. No. 63-43, 38 Stat. 251, 251 (1913) In 1863 and 1864 Congress created a national banking system in the National Bank Acts. As such, it needed a supervisor, though it did already have some supervisory functions covered by the Office of the Comptroller of the currency. See Lev Menand, *Why Supervise Banks? The Foundations of the American Monetary Settlement*, 74 VAND. L. REV. 951, 994 (2021). For an overview of this era, see generally *id.*

⁸⁹ U.S. CONST. art. I, § 8; Federal Reserve Act, Pub. L. No. 63-43, 38 Stat. 251, 251 (1913).

⁹⁰ THOMAS M. HUMPHREY & RICHARD H. TIMBERLAKE, GOLD, THE REAL BILLS DOCTRINE, AND THE FED (2019) (“At the most basic level there is no need for central banks to manage the gold standard.” (quoting Michael D. Bordo, *Gold Standard Theory*, in THE NEW PALGRAVE DICTIONARY OF MONEY AND FINANCE 269 (Peter Newman et al. eds., 1992))).

⁹¹ See *id.*; see also *The Classical Gold Standard*, WORLD GOLD COUNCIL, <https://www.gold.org/history-gold/the-classical-gold-standard> [<https://perma.cc/DD8Z-FY43>]. Moreover, the principal architects of the Federal Reserve Act believed in the so-called Real Bills doctrine and hard-wired that doctrine into the Act. According to that economic school of thought, credit would automatically adjust according to the productive needs of business and agriculture. The original Federal Reserve Act provided that the Federal Reserve banks could only discount real bills, that is, bills attached to production or agriculture. If you had a bill backed by something concrete, then you could get credit; this was designed to ensure that the supply of credit matched productive needs and would not be used for speculation. See generally HUMPHREY & TIMBERLAKE, *supra* note 90.

the Fed in the image of its monetary powers—a technocratic expert over money, but one lacking in much discretion.

The role of the Fed changed somewhat in the 1920s as the System’s leadership developed a more sophisticated understanding of how monetary actions at the Fed could steer the broad economy.⁹² A new economic intellectual elite gained influence at the Fed, including those like Irving Fisher, whose work generally established that the quantity of money, along with its velocity, affected the price level.⁹³ So even as the Fed began in the 1920s to dip its toe into the water of using policy tools to move the price level—regulating the value of money—it always did so on the basis of technocratic decision-making—on the burgeoning science of macroeconomics.⁹⁴

Only a decade later would Congress seriously consider formally delegating its power to “regulate the value” of money, as well as more expansively interpreting that clause.⁹⁵ Still, even when the idea of creating a Federal Monetary Authority within the Fed to actively stabilize prices was first proposed in 1937, congressmen of both political parties widely shared the view that any such new Fed organ should be free of political—i.e., presidential—influence or control.⁹⁶

⁹² See Perry Mehrling, *Retrospectives: Economists and the Fed: Beginnings*, 16 J. ECON. PERSPS. 207, 211 (2002) (economists began embracing “the idea of active management by a central bank” that could “be operated on a scientific basis, using the most advanced statistical and theoretical tools to guide its intervention”).

⁹³ IRVING FISHER, *THE PURCHASING POWER OF MONEY* 14 (1911); see Mehrling, *supra* note 92, at 211 (explaining in modern day terms the quantity theory of money).

⁹⁴ See Mehrling, *supra* note 92, at 211 (“In Fisher’s hands, economic science offered the prospect of keeping the politics out of money even while embracing centralization and active management.”). For a description of macroeconomics, see *FAQs: What is Macroeconomics?*, FED. RSRV. (Oct. 19, 2017), <https://www.federalreserve.gov/faqs/what-is-macroeconomics.htm> [<https://perma.cc/AT39-CN86>].

⁹⁵ See *Monetary Authority Act: Hearings on S. 1990 Before the Subcomm. of the S. Comm. on Agric. & Forestry*, 75th Cong. 116 (1937) (statement of Sen. Elmer Thomas, Member, S. Comm. on Agric. & Forestry) (“The Constitution provides very specifically that the Congress shall have the power to coin money and to regulate the value thereof, and we are only presuming now to consider the advisability of vitalizing that provision of the Constitution. . . . It never has been done, and there have been reasons for it not having been done, but it occurs to some of us that the time has come where it is not only advisable, but absolutely necessary.”).

⁹⁶ See generally *id.*; see also Skinner, *supra* note 19, at 2, 14–16 (discussing the technocratic core of the Fed’s price stability mandate). Now, to be fair, the Treasury Secretary was made an ex officio member of the Federal Reserve Board, though there is no other indication that Congress intended to make the newly created System in any way subservient to the President. See *Andrew W. Mellon*, FED. RSRV. HIST., <https://www.federalreservehistory.org/people/andrew-w-mellon> [<https://perma.cc/UYY7-7JH8>] (“Andrew W. Mellon served as secretary of the Treasury from March 4, 1921, to February 12, 1932. Under the provisions of the original Federal Reserve Act, this meant he was also ex-officio chairman of the Federal Reserve Board.”). It would not be

Congress was also rather disciplined in delegation when it created the U.S. Treasury by statute in 1789.⁹⁷ It held close to the reins. For one, the Treasury's organic statute ensured that responsibilities given to the agency's leadership would be specified in detail and that there would be internal checks and balances.⁹⁸ The Secretary was given a number of highly "specific functions," and other officers in the department—e.g., the Comptroller, Auditor, Treasurer, and Registrar—would be subject to the Senate confirmation process, an important measure of *ex ante* congressional accountability.⁹⁹ Above all, the proliferation of other officers was "meant to provide checks on the Secretary and each other in the crucial matter of safeguarding the integrity of the fiscal and monetary affairs of the nation."¹⁰⁰

Moreover, accountability flowed to Congress at least as much as to the President. The statute required that the Secretary of the Treasury report directly to each house of Congress.¹⁰¹ Tellingly, the President was not mentioned in the statute. In contrast to the statutes constituting the War and Foreign Affairs Department, the Treasury was not initially "denominated an 'Executive Department.'"¹⁰² As Professor Mashaw explains it: "Given that the Treasury was where much of the real power lay in the early structure of the American government . . . Congress seemed jealous of its own authority over the Department."¹⁰³ Put simply, the Treasury began its life as "functionally a part of the Congress."¹⁰⁴

Notably, even well after the Founding, it was not assumed the Treasury—in lieu of Congress—could withdraw funds from the public fisc and spend them.¹⁰⁵

until 1977 that the Fed would get a formal price stability mandate from Congress. *See* Skinner, *supra* note 19, at 3–4.

⁹⁷ *See About: Act of Congress Establishing the Treasury Department*, U.S. DEP'T TREASURY (Oct. 26, 2010, 11:02 AM), <https://home.treasury.gov/history/act-of-congress-establishing-the-treasury-department> [<https://perma.cc/Z3HJ-G38G>].

⁹⁸ *See id.*

⁹⁹ *See* MASHAW, *supra* note 8, at 40.

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at 41 ("The initial Treasury statute thus appears to make the Secretary of the Treasury responsible primarily to Congress rather than to the President.").

¹⁰² *Id.* But *see* Ilan Wurman, *The Removal Power: A Critical Guide*, 2019–2020 CATO SUP. CT. REV. 157, 181 (noting that the Secretary of Treasury "was denominated an 'executive officer'" in the bill providing for salaries).

¹⁰³ MASHAW, *supra* note 8, at 41.

¹⁰⁴ *Id.*

¹⁰⁵ *See* *Knote v. United States*, 95 U.S. 149, 154 (1877) (holding that there could be no delivery of seized funds to a pardoned criminal without formal appropriation law by Congress).

* * *

In summary, The Framers of the Constitution were quite intentional—and parsimonious—in vesting monetary and fiscal powers in the legislature in Article I. For over one hundred years, Congress maintained the dividing line between Congress’s money powers and the President. But throughout the twentieth and twenty-first centuries, when pressed with economic emergency, Congress opted to blur that line and increasingly delegate these powers to the President.

II. THE SHIFT TO PRESIDENTIAL DELEGATION

This Part examines in close detail key instances of statutory delegation that contributed to the birth of the Monetary Executive. In particular, this Part studies delegations that have created statutory bases for a president to affect the value of money—either directly through changes to the supply of money or indirectly through spending programs that affect people’s perception of the government’s ability to repay public debt.

A. *Executive Order and Economic Emergency*

Despite the longstanding historical practice, the Constitution does not expressly supply the President with the authority to issue edicts that resemble laws.¹⁰⁶ By the middle of the twentieth century, the Supreme Court had recognized the constitutional ambiguity around the practice, most directly in the 1952 Steel Seizure Case, *Youngstown Sheet & Tube Co. v. Sawyer*.¹⁰⁷ That case involved the President’s seizure of steel mills to facilitate the Korean War effort; as such, the Court was especially focused on the scope of the President’s power to face off against national emergencies.¹⁰⁸ Although the Court observed that Congress had only recently, in the 1930s, resorted to empowering the President in such respects, it did not have occasion to reflect upon the particular ways in which Congress had already begun to delegate its Article I *money-related powers* to the President to invoke against emergency.¹⁰⁹

¹⁰⁶ VIVIAN S. CHU & TODD GARVEY, CONG. RSCH. SERV., RS20846, EXECUTIVE ORDERS: ISSUANCE, MODIFICATION, AND REVOCATION 2 (2014) (“Just as there is no definition of executive orders, presidential memoranda, and proclamations in the U.S. Constitution, there is, likewise, no specific provision authorizing their issuance.”).

¹⁰⁷ 343 U.S. 579, 643–44 (1952).

¹⁰⁸ *Id.* at 582–84, 643.

¹⁰⁹ See generally *id.* Indeed, Professor McConnell’s framework is likely more instructive, or at least helpful, to illuminate the issue: in lieu of *Youngstown*, Professor McConnell suggests a tripartite framework organized around whether an exercise of power is a prerogative power, a

1. President Roosevelt

The Franklin D. Roosevelt (“FDR”) Administration began in the midst of the Great Depression. Shortly after FDR took office, Congress passed the Emergency Banking Act on March 9, 1933.¹¹⁰ The Act supplied FDR with sweeping powers to address the unfolding banking crisis, including regulating all foreign exchange transactions and gold movements—specifically, in section 2, it gave the Secretary of the Treasury the discretion to compel the surrender of gold.¹¹¹ Section 2 of the Emergency Banking Act had amended section 5(b) of the Trading with the Enemy Act—which applied during wartime only—to apply to peacetime emergencies.¹¹²

Roosevelt took unprecedented monetary action with that power. First, on April 5, 1933, he issued Executive Order 6102 to confiscate—i.e., nationalize—gold from private citizens.¹¹³ The Order required all private citizens and corporations to surrender their gold to the Federal Reserve at the exchange rate of \$20.67 per ounce.¹¹⁴

This confiscation was touted as an emergency measure to support the Federal Reserve’s ability to maintain the money supply.¹¹⁵ At the time, the Federal Reserve Act required that all Federal Reserve notes, the official term for “dollar,” be backed forty percent by gold.¹¹⁶ Due to the Fed’s reduced interest rates, gold was flowing out of the country.¹¹⁷ Accordingly, the Fed’s gold stock was running precariously low, putting into question its ability to maintain the required backing of gold to outstanding currency.¹¹⁸ Confiscating privately owned gold was

delegated power, or a residual power. The presidential actions fall under the delegation category, but they may run afoul of the proviso that they are exercised “subject to statutory specification” or that the actions go beyond what is necessary to attend to the “executive part of the business” of a statute. See McCONNELL, *supra* note 7, at 276–77.

¹¹⁰ *Franklin D. Roosevelt: 1933-1945*, WHITE HOUSE HIST. ASS’N, <https://www.whitehousehistory.org/bios/franklin-roosevelt> [<https://perma.cc/C7C9-A5C4>]; Emergency Banking Act, Pub. L. No. 73-1, 48 Stat. 1 (1933).

¹¹¹ Emergency Banking Act § 3; Richardson et al., *supra* note 59.

¹¹² Emergency Banking Act § 2; Trading with the Enemy Act, Pub. L. 65-91, § 5(b), 40 Stat. 411, 415 (1917) (codified as amended at 50 U.S.C. §§ 4301–41).

¹¹³ Exec. Order No. 6102 (Apr. 5, 1933), *reprinted in* 2 THE PUBLIC PAPERS AND ADDRESSES OF FRANKLIN D. ROOSEVELT 111, 112 (1938); *see* Bordo, *supra* note 59.

¹¹⁴ *See* Bordo, *supra* note 59.

¹¹⁵ *See* Greene, *supra* note 15.

¹¹⁶ Federal Reserve Act, Pub. L. No. 63-43, § 16, 38 Stat. 251, 266 (1913) (codified as amended in scattered sections of 21 U.S.C.). This provision was found in the original section 11(c). *See* Richardson et al., *supra* note 59.

¹¹⁷ *See* Richardson et al., *supra* note 59.

¹¹⁸ *Id.*

one sure way to replenish the Fed's gold supply.¹¹⁹ Increasing the Fed's gold stores by confiscation would also handily allow the Fed to issue more Federal Reserve notes, thereby inflating the money supply, consistent with FDR's overall economic policy goals.¹²⁰

Shortly after, on April 20, 1933, FDR suspended the gold standard with Executive Order No. 6111.¹²¹ The proclamation prohibited all exports of gold and the Treasury and other financial institutions would no longer be permitted to convert currency and deposits into gold.¹²² This halted all gold outflows, suspended the basic premise of a gold-backed paper currency, and effectively abandoned the gold standard.¹²³ Congress would later, on June 5, 1933, facilitate Roosevelt's aims by abrogating all gold clauses in private contract through a Joint Resolution.¹²⁴ From the vantage point of the Constitution, the deprivation of property was quite remarkable.¹²⁵

Roosevelt also wanted to cause inflation. Indeed, at the same time that Roosevelt took the United States off the gold standard, he "pledged to seek broad powers from Congress to raise prices."¹²⁶ Con-

¹¹⁹ *Id.*

¹²⁰ *Id.*; see also James W. Angell, *Gold, Banks and the New Deal*, 49 POL. SCI. Q. 481, 485 (1934) (noting that President Roosevelt took both steps "designed only to deal with the immediate emergency" and other steps that "were of a more permanent character, and reflected the adoption of quite new monetary and banking policies").

¹²¹ Exec. Order No. 6111 (Apr. 20, 1933), <https://www.presidency.ucsb.edu/documents/executive-order-6111-transactions-foreign-exchange> [<https://perma.cc/4XK5-JPRW>]. For a history of the gold standard from World War I to the New Deal era, see generally Leland Crabbe, *The International Gold Standard and U.S. Monetary Policy from World War I to the New Deal*, 1989 FED. RSRV. BULL. 423, <https://fraser.stlouisfed.org/files/docs/meltzer/craint89.pdf> [<https://perma.cc/E8XR-PBUB>].

¹²² Exec. Order No. 6111, *supra* note 121.

¹²³ Richardson et al., *supra* note 59.

¹²⁴ H.R.J. Res. 192, 73d Cong. (1933).

¹²⁵ U.S. CONST. amend. V ("No person shall . . . be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation." (emphasis added)). Seizing private gold at a forced exchange and subsequently devaluing the dollar alters private contract to the benefit of debtors and the detriment of creditors. Remember: since gold clauses had been struck from contracts by Congress's June 1933 Joint Resolution, private parties would be compelled to accept dollars in lieu of gold in satisfaction of obligations already made—but the exchange would be at the new gold equivalent price. H.R.J. Res. 192. To illustrate, consider the following hypothetical contract that is denominated in gold, say, 1,000 ounces. Before the devaluation, the creditor would be owed back the equivalent of \$48.38. After the devaluation, the creditor would only be repaid \$28.57. For Madison in 1800, most worrisome were those delegations to the President by which "property [is] deprived of its value to the owner." See Wurman, *supra* note 13, at 1513 (quoting JAMES MADISON, *The Report of 1800*, in 17 THE PAPERS OF JAMES MADISON 303, 325 (David B. Mattern et al. eds., 1991)).

¹²⁶ Andrew Jalil & Gisela Rua, *Inflation Expectations and Recovery from the Depression in 1933: Evidence from the Narrative Record* 14 (Fed. Rsrv. Bd., Working Paper No. 2015-029,

gress complied. On May 12, 1933, Congress gave Roosevelt the additional monetary powers he requested, in Title III of the Agricultural Adjustment Act.¹²⁷ This provision came to be known as the “Thomas Inflation Amendment” after its sponsor, Elmer Thomas, and in light of the objective of the powers.¹²⁸

The Thomas Amendment gave the President three main categories of monetary power. First, it gave the President the power to strongly encourage the Reserve Banks of the Federal Reserve System to buy up to \$3 billion in Treasury bonds—today, we would refer to that as debt monetization.¹²⁹ Second, should the \$3 billion in asset purchases prove insufficient, or the Reserve Banks unwilling, Section 43(b)(1) of the Act gave the President the power to directly inflate the money supply by directing the Treasury to print \$3 billion in United States notes (greenbacks).¹³⁰ Finally, the Act gave the President the power to reduce the gold content of the dollar by fifty percent—the Gold Reserve Act of 1934 later amended that figure to sixty percent.¹³¹

The unprecedented nature of these powers cannot be overstated. At the time, they were recognized as a total grant of power to the President to control monetary affairs.¹³² *The Economist* reported on the Thomas Amendment “as giving President Roosevelt dictatorial powers to control inflation: the country has exchanged a President with little effective power for a currency dictator.”¹³³ One notable economist of the times, Edwin Kemmerer, remarked that the Thomas Amendment gave

the President and his appointees a legal authority over the nation’s currency that is almost complete. A Stalin or a Hitler could hardly have more. The things that the President has legal authority to do to the currency directly and their

2015), https://www.federalreserve.gov/econresdata/feds_2015_files_2015029pap.pdf [perma.cc/G42A-JXDB].

¹²⁷ Agricultural Adjustment Act, Pub. L. No. 73-10, § 43, 48 Stat. 31, 51–53 (1933) (codified as amended at 31 U.S.C §§ 5301(a)–(c), 5304(1)).

¹²⁸ See generally Jalil & Rua, *supra* note 126. There is very little scholarship or commentary on the Thomas Inflation Amendment. The principal works consist of Elmus Wicker, *Roosevelt’s 1933 Monetary Experiment*, 57 J. AM. HIST. 864 (1971) and John Hanna, *The Banking Act of 1935*, 22 VA. L. REV. 757 (1936).

¹²⁹ Agricultural Adjustment Act § 43(a); see Thornton, *supra* note 20, at 30 (defining the phrase “monetizing the debt”).

¹³⁰ Agricultural Adjustment Act § 43(b)(1).

¹³¹ *Id.* § 43(b)(2); Gold Reserve Act of 1934, Pub. L. No. 73-87, § 12, 48 Stat. 337, 342–43.

¹³² See Jalil & Rua, *supra* note 126, at 15.

¹³³ *Id.* (internal quotation marks omitted).

necessary implications could give us a gold standard, a silver standard, a bimetallic standard, a paper money standard or a commodity dollar standard. They could give us serious deflation or a runaway inflation.¹³⁴

And of course, it completely suspended the Fed's independence to decide the best monetary course for the economy.

The "most dramatic use of the Thomas Amendment came on January 31, 1934."¹³⁵ With Presidential Proclamation No. 2072, Roosevelt devalued the dollar, just as Congress authorized him to do in the Thomas Amendment, as amended by the Gold Reserve Act.¹³⁶ Roosevelt decreased the gold content of the dollar to 40.94% which meant that the government's fixed price for gold was increased to \$35 per ounce.¹³⁷ The effect was to increase the value of gold on the Federal Reserve's balance sheet by sixty-nine percent but massively devalue the credit assets of private parties whose contracts had been denominated in gold and now had to accept paper.¹³⁸ In regard to this executive action, Roosevelt's "emergency" was again an economic one—deflation. Apparently, FDR believed that economic recovery amid the Great Depression could not begin *until* the price level had risen and boosted consumer sentiment.¹³⁹ And, to that end, he thought that devaluing the dollar could spur reflation.¹⁴⁰

These Executive Actions—and the congressional delegations that enabled them—were far afield from the constitutional norms theretofore.¹⁴¹ By the 1930s, the dangers that had motivated the Framers to guard against monetary delegations in the first place had crystallized

¹³⁴ See George Selgin, *The New Deal and Recovery, Part 4: FDR's Fed*, CATO INST. (July 6, 2020, 4:55 PM), <https://www.cato.org/blog/new-deal-recovery-part-4-fdrs-fed> [<https://perma.cc/D59R-QH7V>].

¹³⁵ David D. Webb, *Thomas Amendment*, OKLA. HIST. SOC'Y, <https://www.okhistory.org/publications/enc/entry.php?entry=th007> [<https://perma.cc/QSB5-E367>].

¹³⁶ Proclamation No. 2072 (Jan. 31, 1934), <https://www.presidency.ucsb.edu/documents/proclamation-2072-fixing-the-weight-the-gold-dollar> [<https://perma.cc/4WEC-NL5Y>].

¹³⁷ See George Selgin, *The New Deal and Recovery, Part 7: FDR and Gold*, ALT-M (Aug. 7, 2020), <https://www.alt-m.org/2020/08/07/the-new-deal-and-recovery-part-7-fdr-and-gold/> [<https://perma.cc/D7G4-F5FR>]; Robert G. Anderson, *Gold Is Legal, But . . .*, FOUND. FOR ECON. EDUC. (Jan. 1, 1975), <https://fee.org/articles/gold-is-legal-but/> [<https://perma.cc/9MV2-ZA3E>].

¹³⁸ See Selgin, *supra* note 137; ELWELL, *supra* note 56.

¹³⁹ Wicker, *supra* note 128, at 866 ("A rise in prices, the President thought, was a necessary condition for initiating a change in economic activity.").

¹⁴⁰ FDR also disregarded markets in favor of Executive Branch power to effectuate the devaluation itself. See Richardson et al., *supra* note 59. The overall program thus aimed to raise domestic commodity prices, returning them to 1926 levels, while also recalibrating balance of payments by encouraging exports and discouraging imports. *Id.* Part of this effort involved establishing the Reconstruction Finance Corporation and instructing it to buy gold. *Id.*

¹⁴¹ *Id.*

into a politicized use of money.¹⁴² FDR's objective of boosting the price level stemmed from a belief that the general public—and farmers in particular—would perceive a boost in price levels as a proxy for good business conditions and thus the political *sine qua non* to restoring confidence in the economy.¹⁴³ FDR had been an ardent supporter of various spending programs to raise the price level; he welcomed these new monetary powers from Congress in order to further that fiscal aim.¹⁴⁴

Federal Reserve officials at the time vehemently disagreed with the President's decided course of action in regard to the money supply.¹⁴⁵ For fear that they would be formally compelled to monetize the deficit—per the Thomas Amendment—the Reserve banks felt compelled to acquiesce to presidential “requests” to buy government debt, and so they liberally engaged in open market operations very much against their better judgment.¹⁴⁶ Overall, FDR's inflationary policy pressure “was viewed as totally irresponsible by all Federal Reserve officials.”¹⁴⁷ This led “[o]fficers and directors of the Federal Reserve Bank of New York, . . . [to] ‘debate[] whether they could ethically implement a policy which they considered to be wholly unsound.’”¹⁴⁸ They recognized that the Thomas Amendment had made the Federal Reserve “subservient to the President” and “[t]he Open Market Committee continued to purchase securities in October for no other reason than it did not wish to precipitate an open conflict with the President.”¹⁴⁹ Just a few years later, during hearings on the Banking Act of 1935, one expert remarked to Congress that “[t]he President has today full power to proceed on virtually any monetary or credit theory that he wishes to proceed on, under the powers granted by the Thomas amendment.”¹⁵⁰ Ironically, Congress had given the President the power to undermine its own monetary agent, the Federal Reserve.

The question of repealing portions of the Thomas Amendment arose for Congress in 1945. In May 1945, the then-Chairman of the

¹⁴² See *id.* (noting these fiscal goals included “rais[ing] American prices of commodities . . . [and] lower[ing] prices of American goods abroad”).

¹⁴³ See Wicker, *supra* note 128, at 866.

¹⁴⁴ See *id.* at 867–88.

¹⁴⁵ See *id.* at 870.

¹⁴⁶ *Id.* at 870–71.

¹⁴⁷ *Id.* at 867.

¹⁴⁸ Richardson et al., *supra* note 59 (quoting LESTER V. CHANDLER, AMERICAN MONETARY POLICY, 1928–1941, at 289 (1971)).

¹⁴⁹ Wicker, *supra* note 128, at 873.

¹⁵⁰ *Banking Act of 1935: Hearings on S. 1715 and H.R. 7617 Before a Subcomm. of the S. Comm. on Banking and Currency, 74th Cong. 436 (1935).*

Federal Reserve, Marriner Eccles, sought advice from his general counsel, Howard Hackley, about the Thomas Amendment and specifically “the Situation If It Were Repealed” by a bill pending in the House of Representatives.¹⁵¹ Hackley’s analysis was that several of the provisions were now moot: the section 43(b)(2) powers—in relation to fixing the weight of the gold dollar—had expired;¹⁵² the President’s ability to coin unlimited silver was likely superseded by the Silver Purchase Act; and the greenback provision may have been repealed by portions of the Reserve Ratio bill.¹⁵³

But three remnants still remained. For one, the President’s ability to direct the Reserve Banks to engage in open market operations to purchase government debt seemed uninterrupted by any intervening legislation.¹⁵⁴ In addition, section 43(a) had supplied a rather broad catchall authority that also seemed untouched: that the Federal Reserve Board could, with consultation from the Secretary of the Treasury, compel the Reserve Banks “to take such action as may be necessary, in the judgment of the Board and of the Secretary of the Treasury, to prevent undue credit expansion.”¹⁵⁵ Hackley thought it preferable to *preserve* that catchall power. His memo noted: “it would seem most unwise, at a time when control of credit is particularly important, to repeal any provision of law which may be of assistance in meeting inflationary forces likely to develop.”¹⁵⁶

Over the years, all but one provision of the Thomas Amendment were repealed.¹⁵⁷ That which was originally codified as section 821 in title 31 of the U.S. Code remained, and in 1982 that provision was recodified into section 5301.¹⁵⁸ Section 5301(a) provides:

The President may direct the Secretary of the Treasury to make an agreement with the Federal reserve banks and the

¹⁵¹ Memorandum from Howard H. Hackley, Gen. Couns., Fed. Rsrv. Bd. to Marriner S. Eccles, Chairman, Fed. Rsrv. Bd. 1 (May 16, 1945) [hereinafter Hackley Memo], https://fraser.stlouisfed.org/files/docs/historical/eccles/046_13_0002.pdf [<https://perma.cc/5TM9-JMHS>].

¹⁵² The Gold Reserve Act of 1934, Section 12, set an expiration date of this provision of 1936. Gold Reserve Act of 1934, Pub. L. No. 73-87, § 12, 48 Stat. 337, 342–43. The Hackley Memo appears to state that this provision expired in 1943. *See* Hackley Memo, *supra* note 151, at 1.

¹⁵³ Hackley Memo, *supra* note 151, at 1–2.

¹⁵⁴ *Id.*

¹⁵⁵ Agricultural Adjustment Act, Pub. L. No. 73-10, § 43(a), 48 Stat. 31, 51–52 (1933) (codified as amended at 31 U.S.C §§ 5301(a)–(c), 5304(1)).

¹⁵⁶ Memorandum from Howard H. Hackley, Gen Couns., Fed. Rsrv. Bd. to Marriner S. Eccles, Chairman, Fed. Rsrv. Bd. 2 (May 19, 1945), https://fraser.stlouisfed.org/files/docs/historical/eccles/046_13_0002.pdf [<https://perma.cc/5TM9-JMHS>].

¹⁵⁷ *Compare* Agricultural Adjustment Act § 43(a), *with* 31 U.S.C. § 5301 (2018).

¹⁵⁸ 31 U.S.C. § 5301.

Board of Governors . . . when the President decides that the foreign commerce of the United States is affected adversely because . . . an economic emergency requires an expansion of credit; or . . . an expansion of credit is necessary so that the United States Government and the governments of other countries can stabilize the value of coins and currencies of a country.¹⁵⁹

The lasting impacts of the Thomas Amendment provision are quite significant. For one, as it exists today, section 5301 gives the President broad power to more or less direct the Federal Reserve in matters of global economic emergency or currency affairs—today, a wide range of contexts to be sure.¹⁶⁰ In addition, section 5301(c) retains that “[w]ith the approval of the [Treasury] Secretary, the Board may require Federal reserve banks to take action the Secretary and Board consider necessary to prevent unreasonable credit expansion.”¹⁶¹

The potency of these latent, sleeping powers cannot be overstated. There is a wide range of circumstances under which a President, directing the Treasury Secretary, could use these powers to exert significant control over money and credit. Per the language of section 5301(a), nearly any global disruption could be said to require an expansion of credit.¹⁶² Based on such an assessment a president could, for example, strongly influence if not direct the Fed to embark on a policy of quantitative easing, whereby the central bank purchases trillions of dollars of government bonds on the open market, in the name of “credit expansion.”¹⁶³ Effectively, this could amount to statutory authority to order the monetizing of the federal deficit.

Section 5301(c) is still more troubling yet. Here, the President has an overt power of direction to “prevent” credit expansion—but for what purpose, under what conditions, for how long, and in what way? The statute does not say. Consequently, any future president could latch on to this provision to restrain credit in any sector of the economy that they find unpalatable to the administration’s goals.

¹⁵⁹ *Id.* § 5301(a)(3)–(4).

¹⁶⁰ *See generally id.*

¹⁶¹ *Id.* § 5301(c).

¹⁶² *Id.* § 5301(a).

¹⁶³ For a discussion of quantitative easing, see Eric Milstein, Tyler Powell & David Wessel, *What Does the Federal Reserve Mean When It Talks About Tapering?*, BROOKINGS (Jan. 27, 2022), <https://www.brookings.edu/blog/up-front/2021/07/15/what-does-the-federal-reserve-mean-when-it-talks-about-tapering/> [<https://perma.cc/8SQU-PLZC>]. For a discussion of the potential problems associated with quantitative easing, see HOUSE OF LORDS REPORT, *supra* note 24; *see also infra* Section III.B.

As for the Emergency Banking Act, the emergency that Roosevelt declared lasted from 1933 to 1978, when Congress formally terminated FDR's emergency.¹⁶⁴ But the legacy of the Emergency Banking Act lived on and was reincarnated in future financial crisis emergency legislation, as we will soon see.

2. *Presidents Johnson and Nixon*

As just discussed, after Roosevelt's 1933 suspension of the Gold Standard, domestically, dollars could only henceforth be converted to gold for international transactions.¹⁶⁵ This quasi-gold standard existed until World War II. After the war, delegates from forty-four countries convened at Bretton Woods, New Hampshire to discuss what could be done to maintain currency stability in an economically integrated—ideally more harmonious—world.¹⁶⁶

The delegates to the Bretton Woods conference drew upon lessons of the prewar gold standard but sought to modernize it in light of aspiring international economic integration and cooperation.¹⁶⁷ In their currency agreement, the delegates agreed to an exchange rate regime that would use gold *and U.S. dollars* as its anchor.¹⁶⁸ According to the plan, the values of all other currencies would be fixed relative to the U.S. dollar, and the dollar's value would be expressed in gold at the prevailing price of \$35 per ounce.¹⁶⁹ Other countries would continue to keep gold reserves, but would generally settle their accounts with dollars.¹⁷⁰

¹⁶⁴ This was done with the passage of the National Emergencies Act, passed into law on September 14, 1976. *See* National Emergencies Act, Pub. L. No. 94-412, § 101(a), 90 Stat. 1255 (1976) ("All powers and authorities possessed by the President . . . as a result of the existence of any declaration of national emergency in effect on the date of enactment of this Act are terminated two years from the date of such enactment."). The International Emergency Economic Powers Act, passed into law on December 28, 1977, restricted the Trading with the Enemy Act to wartime. *See* International Emergency Economic Powers Act, Pub. L. No. 95-223, § 101(a), 91 Stat. 1625, 1625 (1977). It repealed the emergency clause of section 12 of the Gold Reserve Act and arranged for that authority to expire according to the National Emergencies Act. *See id.* § 101(b).

¹⁶⁵ ELWELL, *supra* note 56, at 9–10.

¹⁶⁶ Sandra Kollen Ghizoni, *Creation of the Bretton Woods System*, FED. RESRV. HIST. (Nov. 22, 2013), <https://www.federalreservehistory.org/essays/bretton-woods-created> [<https://perma.cc/2GFU-24CR>].

¹⁶⁷ *See id.*

¹⁶⁸ *Nixon and the End of the Bretton Woods System, 1971–1973*, U.S. DEP'T. OF STATE: OFF. OF THE HISTORIAN, <https://history.state.gov/milestones/1969-1976/nixon-shock> [<https://perma.cc/R76F-7S5W>].

¹⁶⁹ *Id.*

¹⁷⁰ ELWELL, *supra* note 56, at 11.

A new international monetary institution—the International Monetary Fund (“IMF”)—was also created to facilitate this currency arrangement.¹⁷¹ Under the old international monetary regime, countries with currencies that were overvalued experienced gold outflows and subsequent deflation until the currency’s value appreciated in line with market forces.¹⁷² The IMF would be used to assist nations experiencing short-term payment imbalances.¹⁷³

However, the basic design of this new *international* monetary system eventually posed *domestic* monetary and fiscal problems in the United States. Because the system was set up to mirror the old gold standard, with member countries pegged to the dollar and the dollar pegged to gold, the United States would need to engage in contractionary monetary policy whenever gold flowed out of the country.¹⁷⁴ This is because while the dollar is backed by (but not convertible with) gold, the Federal Reserve Banks have to maintain a minimum ratio of gold reserves to currency and deposits.¹⁷⁵ As such, when gold flows out of the country, the money supply must necessarily shrink to maintain that gold-to-dollar ratio.¹⁷⁶

The Fed would need to raise interest rates to help restore this international balance.¹⁷⁷ The mechanism is as follows: higher rates and a contracting money supply cause price levels to fall; with a weaker dollar, exports increase, U.S. goods now seem cheaper to foreigners, and the U.S. experiences a balance of payments surplus.¹⁷⁸ This prompts gold to flow back into the country.¹⁷⁹ Internationally, as such, this monetary system was set up to be self-correcting in line with the nature of a true gold standard.¹⁸⁰

¹⁷¹ See Ghizoni, *supra* note 166.

¹⁷² ELWELL, *supra* note 56, at 11–12.

¹⁷³ *IMF Lending*, INT’L MONETARY FUND (Dec. 2021), <https://www.imf.org/en/About/Factsheets/IMF-Lending>.

¹⁷⁴ Robert L. Hetzel, *Launch of the Bretton Woods System*, FED. RESRV. HIST. (Nov. 22, 2013), <https://www.federalreservehistory.org/essays/bretton-woods-launched> [https://perma.cc/54DV-HVXD].

¹⁷⁵ See Federal Reserve Act., Pub. L. No. 63-43, § 16, 38 Stat. 251, 265–68 (1913) (codified as amended in scattered sections of 21 U.S.C.).

¹⁷⁶ Crabbe, *supra* note 121, at 427 (“The required minimum ratio limited the Federal Reserve’s authority to augment the money supply, which could continue to expand only so long as gold flowed into reserves.”).

¹⁷⁷ Hetzel, *supra* note 174.

¹⁷⁸ *Id.*

¹⁷⁹ See *id.*

¹⁸⁰ See *id.*; see generally Michael D. Bordo, *The Bretton Woods International Monetary System: A Historical Overview*, in *A RETROSPECTIVE ON THE BRETTON WOODS SYSTEM: LESSONS*

But it was incompatible with the fiscal goals of the 1960s Presidents. By 1964, the Johnson Administration was committed to a policy of full employment—thought to be around four percent—a politically and fiscally oriented goal that had its roots in Roosevelt-era promises that the government could and should guarantee full employment.¹⁸¹ This presidential goal made it politically very difficult for the Fed to raise rates when needed, as the IMF system required during that period.¹⁸²

The President overrode the international monetary mechanism in favor of domestic concerns by imposing capital controls. Executive Order 11,387, signed January 1, 1968, limited lending abroad and foreign direct investment.¹⁸³ Specifically, the Order empowered the Secretary of Commerce to “require, as he determines to be necessary or appropriate to strengthen the balance of payments position of the United States, that any person . . . [with] as much as a ten percent interest in the voting securities, capital or earnings of . . . [a] foreign business” repatriate related earnings or bank deposits to the United States.¹⁸⁴

To ground his order in a statute,¹⁸⁵ President Johnson relied on the powers afforded to the President in section 5(b) of the Trading with the Enemy Act (“TWEA”)—the very same powers Roosevelt used, inherently, to suspend the Gold Standard in 1933.¹⁸⁶

FOR INTERNATIONAL MONETARY REFORM 3 (Michael D. Bordo & Barry Eichengreen eds., 1993).

¹⁸¹ See Lyndon B. Johnson, U.S. President, Annual Message to the Congress: The Economic Report of the President (Jan. 28, 1965), in AM. PRESIDENCY PROJECT, <https://www.presidency.ucsb.edu/documents/annual-message-the-congress-the-economic-report-the-president-11> [<https://perma.cc/W4MN-B3VR>]; see also Salib & Skinner, *supra* note 18, at 964–65. For a discussion on the fiscal nature of a full employment goal, see Skinner, *supra* note 19.

¹⁸² See Salib & Skinner, *supra* note 18, at 963–65 (discussing President Johnson’s pressuring of Fed Chair Martin not to raise rates).

¹⁸³ See Exec. Order No. 11,387, 3 C.F.R. 437 (1969).

¹⁸⁴ *Id.*

¹⁸⁵ It will be recalled that just a decade earlier, the Supreme Court had ruled in *Youngstown* that executive orders must be grounded in a grant of authority from a statute or an express Article II power. *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 585 (1952) (“The President’s power, if any, to issue the order must stem either from an act of Congress or from the Constitution itself.”). The President’s legal advisors would no doubt have been cognizant of this.

¹⁸⁶ Trading With the Enemy Act, Pub. L. No. 65-91, § 5(b), 40 Stat. 411, 415 (1917) (codified as amended at 50 U.S.C. §§ 4301–41). As discussed, in section 2 of the Emergency Banking Act, Congress extended this provision of the TWEA so that Roosevelt could use its powers outside of war in any national emergency so declared by the President. Emergency Banking Act, Pub. L. No. 73-1, § 2, 48 Stat. 1, 1–2 (1933).

Invocation of the TWEA, however, required an emergency.¹⁸⁷ So President Johnson justified this resort to the TWEA with President Truman's December 1950 Proclamation No. 2914, which had proclaimed a national emergency given "events in Korea and elsewhere."¹⁸⁸ Of course, this was entirely pretextual: the United States had not been engaged in an armed conflict with Korea since 1953 (the year now being 1968), and President Johnson's desire to flout the Bretton Woods monetary arrangement in favor of domestic employment goals was totally unrelated to that conflict.¹⁸⁹

One year later, Richard Nixon was in office. It had become increasingly apparent that there were structural challenges presented by the United States' role in upholding the Bretton Woods Exchange Rate System.¹⁹⁰ As the world demanded dollars as reserves, the United States' deficits grew and the Treasury's stock of gold decreased, creating the risk that the United States would at some point be unable to redeem dollars for gold as expected under Bretton Woods.¹⁹¹ This, along with other events, eventually sparked massive speculation against the U.S. dollar in May 1971.¹⁹²

In a televised speech on August 15, 1971, Nixon unilaterally "closed" the "gold window,"¹⁹³ pronouncing that the United States would no longer convert foreign-held dollars to gold in line with the Bretton Woods system.¹⁹⁴ At the same time, Nixon announced several

¹⁸⁷ Trading With the Enemy Act § 5(b); Emergency Banking Act § 2.

¹⁸⁸ Proclamation No. 2914, 15 Fed. Reg. 9029 (Dec. 19, 1950).

¹⁸⁹ See James L. Butkiewicz & Scott Ohlmacher, *Ending Bretton Woods: Evidence from the Nixon Tapes*, 74 ECON. HIST. REV. 922, 925 (2021) (discussing international factors that put domestic pressure on the Bretton Woods arrangement).

¹⁹⁰ *Id.* at 924–27.

¹⁹¹ See *id.* at 923–24. This state of affairs is also referred to as a "Triffin dilemma." As Michael Bordo and Robert McCauley explain the theory as originally set out by Robert Triffin:

If the United States eliminated its "overall balance of payments deficits"—its accumulation of short-term liabilities to the rest of the world—it would deprive the world economy of international liquidity needed for the expansion of global trade. If the United States did continue to provide international liquidity, then eventually US policy would be unable to lower interest rates without a run on the gold stock. Either way, deflation and depression threatened.

Michael D. Bordo & Robert N. McCauley, *Triffin: Dilemma or Myth?* 3 (Nat'l Bureau of Econ. Rsch., Working Paper No. 24,195, 2018).

¹⁹² See Butkiewicz & Ohlmacher, *supra* note 189, at 928–30.

¹⁹³ See Ghizoni, *supra* note 16.

¹⁹⁴ Edwin L. Dale Jr., *Severs Link Between Dollar and Gold*, N.Y. TIMES (Aug. 16, 1971), <https://www.nytimes.com/1971/08/16/archives/severs-link-between-dollar-and-gold-a-world-effect-unilateral-us.html> [<https://perma.cc/3K63-9N66>]; Richard Nixon, U.S. President, Address to the Nation Outlining a New Economic Policy: The Challenge of Peace (Aug. 15, 1971), in AM. PRESIDENCY PROJECT, <https://www.presidency.ucsb.edu/documents/address-the-nation-outlin->

other domestic economic policies, including, for the first time in United States peacetime history, wage and price controls.¹⁹⁵ Specifically, “[a]fter a 90-day freeze, increases would have to be approved by a ‘Pay Board’ and a ‘Price Commission,’ with an eye toward eventually lifting controls.”¹⁹⁶ He described these reforms to the public as targeting a mix of monetary and fiscal problems: “unemployment, inflation, and international speculation.”¹⁹⁷ He referred to these policies as his “New Economic Plan”—the world would refer to it as the “Nixon Shock.”¹⁹⁸ Monetary and fiscal policy blended and blurred in the presidency once again.

Closing the gold window had far-reaching monetary implications. Internationally, the changes largely benefited the United States.¹⁹⁹ Without the United States’ participation in the convertibility regime, it was inevitable that what was once a fixed-rate exchange regime would become a floating-rate regime.²⁰⁰ And without gold to parallel the dollar, the dollar’s status as *the* reserve currency of the world would be cemented.²⁰¹ Domestically, this impact was to launch the United States into a system of fiat, paper money for the first time since the Civil War. Dollars were no longer backed by gold; the money supply was no longer constrained by gold reserves—henceforth the dollar would be backed only by the full and good faith of the U.S. government.²⁰²

Without a doubt, this was a significant and unprecedented exercise of presidential power over the monetary system.²⁰³ And, like

ing-new-economic-policy-the-challenge-peace#axzz1V6aVsxZ [https://perma.cc/2T4U-Z88N]; Ghizoni, *supra* note 16.

¹⁹⁵ See *The New Economic Policy*, N.Y. TIMES (Aug. 17, 1971), <https://www.nytimes.com/1971/08/17/archives/the-new-economic-policy.html> [https://perma.cc/8MZ4-2AZB].

¹⁹⁶ Gene Healy, *Remembering Nixon’s Wage and Price Controls*, WASH. EXAM’R (Aug. 15, 2011, 12:00 AM), <https://www.washingtonexaminer.com/remembering-nixons-wage-and-price-controls> [https://perma.cc/9STZ-38VE].

¹⁹⁷ Nixon, *supra* note 194 (“Prosperity without war requires action on three fronts: We must create more and better jobs; we must stop the rise in the cost of living; we must protect the dollar from the attacks of international money speculators.”). See 15 U.S.C. § 1022e(c), which gives the President power to combat inflation with certain policy measures. For examples, the President can take action to “alleviat[e] shortages of goods, services, labor and capital . . . to aid in stabilizing prices.” *Id.* Broadly, this statute also gives the President the power to take “other administrative actions . . . as the President deems desirable, to promote reasonable price stability.” *Id.*

¹⁹⁸ Nixon, *supra* note 194; Butkiewicz & Ohlmacher, *supra* note 189, at 924.

¹⁹⁹ See Butkiewicz & Ohlmacher, *supra* note 189, at 936–37.

²⁰⁰ See *id.* at 937.

²⁰¹ See generally *id.*

²⁰² See Nixon, *supra* note 194.

²⁰³ Partly, Nixon intended the policies to be shocking in order to show great strength to the

other presidents exercising great monetary power, Nixon had latched on to an emergency.²⁰⁴ In his televised speech, Nixon referred to the speculation against the dollar as a “monetary crisis” and “an all-out war on the American dollar.”²⁰⁵ But Nixon did not officially close the gold window via an executive order or proclamation as Roosevelt had done during the Depression. Rather, the apparent source of Nixon’s power to end the United States’ participation in Bretton Woods convertibility must have been inferred from the overall discretion that Congress had given the President when it formalized the United States’ role in the Bretton Woods system in 1945.²⁰⁶

After the IMF was established in 1944, each of the member states agreed that they would only deal with the Fund through their nation’s respective “Treasury, central bank, stabilization fund or other similar fiscal agency.”²⁰⁷ Perhaps for that reason, when Congress passed the Bretton Woods Agreements (“BWA”) Act—setting out the United States’ commitments to the Fund and the currency regime more broadly—it placed the President at the helm of the arrangement.²⁰⁸ Section 2 of the BWA Act gave the President the ability to accept any “Articles of Agreement” of the Fund; these would serve as the institution’s governing rules.²⁰⁹ But the BWA Act stipulated to them *ex ante*: the Articles of Agreement could be agreed to, and revised, by the members of the new IMF without review or ratification by Congress.²¹⁰

American public. Butkiewicz & Ohlmacher, *supra* note 189, at 935 (noting that Treasury Secretary Connally had persuaded Nixon at Camp David that “[i]t will be an act of great awareness, great statesmanship, and great courage, and must be presented to the people this way” (quoting H.R. HALDEMAN, *THE HALDEMAN DIARIES: INSIDE THE NIXON WHITE HOUSE* 341 (1994))).

²⁰⁴ See Nixon, *supra* note 194.

²⁰⁵ *Id.*; cf. Butkiewicz & Ohlmacher, *supra* note 189, at 942–43 (affirming, on their review of the relevant Nixon tapes, that although speculation may have forced the decision on August 15, the policy had already been designed at Camp David beforehand). *But see* Christoffer J.P. Zoeller & Nina Bandelj, *Crisis as Opportunity: Nixon’s Announcement to Close the Gold Window*, 5 *SOCIUS* 1, 6 (2019) (arguing that the language of crisis was pretextual, and that “these disruptions provided a public justification for a course of action already decided upon before May 1971, rather than being action-forcing events”). For a comprehensive treatment of that Camp David meeting, see JEFFREY E. GARTEN, *THREE DAYS AT CAMP DAVID: HOW A SECRET MEETING IN 1971 TRANSFORMED THE GLOBAL ECONOMY* 166–245 (2021).

²⁰⁶ See Zoeller & Bandelj, *supra* note 205, at 10–11.

²⁰⁷ Articles of Agreement of the International Monetary Fund art. V, § 1, July 22, 1944, 60 Stat. 1401, 2 U.N.T.S. 39.

²⁰⁸ Bretton Woods Agreements Act, Pub. L. No. 79-171, 59 Stat. 512 (1945) (codified as amended at 22 U.S.C. §§ 286 to 286k, 31 U.S.C. § 5302(d), 18 U.S.C. § 955).

²⁰⁹ *Id.* § 2.

²¹⁰ *Id.* For the original 1944 articles of agreement, see Articles of Agreement of the International Monetary Fund art. V § 1, July 22, 1944, 60 Stat. 1401, 2 U.N.T.S. 39.

In turn, section 4 of the BWA Act created a domestic governance arrangement to make decisions on the United States' behalf concerning the Articles of Agreement.²¹¹ It established a "National Advisory Council on International Monetary and Financial Problems" which placed the Treasury Secretary in charge.²¹² The Council would "recommend to the President general policy directives" to guide the United States representatives to the Fund,²¹³ and any decisions to be made under the Fund's Articles of Agreement would be made by the Council "under the general direction of the President."²¹⁴ So, even though Nixon appears to have disregarded the Articles of Agreement themselves, which required consent from the other members before changing the convertibility regime,²¹⁵ Congress, it would seem, had already given him the power to do so at his will.

Possibly, Congress believed that delegating these Bretton Woods powers to the President was justified by the foreign affairs aura of the system.²¹⁶ But that assessment was arguably mistaken. The President eventually used this power to revise the international monetary order in a way that would implicate monetary policy and money supply—not foreign affairs—most profoundly. Here too, the President used this monetary power to accomplish fiscal goals. The historical evidence shows that Nixon wanted to devalue the dollar to effectuate expansionary monetary policy to ultimately boost employment, which he perceived necessary to win the next election.²¹⁷

²¹¹ Bretton Woods Agreement Act § 4.

²¹² *Id.* § 4(a).

²¹³ *Id.* § 4(b)(1).

²¹⁴ *Id.* § 4(b)(4).

²¹⁵ See IMF, Articles of Agreement art. 3, § 2, 60 Stat. 1401; see also Butkiewicz & Ohlmacher, *supra* note 189, at 936 (noting that Nixon did not request IMF approval before the announcement).

²¹⁶ It bears emphasis that the President does have considerable unilateral authority to use economic sanctions (fashioned through executive order) to address emergencies of foreign affairs. The Trading with the Enemy Act initially instantiated this power and later, the International Emergency Economic Powers Act ("IEEPA") supplied the basis for the Executive Branch's modern sanctions regime. See International Emergency Economic Powers Act, 50 U.S.C. § 1701 et seq. However, this Article distinguishes the president's legitimate constitutional authority to gate access to the U.S. economy for national security purposes—"to affect a situation entirely external to the United States, and falling within the category of foreign affairs"—from the substantive influence over monetary policy, the money supply, and fiscal spending that is discussed herein—matters which "relate[] solely to internal affairs". *United States v. Curtiss-Wright Export Corp.*, 299 U.S. 304, 315 (1936). See Christina Parajon Skinner, *Payments and Foreign Policy*, 60 HARV. J. ON LEGIS. (forthcoming 2023) (discussing the president's authority to use the banking system to effectuate sanctions and to prevent global money laundering).

²¹⁷ See Zoeller & Bandelj, *supra* note 205, at 6.

As in other instances of Presidential exercise of monetary power, it undermined the Fed. Tellingly, Nixon wanted to conceal his planned course of action from the Fed. After the plans for closing the gold window had been laid out at Camp David in early August 1971, Nixon was most adamant to keep the then-Fed Chair, Arthur Burns, largely in the dark.²¹⁸ Speaking to Treasury Secretary John Connally, Nixon said: “Now, let’s keep Arthur [Burns] out of this game, at this point, because Arthur does not, is not going to play the game our way and then we’ll program him just as we did at Camp David.”²¹⁹

The wage and price controls were a slightly different matter. Nixon did issue Executive Order No. 11,615 to formalize that program, which had some basis in legislation.²²⁰ Exactly one year before Nixon “shocked” the world, Congress had passed the Economic Stabilization Act of 1970.²²¹ Section 202 of that law was titled—quite unabashedly—“Presidential authority.”²²² It authorized the President “to issue such orders and regulations as he may deem appropriate to stabilize prices, rents, wages, and salaries at levels not less than those prevailing on May 25, 1970.”²²³ Further, it gave the President plenary power to administer the program within the Executive Branch: “The President may delegate the performance of any function under this title to such officers, departments, and agencies of the United States as he may deem appropriate.”²²⁴

Such a wide-ranging delegation to straitjacket the economy was an impressive delegation of Congress’s fiscal power—it turned completely on its head the Founding-era commitment to keep the levers of the economy largely out of presidential hands.²²⁵ The statute authorizing these actions eventually expired on April 30, 1974.²²⁶ But not before significant damage to the economy had been done. The program ushered in a decade of stagflation—high inflation, slow growth—which adversely impacted living standards for millions of Americans.²²⁷

²¹⁸ See Butkiewicz & Ohlmacher, *supra* note 189, at 932–40.

²¹⁹ *Id.* at 935 (quoting Audio tape: Conversation 014-151 of the White House Tapes (Nov. 17, 1971)) (on file with Nixon Library), <https://www.nixonlibrary.gov/white-house-tapes/014> [<https://perma.cc/A9UX-RDHB>].

²²⁰ Exec. Order No. 11,615, 36 Fed. Reg. 15,727 (Aug. 17, 1971).

²²¹ Economic Stabilization Act of 1970, Pub. L. No. 91-379, 84 Stat. 799.

²²² *Id.* § 202.

²²³ *Id.*

²²⁴ *Id.* § 203.

²²⁵ See U.S.H.R.: HIST., ART & ARCHIVES, *supra* note 69.

²²⁶ Economic Stabilization Act Amendments of 1973, Pub. L. No. 93-28, § 8, 87 Stat. 27, 29.

²²⁷ See William N. Walker, Opinion, *Nixon Taught Us How Not to Fight Inflation*, WALL

However objectively wrongheaded the policy was, vestiges of the delegation remain in precedent and popular imagination even if not in statute. Today, in 2022, there are parallels to the economic conditions that existed in 1971—high inflation and large trade deficits.²²⁸ China has developed a digital currency which may again pose challenges for our currency.²²⁹ We may yet see the ghost of Nixon’s shock emerge: wage and price controls gained some popular appeal in 2021, and COVID-19 supplied a national emergency for a president to grab onto.²³⁰

As for the BWA Act, it continues to formally empower the President in all areas involving currency and America’s ongoing IMF obligations.²³¹ As the next Section will discuss, these BWA Act powers, combined with ongoing authorization of the Exchange Stabilization Fund (“ESF”), have effectively conferred upon the President his own “power of the purse” which could also be inflationary.

B. *Exchange Stabilization Fund*

The Exchange Stabilization Fund is the closest thing the Treasury—and hence the President—has to a discretionary fund.²³² It was established in section 10 of the Gold Reserve Act of 1934.²³³ When Roosevelt devalued the dollar, the U.S. Treasury made a profit because, at the time, the Fed was compelled to transfer its holdings of gold to the Treasury in exchange for gold certificates—but only at the

Str. J. (Aug. 13, 2021, 5:11 PM), <https://www.wsj.com/articles/nixon-fight-inflation-price-controls-stagflation-gas-shortages-biden-democrats-reconciliation-bill-federal-reserve-11628885071> [<https://perma.cc/3NWT-GULC>].

²²⁸ Jeffery E. Garten & Ted O’Callahan, *How the ‘Nixon Shock’ Remade the World Economy*, YALE INSIGHTS (July 13, 2021), <https://insights.som.yale.edu/insights/how-the-nixon-shock-remade-the-world-economy> [<https://perma.cc/7RFJ-4F9A>].

²²⁹ *Id.*

²³⁰ Ben Casselman & Jeanna Smialek, *Price Controls Set Off Heated Debate as History Gets a Second Look*, N.Y. TIMES (Jan. 13, 2022), <https://www.nytimes.com/2022/01/13/business/economy/inflation-price-controls.html> [<https://perma.cc/SZ7Y-8297>]; *Declared National Emergencies Under the National Emergencies Act*, BRENNAN CTR. FOR JUST. (Sept. 9, 2022), <https://www.brennancenter.org/our-work/research-reports/declared-national-emergencies-under-national-emergencies-act> [<https://perma.cc/372A-N984>].

²³¹ See generally Bretton Woods Agreements Act, Pub. L. No. 79-171, 59 Stat. 512 (1945) (codified as amended at 22 U.S.C. §§ 286 to 286k, 31 U.S.C. § 5302(d), 18 U.S.C. § 955).

²³² As Professor Josh Chafetz has observed, “It is true that some presidents, starting with George Washington in his response to the Whiskey Rebellion in 1794, have spent money without congressional appropriations in response to emergencies” but they “have not claimed to be acting legally.” CHAFETZ, *supra* note 67, at 59. Professor Chafetz was speaking about overt commandeering or the select use of the power of impoundment, which is not covered here.

²³³ Gold Reserve Act of 1934, Pub. L. No. 73-87, § 10, 48 Stat. 337, 341–42.

old price of \$20.67 per ounce.²³⁴ The difference between that price and the new (Roosevelt-set) market price of \$35 per ounce was used to initially fund the ESF.²³⁵ Once the ESF's initial capital was in place, it became exempt from congressional appropriation.²³⁶

The first purpose of the ESF was to fund the United States' initial contribution to the IMF (\$1.8 billion), per the Bretton Woods Agreements Act.²³⁷ The BWA Act also created "permanent authority for the ESF."²³⁸ Originally, the ESF was statutorily authorized to deal in gold or foreign exchange to stabilize the exchange value of the dollar.²³⁹ And during the Bretton Woods era, that was more or less how it was used.²⁴⁰ But the Gold Reserve Act gave the President total discretion over how ESF funds would henceforth be used. Specifically, section 10(b) put the ESF "under the exclusive control of the Secretary of the Treasury, with the approval of the President, whose decisions shall be final and *not be subject to review* by any other officer of the United States."²⁴¹

After the collapse of the fixed-rate regime in 1971, Congress slightly revised the purpose of the ESF but retained the general theme of total discretion for the President. If anything, the 1970s era amendments delegated even broader monetary power to the President.²⁴² In the 1976 amendments (effective 1978) Congress removed the language regarding "stabilizing the exchange value of the US dollar" and inserted the more general provision that the ESF could be used, at the President's discretion, for anything "[c]onsistent with the obligations of the Government in the International Monetary Fund on orderly exchange arrangements and a stable system of exchange rates."²⁴³

²³⁴ Selgin, *supra* note 134.

²³⁵ *Id.*

²³⁶ See Anna J. Schwartz, *From Obscurity to Notoriety: A Biography of the Exchange Stabilization Fund*, 29 J. MONEY, CREDIT & BANKING 135, 136 (1997).

²³⁷ MARC LABONTE, BAIRD WEBEL & MARTIN A. WEISS, CONG. RSCH. SERV., IF11474, TREASURY'S EXCHANGE STABILIZATION FUND AND COVID-19 (2020), <https://crsreports.congress.gov/product/pdf/IF/IF11474> [<https://perma.cc/9EB2-SAV9>].

²³⁸ *Id.*

²³⁹ See Gold Reserve Act of 1934, Pub. L. No. 73-87, § 10, 48 Stat. 337, 341–42 ("The fund shall be available for expenditure, under the direction of the Secretary of the Treasury and in his discretion, for any purpose [connected to stabilizing the exchange value of the dollar, and for other things that the Secretary of the Treasury decided to do] with the approval of the President.").

²⁴⁰ See Schwartz, *supra* note 236, at 135–37.

²⁴¹ Gold Reserve Act § 10(b) (emphasis added).

²⁴² See generally Pub. L. No. 95-612, 92 Stat. 3091 (1978) (codified as amended at 31 U.S.C. § 5302).

²⁴³ *Id.*

In effect, that statutory language conferred nearly *carte blanche* to use the ESF for any monetary purpose whatsoever. Article IV of the IMF Articles of Agreement states that the United States should “collaborate with the [IMF] and other members to assure orderly exchange arrangements and to promote a stable system of exchange rates.”²⁴⁴ Members are to fulfill that obligation “by fostering orderly underlying economic and financial conditions and a monetary system that does not tend to produce erratic disruptions.”²⁴⁵ This is a broadly worded mandate, to be sure. And again, the President has full discretion to agree to whatever amendments, and expansions, to these Articles if they so choose.²⁴⁶

It is not surprising that the Fed was quite concerned when the ESF entered the scene in 1934, referring to it as a tool for the Treasury Secretary (and hence the President) “to assume complete control of general credit conditions and to negative any credit policies which the Federal Reserve System might adopt.”²⁴⁷ In that vein, although the Treasury’s spending through the ESF may not have first-order effects that are inflationary, it has on some occasions impinged on the Fed’s autonomy and, more broadly, engaged in politicized public spending. Three examples are instructive.

1. *Stabilization Loans*

Since 1936, the ESF has extended myriad “stabilization loans.”²⁴⁸ In practice, these are loans to favored countries—political decisions about where globally to allocate liquidity, which are made by the Secretary of the Treasury.²⁴⁹

In at least one case the Treasury used the ESF to directly subvert Congress. During the “tequila crisis” of 1994, the value of the Mexican peso had fallen steeply and billions of dollars in foreign investment were fleeing the country.²⁵⁰ Concerned that panic would spread, Presi-

²⁴⁴ Articles of Agreement of the International Monetary Fund art. IV, § 1, Jul. 22, 1944, 60 Stat. 1401, 2 U.N.T.S. 39.

²⁴⁵ *Id.*

²⁴⁶ See Bretton Woods Agreements Act, Pub. L. No. 79-171, § 4(b)(4), 59 Stat. 512, 513 (1945) (codified as amended at 22 U.S.C. §§ 286 to 286k, 31 U.S.C. § 5302(d), 18 U.S.C. § 955).

²⁴⁷ Memorandum from Edward Leon Smead to Eugene Black, Governor, Fed. Rsr. Bd. (Jan. 17, 1934), <https://fraser.stlouisfed.org/archival-collection/records-federal-reserve-system-1344/memo-governor-black-539755/fulltext> [<https://perma.cc/34WW-9EMH>].

²⁴⁸ Schwartz, *supra* note 236, at 136–38, 146–48.

²⁴⁹ *Id.* at 137.

²⁵⁰ Tim Sablik, *The Fed’s “Tequila Crisis,”* ECON FOCUS, First Quarter 2017, at 3, https://www.richmondfed.org/-/media/RichmondFedOrg/publications/research/econ_focus/2017/q1/pdf/federal_reserve.pdf [<https://perma.cc/37QY-GFLG>].

dent Clinton asked Congress to offer Mexico an aid package. Congress refused, so Clinton used the ESF to provide \$20 billion in loans and credits to Mexico.²⁵¹ The President's move flouted the appropriation process, but it also commandeered monetary policy. The ESF did not have enough to fully fund the \$20 billion but it did have substantial foreign currency holdings. The Treasury looked to the Fed, pressuring it to “warehouse” the currency, that is, to swap U.S. dollars for the ESF's currency holdings—in other words, to monetize the Treasury's foreign currency holdings.²⁵²

It is not surprising that the Fed's leaders were disturbed. Cleveland Fed President Jerry Jordan noted in a March 1994 meeting that the use of swap lines in Mexico created a “very troubling pattern,” St. Louis Fed President Thomas Melzer believed it was “setting a very bad precedent” to fund the Treasury's fiscal operation in Mexico, and Fed Board Governor Lawrence Lindsey stated that the “political risk [to the Fed was] enormous” for helping Treasury subvert the will of Congress.²⁵³

In the end, the operation did accomplish its stabilization goals. But this controversy has not gone away as the Fed's practice of using currency swap arrangements to support foreign economies has only grown with the 2008 and 2020 financial crises.²⁵⁴ Certainly, the President has the power to continue to use the ESF to allocate dollars abroad according to his discretion.²⁵⁵

2. *Special Drawing Rights*

Although direct loans may be out of fashion, the allocation of special drawing rights (“SDRs”) is an equally if not a more effective way for the ESF to allocate dollars to favored nations. SDRs are reserve assets issued by the IMF.²⁵⁶ They are allocated based on each

²⁵¹ *Use of the Exchange Stabilization Fund to Provide Loans and Credits to Mexico*, 19 OP. O.L.C. 83, 83 (1995), <https://www.justice.gov/file/21406/download> [<https://perma.cc/KUB6-BUT8>]; Sablik, *supra* note 250, at 5, 20.

²⁵² Sablik, *supra* note 250, at 5.

²⁵³ *Id.*

²⁵⁴ See Christina Parajon Skinner, *Central Bank Activism*, 71 DUKE L.J. 247, 273–76 (2021). This, however, refers to the use of swap lines by the Federal Reserve which are not necessarily guaranteed by the ESF.

²⁵⁵ 1977 amendments require that a loan or credit to a foreign government can only be made for six months unless the President provides Congress with a written statement that unique or emergency circumstances require the loan of credit for more than six months. 31 U.S.C. § 5302(b). As one can see from the foregoing, conjuring an emergency is easy enough to do.

²⁵⁶ *Special Drawing Rights (SDRs)*, INT'L MONETARY FUND, <https://www.imf.org/en/Topics/special-drawing-right>.

member's quota in the IMF.²⁵⁷ So, for instance, if the IMF issues \$100,000,000 in SDRs, each member will get a portion in proportion to their quota. Under the Special Drawing Rights Act of 1968, when the IMF allocates SDRs to the United States, or if the United States otherwise acquires SDRs, they become resources of the ESF—a key source of discretionary funds.²⁵⁸

But, because the statute has been so loosely structured, this system can be used to end-run congressional appropriation. Consider the most recent SDR allocation in August 2021 of \$650 billion.²⁵⁹ Congress requires approval for any SDR allocation where the United States gets over \$120 billion;²⁶⁰ understandably, since the SDR steps in for an appropriation and then augments the ESF. According to news reports, Secretary Yellen at one point planned to break the new allocation into two components to avoid congressional approval.²⁶¹

But perhaps most directly relevant to the concern of fiscal dominance is the role that central banks play in SDRs. Central banks—including the Fed—can technically convert SDRs into currency which could then be used to refinance government debt.²⁶² The Treasury can also manipulate the size of the ESF by buying and selling SDRs. For instance, the Treasury can purchase the SDRs from other countries using dollars in the ESF and other countries can trade in their SDRs with Treasury for dollars.²⁶³ For this reason, they have been referred to cheekily as “IMF booty”²⁶⁴ or “paper gold.”²⁶⁵ The mechanics of the SDR regime, when viewed in light of fiscal dominance, create a mech-

²⁵⁷ *Id.*

²⁵⁸ Special Drawing Rights Act, Pub. L. No. 90-349, 82 Stat. 188 (1968); *Legislative Basis*, U.S. DEP'T TREASURY, <https://home.treasury.gov/policy-issues/international/exchange-stabilization-fund/legislative-basis> [<https://perma.cc/S7Y8-AWQF>].

²⁵⁹ Editorial, *Special Dollars for Dictators*, WALL ST. J. (Mar. 24, 2021, 6:23 PM), <https://www.wsj.com/articles/special-dollars-for-dictators-11616624610> [<https://perma.cc/9HGQ-QM9G>].

²⁶⁰ *Id.*

²⁶¹ *Id.*

²⁶² Tobias Pforr, Fabian Pape & Steffen Murau, *Special Drawing Rights and Elasticity in the International Monetary System*, INST. FOR NEW ECON. THINKING (Mar. 15, 2022), <https://www.ineteconomics.org/perspectives/blog/special-drawing-rights-and-elasticity-in-the-international-monetary-system> [<https://perma.cc/WMM6-PML7>].

²⁶³ See Press Release, U.S. Dep't of the Treasury, FACT SHEET: How an Allocation of International Monetary Fund Special Drawing Rights Will Support Low-Income Countries, the Global Economy, and the United States (Apr. 1, 2021), <https://home.treasury.gov/news/press-releases/jy0095> [<https://perma.cc/Y8DH-WU5B>].

²⁶⁴ Editorial, *supra* note 259.

²⁶⁵ Butkiewicz & Ohlmacher, *supra* note 189, at 925; see also Peter M. Garber, *The Collapse of the Bretton Woods Fixed Exchange Rate System*, in A RETROSPECTIVE ON THE BRETTON WOODS SYSTEM: LESSONS FOR INTERNATIONAL MONETARY REFORM, *supra* note 180, at 462.

anism by which the Treasury can leverage the United States' contributions to the IMF to increase its discretionary spending—in essence, convertible SDRs could supply another way of extracting debt monetization services from the Fed.

3. *Financial Sector Backstops*

The ESF is also, since 2008, used to augment monetary policy and amplify appropriations. There are a few variations on this theme.

In at least one instance, the ESF was used like a lender of last resort, but without congressional approval. In 2008, the Treasury used the ESF to guarantee the money market fund sector.²⁶⁶ To shore up the sector, the Treasury stepped in to guarantee the deposits in MMFs. Effectively, the Treasury used the ESF as a functional equivalent to the kind of insurance supplied to banks by the FDIC as established in the Federal Deposit Insurance Act.²⁶⁷ Yet Congress did not approve the use of the ESF to rescue money market funds. As with the stabilization package to Mexico in the 1990s, no money was lost—in the end, none of the guarantees were invoked.²⁶⁸ Congress would later, in the Emergency Economic Stabilization Act of 2008, require the Treasury Secretary to reimburse the ESF for any funds used in the money market guarantee program and prohibited the Treasury from using the ESF for similar programs in the future.²⁶⁹ Notably, Congress temporarily removed the restrictions during the COVID-19 crisis in 2020 in the CARES Act.²⁷⁰

A second example harkens from 2020, and the \$454 billion Congress appropriated to the ESF to support financial markets.²⁷¹ This

²⁶⁶ See Press Release, U.S. Dep't of the Treasury, Treasury Announces Temporary Guarantee Program for Money Market Funds (Sept. 29, 2008), <https://home.treasury.gov/news/press-releases/hp1161> [<https://perma.cc/E3TR-5QUH>]. Money market funds ("MMFs") had, prior to 2008, generally pegged the value of their shares to the dollar; as a result, shareholders in MMFs had understood them to be interchangeable with ordinary checking accounts at depository institutions. But they were not banks and lacked the backstop of federal insurance guarantees. Accordingly, when the value of the assets of some MMFs dropped precipitously (specifically, those holding the commercial paper of Lehman Brothers), the MMFs "[broke] the buck" and could not honor the 1:1 share for dollar exchange. This state of events precipitated panic and a general run on MMFs. See Whitney Cromie, Myron Kwast & Ashley Mihalik, *Use of Systemic Risk Exceptions for Individual Institutions During the Financial Crisis*, in CRISIS AND RESPONSE: AN FDIC HISTORY, 2008–2013, 74 n.23 (2017); see generally LABONTE ET AL., *supra* note 237.

²⁶⁷ See generally Federal Deposit Insurance Act of 1950, Pub. L. No. 81-797, 64 Stat. 873 (codified as amended at 12 U.S.C. §§ 1811 to 1835a).

²⁶⁸ See Sablik, *supra* note 250, at 5–6.

²⁶⁹ Emergency Economic Stabilization Act of 2008, Pub. L. No. 110-343, 122 Stat. 3765.

²⁷⁰ CARES Act, Pub. L. No. 116-136, § 4015, 134 Stat. 281, 481 (2020).

²⁷¹ *Id.* § 4003.

was a huge injection into the President's discretionary fund. For context, before the COVID-19 crisis, the ESF had somewhere around \$50 billion in funds, so the CARES Act expanded it ninefold.²⁷² The money had very few strings attached.²⁷³ Consistent with the general design of the ESF, Congress allowed the Treasury near total discretion to allocate the funding across passenger air travel carriers, cargo air carriers, and other businesses critical to national security, deciding which companies and in what amounts would get that ESF support.²⁷⁴

The Treasury also used the ESF to guarantee losses (provide credit protection) in the Fed's liquidity facilities to backstop a range of market actors—commercial paper markets, money market funds, primary dealers, and corporate bonds.²⁷⁵ The ESF was thus used to support monetary policy—and pointedly to expand it. As Professor Lev Menand has pointed out, “the Treasury does not have . . . the power of the purse,” but because “past Treasury Secretaries had already made a habit of drawing on it in emergencies . . . it was not clear who was in a position to challenge [Secretary Mnuchin's] decision” in March 2020.²⁷⁶ Whether the Treasury formally dominated the Fed in these arrangements cannot be truly known to outside public observers. But the monetary-fiscal arrangements made possible by the ESF arguably suggest that the fund could one day be used as a beachhead for the Treasury's dominance over monetary policy in episodes of economic turmoil.²⁷⁷

²⁷² See LABONTE ET AL., *supra* note 237.

²⁷³ See *id.*

²⁷⁴ See *id.*

²⁷⁵ See *Secondary Market Corporate Credit Facility*, FED. RESRV. BD. (Oct. 13, 2021), <https://www.federalreserve.gov/monetarypolicy/smccf.htm> [<https://perma.cc/M942-SAAD>].

²⁷⁶ LEV MENAND, *THE FED UNBOUND: CENTRAL BANKING IN A TIME OF CRISIS* 42–44 (2022).

²⁷⁷ Indeed, the battle that ensued between Secretary Mnuchin and Fed Chair Powell over where the balance of the Treasury funds would be returned only corroborates the fact that the Treasury ESF is a potential tool for Fed control. Though Powell would have liked to have the remaining funds on hand for a rainy day, Mnuchin demanded they be returned to the Treasury immediately when the programs expired. See *Letter from Chair Powell to Secretary Mnuchin Regarding Emergency Lending Facilities*, FED. RESRV. BD. (Nov. 20, 2020), <https://www.federalreserve.gov/foia/Letter-from-Chair-Powell-to-Secretary-Mnuchin-20201120.htm> [<https://perma.cc/E8G6-YRRZ>]. Mnuchin wanted to ensure that the funds went into the Treasury's general account—which requires a specific act of Congress before funds can be used—rather than the ESF, a wholly discretionary fund that could be deployed by future presidents. See *id.*

C. *Financial Stability Oversight Council*

Finally, some discussion is warranted regarding the delegations Congress made when it created new financial regulatory *agencies* in the Dodd-Frank Act of 2010 (“Dodd-Frank”).²⁷⁸ The first of these agencies that merits examination is the Financial Stability Oversight Council (“FSOC”). After the financial crisis of 2008, Congress passed Dodd-Frank to address systemic risk—that is, risk that permeates throughout the financial system and creates the potential for future instability.²⁷⁹ Title I was the lodestar of that statute. It empowered the Fed to regulate and supervise large banks more stringently and created a new inter-agency Council of Regulators to focus on these bird’s-eye view stability risks in banks and financial markets.²⁸⁰

This new council is housed within the Treasury Department and spearheaded by the Treasury Secretary.²⁸¹ The FSOC has the power, among others, to designate certain activities as financial stability risks in the United States, and thus make recommendations to the relevant primary regulator as to how best to tackle that risky activity.²⁸² From its inception, the FSOC has been criticized as political, shifting priorities and intensity in line with the outlook of the administration.²⁸³

Most recently, President Biden has, acting through Secretary Yellen, steered the FSOC to push the independent financial regulatory bodies toward the legislative end of regulating climate change.²⁸⁴ In 2021, President Biden issued Executive Order 14,030, requiring a whole-of-government approach to fighting climate change.²⁸⁵ The key provision in that Order was section 3, which addressed “Climate-Related Financial Risk by Financial Regulators.”²⁸⁶ It directed the Treasury Secretary as Chair of FSOC to: (1) assess the financial stability risks of climate change; (2) facilitate climate-related data sharing among members of the FSOC and executive departments and agencies; and (3) issue a report to the President outlining the efforts “by

²⁷⁸ Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 (2010).

²⁷⁹ *See id.*; *see generally* MARC LABONTE, CONG. RSCH. SERV., R47026, FINANCIAL REGULATION: SYSTEMIC RISK (2022).

²⁸⁰ *See* Dodd-Frank Wall Street Reform and Consumer Protection Act §§ 111–12.

²⁸¹ For discussion of the FSOC’s Systemically Important Financial Institutions (“SIFI”) designation power, *see generally* Christina Parajon Skinner, *Regulating Nonbanks: A Plan for SIFI Lite*, 105 GEO. L.J. 1379 (2017).

²⁸² *See* Dodd-Frank Wall Street Reform and Consumer Protection Act § 120.

²⁸³ *See* Skinner, *supra* note 281, at 1408.

²⁸⁴ *See* Exec. Order No. 14,030, 86 Fed. Reg. 27,967 (May 25, 2021).

²⁸⁵ *See id.*

²⁸⁶ *See id.* at 27,968.

FSOC member agencies to integrate consideration of climate-related financial risk in their policies and programs.”²⁸⁷ Because the Fed is a member of the FSOC, this meant that the President could lean on the FSOC to direct the Fed’s analysis and maybe supervisory and regulatory policy.

In turn, the FSOC recommended that the Fed adopt a range of supervisory practices concerning banks’ exposure to climate change.²⁸⁸ The subtext of this recommendation is that Fed supervision should effectively deter banks from lending to brown companies and develop underwriting practices to favor green borrowers instead. This accordingly could be seen as a political maneuver on the Fed given that the Fed does not otherwise have statutory authority—let alone responsibility—to proactively mitigate climate change.²⁸⁹ If this recommendation of the FSOC influences Fed supervision in ways that redirect bank capital, the result will be that the FSOC has functioned as an avenue for the President to influence the allocation of credit in the economy, toward politically favored sectors and away from politically disfavored ones.²⁹⁰ The FSOC may yet prove to be a power available to the President for directing the central bank’s supervisory problems and, as such, a channel for fiscal dominance.

Congress also, in the Dodd-Frank Act, created the Consumer Financial Protection Bureau (“CFPB”). The CFPB is responsible for implementing and enforcing consumer protection laws in the interest of fairness, transparency, and competitiveness.²⁹¹ It has sweeping rulemaking authority to implement, and then enforce, a broad statutory prohibition against “any unfair, deceptive, or abusive act or practice” by consumer-finance institutions.²⁹² The structure of the agency has been a frequent subject of judicial review,²⁹³ including the extent to which the CFPB has contributed to the Monetary Executive.

²⁸⁷ *Id.*

²⁸⁸ See Christina Parajon Skinner, *Central Banks and Climate Change*, 74 VAND. L. REV. 1301, 1311 (2021).

²⁸⁹ See *id.* at 1327, 1364.

²⁹⁰ See *id.* at 1359.

²⁹¹ Consumer Financial Protection Act, 12 U.S.C. §§ 5481–5603.

²⁹² *Id.* § 5536(a)(1)(B). The CFPB director has authority to “prescribe rules and issue orders and guidance, as may be necessary or appropriate to enable the Bureau to administer and carry out the purposes and objectives of the Federal consumer financial laws, and to prevent evasions thereof.” *Id.* § 5512(b)(1). This includes rules “identifying as unlawful unfair, deceptive, or abusive acts or practices” “committed by certain participants in the consumer-finance industry.” *Id.* § 5531(b).

²⁹³ See, e.g., *Seila L. LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct. 2183, 2194 (2020).

In particular, in October 2022, the Fifth Circuit Court of Appeals held that the funding structure of the CFPB violated the separation of powers principles underlying the Appropriations Clause.²⁹⁴ Problematically, in the court’s view, this “sword” inherent in the CFPB’s powers had been improperly paired with a “purse”—more specifically, the CFPB was given its very *own* purse.²⁹⁵ That is, the CFPB is not obligated to seek an appropriation from Congress, like other administrative agencies; but rather, it draws funding directly from the Federal Reserve, which itself is not subject to congressional appropriation.²⁹⁶ According to this “self-actualizing, perpetual funding mechanism . . . the Bureau simply requisitions from the Federal Reserve an amount ‘determined by the Director to be reasonably necessary to carry out’ the Bureau’s functions.”²⁹⁷

The Fifth Circuit held that funding structure “ran afoul of the separation of powers embodied in the Appropriations Clause.”²⁹⁸ While the issue in the case pertained to a congressional delegation to an *agency*, like the President’s relationship with the Secretary of the Treasury, the court noted that the CFPB director’s “presidential subservience exacerbates the constitutional problem[] arising from the [Bureau’s] budgetary independence.”²⁹⁹ For this court, such combination of purse and sword in the CFPB was a threat to political liberty.³⁰⁰

* * *

This Part has demonstrated that contemporary presidents possess a significant array of powers to intervene in the domestic and international monetary systems unilaterally, with executive orders or the Treasury Department’s tools.³⁰¹ While many today accept the Monetary Executive as an established feature of the United States govern-

²⁹⁴ See *Cnty. Fin. Servs. Ass’n of Am. v. Consumer Fin. Prot. Bureau*, No. 21-50826, slip op. at 2, 20–23 (5th Cir. Oct. 19, 2022), <https://www.ca5.uscourts.gov/opinions/pub/21/21-50826-CV0.pdf> [<https://perma.cc/SV8Y-MSKK>].

²⁹⁵ See *id.* at 28–33.

²⁹⁶ See *Seila L.*, 140 S. Ct. at 2193–94. The Fed draws funding from bank fees and assessments as well as money earned on the assets on its balance sheet. Excepting the Fed from the appropriations relates to the distinct importance of the Federal Reserve’s independence from short-term political pressure as the nation’s monetary authority. The logic does not apply at all to the CFPB.

²⁹⁷ *Cnty. Fin. Servs. Ass’n*, slip op. at 29 (quoting 12 U.S.C. § 5497(a)).

²⁹⁸ *Id.* at 32.

²⁹⁹ *Id.* (alterations in original) (quoting *Consumer Fin. Prot. Bureau v. All Am. Check Cashing*, 33 F.4th 218, 234 (5th Cir. 2022) (Jones, J., concurring)).

³⁰⁰ See *id.*

³⁰¹ See, e.g., Exec. Order No. 14,030, 86 Fed. Reg. 27,967 (May 25, 2021).

ment, this office was unrecognized by the Framers and Ratifiers of the Constitution.

III. MONETARY CHECKS AND BALANCES

When viewed in isolation, any single delegation of monetary or fiscal power may seem trifling to the overall health of American democracy. But when one takes a step back to consider the cumulative impact of this past (almost) century of delegations, a different picture emerges. Just as the *Youngstown* Court once warned about presidential power generally, the public must keep watch for “[s]ubtle shifts tak[ing] place in the centers of real power that do not show on the face of the Constitution.”³⁰² This Article has, until this point, urged attention to this subtle monetary transformation.

A. *The Problems of Profligacy and Error*

When boiled down to policy impacts, the power behind a Monetary Executive implicates fiscal profligacy and Fed error—both of which can ultimately undermine the value of the dollar. Let us consider first the implications for fiscal discipline. The Framers were concerned that the government be responsible with debt, evidenced by the text which required the government to finance itself with debt and not with paper money.³⁰³ The government would have to prove to public and sovereign lenders—i.e., the purchasers of the sovereign debt—that the full faith and credit of the United States was meaningful because the government would be run sufficiently prudently to honor its debt-based obligations.³⁰⁴ Although this constraint was eventually relaxed when Congress created paper money,³⁰⁵ the principle of monetary discipline remained so long as the United States backed its dollars with gold. Nixon’s unilateral decision to leave the gold standard and convert the dollar to a fiat currency unmoored monetary discipline from the text of the Constitution.³⁰⁶

Now there is no limit to the amount of dollars the Fed can print (figuratively) and very little limit on how much the Treasury can borrow. In regard to printing money, because there is no requirement to back dollars with some ratio of gold, the Fed has the discretion to

³⁰² *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 653 (1952) (Jackson, J., concurring).

³⁰³ See *supra* Part I; see also McCONNELL, *supra* note 7, at 103–04.

³⁰⁴ See *supra* Part I; see also McCONNELL, *supra* note 7, at 103–04.

³⁰⁵ See *supra* Section I.A.

³⁰⁶ See *supra* Section II.A.2.

issue reserves (i.e., create new money)—by buying government debt—in pursuit of its broadly worded mandate to pursue price stability and maximum employment.³⁰⁷ Where the U.S. debt is concerned, because the dollar is the reserve currency of the world instead of gold, the United States enjoys high demand for its dollars and its debt.³⁰⁸ This encourages the Treasury to borrow and spend, knowing creditors the world over are hungry for U.S. debt. But this status quo, a derivative of President Nixon's choices, is not an immutable guarantee. It thus follows that presidents who end-run Congress or flex the play in statutory joints, in order to spend more, can eventually degrade the quality of our debt.

Also, as this Article has argued, presidential exercises of fiscal-monetary power tend to lead to unforced error. For example, FDR's use of the Reconstruction Finance Corporation to accomplish devaluation spooked investors. Even Maynard Keynes—who was the inspiration for FDR's economic policies—pointed to them as folly.³⁰⁹ In an open letter to the *New York Times*, Keynes wrote that “the recent gyrations of the dollar have looked to me more like a gold standard on the booze than the ideal managed currency of my dreams.”³¹⁰ He continued, “the time has come when uncertainty should be ended. This game of blind man's buff [sic] with exchange speculators serves no useful purpose and is extremely undignified. It upsets confidence, hinders business decisions, [and] occupies the public attention in a measure far exceeding its real importance.”³¹¹

For its part, the Federal Reserve Board leadership believed FDR had the economic causation reversed—FDR believed that a change in the price level would spur economic activity, but the Fed knew from the recessions of 1924 and 1927 that just the opposite was true—changes in economic activity impact the price level.³¹² Regarding wage and price controls, even Nixon knew they would not work. In February 1971, Nixon revealed to Connally his “concern about the

³⁰⁷ Federal Reserve Act of 1913 § 2A, 12 U.S.C. § 225a.

³⁰⁸ For a brief discussion of exorbitant privilege, see Ben S. Bernanke, *The Dollar's International Role: An “Exorbitant Privilege”?*, BROOKINGS (Jan. 7, 2016), <https://www.brookings.edu/blog/ben-bernanke/2016/01/07/the-dollars-international-role-an-exorbitant-privilege-2/> [https://perma.cc/5CQH-QS54].

³⁰⁹ See John Maynard Keynes, *From Keynes to Roosevelt: Our Recovery Plan Assayed*, N.Y. TIMES, Dec. 31, 1933.

³¹⁰ *Id.*

³¹¹ *Id.*

³¹² See Wicker, *supra* note 128, at 866 (“[The Fed] thought [Roosevelt's] monetary logic was naive because it had the causation reversed: a change in the level of economic activity induced a change in prices and not vice versa.”).

freeze”—namely, that “[t]he difficulty with wage-price controls and a wage board as you well know is that the God damned things will not work. They didn’t work even at the end of World War II. They will never work in peacetime.”³¹³ But Connally convinced him that the program would have such popular appeal that the 1972 election would be a certain win:

To the average person in this country this wage and price freeze—to him means you mean business. You’re gonna stop this inflation. You’re gonna try to get control of this economy. . . . If you take all of these actions . . . you’re not going to have anybody . . . left out to be critical of you.³¹⁴

Without a doubt, Nixon used this broad fiscal-monetary power Congress had delegated for politically expedient theatrics.³¹⁵

Ultimately, the crux of the problem lies with the now porous separation between the Legislative and Executive powers concerning monetary matters. In delegating power and not retracting it, Congress seems to have forgotten over time that “[t]he purpose of the Constitution,” as Justice Jackson wrote in his 1952 concurrence, “was not only to grant power, but to keep it from getting out of hand.”³¹⁶ This objective is precisely the sentiment that Madison articulated in *Federalist No. 47*, when he warned against the “accumulation of all powers . . . in the same hands.”³¹⁷

The Framers feared that delegating monetary and fiscal powers to the President would be the Achilles’ heel of our society—our path to Rome.³¹⁸ To avoid that fate, the question going forward is what can and should be done.

B. The Importance of Central Bank Independence

The foregoing has, if anything, underscored the importance of the central bank’s independence—freedom from “fiscal dominance.” U.S. Presidents have certainly always found it politically expedient to manage or massage the Fed—a hot economy is always favorable for the

³¹³ Burton A. Abrams & James L. Butkiewicz, *The Political Economy of Wage and Price Controls: Evidence from the Nixon Tapes*, 170 Pub. Choice 63, 65 (2017). .

³¹⁴ *Id.* at 73.

³¹⁵ *Id.* at 63 (“Nixon understood the impact of his wage and price controls, but chose to trade off longer term economic costs to the economy for his own short-term political gain.”).

³¹⁶ *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 640 (1952) (Jackson, J., concurring).

³¹⁷ THE FEDERALIST NO. 47, *supra* note 14, at 301 (James Madison).

³¹⁸ *Id.*

next election.³¹⁹ The impulses that attend the short-term political cycle are well-known to be inconsistent with optimal monetary policymaking. But today, some seriously entertain the notion that Fed independence is misguided—and many believe that large fiscal spending programs will have no impact on inflation.³²⁰

Although this concept might seem anathema to veteran central bankers, the idea is gaining traction, and the trend correlates to presidential politics. As renowned economist Kenneth Rogoff remarked in 2019:

With the global rise of populism and autocracy, central-bank independence is under threat, even in advanced economies. Since the 2008 financial crisis, the public has come to expect central banks to shoulder responsibilities far beyond their power and remit. . . . Not too long ago, central-bank independence was celebrated as one of the most effective policy innovations of the past four decades, owing to the dramatic fall in inflation worldwide. Recently, however, an increasing number of politicians believe that it is high time to subordinate central banks to the prerogatives of elected officials.³²¹

Since this time, populist groups on the left and right have continued to question, if not outright assault, Fed independence.³²²

Consider just two examples of how the prior and current administrations have considered using the powers discussed herein to pressure or influence the Fed's policy. In 2019, President Trump complained that a strong U.S. dollar was restraining U.S. growth.³²³ A weaker dol-

³¹⁹ See Salib & Skinner, *supra* note 18, at 964–68 (discussing the presidencies in which the President exerted influence on the Fed Chair to keep interest rates low for reasons of political expedience).

³²⁰ See, e.g., Adam Tooze, *The Death of the Central Bank Myth*, FOREIGN POL'Y (May 13, 2020, 2:57 PM), <https://foreignpolicy.com/2020/05/13/european-central-bank-myth-monetary-policy-german-court-ruling/> [<https://perma.cc/B59R-Z7BF>]. Adherents of “Modern Monetary Theory,” which now permeate public discourse, are grounded in the notion that a government can “print money” to fund “exorbitant deficit spending with no repercussions.” Krause et al., *supra* note 26.

³²¹ Kenneth Rogoff, *How Central-Bank Independence Dies*, PROJECT SYNDICATE (May 31, 2019), <https://www.project-syndicate.org/onpoint/how-central-bank-independence-dies-by-kenneth-rogoff-2019-05> [<https://perma.cc/8E9Y-PGR3>].

³²² See Carola Binder, *Presidential Antagonism and Central Bank Credibility*, 33 ECON. & POL. 244, 258 (2021).

³²³ Damian Paletta, *Trump Suggests He Could Take Steps to Weaken U.S. Dollar, Fueling Confusion*, WASH. POST (July 26, 2019, 5:20 PM), https://www.washingtonpost.com/business/economy/trump-shot-down-navarros-recommendation-to-weaken-the-dollar-as-white-house-searches-for-ways-to-juice-the-economy/2019/07/26/5e2e85f6-afc5-11e9-a0c9-6d2d7818f3da_story.html [<https://perma.cc/Z8W6-MF4H>].

lar would have in theory boosted U.S. exports and brought associated political advantage.³²⁴ The Administration insinuated that the Treasury might use its ESF to try and depreciate the dollar—and that it might press the Fed to help.³²⁵

Formally, the Fed is the Treasury's fiscal agent, per section 15 of the Federal Reserve Act.³²⁶ In practice, this should mean little more than bland administration of the Treasury's currency operations. But in politics, the Treasury has before asked the Fed to augment its currency interventions using its own balance sheet.³²⁷ And in fact there is little stopping the Treasury from pressuring the Fed to go further and to warehouse foreign currency interventions so as to augment the ESF's impact on the dollar's value.³²⁸ In the past, the nature of the arrangement between the Treasury and the Fed where currency interventions are concerned has always been rather murky.³²⁹

A second example is presently unfolding and regards President Biden's desire to have the Fed tackle climate change. Because the Fed does not have clear legal authority to use its policy tools to that end,³³⁰ the President may well attempt to influence the Fed's willingness to stretch its mandate by appointing Fed Governors favorable to that cause. What the future holds if this trend toward Fed control continues—through agency (i.e., the Financial Stability Oversight Council) and personnel (Fed Board appointments)—remains unknown. The advent of unconventional monetary policy—i.e., quantitative easing—to fight financial crises makes the Fed's power even more enticing for a president to capture.³³¹

Though not designed as such, quantitative easing ("QE") is inherently a quasi-fiscal action.³³² QE involves the central bank buying trillions of dollars of bonds—this means it extends credit—to combat market turmoil when a major shock erupts.³³³ To be sure, the Fed does not intend to allocate credit per se with its QE program—it limits its purchases to risk-free products like Treasuries and the GSE's mort-

³²⁴ See generally MARC LABONTE, CONG. RSCH. SERV., RL30354, MONETARY POLICY AND THE FEDERAL RESERVE: CURRENT POLICY AND CONDITIONS 11 (2020), <https://fas.org/sgp/crs/misc/RL30354.pdf> [<https://perma.cc/5FGK-PAAP>].

³²⁵ See Paletta, *supra* note 323.

³²⁶ Federal Reserve Act of 1913 § 15, 12 U.S.C. § 391.

³²⁷ Salib & Skinner, *supra* note 18, at 953, 957 (discussing these incidents).

³²⁸ See *id.* at 975.

³²⁹ See *id.* at 975–76.

³³⁰ See Skinner, *supra* note 288, at 1310.

³³¹ See *id.* at 1328.

³³² See GEORGE SELGIN, THE MENACE OF FISCAL QE 7–11 (2020).

³³³ See *id.* at 2–4.

gage-backed securities; but invariably, it does so by injecting credit to the mortgage markets. Around the world other QE programs, like the Bank of England's, have included private corporate bonds in their QE programs thereby allocating credit to some corporate sectors and not others even more overtly.³³⁴ Unavoidably, QE is a monetary-fiscal operation—it comes down only to questions of degree.³³⁵

In the President's hands, QE would be a dangerous weapon of capital allocation as the foregoing has discussed. Any future president could declare an economic emergency and use QE to start dispensing credit to politically preferred sectors.³³⁶ The allocative inefficiency and uncertainty—not to mention inflationary impact—would be considerable.³³⁷

But one need not rely on hypotheticals to be persuaded of the danger of a president accumulating monetary power by controlling the central bank. History is replete with such experiments that all ended in disaster. Latin America has several chilling examples of economic catastrophes that resulted when presidents had too much monetary power and free rein over the central bank.³³⁸ The Kitchener and Fernandez presidencies in Argentina (2003–15); Salvador Allende's experiment with socialism (1970–73); Peru's first Alan Garcia presidency; and Venezuela's Hugo Chávez (and now Maduro) all attempted economic policies that commanded monetary policy via the central banks to accommodate massive government spending projects and initiatives—usually to cater to populist demands.³³⁹ According to

³³⁴ See *id.* at 13–14.

³³⁵ See *id.* at 3–11.

³³⁶ See Dorn, *Fiscal Dominance*, *supra* note 25.

³³⁷ See *id.* An obscure provision of the Federal Reserve Act—which is discussed virtually nowhere in the academic literature or primary source policy documents—would seem to enable this kind of presidential control. Section 10(6) of the Federal Reserve Act provides that the Federal Reserve is “subject to the supervision and control of the Secretary [of the Treasury]” in matters where their jurisdiction overlaps. Federal Reserve Act of 1913 § 10(6), 12 U.S.C. § 246. This provision could supply a dangerous power of direction upon an—even spurious—argument that in QE, the fiscal and monetary prerogatives of the Treasury and Fed do in fact overlap. See Salib & Skinner, *supra* note 18, at 953–57 (discussing § 10(6) as a latent power of direction).

³³⁸ See Sebastian Edwards, *Modern Monetary Theory: Cautionary Tales from Latin America* 15 (Hoover Inst., Econ. Working Paper No. 19106, 2019).

³³⁹ See *id.* at 8. But the economic folly is not limited to populism; fascism can give rise to the danger too. The economic program of Hitler's Hjalmar Schacht—from 1933 to 1939—employed similar techniques of autocratic control of the economy and manipulation of monetary policy. Economically, that too proved unsustainable. See Christopher Kopper, *Banking in National Socialist Germany, 1933–39*, 5 FIN. HIST. REV. 49, 50–51 (1998); Parker Abt, *The Nazi Fiscal Cliff: Unsustainable Financial Practices Before World War II*, 16 GETTYSBURG HIST. J. 20, 53–54 (2017).

one economic historian that has studied these events, all of these experiments “ended up badly, with runaway inflation, huge currency devaluations, and precipitous real wage declines.”³⁴⁰ That assessment is shared widely in the academic circles where economists are “concern[ed] that prosperity has eluded Latin America” and have “a strong suspicion that macroeconomic policies are in part to blame.”³⁴¹

At bottom, the shift in the balance of power from Congress to the President—which has roots in formal law—creates preconditions for the practice of fiscal dominance: the suspension of central bank independence in the name of presidentially determined economic goals.

C. *Congress and the Fed*

This Article has urged attention to the gradual evolution of monetary and fiscal powers to the President—powers long held by Congress, pursuant to Article I of the Constitution. This Article examined how this shift in power from the Legislative to the Executive Branch is likely to adversely impact the quality of our modern monetary policymaking (made by the Fed) and fiscal discipline in general. This Section concludes by considering some means of shielding the Fed against pressure from the President and of the President’s assertions of fiscal dominance.

At first blush, there seem to be obvious checks on the President readily at Congress’s disposal. For example, Congress can rescind statutory powers granted by prior congresses if it perceives them to be used by presidents excessively or in ways the current Congress does not like.³⁴² But in practice, Congress is likely to be too politically constrained at any given moment to clip the wings of presidential power; the public is now so accustomed to the notion that the President is the necessary (and benevolent) actor in an economic emergency. Even when Congress *has* rescinded a given power, the precedent of practice often remains etched on the national memory and becomes a template for future legislative delegations.³⁴³

Alternatively, Congress has inserted automatic sunset clauses in legislation that Congress worries the President might use too broadly or in unintended ways.³⁴⁴ Such provisions essentially serve as expira-

³⁴⁰ Edwards, *supra* note 338, at 3.

³⁴¹ FRANÇOIS R. VELDE, *Foreword to A MONETARY AND FISCAL HISTORY OF LATIN AMERICA, 1960–2017*, at xi (Timothy J. Kehoe & Juan Pablo Nicolini eds., 2021).

³⁴² See generally *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579 (1952).

³⁴³ See *supra* Section II.A.

³⁴⁴ See Jonathan H. Adler & Christopher J. Walker, *Delegation and Time*, 105 IOWA L. REV. 1931, 1936–37 (2020) (discussing the “temporal problems of congressional delegation” in-

tion dates on certain executive powers and thus force periodic legislative scrutiny of the manner of their use.³⁴⁵ But it is also well-known that sunset provisions are routinely disregarded—without consequence—in an emergency.³⁴⁶ Just consider the overall experience with the NEA’s automatic expiration dates and the 1977 Amendments to the ESF that halt overseas lending after six months. Consistently, the President’s object in relation to these limits was not to submit himself to the intended legislative scrutiny, but rather, to work around it.

It seems unlikely that the federal courts can check the President’s assertions of fiscal dominance. As the administrative state has grown swiftly since the New Deal era of the 1930s, so too has the body of law curtailing the administrative state. The Administrative Procedure Act (“APA”) set parameters by which affected citizens can challenge a host of agency actions or decisions.³⁴⁷ And courts in recent years have narrowed the broad agency discretion so long afforded under *Chevron v. Natural Resources Defense Council*.³⁴⁸ For example, the Supreme Court and several Courts of Appeal have more regularly referred to the “major questions doctrine,” which maintains that the courts should not in fact defer to agency interpretations with vast economic or political significance.³⁴⁹ And in a recent oral argument, Justice Gorsuch floated the idea of a “pecuniary interest” test to limit *Chevron* at

volving “broad congressional delegations of authority at one time period [that] become a source of authority for agencies to take later action that could no longer receive legislative support or that was not adequately contemplated, let alone considered, at the time of enactment”).

³⁴⁵ See Roberta Romano, *Regulating in the Dark* 14 (Yale L. & Econ. Rsch. Paper No. 442, 2012), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1974148 [<https://perma.cc/V857-UTEL>].

³⁴⁶ See Antonios Kouroutakis & Sofia Ranchordás, *Snoozing Democracy: Sunset Clauses, De-Juridification, and Emergencies*, 25 MINN. J. INT’L L. 29, 72–73 (2016) (discussing failure of sunset reviews to “impede agencies from continuing ineffective and unnecessary programs”).

³⁴⁷ Administrative Procedure Act, Pub. L. No. 79-404, § 6(a), 60 Stat. 237, 240 (1946). See generally CASS R. SUNSTEIN & ADRIAN VERMEULE, *LAW & LEVIATHAN* (2020) (suggesting how the administrative state can be constitutionally and ultimately morally redeemable).

³⁴⁸ 467 U.S. 837, 842–44 (1984) (creating a doctrine of judicial deference to agency interpretations of statutory agency mandates).

³⁴⁹ See *West Virginia v. EPA*, 142 S. Ct. 2587, 2595 (2022); see also *King v. Burwell*, 576 U.S. 473, 485–86 (2015) (noting that if Congress wants to assign questions to agencies of deep economic and political significance, it will do so expressly); *Util. Air Regul. Grp. v. Env’t Prot. Agency*, 573 U.S. 302, 324 (2014) (same); *Paul v. United States*, 140 S. Ct. 342, 342 (2019) (reaffirming “major policy question” doctrine in denial of certiorari).

“step zero”;³⁵⁰ that is, to apply a presumption against deference where the government’s actions favors its own financial interests.³⁵¹

Surely the monetary and fiscal questions discussed above, which impact the shape, value, and deployment of the dollar, are squarely “major questions” and we should be able to see relief from the federal courts. Yet, these doctrines apply only to agency—not presidential—action. As such, executive orders of the kind discussed in Part II may remain fairly insulated from judicial review.

Treasury actions taken via the ESF also seem relatively shielded from review. In the first instance, it is not clear that the Treasury’s actions are considered agency actions within the APA.³⁵² Even if they were, standing may be difficult to establish. Under the so-called political question doctrine, courts often afford broad deference to the President’s decisions concerning foreign affairs or national security.³⁵³ A court could well consider the ESF’s activities as existing within such off-limits arenas.³⁵⁴ In any case, it would be difficult for any given plaintiff to demonstrate a “concrete” grievance in connection with an ESF program.³⁵⁵

As for the FSOC pressing presidential prerogative on the Fed, there are standing problems there as well. In order to be reviewable, actions must be “final.”³⁵⁶ Accordingly, using the FSOC power of recommendation to exert moral suasion and public shaming of the Fed—i.e., to act on climate change or any other Executive Branch priority—is probably insufficiently related to any APA jurisdictional trigger: a discernible “rule, order, license, sanction, relief, or . . . failure to act.”³⁵⁷ As such, unlike the typical nondelegation doctrine that we see

³⁵⁰ Transcript of Oral Argument at 29, *Becerra v. Empire Health Found.*, No. 20-1312 (U.S. June 24, 2022).

³⁵¹ Cass R. Sunstein, *Chevron Step Zero*, 92 VA. L. REV. 187, 191 (2006) (defining “Step Zero” as “the initial inquiry into whether the *Chevron* framework applies at all”).

³⁵² See Ann Murphy, *A Sea Change in Court Analysis of Treasury Regulations: How the Treasury Department Won the Battle but Lost the War*, A.B.A. (Feb. 25, 2016), https://www.americanbar.org/groups/taxation/publications/abataximes_home/16feb/16feb-ac-murphy-a-sea-change-in-court-analysis-of-treasury-regulations/ [<https://perma.cc/RJ3Y-7VE9>].

³⁵³ See *United States v. Curtiss-Wright Export Corp.*, 299 U.S. 304, 315–27 (1936) (upholding an extremely broad delegation in the foreign affairs context).

³⁵⁴ See generally Curtis A. Bradley, *Chevron Deference and Foreign Affairs*, 86 VA. L. REV. 649, 661 (2000); Henry P. Monaghan, *The Protective Power of the Presidency*, 93 COLUM. L. REV. 1, 47–56 (1993).

³⁵⁵ See, e.g., *Starr Int’l Co. v. United States*, 856 F.3d 953, 964 (Fed. Cir. 2017); *U.S. Army Corps of Eng’rs v. Hawkes Co.*, 578 U.S. 590 (2016); *Reuss v. Balles*, 584 F.2d 461, 469 (D.C. Cir. 1978).

³⁵⁶ 5 U.S.C. § 704.

³⁵⁷ *Id.* § 551(13).

taking shape in courts to limit the breadth of some agency actions, it would seem that the *direct delegation* of monetary and fiscal power to the President seems quite far from the courts' purview.

Overall, it appears that these presidential pathways, once dug, are nearly impossible to retrench. What else can Congress do?

1. *Presidential Checks*

Sunlight has been said to be the best disinfectant to governmental overreach. On that theory, Congress should design a new procedural mechanism for scrutinizing presidential action that is taken in response to an economic emergency. In other areas of emergency action, like national security, the public has become skeptical of overreach, and in response, Congress has more rigorously exercised oversight.³⁵⁸ The presidential treatment of economic emergency, however, is still not treated as such a threat to liberty. But this would have been too sanguine for the Framers, who understood that emergencies “afford a ready pretext for usurpation.”³⁵⁹ Congress may therefore do best in this area to reflect upon the possible design of a new process that would enable better scrutiny and oversight of the President's exercise of fiscal-monetary power in emergency.

Congress still has the power to censure and investigate presidential action generally, and there are methods that might be adapted from other contexts. Consider the process of appointing a special counsel. Since the 1920's Teapot Dome Scandal, the President—at Congress's instruction or request—has from time to time appointed a “special counsel” to investigate offenses that might be criminal in nature.³⁶⁰ In 1978, Congress used the Ethics in Government Act to formalize this process within the Office of the Independent Counsel—an office that sat within the Attorney General's office but was directly accountable to Congress.³⁶¹

³⁵⁸ See, e.g., Andrew Desiderio, *Why Congress Is Finally Starting to Claw Back Its War Powers From the President*, POLITICO (July 7, 2021, 12:00 PM), <https://www.politico.com/news/2021/07/07/congress-aumf-biden-498399> [<https://perma.cc/38WP-PJRP>].

³⁵⁹ *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 650 (1952).

³⁶⁰ See J. Leonard Bates, *The Teapot Dome Scandal and the Election of 1924*, 60 AM. HIST. REV. 303, 311 (1955).

³⁶¹ Ethics in Government Act of 1978, Pub. L. No. 95-521, 92 Stat. 1824. The Ethics in Government Act lapsed in 1999, at which time Department of Justice regulations created the Special Counsel Investigation Office. See JARED P. COLE, CONG. RSCH. SERV., R44857, SPECIAL COUNSEL INVESTIGATIONS: HISTORY, AUTHORITY, APPOINTMENT AND REMOVAL 8 (2019).

The presidential actions discussed here are not within the wheelhouse of the special counsel.³⁶² The point is simply that with some modifications, a similar office could be created to assess the presidential exercise of fiscal or monetary power—especially when the President justifies action by emergency and invokes emergency powers. Regardless of whether such office would be housed in the Attorney General’s office, it would ideally be directly accountable to Congress alone and thus receive its funding from an appropriation rather than the budget of the DOJ. Although this proposal would not prevent future delegations of monetary power, it could curb the exercise of powers already enacted in law. And possibly, the existence of the office would reduce Congress’s incentives to grant sweeping economic power going forward.

2. *The Fed and Fiscal Dominance*

In 1970, Milton Friedman famously wrote that “inflation is always and everywhere a monetary phenomenon,” setting the intellectual stage for the Federal Reserve to take primary responsibility—both in policy and in the public eye—for managing inflation.³⁶³ Although the Fed has statutory responsibility for maintaining stable prices, as the line between what is “monetary” and what is “fiscal” has increasingly blurred, so too have the roles of Congress, the President, and the Fed in contributing to inflation.³⁶⁴ So regardless of whether the Fed has actually crossed that Rubicon, the specter of fiscal dominance might be back.³⁶⁵ As this Article has argued, once the practice of presidential monetary control begins, it is very difficult to check. It is therefore critically important to arrest presidential propensity to dominate the Fed while it is still possible.

Concretely, there are at least two operational changes to Fed policy that might stifle future encroachments. The first change concerns the reinstatement of a monetary rule. There is a long literature discussing the merits and demerits of monetary policy rules versus discretion.³⁶⁶

³⁶² *Id.* at 11–14.

³⁶³ FRIEDMAN, *supra* note 26, at 24.

³⁶⁴ *See supra* note 19 and accompanying text.

³⁶⁵ *See supra* note 25 and accompanying text.

³⁶⁶ *See generally* Charles I. Plosser, *Commitment, Rules, and Discretion*, 36 CATO J. 251 (2016); Alexander William Salter, *Is There a Self-Enforcing Monetary Constitution?*, 25 CONST. POL. ECON. 280 (2014); Alexander William Salter, *An Introduction to Monetary Policy Rules* (Dec. 2014) (unpublished manuscript) (on file with the Mercatus Center).

Generally, those who favor discretion point to the wisdom in *not* tying the Fed's hands in times of crisis.³⁶⁷ As recent experience confirms, when financial crisis hits the Fed has a battery of ammunition to fire—liquidity facilities,³⁶⁸ QE,³⁶⁹ and reducing interest rates.³⁷⁰ Much of this would not have been possible under an old-world regime like the Gold Standard.³⁷¹

But discretion has some drawbacks, especially political ones. Discretion creates space for Executive Branch pressure, influence, or force.³⁷² Indeed, others have pointedly argued that “without a credible monetary rule, ‘the President’s objectives and plans will continue to be the dominant input in the conduct of monetary policy.’”³⁷³ A version of this problem has been labeled the “time inconsistency problem”: if central bankers cannot credibly commit to doing the difficult thing over the longer-term—e.g., not expand the money supply in response to presidential pressure—their near-term promises to that effect will not be believed and inflation expectations will get out of hand.³⁷⁴ In short, there is an independence corollary.

Influential economists have proposed several monetary rules that the Fed might use in lieu of the Gold Standard—namely, targeting money supply growth (Milton Friedman), interest rates (John Taylor), inflation (current Fed practice), or nominal GDP (Scott Sumner).³⁷⁵ This short concluding overview cannot do full justice to the subject of the costs and benefits of each type of rule. But among these rules, it bears mentioning in closing that nominal GDP (i.e., nominal income) targeting is likely to be the most helpful for the specific matter discussed here—that is, checking presidential exercise of pecuniary power.³⁷⁶

³⁶⁷ See Plosser, *supra* note 366, at 252.

³⁶⁸ See generally LABONTE, *supra* note 324.

³⁶⁹ See SELGIN, *supra* note 332, at 3–11.

³⁷⁰ See CONTI-BROWN, *supra* note 32, at 51.

³⁷¹ See generally ELWELL, *supra* note 56.

³⁷² See generally Skinner, *supra* note 19.

³⁷³ Dorn, *supra* note 27, at 579 (quoting Robert E. Weintraub, *Congressional Supervision of Monetary Policy*, 4 J. MONETARY ECON. 341, 360 (1978)).

³⁷⁴ See Plosser, *supra* note 366, at 252.

³⁷⁵ See generally DAVID BECKWORTH, FACTS, FEARS, AND FUNCTIONALITY OF NGDP LEVEL TARGETING: A GUIDE TO A POPULAR FRAMEWORK FOR MONETARY POLICY (2019), <https://www.mercatus.org/system/files/beckworth-ngdp-targeting-mercatus-special-study-v2.pdf> [<https://perma.cc/Q8FS-SG5P>]; Scott B. Sumner, *Nominal GDP Targeting: A Simple Rule to Improve Fed Performance*, 34 CATO J. 315 (2014).

³⁷⁶ See Joshua R. Hendrickson, *How Should the Central Bank Determine Its Target for Nominal Income Growth?*, MERCATUS CTR. (June 13, 2019), <https://www.mercatus.org/publica->

NGDP targeting requires the central bank to choose a target growth rate for nominal income (measured as nominal GDP). When nominal income falls below the target, the Fed would increase the money supply (i.e., by reducing interest rates) and vice versa.³⁷⁷ There are two relevant advantages to this rule. For one, it displaces a “dual mandate” where the Fed targets price stability and employment. The goal of maximum employment has become so ambiguous and so fiscal in nature that it has invited extensive political pressure.³⁷⁸ Additionally, NGDP targeting can improve fiscal discipline. Increased government spending directly increases nominal incomes, which would then prompt the Fed to contract the money supply—higher government spending would in turn lead to higher interest rates, making substantial spending much less popular.

The second possible bulwark against political pressure is the elimination of the Fed’s ability to pay interest on excess reserves. Since 2008 the Fed has operated what is referred to commonly as a “floor system,” or an “ample-reserves framework,” and it does so by paying interest on the excess reserves that banks hold in their accounts at the Federal Reserve banks.³⁷⁹ This is referred to as “IOER.”³⁸⁰ In effect, the Board of Governors regulates overnight rates by setting and administering this interest rate which, in turn, makes banks unwilling to part with reserves for any lower rate.³⁸¹ As it pertains to fiscal dominance, the concern with IOER is that it divorces the size of the Fed’s balance sheet from its stance on monetary policy—which is to say that regardless of how large the Fed’s balance sheet grows from buying assets, it can still use the IOR power to influence the amount that banks are lending and at what price, thereby expanding or contracting

tions/monetary-policy/how-should-central-bank-determine-its-target-nominal-income-growth [https://perma.cc/39EC-SPH9].

³⁷⁷ See generally BECKWORTH, *supra* note 375.

³⁷⁸ See Skinner, *supra* note 254, at 283–85; see generally BECKWORTH, *supra* note 375; Sumner, *supra* note 375.

³⁷⁹ See Jane Ihrig, Zeynep Senyuz & Gretchen C. Weinbach, *Implementing Monetary Policy in an “Ample-Reserves” Regime: The Basics (Note 1 of 3)*, FED. RES. BD. (July 1, 2020), <https://www.federalreserve.gov/econres/notes/feds-notes/implementing-monetary-policy-in-an-ample-reserves-regime-the-basics-note-1-of-3-20200701.htm> [https://perma.cc/N2LR-JBGT]; see also Ben S. Bernanke & Donald Kohn, *The Fed’s Interest Payments to Banks*, BROOKINGS (Feb. 16, 2016), <https://www.brookings.edu/blog/ben-bernanke/2016/02/16/the-feds-interest-payments-to-banks/> [https://perma.cc/87VH-P3EX]. Formally, Congress gave the Fed power to pay interest on reserves in the 2006 Financial Services Regulatory Relief Act. Operationally, the Fed’s choice of rate (benchmarked to its primary credit rate) is what creates the so-called floor system. See SELGIN, *supra* note 332, at 79–81.

³⁸⁰ See Ihrig et al., *supra* note 379.

³⁸¹ *Id.*

the flow of credit and, in turn, the economy.³⁸² But a completely unconstrained balance sheet as such creates space for political pressure—to engage in politically motivated bond purchases or debt monetization—that would not, in theory, interfere with the Fed’s target interest rate. Congress authorized the Fed to engage in IOR policy in 2008 in the heat of the global financial crisis, and it could, now that inflation and fiscal dominance loom ever larger, consider rescinding or curtailing this authority.³⁸³

CONCLUSION

Today, the President has accumulated an impressive cache of monetary-fiscal power sufficient to dominate the Federal Reserve. Regardless of whether the 2022 episode of inflation is the byproduct of fiscal dominance, events as they have unfolded fired a warning shot across the bow. Since the 1930s, Congress has steadily delegated a host of monetary-fiscal powers to the President, which establishes a legal basis for influencing the Fed’s decisions about monetary policy in reaction to a president’s fiscal measures and goals. This drift from the constitutional baseline poses threats to the central bank’s independence but also presses broader social concerns surrounding fiscal discipline and the prospects for the dollar and the continued ability of representative democracy to safeguard liberal economic values in private property and contract.

³⁸² See DAVID BECKWORTH, *THE GREAT DIVORCE: THE FEDERAL RESERVE’S MOVE TO A FLOOR SYSTEM AND THE IMPLICATIONS FOR BANK PORTFOLIOS* (2018), <https://www.mercatus.org/system/files/beckworth-great-divorce-mercatus-research-v1.pdf> [https://perma.cc/GDA2-GFJS].

³⁸³ Financial Services Regulatory Relief Act of 2006, Pub. L. No. 109-351 § 201, 120 Stat. 1966, 1968–69 (authorizing IOR); Emergency Economic Stabilization Act of 2008, Pub. L. No. 110-343, § 128, 122 Stat. 3765, 3796 (accelerating the effective date to October 1, 2008).

NOTE

Incorporating the Social Cost of Greenhouse Gases into the Federal Procurement Lifecycle

*Evan Matsuda**

ABSTRACT

Federal procurement has an important role to play in mitigating and adapting to climate change. The massive scale of the government's purchasing power—more than \$600 billion in Fiscal Year 2022—puts the federal government in a unique position to mitigate anthropogenic climate change by purchasing and creating markets for products and services with lower greenhouse gas emissions. The Biden Administration has recognized the potential climate impact of federal procurement, but policy direction alone will fail to curb anthropogenic contributions to rising global temperatures without specific and mandatory implementation schemes.

To ensure prioritization of low emissions solutions, the government must overcome the temptations of low up-front purchase prices and internalize the less obvious costs associated with greenhouse gas emissions. Two methodologies have developed which, when combined, can do exactly that: (1) greenhouse gas accounting and (2) the social cost of greenhouse gases ("SC-GHG"). First, greenhouse gas accounting has developed for tracking and reporting firms' greenhouse gas emissions, and it can be used by prospective offerors to estimate the total greenhouse gas emissions associated with their

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government contract proposals. Second, the SC-GHG metric quantifies the cost to society, in dollars, of one metric ton of greenhouse gas emissions. If prospective offerors use greenhouse gas accounting methodologies to estimate the emissions associated with their proposals, purchasing agencies can then apply the SC-GHG metric to those estimates to quantify—and therefore compare—the expected social cost of greenhouse gas emissions of each proposal.

This Note advocates for wielding the federal government’s purchasing power to mitigate climate change by accounting for the social cost of greenhouse gases at four key stages of the federal procurement process: (1) acquisition planning, (2) solicitation, (3) evaluation, and (4) quality assurance. To prevent potential burdens on low-value transactions with smaller potential impacts on climate change, this Note further suggests limiting mandatory incorporation of the social cost of greenhouse gases to high-value contracts above a specified dollar threshold.

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INTRODUCTION

One week into his tenure as President of the United States, President Biden signed Executive Order 14,008, “Tackling the Climate Crisis at Home and Abroad,” which in part called for the prioritization of environmental sustainability in the federal government’s acquisition of goods and services.¹ Among the executive order’s specific directives, President Biden called for the electrification of government vehicle fleets, including that of the United States Postal Service (“USPS”).² One month later, USPS entered into a multi-billion-dollar ten-year contract to replace its decades-old fleet of over 200,000 mail delivery vehicles with a Next Generation Delivery Vehicle (“NGDV”) developed by Oshkosh Defense, LLC (“Oshkosh”).³ Critically, however, USPS rejected the vendor that offered a fully electric prototype⁴ and selected Oshkosh’s proposal for an NGDV powered by internal combustion of fossil fuels with the option to transition to electric bat-

¹ Exec. Order No. 14,008, 86 Fed. Reg. 7619, 7623 (Jan. 27, 2021) (“It is the policy of my Administration to lead the Nation’s effort to combat the climate crisis . . . by aligning the management of Federal procurement . . . to support robust climate action.”).

² *Id.* at 7624 (“The plan shall aim to use . . . all available procurement authorities to achieve or facilitate . . . clean and zero-emission vehicles for Federal, State, local, and Tribal government fleets, including vehicles of the United States Postal Service.”).

³ *Next Generation Delivery Vehicle (NGDV) Contract Award*, SAM.GOV (Feb. 23, 2021) [hereinafter *Contract Award*], <https://sam.gov/opp/1e56c386808444d886124fc1927f4eb0/view> [https://perma.cc/CS3J-P3YH] (awarding the contract and announcing an initial commitment of \$482 million); see also *Oshkosh Defense Receives First Order for Next Generation Delivery Vehicle Fleet*, OSHKOSH (Mar. 24, 2022), <https://www.oshkoshcorp.com/en/news/3-24-22-first-ngdv-fleet-order> [https://perma.cc/6NY4-CPLK] (“The initial order is for 50,000 NGDVs and is valued at \$2.98 Billion.”); Anna Phillips & Jacob Bogage, *Biden Officials Push to Hold Up \$11.3 Billion USPS Truck Contract, Citing Climate Change*, WASH. POST (Feb. 2, 2022), <https://www.washingtonpost.com/climate-environment/2022/02/02/usps-trucks-epa-climate-change> [https://perma.cc/NKW3-46G3] (estimating an overall contract value of \$11.3 billion); *U.S. Postal Service Awards Contract to Launch Multi-Billion-Dollar Modernization of Postal Delivery Vehicle Fleet*, U.S. POSTAL SERV. (Feb. 23, 2021), <https://about.usps.com/newsroom/national-releases/2021/0223-multi-billion-dollar-modernization-of-postal-delivery-vehicle-fleet.htm> [https://perma.cc/PZ8E-MH9G].

⁴ See Complaint at 2, *Workhorse Grp. Inc. v. United States*, No. 1:21-cv-01484 (Fed. Cl. June 28, 2021) (protesting the award of the NGDV contract to Oshkosh), *withdrawn*, (Sept. 14, 2021).

tery drivetrains in the future.⁵ The USPS, under direction from the President to electrify its fleet, chose to replace the country's largest vehicle fleet⁶ with a primarily fossil-fuel-driven solution. The procurement process failed to reflect the Administration's prioritization of "robust climate action."⁷

Climate change presents a serious problem with broad impacts in the United States and globally. Scientific consensus has concluded that human activity is a significant driver of the ongoing changes in Earth's climate systems.⁸ In particular, greenhouse gas emissions from burning fossil fuels constitute the primary anthropogenic driver of climate change by substantially increasing the concentration of greenhouse gases in the atmosphere, thereby raising average global temperatures.⁹ Because human activity contributes to the intensifica-

⁵ *Id.* at 3; Motion to Dismiss Plaintiff's Complaint at 4, *Workhorse Grp. Inc. v. United States*, No. 1:21-cv-01484 (Fed. Cl. July 6, 2021) ("In contrast to Workhorse's all-electric approach, Oshkosh proposed a more flexible approach that utilized an internal-combustion-engine vehicle in the near term with the option to transition to an electric vehicle in the medium to long term."). USPS has stated that it plans to place ten percent of its orders under the contract for battery electric versions of the NGDV, but a ninety percent internal combustion engine fleet falls far short of the fully electric solutions proposed by other offerors and contemplated by President Biden's executive orders. *Compare* U.S. POSTAL SERV., RECORD OF DECISION AND RECORD OF ENVIRONMENTAL CONSIDERATION: NEXT GENERATION DELIVERY VEHICLE ACQUISITIONS 1, app. A at 3-1 (2022) [hereinafter RECORD OF DECISION], https://uspsngdveis.com/documents/USPS%20NGDV%20Acquisitions%20NEPA%20Record%20of%20Decision_2.23.22.pdf [https://perma.cc/L56F-28E3], with Exec. Order No. 14,008, 86 Fed. Reg. 7619, 7624 (Jan. 27, 2021).

⁶ USPS OFF. OF INSPECTOR GEN., DELIVERY VEHICLE ACQUISITION STRATEGY 1, 4 (2020), <https://www.uspsoig.gov/sites/default/files/document-library-files/2020/19-002-R20.pdf> [https://perma.cc/L3CM-4T4U].

⁷ Exec. Order No. 14,008, 86 Fed. Reg. 7619, 7624 (Jan. 27, 2021). President Biden has passed multiple climate-related executive orders since Executive Order 14,008, including a December 2021 order that directly addresses the acquisition of zero-emissions vehicle fleets. *See* Exec. Order No. 14,057, 86 Fed. Reg. 70,935, 70,935 (Dec. 8, 2021) ("Through a coordinated whole-of-government approach, the Federal Government shall use its scale and procurement power to achieve . . . 100 percent zero-emission vehicle acquisitions by 2035, including 100 percent zero-emission light-duty vehicle acquisitions by 2027."); *see also* Exec. Order No. 14,037, 86 Fed. Reg. 43,583, 43,583 (Aug. 5, 2021) ("America must lead the world on clean and efficient cars and trucks."). The consistent messaging is encouraging but transitioning from policy priority to practice still requires clear implementation mechanisms.

⁸ *See* IPCC WORKING GRP. 1, CLIMATE CHANGE 2021: THE PHYSICAL SCIENCE BASIS, SUMMARY FOR POLICYMAKERS SPM-1, SPM-5 (2021) [hereinafter PHYSICAL SCIENCE BASIS] ("It is unequivocal that human influence has warmed the atmosphere, ocean and land. Widespread and rapid changes in the atmosphere, ocean, cryosphere and biosphere have occurred.").

⁹ *See, e.g., Overview of Greenhouse Gases*, EPA (May 16, 2022), <https://www.epa.gov/ghgemissions/overview-greenhouse-gases> [https://perma.cc/WD7U-3BV8]. "Anthropogenic"—meaning "caused or produced by humans"—is commonly used in climate change literature to differentiate between human causes and natural climate variations. *Anthropogenic*, DICTION-

tion and acceleration of climate change, human activity also has the potential to mitigate that intensification and acceleration.¹⁰

The federal government, as the single largest purchaser of goods and services in the world, is uniquely positioned to mitigate anthropogenic climate change.¹¹ To do so, the federal government can leverage its procurement system to generate two interrelated benefits: first, by purchasing goods and services that emit fewer greenhouse gases throughout their lifecycle, the government will reduce its direct contributions to climate change; second, by creating demand for low-emissions solutions, the government will indirectly increase the development and market-wide availability of environmentally sustainable goods and services.¹² Achieving both benefits will require consistent prioritization of low-emissions solutions across agencies, which will in turn require a broadly applicable metric for tracking greenhouse gas emissions that can be incorporated throughout the legal frameworks that regulate public procurement at the federal level.¹³

ARY.COM, <https://www.dictionary.com/browse/anthropogenic> [<https://perma.cc/F8BE-LFK9>]; see, e.g., Cynthia Rosenzweig et al., *Attributing Physical and Biological Impacts to Anthropogenic Climate Change*, 453 NATURE 353, 353 (2008).

¹⁰ See IPCC WORKING GRP. III, CLIMATE CHANGE 2022: MITIGATION OF CLIMATE CHANGE, SUMMARY FOR POLICYMAKERS (2022) [hereinafter MITIGATION OF CLIMATE CHANGE] (synthesizing and summarizing the most current scientific data on the effects of human-led climate change mitigation efforts).

¹¹ See, e.g., *Selling Greener Products and Services to the Federal Government*, EPA (Apr. 28, 2022), <https://www.epa.gov/sustainable-marketplace-greener-products-and-services/selling-greener-products-and-services-federal> [<https://perma.cc/5TAQ-86VV>].

¹² See Exec. Order No. 14,057, 86 Fed. Reg. 70,935, 70,935 (Dec. 8, 2021) (“As the single largest land owner, energy consumer, and employer in the Nation, the Federal Government can catalyze private sector investment and expand the economy and American industry by transforming how we build, buy, and manage electricity, vehicles, buildings, and other operations to be clean and sustainable.”).

¹³ The Federal Acquisition Regulation (“FAR”), located in Title 48 of the Code of Federal Regulations, is the principal document regulating the procurement process for federal executive agencies in the United States. See FAR 1.101; 48 C.F.R. ch. 1 (2021). Thirty executive agencies also have agency-specific regulations that supplement the FAR. See, e.g., Defense Federal Acquisition Regulation Supplement (“DFARS”), 48 C.F.R. ch. 2 (2021) (establishing acquisition regulations specific to the Department of Defense); see also *Regulations*, ACQUISITION.GOV, <https://www.acquisition.gov/content/regulations> [<https://perma.cc/YBC6-XLEA>] (listing and providing links to all of the agency supplements to the FAR). The FAR expressly contemplates these agency-specific supplements and refers to the resulting combination of regulations as the Federal Acquisition Regulation System (“FAR System”). See generally FAR pt. 1 (providing general information about the FAR System, including the role of agency supplements). Note that the FAR System does not regulate USPS procurements. 7-7.1 *Federal Laws Applicable to the Postal Service*, U.S. POSTAL SERV., https://about.usps.com/manuals/spp/html/spp7_035.htm [<https://perma.cc/KP7B-VGD7>] (“[T]he Postal Service is not subject to the FAR.”). This Note does not offer a solution for USPS procurements but rather uses the high-profile NGDV acqui-

Since 2009, an interagency working group has focused on developing just such a metric: SC-GHG.¹⁴ The SC-GHG tool¹⁵ quantifies—with a standardized, scientifically founded methodology—the social cost, in dollars, of one metric ton of greenhouse gas emissions.¹⁶ Correspondingly, the private sector has developed and adopted methodologies for tracking and reporting greenhouse gas emissions.¹⁷ Prospective offerors should use these greenhouse gas accounting methodologies to estimate the total expected emissions associated with products and services offered to the government. With those estimates, purchasing agencies will be able to multiply the expected tonnage of greenhouse gas emissions by SC-GHG multipliers to quantify the expected social cost of emissions associated with each proposed solution.

This Note advocates that the federal government should wield its unique power to mitigate climate change by accounting for the social cost of greenhouse gases—utilizing SC-GHG values in conjunction with mandatory greenhouse gas emissions estimates by offerors—at four key stages of the federal procurement process: (1) acquisition planning, (2) solicitation, (3) evaluation, and (4) quality assurance. To prevent undue burdens on low-value transactions with smaller potential impact on climate change, this Note further suggests limiting mandatory consideration of the social cost of greenhouse gases to high-value contracts above a specified dollar threshold.

Part I provides background information about the potential for federal public procurement to mitigate the progression of climate change and the procurement system's failure to live up to that potential so far. Part II addresses overcoming the barrier to sustainable procurement implementation created by the longstanding prioritization

tion to demonstrate the stakes involved and the substantial impact that prioritization of cost over environmental impact can have in federal procurements.

¹⁴ See generally INTERAGENCY WORKING GRP. ON SOC. COST OF GREENHOUSE GASES, TECHNICAL SUPPORT DOCUMENT: SOCIAL COST OF CARBON, METHANE, AND NITROUS OXIDE INTERIM ESTIMATES UNDER EXECUTIVE ORDER 13990 (2021) [hereinafter IWG INTERIM ESTIMATES] (explaining the history and development of SC-GHG).

¹⁵ This Note refers repeatedly to both the SC-GHG tool and the social cost of greenhouse gases as a broader concept. All uses of “SC-GHG” in acronym form refer to the specific tool that quantifies the monetary value of one ton of greenhouse gases. All other uses of “social cost of greenhouse gases” refer to the broader concept of social impacts from greenhouse gas emissions.

¹⁶ IWG INTERIM ESTIMATES, *supra* note 14, at 2.

¹⁷ See *About Us*, GREENHOUSE GAS PROTOCOL, <https://ghgprotocol.org/about-us> [<https://perma.cc/A38C-J4S9>]; see also *Greenhouse Gas Reporting Program (GHGRP)*, EPA (Nov. 3, 2022), <https://www.epa.gov/ghgreporting> [<https://perma.cc/XW35-8HTL>] (providing a centralized location for greenhouse gas reporting data published for public availability every year).

of low up-front purchase prices. Finally, Part III discusses implementing mandatory consideration of the social cost of greenhouse gases in the federal procurement process and suggests considering a dollar threshold below which the proposed requirements do not apply.

I. THE UNDERUTILIZED POTENTIAL OF THE FEDERAL PROCUREMENT SYSTEM TO MITIGATE CLIMATE CHANGE

Climate change is increasing in severity and will continue to impact humanity for the foreseeable future.¹⁸ The news broadcasts a seemingly continuous stream of devastating climate events in the United States and around the world.¹⁹ Disaster-relief spending data and meta-analysis of climate impact studies corroborate the apparent intensification of climate change portrayed by the news.²⁰ In 2021, the United States experienced twenty separate billion-dollar weather and climate disasters, costing a total of \$152.6 billion.²¹ The costs of weather and climate disasters for the past five years total more than one-third of the combined disaster costs of the last forty-three years, accounting for inflation.²²

The 2021 climate change assessment report by the United Nations Intergovernmental Panel on Climate Change (“IPCC”)²³ underscores the scale and increasing intensity of climate change, in addition to es-

¹⁸ See generally PHYSICAL SCIENCE BASIS, *supra* note 8.

¹⁹ See, e.g., Adam Wernick, *Climate Change Is Driving Extreme Weather Events Around the World in 2021*, THE WORLD (Sept. 6, 2021, 3:45 PM), <https://theworld.org/stories/2021-09-06/climate-change-driving-extreme-weather-events-around-world-2021> [<https://perma.cc/N5XT-9SZC>]; Sarah Kaplan & Andrew Ba Tran, *Nearly 1 in 3 Americans Experienced a Weather Disaster This Summer*, WASH. POST (Sept. 4, 2021, 1:35 PM), <https://www.washingtonpost.com/climate-environment/2021/09/04/climate-disaster-hurricane-ida> [<https://perma.cc/P2NH-Q98L>]; Annabelle Timsit & Sarah Kaplan, *At Least 85 Percent of the World's Population Has Been Affected by Human-Induced Climate Change, New Study Shows*, WASH. POST (Oct. 11, 2021, 12:00 PM), <https://www.washingtonpost.com/climate-environment/2021/10/11/85-percent-population-climate-impacts> [<https://perma.cc/7UWC-42YZ>].

²⁰ See Max Callaghan et al., *Machine-Learning-Based Evidence and Attribution Mapping of 100,000 Climate Impact Studies*, 11 NATURE CLIMATE CHANGE 966, 966 (2021) (“[A]ttributable anthropogenic impacts may be occurring across 80% of the world’s land area, where 85% of the population reside.”); *Billion-Dollar Weather and Climate Disasters: Time Series*, NAT’L OCEANIC & ATMOSPHERIC ADMIN. NAT’L CTRS. FOR ENV’T INFO., <https://www.ncdc.noaa.gov/billions/time-series> [<https://perma.cc/AF7Q-L4TF>].

²¹ *Billion-Dollar Weather and Climate Disasters: Time Series*, *supra* note 20. There were eighteen additional billion-dollar weather and climate disaster events in 2022. *Id.*

²² *Id.* The five-year cost average of such events has reached \$157.6 billion per year. *Id.*

²³ Since 1990, the IPCC has published a climate change assessment report every five to eight years that evaluates and synthesizes the most current scientific publications regarding the impacts and scientific basis of climate change. *About the IPCC*, IPCC, <https://www.ipcc.ch/about> [<https://perma.cc/RW5H-RC6L>]. In 2021 and 2022 the IPCC’s working groups released their contributions for the IPCC’s Sixth Assessment Report. PHYSICAL SCIENCE BASIS, *supra* note 8; MIT-

establishing the anthropogenic contributions to those changes.²⁴ The report highlights, for example, that “[h]uman influence has warmed the climate at a rate that is unprecedented in at least the last 2,000 years,”²⁵ resulting in “increases in the frequency and intensity of hot extremes, marine heatwaves, and heavy precipitation, agricultural and ecological droughts in some regions, [the] proportion of intense tropical cyclones, as well as reductions in Arctic sea ice, snow cover and permafrost.”²⁶

The primary anthropogenic driver of these changes is greenhouse gas emissions, specifically carbon dioxide (“CO₂”) emitted from the burning of fossil fuels.²⁷ The main sources of human CO₂ emissions in the United States are transportation, electricity generation, and industry, together accounting for eighty percent of 2020 CO₂ emissions.²⁸

Unfortunately, the magnitude and severity of anthropogenic climate change likely mean that individual action is insufficient.²⁹ Mitigating the society-wide impacts of climate change will require continued innovation from private industry and coordinated leadership and guidance from the government.³⁰

This Part considers the potential role of federal public procurement in mitigating anthropogenic climate change, examines the failure of the government to fulfill that role, and addresses why such failures will likely continue without additional regulatory action.

A. *The Potential Climate Impact of Federal Public Procurement*

The federal procurement system’s immense spending power is a key government tool for mitigating and adapting to climate change. The federal government spent more than \$600 billion through con-

IGATION OF CLIMATE CHANGE, *supra* note 10; IPCC WORKING GRP. II, CLIMATE CHANGE 2022: IMPACTS, ADAPTION AND VULNERABILITY (2022).

²⁴ See PHYSICAL SCIENCE BASIS, *supra* note 8.

²⁵ *Id.* at SPM-7.

²⁶ *Id.* at SPM-19.

²⁷ *Id.* at SPM-8, SPM-16, SPM-37; *Overview of Greenhouse Gases*, *supra* note 9.

²⁸ *Overview of Greenhouse Gases*, *supra* note 9.

²⁹ See, e.g., DAVID WALLACE-WELLS, THE UNINHABITABLE EARTH: LIFE AFTER WARMING 186–89 (2019) (“[T]he climate crisis demands political commitment well beyond the easy engagement of rhetorical sympathies, comfortable partisan tribalism, and ethical consumption.”).

³⁰ See CARSTEN HANSEN, WAKING THE TRILLION-DOLLAR GIANT: SUSTAINABLE PROCUREMENT (SPP) AND THE 2030 SDG AGENDA 7, 9–10 (2020), [https://www.greengrowthknowledge.org/sites/default/files/SPP%20Article%20-%20Waking%20the%20Giant%20\(Carsten%20Hansen%202020\)%20\(Final\)%2001%20October%202020.pdf](https://www.greengrowthknowledge.org/sites/default/files/SPP%20Article%20-%20Waking%20the%20Giant%20(Carsten%20Hansen%202020)%20(Final)%2001%20October%202020.pdf) [https://perma.cc/NC8J-CTTV].

tracts in Fiscal Year 2022,³¹ making it the single largest purchaser of goods and services in the world.³²

The magnitude of the federal government's procurement spending creates unique potential for government contracts to significantly impact climate change mitigation efforts in two interrelated ways. First, the enormous quantity of goods and services purchased by the government significantly impacts the environment through greenhouse gas emissions related to manufacturing, transportation, maintenance, fueling, and disposal.³³ Second, the demand created by the government's commitment to purchasing environmentally sustainable solutions can shape markets and increase the innovation and corresponding supply of goods and services that will proliferate throughout public and private markets.³⁴ If greenhouse gas emissions are the primary anthropogenic source of climate change, then consistent prioritization of solutions associated with lower greenhouse gas emissions has substantial potential to slow the progression of anthropogenic climate change.

President Biden has consistently recognized the critical role that federal public procurement can play in broader climate change policy,³⁵ but even with directives from the President, on-the-ground im-

³¹ *Advanced Search*, USA SPENDING.GOV, <https://www.usaspending.gov/search/?hash=3344709d2de59d1c6c19104655195265> [<https://perma.cc/P4ES-6L8M>] (select "Start Searching Awards," filter for awards from "FY 2022" under the "Time Period" dropdown, and filter for Contracts and Contract IDVs under the "Award type" dropdown).

³² *Selling Greener Products and Services to the Federal Government*, *supra* note 11.

³³ See, e.g., Tanya Filer, *How Governments Can Turn Procurement into a Climate Innovation Tool*, BROOKINGS (Sept. 16, 2021, 10:32 PM), <https://www.brookings.edu/techstream/how-governments-can-turn-procurement-into-a-climate-innovation-tool> [<https://perma.cc/Y5J7-WBVZ>].

³⁴ See *id.*; Steven L. Schooner & Evan Matsuda, *Sustainable Procurement: Building Vocabulary to Accelerate the Federal Procurement Conversation*, 21-10 BRIEFING PAPERS 1, 2 (2021); Sarah Gibbens, *What If the World's Biggest Customer Went Green? The U.S. Government Wants to Find Out*, NAT'L GEOGRAPHIC (Mar. 23, 2021), <https://www.nationalgeographic.com/environment/article/what-if-worlds-biggest-customer-went-green-us-government-wants-to-find-out> [<https://perma.cc/U5WN-RA97>].

³⁵ See, e.g., Exec. Order No. 14,008, 86 Fed. Reg. 7619, 7623-24 (Jan. 27, 2021) ("It is the policy of my Administration to lead the Nation's effort to combat the climate crisis by example—specifically, by aligning the management of Federal procurement . . . to support robust climate action. By providing an immediate, clear, and stable source of product demand . . . my Administration will help to catalyze private sector investment into, and accelerate the advancement of America's industrial capacity to supply, domestic clean energy, buildings, vehicles, and other necessary products and materials."); Exec. Order No. 14,030, 86 Fed. Reg. 27,967, 27,969 (May 20, 2021) ("The Federal Acquisition Regulatory Council . . . shall consider amending the Federal Acquisition Regulation (FAR) to . . . ensure that major Federal agency procurements minimize the risk of climate change . . ."); Exec. Order No. 14,057, 86 Fed. Reg. 70,935, 70,935 (Dec. 8, 2021) ("[T]he Federal Government shall use its scale and procurement power to

plementation has not reflected the Administration’s prioritization of environmentally sustainable procurement.³⁶

B. A Lost Opportunity: The United States Postal Service Purchased up to 165,000 Fossil-Fuel-Powered “Next Generation” Delivery Vehicles

USPS maintains the largest vehicle fleet in the United States with over 200,000 delivery and collection vehicles.³⁷ As part of President Biden’s plan to revitalize the government’s sustainability efforts, Executive Order 14,008 created a National Climate Task Force and directed it to “use . . . all available procurement authorities to achieve or facilitate . . . clean and zero-emission vehicles for . . . government fleets, *including vehicles of the United States Postal Service*.”³⁸

One month after President Biden signed Executive Order 14,008, however, USPS awarded a ten-year indefinite-delivery, indefinite-quantity³⁹ contract to Oshkosh for a fossil-fuel-driven delivery vehicle—expected to operate at only 8.6 miles per gallon—to replace the decades-old Grumman Long Life Vehicle fleet.⁴⁰ The contract estab-

achieve . . . 100 percent zero-emission vehicle acquisitions by 2035 . . . a net-zero emissions building portfolio by 2045 . . . a 65 percent reduction in scope 1 and 2 greenhouse gas emissions . . . [and] net-zero emissions from Federal procurement . . .”).

³⁶ See, e.g., Letter from Vicki Arroyo, Assoc. Adm’r, EPA, to Jennifer Beiro-Réveill , Senior Dir. of Env’t Affs. & Corp. Sustainability, USPS (Feb. 2, 2022) [hereinafter EPA Letter to USPS] (“[The Postal Service’s proposal] is plainly inconsistent with . . . specific national policies to move with deliberate speed toward clean, zero-emitting vehicles, including Executive Orders 14008 and 14037 and their policies . . .”).

³⁷ USPS OFF. OF INSPECTOR GEN., *supra* note 6.

³⁸ Exec. Order No. 14,008, 86 Fed. Reg. 7619, 7623–24 (Jan. 27, 2021) (emphasis added).

³⁹ Indefinite-delivery, indefinite-quantity contracts, commonly referred to as “IDIQ” contracts, specify a minimum purchase requirement but otherwise do not define the quantity of supplies or services that the government will purchase over the life of the contract. See *generally* FAR subpart 16.5 (establishing the regulations for IDIQ contracts). The purchasing agency issues orders for supplies or services as needed under the contract. FAR 16.501-1.

⁴⁰ *Contract Award*, *supra* note 3; see also EPA Letter to USPS, *supra* note 36 (“[T]he proposed new internal combustion engine (ICE) vehicles are expected to achieve only 8.6 miles per gallon (mpg), barely improving over the decades old long-life vehicles that achieve 8.2 mpg.”). Notably, Oshkosh’s NGDV proposal allows USPS to purchase electric versions of its vehicles at additional cost, but USPS initially expected to place only ten percent of its orders for the electric version of the NGDV, meaning ninety percent of its orders would be for the 8.6 mpg internal combustion version. See RECORD OF DECISION, *supra* note 5, at 1 to 2, app. A at 3-1. After months of criticism and pressure from Congress and the public, USPS announced commitments to increase the percentage of electric NGDV orders first to twenty percent and then to fifty percent, with the overall expectation that forty percent of the new fleet would be electric. *Postal Service Modernization Enables Expanded Electric Vehicle Opportunity*, USPS (July 20, 2022), <https://about.usps.com/newsroom/national-releases/2022/0720-postal-service-modernization-enables-expanded-electric-vehicle-opportunity.htm> [<https://perma.cc/CKT6-L2XC>]; see, e.g., Jacob Bogage, *16 States, D.C., Climate Activists Sue USPS to Block Truck Purchase*, WASH. POST

lished a quantity range of 50,000 to 165,000 NGDVs manufactured over the ten-year contract period.⁴¹ On top of the sheer quantity of vehicles, USPS expects them to last for decades.⁴² The Statement of Objectives in the NGDV acquisition's request for proposals set the minimum vehicle lifecycle for the new NGDVs at twenty years.⁴³ 165,000 fossil-fuel-driven mail delivery and collection vehicles will emit an enormous quantity of carbon dioxide over twenty years.⁴⁴

This acquisition presented the USPS with a perfect, critically important opportunity to implement the climate change priorities of the federal government under the Biden Administration.⁴⁵ Nevertheless, USPS awarded the contract to Oshkosh for an internal combustion engine delivery vehicle, citing cost as a key factor in the decision.⁴⁶

Without a clear, standardized mechanism for integrating the evaluation of environmental factors into the legal frameworks regulating government procurement, the sustainable procurement directives from President Biden and general policy prioritization of climate

(Apr. 28, 2022, 11:04 AM), <https://www.washingtonpost.com/business/2022/04/28/usps-trucks-lawsuit/> [https://perma.cc/TA7S-U9YV]; Jory Heckman, *Challenge to USPS Fleet Cost Analysis Advances to House Floor After Committee Vote*, FED. NEWS NETWORK (May 11, 2022, 3:57 PM), <https://federalnewsnetwork.com/agency-oversight/2022/05/challenge-to-usps-fleet-cost-analysis-advances-to-house-floor-after-committee-vote/> [https://perma.cc/84ZD-P7GE]. Forty percent is undoubtedly an improvement over ten percent, but the NGDV procurement as it currently stands will still result in U.S. reliance on a majority fossil-fuel driven postal fleet for the next twenty years. To prioritize the climate impact of federal procurements meaningfully and reliably, environmental concerns must play a prominent role when planning and competing government contracts, not post-award in response to widespread criticism.

⁴¹ *Contract Award*, *supra* note 3.

⁴² See U.S. POSTAL SERV., NEXT GENERATION DELIVERY VEHICLE (NGDV) PROTOTYPE DESIGN: STATEMENT OF OBJECTIVES SECTION B 1 (2015).

⁴³ *Id.*

⁴⁴ See EPA Letter to USPS, *supra* note 36, at 3 (“The [greenhouse gas] emissions from the inefficient new ICE vehicles will total nearly 20 million metric tons of carbon dioxide equivalent over the vehicles’ 20-year expected lives, equivalent to the annual emissions from 4.3 million passenger vehicles or 5 coal-fired power plants.” (footnote omitted)).

⁴⁵ See *id.* (“The Postal Service’s proposal as currently crafted represents a crucial lost opportunity to more rapidly reduce the carbon footprint of one of the largest government fleets in the world . . . [and] is plainly inconsistent with . . . specific national policies to move with deliberate speed toward clean zero-emitting vehicles, including Executive Orders 14008 and 14037 and their policies. . . . [A] fully informed Postal Service NGDV decision on this unparalleled opportunity for the federal government to lead by example on climate and clean energy innovation is essential.” (footnotes omitted)).

⁴⁶ See Jacob Bogage, *Biden’s Spending Package Would Give USPS \$6 Billion to Replace Dangerous Mail Trucks with Electric Vehicles*, WASH. POST (Oct. 29, 2021, 2:26 PM), <https://www.washingtonpost.com/business/2021/10/29/biden-usps-dejoy-trucks/> [https://perma.cc/KQM8-6YVE] (“DeJoy told House panels in February and March that the agency could only afford to make 10 percent of the NGDV fleet electric without additional funding from Congress.”).

change mitigation will not overcome institutional inertia.⁴⁷ Although individual contracting officers and evaluation teams⁴⁸ within agencies may—and indeed should—*choose* to prioritize environmental impacts in procurement decisions,⁴⁹ once-in-a-generation multi-billion-dollar procurement opportunities are too critical to the government’s climate change mitigation efforts to leave up to the contracting officer’s discretion.⁵⁰

C. *Fundamental Barrier: The Preference for Low Up-Front Purchase Prices*

Leaving the incorporation of environmental concerns up to the discretion of individual contracting officers is especially unlikely to yield results because of an ingrained preference for low up-front purchase prices, referred to by procurement experts as the tyranny of low price.⁵¹ Prioritizing price is not inherently problematic; indeed the

⁴⁷ Note that the sustainable procurement directives in President Biden’s executive orders generally use broad, aspirational language with distant time horizons; the directives do not create specific, enforceable requirements for the acquisition workforce. *See, e.g.*, Exec. Order No. 14,008, 86 Fed. Reg. 7619, 7623–24 (Jan. 27, 2021); Exec. Order No. 14,057, 86 Fed. Reg. 70,935, 70,935 (Dec. 8, 2021). Wholesale implementation of the sustainable procurement policy priorities espoused by the Biden Administration will require specific, well defined legal mandates in the FAR. To be clear, the FAR does not apply to the USPS; my suggestions in Part III would not affect USPS procurements moving forward. *See* 7-7.1 *Federal Laws Applicable to the Postal Service*, *supra* note 13. Rather, the NGDV acquisition provides a useful warning of the substantial impact that the prioritization of cost over environmental impact can have in federal procurements if no manageable climate-related legal requirements are introduced as a counterbalance to the preference for low cost.

⁴⁸ *See generally* FAR subpart 15.3 (describing source selection procedures). Contracting officers have the authority to bind the government under contract but do not always possess the technical expertise to evaluate proposals, so they may form evaluation teams to select the most suitable proposal based on the criteria established for each acquisition. *See* FAR 15.303.

⁴⁹ For a good example of an agency *choosing* to prioritize environmental impacts in the procurement process, see the recent solicitation issued by the United States Agency for International Development (“USAID”) for global health supply chain programs. *See* USAID, REQUEST FOR PROPOSALS (RFP) No. 7200AA22R00011, at 30, 51 (2022).

⁵⁰ USPS’s exercise of discretion in this acquisition has come under the scrutiny of the EPA, the Government Accountability Office, and the House Committee on Oversight and Reform. *See* EPA Letter to USPS, *supra* note 36; U.S. GOV’T ACCOUNTABILITY OFF., GAO-22-105931, FLEET MANAGEMENT: PRELIMINARY OBSERVATIONS ON ELECTRIC VEHICLES IN THE POSTAL AND FEDERAL FLEETS (2022); Press Release, House Comm. on Oversight & Reform, At Hearing, Oversight Committee Urges Postal Service to Rapidly Electrify Delivery Fleet (Apr. 5, 2022), <https://oversight.house.gov/news/press-releases/at-hearing-oversight-committee-urges-postal-service-to-rapidly-electrify> [<https://perma.cc/C4LM-UFWL>].

⁵¹ *See, e.g.*, Roger Waldron, *The Tyranny of Low Price and Other Challenges*, FED. NEWS NETWORK (Dec. 10, 2021, 11:20 AM), <https://federalnewsnetwork.com/commentary/2021/12/the-tyranny-of-low-price-and-other-challenges> [<https://perma.cc/C8UP-QYTQ>]; Steven L. Schooner & Markus Speidel, ‘Warming Up’ to Sustainable Procurement, 60 CONT. MGMT. 32, 37 (Oct.

Competition in Contracting Act (“CICA”) *requires* purchasing agencies to “include cost or price to the Federal Government as an evaluation factor that must be considered in the evaluation of proposals.”⁵²

This makes sense. Government procurements are funded by taxpayers.⁵³ The government “has a responsibility to act as a careful steward of taxpayer dollars, ensuring that Federal funds are used for purposes that are appropriate, cost effective, and important to the core mission of executive departments and agencies.”⁵⁴ When the government spends over \$600 billion dollars of appropriated funds in one year through contracts, careful stewardship of taxpayer dollars must involve evaluation of offers based on cost or price.

Prioritization of low price has become a problem in public procurement, largely as a result of a strong tendency of decision-makers to focus on the up-front purchase price of goods and services⁵⁵ as opposed to more complicated analyses that consider costs throughout a procurement’s lifecycle.⁵⁶ Unfortunately, this also is understandable. Purchase price is relatively simpler to evaluate, and the acquisition workforce is perennially overworked and understaffed.⁵⁷ Contracting officers are unlikely to create extra time-consuming work by writing

2020) (“Since time immemorial, and increasingly since the acquisition reform initiatives of the 1990s, our profession has struggled to escape the tyranny of ‘low price.’”).

⁵² 41 U.S.C. § 3306(c)(1)(B).

⁵³ Indeed, the use of appropriated funds is a fundamental feature of “acquisition” as defined in the FAR. *See* FAR 2.101 (“*Acquisition* means the acquiring by contract *with appropriated funds* of supplies or services . . . by and for the use of the Federal Government . . .” (emphasis added)). Agencies strictly cannot obligate more money through contracts than the amount appropriated by Congress. *See* 31 U.S.C. § 1341; *United States v. MacCollom*, 426 U.S. 317, 321 (1976) (“[T]he expenditure of public funds is proper only when authorized by Congress.”).

⁵⁴ Memorandum from Shaun Donovan, Dir., Off. of Mgmt. & Budget, to Heads of Exec. Dep’ts & Agencies 1 (Nov. 25, 2016), <https://obamawhitehouse.archives.gov/sites/default/files/omb/memoranda/2017/m-17-08.pdf> [<https://perma.cc/NQ7F-7QK8>]; *see also* *About*, U.S. Gov’t ACCOUNTABILITY OFF., <https://www.gao.gov/about> [<https://perma.cc/EJ5D-8ZBK>]; Budget and Accounting Act of 1921, Pub. L. No. 67-13, § 312, 42 Stat. 20, 25–26 (codified as amended at 31 U.S.C. § 712) (establishing the General Accounting Office, now called the Government Accountability Office, to, in part, “make recommendations looking to greater economy or efficiency in public expenditures”).

⁵⁵ *See* Schooner & Speidel, *supra* note 51, at 37.

⁵⁶ *See generally* John J. Czarnecki & Steven Van Garsse, *What Is Life-Cycle Costing?*, in *COST AND EU PUBLIC PROCUREMENT LAW: LIFE-CYCLE COSTING FOR SUSTAINABILITY 3* (Marta Andhov et al. eds., 2020) (providing an overview of lifecycle cost analysis).

⁵⁷ *See* Steven L. Schooner & Daniel S. Greenspahn, *Too Dependent on Contractors? Minimum Standards for Responsible Governance*, 8 J. CONT. MGMT. 9, 15–16 (2008) (explaining that significant reductions in the government’s acquisition workforce in the 1990s and massive increases in procurement spending since 9/11 have led to an “understaffed, under-resourced, and underappreciated” contracting workforce).

requests for proposals that require complex, contract-specific lifecycle cost evaluations.⁵⁸

By focusing on low purchase prices and neglecting lifecycle costs, the government fails to appropriately consider the myriad costs associated with unmitigated climate change progression. Unlike to an individual consumer, the environmental effects of public procurements are not externalities to the federal government—the government will bear substantial portions of the disaster relief costs, healthcare costs, and crop-cycle disruption costs associated with higher average global temperatures.⁵⁹ As such, even in purely financial terms, focusing on low up-front purchase prices may fail to provide the lowest cost solutions to the government’s needs.⁶⁰ In environmental terms, focusing on low purchase prices will continue to bypass more environmentally sustainable solutions that may have higher up-front prices, but which are necessary to mitigate the worsening impacts of climate change.

II. OVERCOMING THE TYRANNY OF LOW PRICE

Procurement spending invokes three levels of government interests: (1) the acute needs of purchasing agencies, (2) policy priorities undergirding and created by the procurement process itself, and (3) broader public policy objectives implicated by the massive scale of federal public procurement.

First, the government enters into contracts because agencies need products and services to carry out their missions.⁶¹ For example, as discussed in Part I, the Postal Service contracted with Oshkosh because it needs package delivery vehicles to “provide prompt, reliable, and efficient . . . postal services to all communities.”⁶² The United

⁵⁸ See Czarnezki & Van Garsse, *supra* note 56, at 14–15.

⁵⁹ See, e.g., *Billion-Dollar Weather and Climate Disasters: Time Series*, *supra* note 20; Vijay S. Limaye, Wendy Max, Juanita Constible & Kim Knowlton, *Estimating the Health-Related Costs of 10 Climate-Sensitive U.S. Events During 2012*, 3 *GEOHEALTH* 245, 245–46, 254–59 (2019), <https://agupubs.onlinelibrary.wiley.com/doi/epdf/10.1029/2019GH000202> [<https://perma.cc/S42L-LHSJ>].

⁶⁰ See Schooner & Matsuda, *supra* note 34, at 7–8 (adding that fossil fuel subsidies artificially lower the purchase price of fossil-fuel-dependent solutions).

⁶¹ See FAR 1.102(a) (“The vision for the Federal Acquisition System is to deliver on a timely basis the best value product or service to the customer”); John Wm. Whelan & Edwin C. Pearson, *Underlying Values in Government Contracts*, 10 *J. PUB. L.* 298, 302 (1961) (“[The government’s] objective is not to make contracts in order to make money. In the large sense, it makes contracts to fulfill governmental needs, ultimately those of the people governed.”).

⁶² 39 U.S.C. § 101(a) (“The Postal Service shall have as its basic function the obligation to provide postal services to bind the Nation together through the personal, educational, literary,

States government does not manufacture vehicle fleets, so agencies in need of vehicles enter into contracts with companies that do.⁶³

Second, by reaching out into the marketplace to procure products and services from the private sector, the public procurement process creates its own web of often conflicting policy priorities.⁶⁴ The focus on low purchase prices is one example of a policy born out of the procurement process itself. The government must also balance, for example, competition, risk aversion, and efficiency every time it seeks to procure a solution to meet its needs.⁶⁵ The government faces these policy considerations each time it engages in procurement at any scale.⁶⁶

Third, the massive volume of federal public procurement creates the potential for government to address broader policy goals through its cumulative allocation of hundreds of billions of dollars annually.⁶⁷ Indeed, “fulfilling public policy objectives” is a central guiding principle of the federal acquisition system.⁶⁸ The federal government has long incorporated broad public policy goals into the procurement process.⁶⁹ By adopting programs that serve overarching policies through

and business correspondence of the people.”); *see also* Motion to Dismiss Plaintiff’s Complaint at 2–3, *Workhorse Grp., Inc. v. United States*, No. 1:21-cv-01484 (Fed. Cl. July 6, 2021).

⁶³ *See* Whelan & Pearson, *supra* note 61, at 302 (“The Government acquires personal services by contract when such services are unavailable from government employees.”). As a service-oriented example, consider the billion-dollar Department of Health and Human Services contract with Walgreen Co. to provide on-site laboratory services for processing COVID-19 tests. *See* *Definitive Contract PIID 75P00120C00028*, USA SPENDING.GOV, https://www.usaspending.gov/award/CONT_AWD_75P00120C00028_7570_-NONE_-NONE- [https://perma.cc/6GEJ-SWWZ]; *COVID-19 Self-Swab and Point-of-Care Testing Public-Private Partnership*, SAM.GOV, <https://sam.gov/opp/48d1a3e3f36e4738a47b894e1c7d0bfc/view> [https://perma.cc/N477-H94T]. The federal government does not have the capacity to process self-swab testing at scale, so it contracts with a company that does.

⁶⁴ *See generally* Steven L. Schooner, *Desiderata: Objectives for a System of Government Contract Law*, 11 PUB. PROCUREMENT L. REV. 103, 103 (2002) (identifying nine goals of government procurement systems: “(1) competition; (2) integrity; (3) transparency; (4) efficiency; (5) customer satisfaction; (6) best value; (7) wealth distribution; (8) risk avoidance; and (9) uniformity”).

⁶⁵ *See id.*

⁶⁶ *See id.*

⁶⁷ *See* Whelan & Pearson, *supra* note 61, at 302 (“Government contracts produce effects which may not be included among their purposes but which foreseeably and almost inevitably flow from them.”).

⁶⁸ FAR 1.102(a) (“The vision for the Federal Acquisition System is to deliver on a timely basis the best value product or service to the customer, while maintaining the public’s trust and fulfilling public policy objectives.”).

⁶⁹ For example, nearly a century ago, the Buy American Act of 1933 prioritized support for American industry over low contract prices, and the government continues to prioritize domestic content restrictions in federal procurements. *See* Buy American Act, 41 U.S.C.

public procurements, the government has demonstrated its willingness to place certain policy goals above low purchase prices.⁷⁰

A. *The Prioritization of Small Businesses over Lowest Purchase Price*

The Small Business Act,⁷¹ as implemented in Federal Acquisition Regulation (“FAR”) Part 19,⁷² offers a prominent example of the government’s willingness to prioritize broader policy objectives over securing the lowest purchase price available. The Small Business Act establishes the government-wide goal that small businesses receive at least twenty-three percent of the total value of federal prime contract awards each fiscal year.⁷³ Although agencies may not award contracts to small businesses if the contracts’ costs to the government exceed fair market price,⁷⁴ the Small Business Act nevertheless ensures that purchase price takes a back seat to the public policies associated with supporting small businesses.⁷⁵ By setting aside nearly a quarter of the

§§ 8301–8305; *see also* FAR subpart 25.1; Trade Agreements Act of 1979, 19 U.S.C. §§ 2501–2581; 10 U.S.C. § 2533a (referred to as the Berry Amendment). *See generally* DAVID H. CARPENTER & BRANDON J. MURRILL, CONG. RSCH. SERV., R46748, THE BUY AMERICAN ACT AND OTHER FEDERAL PROCUREMENT DOMESTIC CONTENT RESTRICTIONS (2022) (providing a description of the domestic content restrictions for federal government procurements).

⁷⁰ *See* Romeo N. Niyongere, *European-Style Green Public Procurement in the American Context: What It Could Look Like*, 49 PUB. CONT. L.J. 785, 798 (2020) (“Federal procurement historically has been used as a policy instrument for objectives such as creating and safeguarding opportunities for small businesses, obtaining quality goods at low prices through competition, protecting American manufacturing from foreign competition, and promoting non-discrimination and affirmative action.” (footnotes omitted)).

⁷¹ 15 U.S.C. §§ 631–657.

⁷² FAR pt. 19.

⁷³ 15 U.S.C. § 644(g)(1)(A)(i); *see also* ROBERT JAY DILGER & R. CORINNE BLACKFORD, CONG. RSCH. SERV., R45576, AN OVERVIEW OF SMALL BUSINESS CONTRACTING 29–30 (2022) (“The current federal small business procurement goals are . . . at least 23.0% of the total value of all small business eligible prime contract awards to small businesses for each fiscal year.”). Agencies accomplish this allocation of procurement spending through small business set-asides, which in general require contracting officers to limit competition contracts to small businesses—thereby excluding larger firms that may be able to offer cheaper solutions through economies of scale—for every contract for which the contracting officer expects at least two small businesses to submit offers. FAR subpart 19.5; *see also* Kingdomware Techs., Inc. v. United States, 579 U.S. 162 (2016) (holding that the Department of Veterans Affairs *must* limit competition for contract award to veteran-owned small businesses when the contracting officer reasonably expects at least two such businesses to submit offers).

⁷⁴ FAR 19.501(f). Note that fair market price does not mean lowest price available. If small businesses routinely offered competitive prices compared with large contractors, small business set-asides would not be necessary.

⁷⁵ Title 15 of the U.S. Code explains the government’s policy of supporting small businesses as follows:

The essence of the American economic system of private enterprise is free competi-

federal government's procurement budget to promote small businesses, the government wields the market-shaping power of its purse for non-price-related policies.

Similar to the federal government's longstanding recognition that the broad social benefits associated with promoting small businesses outweigh the negatives of potentially higher up-front purchase prices, the Biden Administration has expressed its recognition of the broad social benefits associated with limiting the federal government's contributions to climate change through greenhouse gas emissions.⁷⁶ The federal procurement system provided an impactful lever for promoting small businesses, so the Small Business Act incorporated into the FAR the government's public policy interest in promoting small businesses.⁷⁷ The Federal Acquisition Regulatory Council ("FAR Council")⁷⁸ should similarly incorporate into the FAR the government's public policy interest in mitigating climate change.⁷⁹

That said, in the already highly complex federal procurement system, some public policy objectives are more difficult to address than others because of a lack of workable metrics.

B. *What Gets Measured Gets Managed*

Notably, the implementation of small business set-asides relies on a straightforward metric. The Small Business Administration ("SBA")⁸⁰ provides a table of small business size standards broken

tion. Only through full and free competition can free markets, free entry into business, and opportunities for the expression and growth of personal initiative and individual judgment be assured. The preservation and expansion of such competition is basic not only to the economic well-being but to the security of this Nation. Such security and well-being cannot be realized unless the actual and potential capacity of small business is encouraged and developed.

15 U.S.C. § 631(a).

⁷⁶ See, e.g., Exec. Order No. 14,008, 86 Fed. Reg. 7619 (Jan. 27, 2021); Exec. Order No. 14,057, 86 Fed. Reg. 70,935 (Dec. 8, 2021).

⁷⁷ 15 U.S.C. § 631–57; FAR pt. 19.

⁷⁸ The FAR Council "manages coordinates controls and monitors [sic] the maintenance and issuance of changes in the FAR." *About the FAR Council*, ACQUISITION.GOV, <https://www.acquisition.gov/far-council> [<https://perma.cc/9Y9G-WK82>]; see also 41 U.S.C. § 1303(a)(1) ("[The FAR Council] shall jointly issue and maintain . . . a single Government-wide procurement regulation, to be known as the Federal Acquisition Regulation."). The FAR Council consists of four members: (1) the Administrator for Federal Procurement Policy, (2) the Secretary of Defense, (3) the Administrator of National Aeronautics and Space, and (4) the Administrator of General Services. 41 U.S.C. § 1302.

⁷⁹ See *infra* Part III.

⁸⁰ The SBA was created by the Small Business Act "to carry out the policies of [the Act]:" namely "full and free competition," "economic well-being," and "the security of this Nation." 15 U.S.C. § 631(a), 633.

down by sector (e.g., manufacturing), subsector (e.g., food manufacturing), and industry title (e.g., dog and cat food manufacturing).⁸¹ The classification system provides a size cutoff for each industry based either on average annual receipts or average employment numbers.⁸² Offerors can therefore easily determine whether they qualify as a small business for the purposes of the Small Business Act and its mandatory set-asides.⁸³ The simplicity of the metric plays a key role in the feasibility of its implementation.

As the world of business management has recognized, “what gets measured gets managed.”⁸⁴ Metrics provide the data upon which executives and policymakers base their decisions. What typically gets measured, though, is that which is easy to measure, not necessarily that which is useful.⁸⁵ In the federal public procurement space, with its overworked and understaffed acquisition workforce, it is especially critical that evaluative metrics are both simple to apply *and* effective.⁸⁶

C. Climate Metrics

To incorporate environmental concerns into procurements across agencies and contract types, the procurement process needs a broadly applicable and straightforward metric for the climate impact of proposed solutions. And that metric needs to work; it needs to reliably internalize environmental externalities, or at least mandate their consideration so they cannot be set aside in favor of easier fossil-fuel based solutions with lower up-front prices.

1. The Social Cost of Greenhouse Gases

In 2009, President Obama created the Interagency Working Group on the Social Cost of Greenhouse Gases (“IWG”) “to develop

⁸¹ 13 C.F.R. § 121.201 (2021); *see also* *Table of Size Standards*, U.S. SMALL BUS. ADMIN. (effective July 14, 2022), <https://www.sba.gov/document/support—table-size-standards> [<https://perma.cc/M9B5-CB3M>]. These standards were created and are regularly updated under the North American Industry Classification System (“NAICS”), developed jointly by North American Free Trade Agreement countries, and first published in 1997. *See* OFF. OF MGMT. & BUDGET, EXEC. OFF. OF THE PRESIDENT, NORTH AMERICAN INDUSTRY CLASSIFICATION SYSTEM 3 (2017).

⁸² 13 C.F.R. § 121.201.

⁸³ FAR 19.301.

⁸⁴ Management consultant Peter Drucker is commonly credited with the full saying: “What gets measured gets managed—even when it’s pointless to measure and manage it, and even if it harms the purpose of the organization to do so.” Paul Barnett, *If What Gets Measured Gets Managed, Measuring the Wrong Thing Matters*, 19 CORP. FIN. REV. 5, 5 (2015).

⁸⁵ *See id.*; Schooner & Matsuda, *supra* note 34, at 5.

⁸⁶ *See* Schooner & Greenspahn, *supra* note 57, at 15–16.

a consistent set of estimates” for the monetary value of CO₂ emissions reductions.⁸⁷ The need for a consistent monetary value for the cost of CO₂ emissions arose from a 2008 opinion by the Court of Appeals for the Ninth Circuit that struck down a National Highway Traffic Safety Administration (“NHTSA”) fuel economy standard because the agency failed to monetize the benefits of greenhouse gas emissions when determining the new standard.⁸⁸ Following the Ninth Circuit’s decision, “[f]ederal agencies began regularly incorporating social cost of carbon [(“SC-CO₂”)] estimates in benefit-cost analyses”⁸⁹ Because agency decisions suddenly required a monetized value for the benefits or costs associated with reductions or increases in CO₂ emissions, the government needed to develop a value that agencies across the federal government could consistently, reliably, and accurately apply to their decision making processes.⁹⁰

To that end, the IWG published its first set of SC-CO₂ values in 2010 for use by government agencies in their cost-benefit analyses.⁹¹ The IWG continued to update the SC-CO₂ values based on evolving methodologies, in addition to publishing values for the social cost of methane and of nitrous oxide.⁹² This set of values is collectively called SC-GHG.⁹³ Each SC-GHG value reflects “the societal value of reducing emissions of the gas in question by one metric ton.”⁹⁴

⁸⁷ See KATE C. SHOUSE, CONG. RSCH. SERV., IF11844, SOCIAL COST OF GREENHOUSE GASES: ISSUES FOR CONGRESS 2 (2021).

⁸⁸ See *Ctr. for Biological Diversity v. NHTSA*, 538 F.3d 1172, 1202–03 (9th Cir. 2008) (holding that NHTSA’s failure to monetize the benefit of carbon emissions reduction was arbitrary and capricious, and remanding the case to NHTSA to include a monetized value).

⁸⁹ IWG INTERIM ESTIMATES, *supra* note 14, at 2; see also Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,736 (Sept. 30, 1993).

⁹⁰ IWG INTERIM ESTIMATES, *supra* note 14, at 2.

⁹¹ *Id.* at 2–3.

⁹² *Id.*

⁹³ *Id.* at 2.

⁹⁴ *Id.* The IWG summarizes SC-GHG as follows:

The SC-GHG is the monetary value of the net harm to society associated with adding a small amount of that [greenhouse gas] to the atmosphere in a given year. In principle, it includes the value of all climate change impacts, including (but not limited to) changes in net agricultural productivity, human health effects, property damage from increased flood risk [and] natural disasters, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services. The SC-GHG, therefore, should reflect the societal value of reducing emissions of the gas in question by one metric ton.

Id.

Disbanded by President Trump in 2017⁹⁵ and reinstated by President Biden in 2021,⁹⁶ the IWG recently published an updated set of interim SC-GHG values for agencies to utilize while it finalizes new values based on a more comprehensive methodology.⁹⁷

The SC-GHG values are broadly applicable, straightforward, and consistent across government agencies.⁹⁸ The IWG has taken on the complex work of quantifying the social costs associated with greenhouse gas emissions; purchasing agencies need only apply the metric.⁹⁹

However, the SC-GHG values—which reflect the social cost *per ton* of greenhouse gas emissions—do not by themselves provide purchasing agencies with useful comparative information. To provide a useful datapoint for comparing proposals from prospective offerors, the prospective offerors must provide an estimate of the total tonnage of greenhouse gas emissions associated with proposed solutions. By multiplying the SC-GHG dollar value of one ton of emissions by the total tonnage of emissions associated with a proposed solution, a contracting officer can assess the social cost, in dollars, of each proposal considered.¹⁰⁰

2. Greenhouse Gas Accounting

Private industry has been developing and implementing methodologies for measuring greenhouse gas emissions associated with their operations for over two decades.¹⁰¹ The most widely adopted stan-

⁹⁵ Exec. Order No. 13,783, 82 Fed. Reg. 16,093, 16,095 (Mar. 28, 2017) (disbanding the IWG).

⁹⁶ Exec. Order No. 13,990, 86 Fed. Reg. 7037, 7040 (Jan. 20, 2021) (re-establishing the IWG).

⁹⁷ See IWG INTERIM ESTIMATES, *supra* note 14 (publishing and explaining the IWG's interim SC-GHG values and discount rates). Until the IWG publishes the new values, the interim value for the social cost of one ton of CO₂ in 2022 is \$53 per ton at the recommended discount rate of three percent. *Id.* app. at tbl. A-1. If a contractor estimates that performance of its proposal will result in 1,000,000 tons of CO₂ emissions over the life of the contract, the social cost of that contract's CO₂ emissions is \$53,000,000.

⁹⁸ See Richard L. Revesz & Max Sarinsky, *The Social Cost of Greenhouse Gases: Legal, Economic, and Institutional Perspective*, 39 YALE J. ON REGUL. 855, 855 (2022).

⁹⁹ *Id.*

¹⁰⁰ For example, the EPA calculated the emissions associated with the USPS NGDV contract at “nearly 20 million metric tons of carbon dioxide equivalent over the vehicles’ 20-year expected lives Using the current interim social cost of carbon dioxide, the present value of the climate damages from these emissions would exceed \$900 million” EPA Letter to USPS, *supra* note 36 (footnotes omitted).

¹⁰¹ See, e.g., WORLD BUS. COUNCIL FOR SUSTAINABLE DEV. & WORLD RES. INST., THE GREENHOUSE GAS PROTOCOL: A CORPORATE ACCOUNTING AND REPORTING STANDARD (2001).

dards have been developed by the Greenhouse Gas Protocol.¹⁰² The federal government has also developed multiple greenhouse gas accounting methodologies for quantifying emissions related to the government's activities, buildings, fleets, and energy consumption.¹⁰³

Although variations exist among different methodologies, greenhouse gas accounting generally aims to quantify an entity's direct and indirect emissions up and down that entity's supply chain.¹⁰⁴ For example, the Greenhouse Gas Protocol does this by differentiating Scope 1, Scope 2, and Scope 3 emissions.¹⁰⁵ Scope 1 emissions encapsulate the direct emissions from a firm's assets, such as a vehicle fleet's emissions from internal combustion drivetrains.¹⁰⁶ Scope 2 emissions include the indirect emissions that result from powering, heating, and cooling a firm's operations.¹⁰⁷ The lights used to illuminate a workspace do not in and of themselves emit greenhouse gases, but generating the electricity that powers the lights does emit greenhouse gases.¹⁰⁸ Unless the firm in question is itself a power plant—in which case electricity generation would constitute its Scope 1 emissions because its own assets

¹⁰² See *About Us*, *supra* note 17; WORLD BUS. COUNCIL FOR SUSTAINABLE DEV. & WORLD RES. INST., THE GREENHOUSE GAS PROTOCOL: A CORPORATE ACCOUNTING AND REPORTING STANDARD 68 (rev. ed. 2004) [hereinafter REVISED GREENHOUSE GAS PROTOCOL], <https://ghg-protocol.org/sites/default/files/standards/ghg-protocol-revised.pdf> [<https://perma.cc/TAS9-CT74>].

¹⁰³ See *Greenhouse Gas (GHG) Accounting Tools*, NEPA.GOV, <https://web.archive.org/web/20220612174843/https://ceq.doe.gov/guidance/ghg-accounting-tools.html> [<https://perma.cc/ZA95-9X3G>] (listing the several greenhouse gas accounting tools developed and used by government agencies); see also ALBERTA CARPENTER, ELIZA HOTCHKISS & ALICEN KANDT, NAT'L RENEWABLE ENERGY LAB'Y, AN INTERAGENCY PILOT OF GREENHOUSE GAS ACCOUNTING TOOLS: LESSONS LEARNED 3–5, 10–12 (2013), <https://www.nrel.gov/docs/fy13osti/56602.pdf> [<https://perma.cc/EL77-9GSB>].

¹⁰⁴ See *About Us*, *supra* note 17.

¹⁰⁵ See REVISED GREENHOUSE GAS PROTOCOL, *supra* note 102, at 25; MARY SOTOS, GREENHOUSE GAS PROTOCOL, GHG PROTOCOL SCOPE 2 GUIDANCE 5–6 (2015), https://ghg-protocol.org/sites/default/files/standards/Scope%202%20Guidance_Final_Sept26.pdf [<https://perma.cc/TT8G-R3BL>]; WORLD BUS. COUNCIL FOR SUSTAINABLE DEV. & WORLD RES. INST., GREENHOUSE GAS PROTOCOL, CORPORATE VALUE CHAIN (SCOPE 3) ACCOUNTING AND REPORTING STANDARD: SUPPLEMENT TO THE GHG PROTOCOL CORPORATE ACCOUNTING AND REPORTING STANDARD 4–6 (2011) [hereinafter ACCOUNTING AND REPORTING STANDARD], https://ghgprotocol.org/sites/default/files/standards/Corporate-Value-Chain-Accounting-Reporting-Standard_041613_2.pdf [<https://perma.cc/3RBD-XURH>].

¹⁰⁶ See REVISED GREENHOUSE GAS PROTOCOL, *supra* note 102, at 25.

¹⁰⁷ See SOTOS, *supra* note 105, at 5–6.

¹⁰⁸ Even solar and wind power generation involve some greenhouse gas emissions; solar panels and wind turbines must be manufactured and transported, their components must be manufactured and transported, and their raw materials must be mined and processed. See, e.g., Charles Q. Choi, *Solar Power's Greenhouse Emissions Measured*, LIVE SCIENCE (Feb. 26, 2008), <https://www.livescience.com/2324-solar-power-greenhouse-emissions-measured.html> [<https://perma.cc/Q2HM-6CQD>] (noting also that “manufacturing solar cells produces far fewer air pollutants than conventional fossil-fuel-burning power plants”).

do the emitting—the emissions associated with electricity consumption are Scope 2 emissions.¹⁰⁹ Scope 3 emissions include the indirect emissions both upstream and downstream in the value chain.¹¹⁰ Upstream emissions refer to all of the emissions that go into the products, components, or services purchased and subsequently used by a firm in its own operations.¹¹¹ Downstream emissions refer to all of the emissions that result from a firm’s products after it sells them.¹¹²

Because greenhouse gas accounting methodologies differentiate between separate categories of emissions, they are scalable in terms of complexity. For simple, low-dollar procurements, agencies could choose to request only Scope 1 emissions estimates—the easiest to precisely quantify—while high-dollar procurements could require offerors to provide the more comprehensive Scope 2 and Scope 3 emissions estimates as well. FAR implementation of SC-GHG metrics can therefore retain a degree of flexibility for purchasing agencies to tailor their reporting requirements to the size and sophistication of likely offerors as revealed by market research.¹¹³

Although the benefits of one greenhouse gas accounting tool over another exceed the scope of this Note, the proposed incorporation of SC-GHG metrics into the federal procurement process may benefit from a working group dedicated to assessing greenhouse gas accounting methodologies and providing guidance specifically tailored to entities selling products and services to the federal government.¹¹⁴

Regardless of the methodology chosen, as long as the greenhouse gas accounting requirements are consistent for each prospective offeror in a given acquisition, combining greenhouse gas emissions estimates for each proposal with SC-GHG conversion values will allow contracting officers to put a monetary value on the environmental impact of every offeror’s proposal. By establishing a monetary value, contracting officers will be able to evaluate environmental impact from the same qualitative plane as other price-related factors.¹¹⁵

¹⁰⁹ See Schooner & Matsuda, *supra* note 34, at 5–6.

¹¹⁰ ACCOUNTING AND REPORTING STANDARD, *supra* note 105, at 5.

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ See generally FAR pt. 10 (prescribing “policies and procedures for conducting market research to arrive at the most suitable approach to acquiring, distributing, and supporting supplies and services”).

¹¹⁴ See Ceres, Comment Letter on Advance Notice of Proposed Rulemaking Regarding Minimizing the Risk of Climate Change in Federal Acquisitions, at 5, 30 (Jan. 12, 2022), <https://www.regulations.gov/comment/FAR-2021-0016-34987> [<https://perma.cc/2862-V9T8>].

¹¹⁵ See Ctr. for Biological Diversity et al., Comment Letter on Advance Notice of Proposed Rulemaking Regarding Minimizing the Risk of Climate Change in Federal Acquisitions, at 12

III. INCORPORATING THE SOCIAL COST OF GREENHOUSE GASES INTO THE FEDERAL PROCUREMENT LIFECYCLE FOR CONTRACTS ABOVE A THRESHOLD VALUE

Even though SC-GHG is a broadly applicable metric, and even though greenhouse gas accounting methods are becoming more widely known and applied by industry, the incorporation of the social cost of greenhouse gases into federal procurements unavoidably increases transaction costs.¹¹⁶ Wholesale adoption of the methods described in Section II.C is therefore unlikely without incorporating the procedures into the FAR and requiring their use in every acquisition.¹¹⁷

This Part describes the stages of the procurement process in which mandatory consideration of the social cost of greenhouse gases should be incorporated, including the locations in the FAR that correspond with those stages of the process. This Part then suggests limiting mandatory consideration of the social cost of greenhouse gases to high dollar value contracts in recognition of the higher transaction costs associated with introducing novel evaluation criteria.

(Jan. 13, 2022), <https://www.regulations.gov/comment/FAR-2021-0016-34997> [<https://perma.cc/G6CK-NCRH>].

¹¹⁶ See generally José Guilherme Ferraz de Campos & Adriana Marotti de Mello, *Transaction Costs in Environmental Purchasing: Analysis Through Two Case Studies*, 10 J. OPERATIONS & SUPPLY CHAIN MGMT. 87 (2017) (identifying and analyzing various transactions costs involved in the supplier selection process for environmental purchasing). Although the article examines supplier selection among private companies, the transaction cost economics are equally applicable to public procurements. *Id.* at 95 (“As the number of defined criteria increase, the search for suppliers becomes more expensive . . .”).

¹¹⁷ The FAR currently contains an entire part dedicated to environmental concerns, but it has failed and will continue to fail to impact procurements at the scale needed to address the climate crisis. See FAR pt. 23; see also Niyongere, *supra* note 70, at 802 (“[W]hile . . . the FAR demonstrate[s] an increased emphasis on environmental considerations in federal procurement, [it] generally do[es] not require federal agencies to purchase environmentally preferable products in any specific procurement. . . . [I]n the absence of clear and comprehensive language and legally binding requirements, significant gaps exist in green federal purchasing.” (footnote omitted)). In addition to lacking legally binding requirements, FAR Part 23 draws its authority from executive orders that are multiple generations out of date. See FAR 23.102; FAR 23.201; FAR 23.402; FAR 23.702; FAR 23.801; FAR 23.901. Moreover, multiple unrelated public policies have been shoehorned into FAR Part 23, leading to diluted and cumbersome regulations that fail to provide clear, useful guidance to contracting officers. See FAR subpart 23.5 (addressing drug use in the workplace); FAR subpart 23.11 (discouraging texting while driving). If updated and pared down, FAR Part 23 may be useful as a centralized location that lists all the places in the FAR where the social cost of greenhouse gases gets incorporated, but FAR Part 23 will not suffice on its own; the social cost of greenhouse gases must be incorporated directly into the parts of the FAR associated with each phase of the procurement process.

A. Incorporating the Social Cost of Greenhouse Gases into the Federal Procurement Process

If the government wants agencies to internalize the costs associated with greenhouse gases and enter into contracts that minimize emissions, contracting officers and other source selection authorities must compare the social cost of greenhouse gases associated with each proposal and choose solutions with lower expected emissions. A comparative evaluation of the social cost of greenhouse gases during source selection is therefore critical, but evaluation alone is not enough; contracting officers must also determine the appropriate emissions estimation requirements for each acquisition, prospective offerors must be aware of those requirements while preparing their proposals, contracting officers must communicate the evaluation factors they will consider during source selection, and government officials and disappointed offerors alike must have procedures in place to verify that emissions estimates align with actual performance under the resulting contracts. Effective incorporation therefore requires express contemplation of the social cost of greenhouse gases during (1) acquisition planning, (2) solicitation, (3) evaluation, and (4) quality assurance.

1. Acquisition Planning

The acquisition planning phase is arguably the most critical stage of the procurement process for incorporating the social cost of greenhouse gases because acquisition planning determines “the overall strategy for managing the acquisition.”¹¹⁸ Part II of this Note discussed the policy considerations that the government must consider each time it seeks a procurement-based solution to its needs.¹¹⁹ Acquisition planning is the stage of the process during which agencies decide the appropriate balance of those policies for each acquisition.¹²⁰ For the social cost of greenhouse gases to play a role in source selection, agencies must prioritize it during acquisition planning.

FAR Part 7, which governs the acquisition planning phase of the procurement process,¹²¹ should require prioritization of the social cost

¹¹⁸ FAR 2.101 (defining acquisition planning as “the process by which the efforts of all personnel responsible for an acquisition are coordinated and integrated through a comprehensive plan for fulfilling the agency need in a timely manner and at a reasonable cost”).

¹¹⁹ See *supra* notes 61–70 and accompanying text.

¹²⁰ See FAR 7.102.

¹²¹ FAR pt. 7.

of greenhouse gases in FAR 7.102.¹²² FAR 7.102 prescribes the policy considerations that agencies must consider during acquisition planning.¹²³ Specifically, purchasing agencies must perform acquisition planning and market research for all acquisitions to promote (1) acquisition of commercial products and services “to the maximum extent practicable,”¹²⁴ (2) full and open competition,¹²⁵ (3) selection of the appropriate contract type,¹²⁶ and (4) consideration of preexisting contracts to fulfill agency requirements before awarding new contracts.¹²⁷

FAR 7.102 should incorporate a fifth general policy priority: acquisition of products and services that minimize the social cost of greenhouse gases.

2. Solicitation

Purchasing agencies should also expressly state in their solicitations the intention to consider the social cost of greenhouse gases during evaluation and source selection.¹²⁸ More specifically, solicitations must request greenhouse gas emissions estimates and describe the acceptable accounting methodologies, the extent to which Scope 1, Scope 2, and Scope 3 estimates are required, and any additional greenhouse gas accounting details specific to the acquisition.

The ability—both practically and legally—of a contracting officer to consider the social cost of greenhouse gases during the remainder of the procurement process depends on its explicit inclusion in the solicitation.¹²⁹ From a practical standpoint, a solicitation must request

¹²² FAR 7.102 (prescribing the procurement policies agencies must promote and provide for during acquisition planning).

¹²³ *See id.*

¹²⁴ FAR 7.102(a)(1). *See generally* FAR pt. 12 (“This part . . . implements the Federal Government’s preference for the acquisition of commercial products and commercial services . . . by establishing acquisition policies more closely resembling those of the commercial marketplace and encouraging the acquisition of commercial products and commercial services.”).

¹²⁵ *See* FAR 7.102(a)(2). *See generally* FAR pt. 6 (“This part prescribes policies and procedures to promote full and open competition in the acquisition process . . .”).

¹²⁶ FAR 7.102(a)(3). *See generally* FAR pt. 16 (“This part describes types of contracts that may be used in acquisitions. It prescribes policies and procedures and provides guidance for selecting a contract type appropriate to the circumstances of the acquisition.”).

¹²⁷ FAR 7.102(a)(4). *See generally* FAR 8.002–.004 (prescribing the use of mandatory and preferred sources to meet agency requirements); FAR subpart 17.5 (prescribing policies and procedures regarding interagency acquisitions).

¹²⁸ Solicitations, in the context of the FAR, are “any request to submit offers or quotations to the Government.” FAR 2.101.

¹²⁹ 41 U.S.C. § 3306(b)(1)(A); FAR 15.203(a)(4); 41 U.S.C. § 3701(a); FAR 15.305(a).

information from prospective offerors so that offerors can design their proposals around the appropriate solicitation requirements.

From a legal standpoint, CICA requires that all evaluation factors used to assess proposals be included in the solicitation.¹³⁰ A contracting officer cannot base source selection on any factors not expressly contemplated in the solicitation.¹³¹ Thus, CICA's solicitation requirements, reflected in FAR 15.203(a)(4), already provide the regulatory framework that would require incorporating the social cost of greenhouse gases at the solicitation stage.¹³² No additional regulation of the solicitation process would be needed.

3. *Evaluation*

The evaluation phase of the procurement process is where the contracting officer or other source selection authority would compare the relative social cost of greenhouse gases for each proposal submitted by an offeror. As such, the FAR should require that the social cost of greenhouse gases be used as an evaluation factor in every acquisition.

Prior to the FAR Part 15 rewrite in 1997,¹³³ FAR 15.605(b)(1)(iv) mandated: "Environmental objectives, such as promoting waste reduction, source reduction, energy efficiency, and maximum practicable recovered material content . . . shall also be considered in every source selection, when appropriate."¹³⁴ Unfortunately, the 1997 rewrite removed environmental objectives from the list of mandatory evaluation criteria in negotiated procurements.¹³⁵

In the current iteration of the FAR, section 15.304 contains an equivalent list of mandatory evaluation factors for negotiated procurements, and the previous mention of environmental objectives is absent.¹³⁶ The current mandatory evaluation factors include "[p]rice

¹³⁰ 41 U.S.C. § 3306(b)(1)(A); FAR 15.203(a)(4).

¹³¹ The contracting officer must always evaluate offers in the manner the solicitation indicates, whether the solicitation is an invitation for bids ("IFB") or a request for proposals ("RFP"). 41 U.S.C. § 3701(a) ("An executive agency shall evaluate sealed bids and competitive proposals, and award a contract, based solely on the factors specified in the solicitation."); FAR 15.305(a); *see also, e.g.*, EFS Ebrex SARL, B-416076, 2018 CPD ¶ 201 (Comp. Gen. June 4, 2018) (sustaining a post-award protest because purchasing agency's source selection decision applied evaluation factors not stated in the solicitation).

¹³² *See* 41 U.S.C. § 3306(b)(1)(A); FAR 15.203(a)(4).

¹³³ 62 Fed. Reg. 51,224 (Sept. 30, 1997).

¹³⁴ FAR 15.605(b)(1)(iv) (1996).

¹³⁵ *See* FAR 15.304(c) (1997); Schooner & Speidel, *supra* note 51, at 38 & n.36.

¹³⁶ *See* FAR 15.304(c).

or cost to the Government,”¹³⁷ “quality of the product or service”¹³⁸ “[p]ast performance,”¹³⁹ and “small business subcontracting participation in the subcontracting plan.”¹⁴⁰

FAR 15.304 should reincorporate environmental objectives as a mandatory evaluation factor and specifically mention the social cost of greenhouse gases by adding the following language: “Environmental impact, including the social cost of greenhouse gases, shall be considered in every source selection, when appropriate.”¹⁴¹

This environmental impact evaluation factor should contain a subdivision that describes the SC-GHG metric and prescribes its use as the default method for considering the social cost of greenhouse gases in every source selection.¹⁴²

4. *Quality Assurance*

Even if contracting officers successfully prioritize greenhouse gas emissions and select contractors based on comparative evaluation of the social cost of greenhouse gases, the above recommendations will likely fail to meaningfully reduce the government’s greenhouse gas emissions without quality assurance mechanisms to verify that emissions estimates at the source selection stage reasonably correspond with actual contract performance.

The FAR implementation of the Small Business Act provides an example of how verification mechanisms can work in practice.¹⁴³ Small business set-asides rely on representations by offerors about the size of their business, and the acquisition process includes mechanisms for maintaining the integrity of those representations.¹⁴⁴ Likewise here, incorporating the social cost of greenhouse gases will require representations by offerors of their Scope 1, Scope 2, and Scope 3 green-

¹³⁷ FAR 15.304(c)(1).

¹³⁸ FAR 15.304(c)(2).

¹³⁹ FAR 15.304(c)(3)(i).

¹⁴⁰ FAR 15.304(c)(4).

¹⁴¹ To be clear, this Note suggests requiring evaluation of environmental impact *in addition to* the existing mandatory evaluation factors. As such, it may be possible for a source selection authority to conclude that a more environmentally damaging proposal will provide the best value to the government even after weighing the social cost of greenhouse gases. Differences in price or quality, for example, may outweigh the differences in environmental impact. Critically, though, environmental impact would always play a role in the selection process even if it did not tip the scales in every acquisition.

¹⁴² See *supra* Section II.C.1.

¹⁴³ See generally FAR subpart 19.3 (prescribing the process for determining and reporting small business status).

¹⁴⁴ See *id.*

house gas emissions. Without protest mechanisms designed to push back against erroneous greenhouse gas emissions representations—whether intentionally misleading or merely careless—agency reliance on contractor representations may lead to arbitrary, inaccurate, and potentially regime-damaging results.¹⁴⁵

FAR Part 46 “prescribes policies and procedures to ensure that supplies and services acquired under Government contract conform to the contract’s quality and quantity requirements.”¹⁴⁶ The procedures and provisions of FAR Part 46 should be expanded to expressly incorporate greenhouse gas emissions as a default contract quality requirement that is subject to inspection.¹⁴⁷ Due to the potential complexity of verifying greenhouse gas emissions, purchasing agencies should identify and recommend acceptable independent verifying bodies that can evaluate contractors’ performance in light of emissions estimates.¹⁴⁸

As greenhouse gas accounting methodologies mature and the private and public sectors gain expertise and familiarity with quantifying Scope 1, Scope 2, and Scope 3 emissions, appropriate assessment and verification methods will likely evolve as well. As such, contracting

¹⁴⁵ See, e.g., John Gardella, *Greenwashing and the SEC: The 2022 ESG Target*, NAT’L L. REV. (Jan. 18, 2022), <https://www.natlawreview.com/article/greenwashing-and-sec-2022-esg-target>; [https://perma.cc/YQ2Z-UNMB]; see also Adam Hayes, *What is Greenwashing? How It Works, Examples, and Statistics*, INVESTOPEDIA (Nov. 8, 2022), <https://www.investopedia.com/terms/g/greenwashing.asp> [https://perma.cc/X532-7CRH] (“Greenwashing is the process of conveying a false impression or misleading information about how a company’s products are environmentally sound.”); Kate Bailey, *It’s Time to Remove the Recycling Symbol from Plastics*, WASTE360 (Nov. 16, 2020), <https://www.waste360.com/plastics/its-time-remove-recycling-symbol-plastics-commentary> [https://perma.cc/3C7C-HUN8] (describing how manufacturers’ inaccurate representations of product recyclability undermines consumer participation in recycling efforts).

¹⁴⁶ FAR pt. 46.

¹⁴⁷ See FAR 46.201 (describing the general contract quality requirements and inspection expectations to which this Note proposes greenhouse gas emissions verification should be added).

¹⁴⁸ See FAR 46.103 (describing the contracting office’s responsibility to determine and communicate “inspection and testing requirements or . . . a quality assurance surveillance plan” during the contract formation process); FAR 46.104 (describing the administrative contracting officer’s responsibility to apply the quality assurance procedures in accordance with the direction of the of the contracting office); FAR 46.105 (describing the contractor’s responsibility to meet its quality assurance obligations). The Science Based Target initiative (“SBTi”) is one example of an independent body that performs assessment and validation of greenhouse gas emission targets based on the Greenhouse Gas Protocol standards described in Section II.C.2. See *About Us*, SCI. BASED TARGETS, <https://sciencebasedtargets.org/about-us> [https://perma.cc/S4ZR-NUPJ]; SCI. BASED TARGETS, *SBTi CRITERIA AND RECOMMENDATIONS* (5th ed. 2021), <https://sciencebasedtargets.org/resources/files/SBTi-criteria.pdf> [https://perma.cc/7VF7-GGBR]; *supra* Section II.C.2.

officers need to retain a degree of flexibility.¹⁴⁹ FAR Part 46 should include greenhouse gas emissions verification as a default component of quality assurance procedures while maintaining the ability to incorporate developments in the field of greenhouse gas accounting.

B. Limiting Mandatory Consideration of the Social Cost of Greenhouse Gases to Contracts Above a Threshold Value

The climate and social benefits of requiring purchasing agencies to consider the social cost of greenhouse gases every time they procure a product or service are clear. The cumulative purchasing power of the federal government can mitigate—or intensify—anthropogenic contributions to climate change through greenhouse gas emissions.¹⁵⁰ In some circumstances, however, the procedural downsides may outweigh those benefits. Most notably, determining the social cost of greenhouse gases requires thorough greenhouse gas emissions estimates by prospective contractors, and emissions estimates require time, resources, and expertise. For some firms hoping to sell to the government, those increased transaction costs may become prohibitively high.¹⁵¹

To limit the negative impact of higher transaction costs on competition—and consequently on price, quality, and transparency¹⁵²—the FAR Council should establish a dollar threshold below which acquisitions are exempt from mandatory evaluation of the social cost of greenhouse gases.¹⁵³ Requiring purchasing agencies to consider the so-

¹⁴⁹ See FAR 46.201(a) (“The type and extent of contract quality requirements needed depends on the particular acquisition and may range from inspection at time of acceptance to a requirement for the contractor’s implementation of a comprehensive program for controlling quality.”).

¹⁵⁰ See Schooner, *supra* note 64, at 108–09.

¹⁵¹ See Ferraz de Campos & Marotti de Mello, *supra* note 116, at 87, 96.

¹⁵² See Schooner, *supra* note 64, at 104–06 (explaining the interconnectedness of procurement policies that the government must balance in every acquisition).

¹⁵³ This Note does not intend to disregard the substantial climate impact of the enormous number of smaller contracts the government enters into each year. See *Advanced Search*, USASPENDING.GOV, <https://www.usaspending.gov/search/?hash=B143c69929a4dcb8f0b2a6c1649e402d> [https://perma.cc/569W-VPJW] (select “Start Searching Awards,” filter for awards from “FY 2020” under the “Time Period” dropdown, and filter for “\$1,000,000 & Under” under the “Award Amount” dropdown) (showing 5,410,618 contracts awarded in Fiscal Year 2020 for \$1 million or less). There are more efficient ways to internalize the environmental effects of smaller contracts through, for example, eco-labels and the GSA Advantage! Environmental Aisle. See *Introduction to Ecolabels and Standards for Greener Products*, EPA, <https://www.epa.gov/greenerproducts/introduction-ecolabels-and-standards-greener-products> [https://perma.cc/9A33-T2EX]; *GSA Advantage! Environmental Program Aisle*, GEN. SERVS. ADMIN., <https://www.gsa.advantage.gov/advantage/search/specialCategory.do?cat=ADV.ENV> [https://perma.cc/QE73-

cial cost of greenhouse gases for high dollar value contracts will maximize the government's climate change mitigation efforts while minimizing negative impacts on competition. Furthermore, high dollar value contracts generally attract large, well-established contractors that are more likely to have sophisticated compliance regimes in place and the capacity to provide and verify greenhouse gas estimates in their proposals.¹⁵⁴

The FAR System already recognizes the value in streamlining acquisition procedures for relatively smaller contracts in its simplified acquisition¹⁵⁵ and micro-purchase procedures.¹⁵⁶ Purchases below the simplified acquisition threshold of \$250,000,¹⁵⁷ for example, are subject to simplified contracting procedures to “promote efficiency and economy in contracting and to avoid unnecessary burdens for agencies and contractors.”¹⁵⁸

By mandating that purchasing agencies evaluate offers in light of the estimated social cost of the proposals' expected greenhouse gas emissions while exempting acquisitions below the specified dollar threshold, the government will maximize its climate change mitigation efforts while minimizing detrimental side effects.

CONCLUSION

Slowing the progression of climate change will require a combination of top-down commitment from political leadership and clear regulatory requirements that ensure the incorporation of environmental concerns into the federal government's largest acquisitions. President Biden has signaled political commitment to wielding the federal gov-

3JDL]. Moreover, purchasing agencies could still *choose* to evaluate the social cost of greenhouse gases for acquisitions below the threshold if market research indicated that doing so would be appropriate.

¹⁵⁴ See Christopher R. Yukins, *Mandatory Disclosure: A Case Study in How Anti-Corruption Measures Can Affect Competition in Defense Markets*, in *ETHICAL DILEMMAS OF THE GLOBAL DEFENSE INDUSTRY* (Daniel E. Schoeni & Tobias Vestner eds., forthcoming 2023) (explaining that mandatory disclosure requirements can harm competition because effective compliance programs are extremely expensive and therefore favor large, established contractors).

¹⁵⁵ See FAR pt. 13 (prescribing simplified acquisition procedures for acquisitions below the simplified acquisition threshold of \$250,000); FAR 2.101 (defining the simplified acquisition threshold).

¹⁵⁶ See FAR subpart 13.2 (prescribing acquisition procedures for acquisitions below the micro-purchase threshold); FAR 2.101 (defining the micro-purchase threshold).

¹⁵⁷ The default threshold is \$250,000; there are other simplified acquisition threshold amounts applicable in specific circumstances described in the FAR. See FAR 2.101.

¹⁵⁸ 41 U.S.C. § 3305(a); see also FAR 13.002 (citing also the reduction of administrative costs and improvement of opportunities for small and disadvantaged businesses “to obtain a fair proportion of Government contracts”).

ernment's massive purchasing power to mitigate anthropogenic climate change. This Note recommends updating the regulatory framework in the FAR to lock in the Administration's political commitment by incorporating the social cost of greenhouse gases into the acquisition planning, solicitation, proposal evaluation, and quality assurance phases of the procurement process. To prevent undue burdens on small acquisitions for which marginal environmental benefits may not outweigh increased transaction costs, this Note further suggests limiting mandatory incorporation to high-value contracts above a specified dollar threshold.

This Note does not attempt to address the myriad parallel efforts that the acquisition community should take, especially in the short term, to proactively incorporate environmental sustainability principles into its procurement practices. Contracting officers and project managers should use their discretion to prioritize acquisitions with low greenhouse gas emissions, but the government also should not indefinitely depend on agency discretion, especially when large acquisitions are at stake. Public procurement practitioners and academics should continue identifying and promoting short- and medium-term best practices. This Note aims to get the ball rolling toward the long-term, dependable, *mandatory* consideration of the social cost of greenhouse gases in the federal procurement process.

NOTE

The Center Cannot Hold: Why the NLRB Should Assert Jurisdiction over Division I Collegiate Athletes

Andrew Mendelson*

ABSTRACT

In 2015, the National Labor Relations Board (“NLRB” or “the Board”) declined to assert jurisdiction over a group of football players at Northwestern University; yet, the following year, the NLRB asserted jurisdiction over a group of student assistants at Columbia University. In the past several years, there has been a proliferation of organizing among student assistants, but virtually no attempts to unionize by collegiate athletes. This Note urges the NLRB to adopt the standard it applied when asserting jurisdiction over undergraduate and graduate assistants to players on collegiate athletic teams. Alternatively, the NLRB should make a new rule categorically asserting jurisdiction over all labor disputes involving collegiate athletes at Division I schools. Looking to the treatment of student assistants as an exemplar, a common-law “right to control” test will find that collegiate athletes qualify as statutory employees, and therefore receive protections for employment-related activities. Adopting this rule will serve to further the purposes of the National Labor Relations Act (“NLRA” or “the Act”) because collegiate players will be able to rely upon it as they engage in concerted activities such as collective bargaining. Asserting jurisdiction is more necessary now than ever due to the dwindling persuasiveness of the amateur model on which collegiate sports

* J.D., expected May 2023, The George Washington University Law School. I would like to thank Professor Charles R. Pollack for his guidance in crafting this Note; the members, associates, and editors of *The George Washington Law Review* for their brilliant editorial work; and my family and friends for their unwavering love and support.

rely. Going through the rulemaking process will also mitigate the NLRB's tendency to fluctuate wildly with shifts in political control.

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INTRODUCTION

Northwestern University offered Kain Colter and eighty-four other teenagers full scholarships to play for its football team.¹ It worked out well for the school; by the time his senior year came along, Colter had helped propel the team all the way to a bowl game.² To

¹ See Northwestern Univ., 362 N.L.R.B. 1350, 1351 (2015).

² See Dave McKenna, *Kain Colter Facing Several Domestic Violence Charges, Described as "Indigent" in Court Filings*, DEFECTOR (June 30, 2021, 10:01 AM), <https://defector.com/kain-colter-facing-several-domestic-violence-charges-described-as-indigent-in-court-filings/> [https://perma.cc/K8FN-VGKK].

manage a chronic ankle injury and multiple severe concussions, though, and out of fear that missing games might result in losing his scholarship,³ Colter developed a habit for pain pills and Toradol.⁴ Pills could only mask his postconcussive symptoms, and Colter believes that the constant cranial trauma caused him to develop Chronic Traumatic Encephalopathy (“CTE”).⁵ Because collegiate players lack bargaining power, they are unable to negotiate with their school, conference, and the National Collegiate Athletic Association (“NCAA”) for benefits related to their health and wellbeing, such as minimizing full-contact practices that carry a heightened risk of concussion.⁶ A year after his bowl appearance, and inspired by a union-centric visit to a steel factory,⁷ Colter concluded that the best way to ensure adequate medical care for the team both during and after their playing days would be to engage in collective bargaining with the school.⁸ He and the team petitioned the NLRB for recognition of the team as a legally protected labor union.⁹ The Board chose to punt the issue, however, declining jurisdiction and thus depriving the players of the ability to unionize and collectively bargain with the school.¹⁰

If the Board had recognized the team as employees, the collegiate players could follow their professional counterparts in bargaining for policies mitigating the risk of head trauma, providing retirement and

³ See *Northwestern Univ.*, 362 N.L.R.B. at 1363 n.31.

⁴ See Rohan Nadkarni, *Kain Colter's Union Battle Cost Him More Than He Ever Expected*, DEADSPIN (Aug. 18, 2015, 3:55 PM), <https://deadspin.com/kain-colters-union-battle-cost-him-more-than-he-ever-ex-1724831203> [<https://perma.cc/R2KL-9J8S>]. Toradol is an anti-inflammatory drug, most commonly prescribed to treat postsurgical pain, with a substantial risk of serious side effects. See Erica Hersh, *What You Should Know Before Taking Toradol for Pain*, HEALTHLINE (Mar. 29, 2019), <https://www.healthline.com/health/is-toradol-a-narcotic> [<https://perma.cc/5A35-R4DQ>].

⁵ See Nadkarni, *supra* note 4; McKenna, *supra* note 2. CTE is a degenerative neurological condition resulting from repeated trauma to the head that can cause symptoms including depression and dementia. See Joe Ward, Josh Williams & Sam Manchester, *110 N.F.L. Brains*, N.Y. TIMES (July 25, 2017), <https://www.nytimes.com/interactive/2017/07/25/sports/football/nfl-cte.html?module=inline> [<https://perma.cc/HJB5-GP9B>] (citing a study of 202 brains of deceased football players, including college players, which found evidence of CTE in eighty-seven percent of scans).

⁶ See Judy George, *Most College Football Head Impacts Occur in Practice, Not Games*, MEDPAGE TODAY (Feb. 1, 2021), <https://www.medpagetoday.com/neurology/headtrauma/90975> [<https://perma.cc/3EBK-7KYV>]; Ben Strauss, *In a First, Northwestern Players Seek Unionization*, N.Y. TIMES (Jan. 28, 2014), <https://www.nytimes.com/2014/01/29/sports/ncaafootball/northwestern-players-take-steps-to-form-a-union.html> [<https://perma.cc/2S5A-CMWN>].

⁷ See Nadkarni, *supra* note 4.

⁸ See Strauss, *supra* note 6.

⁹ See *Northwestern Univ.*, 362 N.L.R.B. 1350, 1350 (2015).

¹⁰ See *id.*

health insurance benefits, and establishing a trust for former players in financial need.¹¹ Collective bargaining may not render college sports risk-free, but it could provide players like Colter recourse to mitigate harm to their long-term health and wellness.¹² In the meantime, a new generation of athletes risk their safety every day playing for Northwestern and other Division I colleges and universities,¹³ and while the institutions continue to thrive financially,¹⁴ the players bearing their insignias lack a voice at the bargaining table.

Today, a number of factors are converging to force the Board's hand in deciding how to treat collegiate athletes. First, the Board's decision in *Trustees of Columbia University*,¹⁵ decided after *Northwestern University*,¹⁶ adopted a more extensive common-law definition of "employee,"¹⁷ which this Note argues would also cover collegiate athletes.¹⁸ Second, the Board's General Counsel, Jennifer Abruzzo, has emphasized her belief that full scholarship athletes qualify as statutory employees.¹⁹ Lastly, prominent recent and ongoing litigation has hinted at labor-related issues inherent in the NCAA model.²⁰ In Justice Kavanaugh's fiery concurrence in *National Collegiate Athletic Association v. Alston*,²¹ for example, he challenged collegiate players to

¹¹ See, e.g., *How the NFLPA Works*, NAT'L FOOTBALL LEAGUE PLAYERS ASS'N, www.nflpa.com/about [<https://perma.cc/8ZQF-M9FR>]. Lacking such resources, Colter has faced multiple charges of domestic violence as well as homelessness and indigency after graduating, all stemming from what he believes to be untreated CTE. See McKenna, *supra* note 2.

¹² See Strauss, *supra* note 6.

¹³ College sports are divided among three divisions: I, II, and III. See generally NCAA, STUDENT-ATHLETE PARTICIPATION 1981-82—2018-19, https://ncaaorg.s3.amazonaws.com/research/sportpart/2018-19RES_SportsSponsorshipParticipationRatesReport.pdf [<https://perma.cc/DQ8G-LSDY>]. Northwestern is one of 351 schools in Division I, which comprised more than 29,200 players in total as of the 2018–19 season. *Id.* at 157.

¹⁴ See Steve Berkowitz, *Big Ten Conference Had Nearly \$759 Million in Revenue in Fiscal 2018, New Records Show*, USA TODAY (May 15, 2019, 6:58 PM), <https://www.usatoday.com/story/sports/2019/05/15/big-ten-revenue-hit-nearly-759-million-fiscal-2018/3686089002/> [<https://perma.cc/XP2A-Q25W>] (reporting that the fourteen teams in the conference received an average of \$54 million for the 2017–18 school year).

¹⁵ 364 N.L.R.B. 1080 (2016).

¹⁶ 362 N.L.R.B. 1350 (2015).

¹⁷ *Columbia*, 364 N.L.R.B. at 1081.

¹⁸ See *infra* Section II.B (discussing the Board's shift in recognizing students as employees).

¹⁹ See Memorandum from Jennifer A. Abruzzo, Gen. Counsel, NLRB, to All Reg'l Dirs., Officers-in-Charge & Resident Officers, NLRB (Sept. 29, 2021), <https://apps.nlr.gov/link/document.aspx/09031d458356ec26> [<https://perma.cc/CNG7-WQ3B>].

²⁰ See *infra* Section II.D (discussing how recent administration changes have impacted the Board's approach to NCAA labor issues).

²¹ Nat'l Collegiate Athletic Ass'n v. Alston, 141 S. Ct. 2141 (2021).

engage in collective bargaining so they could collect a fair portion of revenue.²²

Based on the factors above, it is likely that if a Democrat-majority Board were to rule on the merits of *Northwestern* today, it would hold that the players qualified as statutory employees; it is also probable that a Republican-majority Board would reach the opposite conclusion. Nevertheless, by failing to assert jurisdiction in *Northwestern*, the Board has denied countless collegiate players such as Colter the opportunity to collectively bargain for improved health and safety standards, a fair cut of expanding revenue, and other employment-based rights.²³ The Board's unpredictable approach to asserting jurisdiction over college workers—players and non-players alike—has undoubtedly discouraged other groups of players from organizing, impeding the goals of the Board.²⁴ The Board should therefore build off its 2016 *Columbia* decision and adopt a clear, reliable test for determining jurisdiction in future cases.²⁵

This Note argues that the Board should apply the common-law right to control test in asserting jurisdiction over Division I players, because doing so will be consistent with the Board's treatment of other student workers in higher education.²⁶ Alternatively, the Board should utilize the rulemaking process to ensure that these players receive ongoing statutory protection, thereby providing a predictable expectation for players, schools, and unions after the past decades' political vacillations.²⁷ Part I of this Note provides background on the NLRA and the NLRB, and the history of the Board's jurisdictional determinations regarding private colleges and universities as well as athletes. Part II analyzes why the current situation justifies assertion of the Board's jurisdiction over collegiate players, as doing so would

²² *Id.* at 2168 (Kavanaugh, J., concurring).

²³ As of April 2022, there have been no prominent pushes for unionization by college players since that from the Northwestern team. See Alan Blinder & Billy Witz, *In Push to Play, College Football Stars Show Sudden Unity*, N.Y. TIMES (Apr. 29, 2021), <https://www.nytimes.com/2020/08/10/sports/ncaaf-football/coronavirus-college-football-players.html> [<https://perma.cc/62K7-783J>]. Football players hinted at creating a Division-wide player's association as part of their push to return to competition in the midst of the COVID-19 outbreak in the fall of 2020; however, this idea did not materialize. See *id.*

²⁴ See *Trs. of Columbia Univ.*, 364 N.L.R.B. 1080 (2016); *Northwestern Univ.*, 362 N.L.R.B. 1350 (2015).

²⁵ As of April 2022, a piece of legislation is pending in Congress that would grant the Board jurisdiction over all colleges and universities, both public and private. See College Athlete Right to Organize Act, S. 1929, 117th Cong. (2021). Even in the unlikely event it passes, however, the Board will still need to adopt a more clearly defined jurisdictional standard.

²⁶ See *Columbia*, 364 N.L.R.B. at 1081.

²⁷ See *infra* Section III.

further the policies of the Act on a more lasting basis. Finally, Part III recommends asserting jurisdiction over and applying the right to control test to Division I players or, alternatively, to issue a rule declaring jurisdiction over these players moving forward.

I. THE BOARD'S SCRAMBLED JURISDICTION OVER STUDENTS AND ATHLETES

The Board's mission is to further the purposes of the Act—that is, to protect the rights of employers and employees, encourage collective bargaining, and resolve employment disputes.²⁸ The Act permits the Board to decline jurisdiction in instances where “the effect of such labor dispute on commerce is not sufficiently substantial.”²⁹ The Board has a scattered history of asserting and declining—and then asserting again—jurisdiction over workers at higher education institutions.³⁰ No exception to this oscillating approach, the Board has asserted jurisdiction over athletes in fits and starts, up to its significant decision to decline jurisdiction over collegiate athletes in *Northwestern*.³¹ Because of the rapidly changing legal discourse surrounding the idea of amateurism in sports, the Board's handling of collegiate players is a hot button issue today.³²

A. Overview of the NLRA and the Goals of the Board

President Roosevelt signed the NLRA into law in 1935, in the midst of the New Deal.³³ Congress intended the Act to promote peaceful labor relations between employers and employees in order to minimize disruptions to interstate commerce.³⁴ After an inauspicious start, the 1947 Taft-Hartley Act overcame President Truman's veto and cemented the contours of the NLRA, leading to the version of the Act that applies today.³⁵ The Act's protection covers employees in most industries with ties to interstate commerce.³⁶ Its broad—albeit

²⁸ See 29 U.S.C. § 151.

²⁹ *Id.* § 164(c).

³⁰ See *infra* Section I.B.

³¹ See *infra* Section I.C.

³² See *infra* Section I.D.

³³ See *About NLRB: 1935 Passage of the Wagner Act*, NLRB, <https://www.nlr.gov/about-nlr/who-we-are/our-history/1935-passage-of-the-wagner-act> [<https://perma.cc/H8WE-MB9M>].

³⁴ See 29 U.S.C. § 151.

³⁵ See *About NLRB: 1947 Taft-Hartley Passage and NLRB Structural Changes*, NLRB, <https://www.nlr.gov/about-nlr/who-we-are/our-history/1947-taft-hartley-passage-and-nlr-structural-changes> [<https://perma.cc/UR9X-KU6D>]; see also PHILIP YALE NICHOLSON, *LABOR'S STORY IN THE UNITED STATES* 250–54 (2004).

³⁶ See *About NLRB: Jurisdictional Standards*, NLRB, <https://www.nlr.gov/about-nlr/>

circular—language defines “employee” as “any employee . . . , unless [the Act] explicitly states otherwise.”³⁷ Few enumerated exceptions appear in the statutory text.³⁸ Courts and the Board have applied the negative-implication canon based on these listed exceptions,³⁹ holding that by enumerating specific exceptions, nonenumerated categories qualify as statutory employees.⁴⁰ Although the House proposed excepting as statutory employers any entity “organized and operated exclusively for religious, charitable, scientific, literary, or *educational* purposes,”⁴¹ the Senate rejected this exception from the 1947 Taft-Hartley Amendment,⁴² and it never appeared in subsequent versions.⁴³

The NLRA provides and protects the right of employees to engage in concerted activity.⁴⁴ If a bargaining unit of employees demonstrates a sufficient “showing of a substantial interest” in union representation, a labor organization may petition an NLRB regional office for an election.⁴⁵ If the election is conclusive, then a Regional Director will issue a certification requiring the employer to recognize

rights-we-protect/the-law/jurisdictional-standards [https://perma.cc/NFX8-MYA9]. This era saw an expansive interpretation of interstate commerce, as demonstrated by Congress’s reach under the Commerce Clause at this time. *See, e.g., Wickard v. Filburn*, 317 U.S. 111 (1942).

³⁷ 29 U.S.C. § 152(3). The definition of “employee” is statute specific. *See, e.g.,* 29 U.S.C. § 203(e); I.R.C. § 7701(a)(20). A worker may therefore receive statutory protection as an employee under one statute, but not under another.

³⁸ 29 U.S.C. § 152(3). The only enumerated exceptions are public employees, agricultural laborers, domestic workers, those working for their family or spouse, independent contractors, supervisors, and railway workers. *Id.*

³⁹ *See* ANTONIN SCALIA & BRYAN A. GARNER, *READING LAW* at 107–11 (2012) (defining the negative-implication canon as the presumption that expressing one thing implies that other things are not included).

⁴⁰ *See, e.g., NLRB v. Town & Country Elec., Inc.*, 516 U.S. 85, 90–91 (1995).

⁴¹ H.R. 3020, 80th Cong. § 2 (1947) (emphasis added), *reprinted in* STAFF OF S. COMM. ON LAB. & PUB. WELFARE, 93D CONG., *LEGISLATIVE HISTORY OF THE LABOR-MANAGEMENT RELATIONS ACT, 1947* 34 (Comm. Print 1974).

⁴² S. 1126, 80th Cong. (1947), *reprinted in* 1 *LEGISLATIVE HISTORY OF THE LABOR MANAGEMENT RELATIONS ACT, 1947*.

⁴³ *See* *COLLECTIVE BARGAINING IN HIGHER EDUCATION* 23–24 (Thomas M. Mannix ed., 1975). According to the Board, the Senate may have omitted the additional exceptions because these types of nonprofit institutions lacked substantial effects on commerce and thus were beyond the Act’s reach. *Trs. of Columbia Univ.*, 97 N.L.R.B. 424, 427 (1951).

⁴⁴ 29 U.S.C. § 157. Concerted activities include organizing, forming, or joining a labor union, and collective bargaining. *Id.*

⁴⁵ *Id.* § 158(b)(7)(C). Although the statute requires a thirty percent showing, unions typically seek seventy percent before acting. *See* NICOLE BUFFALANO, DREW GNIEWEK & FRANCISCO GUZMÁN, MORGAN LEWIS, *COLLECTIVE BARGAINING FOR COLLEGE SPORTS? NCAA V. ALSTON OPENS THE DOOR TO LABOR ISSUES* 14 (2021), <https://www.morganlewis.com/-/media/files/publication/presentation/webinar/2021/what-future-student-athlete-organizing-and-bargaining-could-look-like.pdf> [https://perma.cc/96RW-BQFZ].

the union.⁴⁶ Alternatively, instead of petitioning the NLRB, a unit may request that their employer voluntarily recognize them as a union.⁴⁷ Once recognized, the Act grants the right to employees in the unit to collectively bargain via selected representatives with their employer.⁴⁸ Furthermore, if employers interfere with or restrain employees' attempts to engage in concerted activity or collective bargaining,⁴⁹ the Board has authority to intervene.⁵⁰

The Act charges the Board with the goals of encouraging collective bargaining and protecting employees' right to organize.⁵¹ The Board comprises five members appointed by the President for terms of five years.⁵² Due to staggered schedules, the President appoints three out of five members of the Board,⁵³ as well as the General Counsel.⁵⁴ This process allows the Board and its General Counsel to align policies with the party of each presidential administration.⁵⁵

The Board has broad jurisdiction to resolve labor disputes between workers and private—but not public⁵⁶—employers.⁵⁷ In asserting jurisdiction, the Board has adjudicative authority to resolve labor disputes between a group of employees and the group's employer.⁵⁸ The Board may decline jurisdiction if, in its discretion, a labor dispute has such an insubstantial effect on commerce that asserting jurisdiction would not be warranted.⁵⁹ The Board has noted that, although it is not necessarily compelled to assert jurisdiction when disputes in-

⁴⁶ See NLRB, CASEHANDLING MANUAL PART TWO: REPRESENTATION PROCEEDINGS 11470 (2020), <https://www.nlr.gov/sites/default/files/attachments/pages/node-174/chm-part-ii-rep2019published-9-17-20.pdf> [<https://perma.cc/P4WU-7GBL>]. For an election to be conclusive, a majority of those in the bargaining unit must vote in the affirmative. *See id.*

⁴⁷ *See* 29 U.S.C. § 159(c)(1)(A).

⁴⁸ *See id.* § 157. Collective bargaining is a process through which a union negotiates with an employer over terms and conditions of employment for all workers in a bargaining unit. BUFFALANO ET AL., *supra* note 45.

⁴⁹ 29 U.S.C. § 158.

⁵⁰ *Id.* § 160.

⁵¹ *Id.* § 151.

⁵² *Id.* § 153(a).

⁵³ *See id.*

⁵⁴ *Id.* § 153(d).

⁵⁵ *See* Timothy Noah, *The National Labor Relations Board Is Finally Doing Its Job*, NEW REPUBLIC (Jan. 7, 2022), <https://newrepublic.com/article/164800/jennifer-abruzzo-nlr-enforce-biden-union-agenda> [<https://perma.cc/B5GU-7UKE>].

⁵⁶ Public employees receive similar protection from other agencies. For example, the Merit Systems Protection Board protects federal employees from inappropriate conduct by employers in a similar manner to how the NLRB protects private employees. *See* 5 U.S.C. § 2301(b).

⁵⁷ *See* 29 U.S.C. § 160.

⁵⁸ *See id.* § 151.

⁵⁹ *Id.* § 164(c).

volve substantial effects on interstate commerce, Congress strongly prefers that it does so.⁶⁰

Finally, the Act confers on the Board the authority to undertake rulemaking⁶¹ as permitted by the Administrative Procedure Act.⁶² The Supreme Court has affirmed the Board's authority to issue general rules decoupled from individual adjudicative matters.⁶³ The Board has previously engaged in rulemaking when its prior decisions left important issues unresolved or ambiguous.⁶⁴

B. *NLRB's Jurisdiction over Colleges and Universities*

For decades after the Act passed, the Board was reluctant to assert jurisdiction over private colleges and universities.⁶⁵ In the new century, however, the Board signaled a shift in how it viewed student workers, recognizing student assistants at New York University as statutory employees.⁶⁶ The Board then demonstrated its tendency to vacillate in the political winds when it reached the opposite result four years later regarding a class of student workers at Brown University, based on the theory that student workers have a primarily educational relationship with their school.⁶⁷ Then, in 2016, not only did the Board assert jurisdiction over student workers at Columbia University, but it rejected the "primarily educational" test in favor of the common-law "right to control" test, thereby extending statutory coverage to more student workers than ever before.⁶⁸

1. *Early History*

The Board first asserted jurisdiction over workers at a private school in 1944.⁶⁹ Soon after, in *Trustees of Columbia University* ("*Columbia I*"),⁷⁰ the Board declined jurisdiction over a group of library workers at a private university based on the premise that the group's connection to educational activities of the school outweighed labor-

⁶⁰ See *Cornell Univ.*, 183 N.L.R.B. 329, 332 (1970).

⁶¹ 29 U.S.C. § 156.

⁶² 5 U.S.C. §§ 551–59.

⁶³ *Am. Hosp. Ass'n v. NLRB*, 499 U.S. 606, 614 (1991).

⁶⁴ See *Joint Employer Status Under the National Labor Relations Act*, 85 Fed. Reg. 11184, 11228 (Feb. 26, 2020) (codified at 29 C.F.R. § 103 (2020)) (stating the Board's preference for rulemaking that "foster[s] predictability and consistency").

⁶⁵ See *infra* Section I.B.1.

⁶⁶ See *infra* Section I.B.2.

⁶⁷ See *infra* Section I.B.2.

⁶⁸ See *infra* Section I.B.3.

⁶⁹ See *Henry Ford Trade Sch.*, 58 N.L.R.B. 1535, 1537 (1944).

⁷⁰ 97 N.L.R.B. 424 (1951).

related concerns.⁷¹ In other words, even though the Board acknowledged that the school had a sufficient impact on interstate commerce, the Board opted to decline jurisdiction because the school's sole purpose—ostensibly—was to educate students.

About two decades later, the Board reversed course and asserted jurisdiction over non-student workers in *Cornell University*.⁷² In reaching this decision, the Board cited the lack of a bright line rule when choosing whether to assert jurisdiction.⁷³ It also reasoned that because more time had passed since the Act's passage, the Board's previous justification for declining jurisdiction over colleges and universities—the notion that their sole purpose was to educate students—no longer applied.⁷⁴ In a break from *Columbia I*, the *Cornell* Board stated that declining jurisdiction despite schools' substantial effects on commerce had led to an abstract dividing line between “purely commercial” and noncommercial activities that had been hard to define in practice.⁷⁵ In 1970, the Board issued a rule solidifying the *Cornell* approach to asserting jurisdiction over “any private nonprofit college or university [with] a gross annual revenue . . . of not less than \$1 million.”⁷⁶ In explaining why it published the rulemaking, which still applies today, the Board stated that it prefers a test that “has the advantages of simplicity and ease of application,” and thus promotes consistency and reliability for employers and employees.⁷⁷

The issue of whether the Board will assert jurisdiction over *student* workers at private colleges and universities has been subject to extreme vicissitudes in the past half-century, reflecting political trends. In its 1972 *Adelphi University*⁷⁸ decision, the Board asserted jurisdiction over the bargaining unit at issue only after excluding graduate student workers from the unit.⁷⁹ Because the graduate assistants' positions depended on their continued enrollment as students, the Board found that they were “primarily students,” despite performing several faculty-like duties.⁸⁰ Due to the students' exclusion from the bargaining unit, the question of whether a unit comprising only stu-

⁷¹ See *id.* at 425.

⁷² 183 N.L.R.B. 329 (1970).

⁷³ See *id.* at 331.

⁷⁴ See *id.* at 331–32.

⁷⁵ See *id.* at 331.

⁷⁶ 29 C.F.R. § 103.1 (2019).

⁷⁷ Other Rules, 35 Fed. Reg. 18370, 18371 (Dec. 3, 1970) (to be codified at 29 C.F.R. § 103.1).

⁷⁸ 195 N.L.R.B. 639 (1972).

⁷⁹ See *id.* at 640.

⁸⁰ See *id.*

dent workers could receive statutory recognition remained unanswered.⁸¹

Two years after *Adelphi*, the Board issued a decision on the merits regarding student workers' statutory coverage, concluding that graduate student research assistants do not qualify for statutory protection.⁸² In *Leland Stanford Junior University*,⁸³ the Board held that the graduate research assistants were primarily students and therefore were not employees under the Act's coverage.⁸⁴ This approach to jurisdiction was consistent for the remainder of the twentieth century.

2. *Chaos Theory: New York University, Brown, and the New Millennium*

The new century brought significant shifts in the Board's policy towards bargaining units containing students. In *New York University*,⁸⁵ the Board—comprising a majority of members appointed by President Clinton—overruled twenty-five years of precedent by asserting jurisdiction and finding that a group of graduate student assistants qualified as employees.⁸⁶ The Board concluded that the graduate assistant petitioners fit into the Act's broad text.⁸⁷ It reached this conclusion because the students met the conventional common-law “right to control” test in relation to the university,⁸⁸ the test that the Supreme Court applies when statutes fail to define the term “employee” adequately.⁸⁹ The first prong of the test is whether a worker performs services for another while the other retains the right to control the “manner and means” by which the work is performed.⁹⁰ The second prong is whether the worker performs the services in exchange for compensation.⁹¹ Compensation in this regard does not necessarily constitute regularly tendered paychecks; it may comprise other forms of remuneration.⁹² Because the research assistants satisfied the two

⁸¹ See *id.*

⁸² See *Leland Stanford Junior Univ.*, 214 N.L.R.B. 621, 621–23 (1974).

⁸³ See *id.*

⁸⁴ See *id.* at 623.

⁸⁵ 332 N.L.R.B. 1205 (2000).

⁸⁶ See *id.* at 1209.

⁸⁷ See *id.* at 1205.

⁸⁸ See *id.* at 1206. Although historically also known as the master-servant test, this Note opts to follow modern nomenclature in referring to it as the right to control test.

⁸⁹ See, e.g., *NLRB v. Town & Country Elec.*, 516 U.S. 85, 93–94 (1995).

⁹⁰ See *Cnty. for Creative Non-Violence v. Reid*, 490 U.S. 730, 751 (1989).

⁹¹ See *N.Y. Univ.*, 332 N.L.R.B. at 1206.

⁹² See, e.g., *Seattle Opera v. NLRB*, 292 F.3d 757, 762, 775 (D.C. Cir. 2002) (holding that

prongs of the test, and the Act failed to enumerate students as an exception, the Board recognized the student workers as employees.⁹³

The shift in policy that characterized *New York University* was short-lived, however, as the Board under President George W. Bush declined to recognize the employment status of a similar group of graduate assistants and proctors in *Brown University*⁹⁴ just four years later. The Board asserted jurisdiction but ruled that the group did not constitute employees, returning to the “primarily students” framework.⁹⁵ In justifying this reversion, the Board pointed to the Supreme Court’s distinction between rigid hierarchies common in industrial workplaces, which Congress purportedly intended the Act to cover, and academic settings, which do not fit as neatly into such hierarchies.⁹⁶

The *Brown* Board also emphasized the premise that graduate student workers have both an educational and economic relationship with the school, but the former outweighs the latter.⁹⁷ In support of this conclusion, the Board noted that the petitioners devoted more hours per week to their classes than to their assistant work, and that teaching was a degree requirement for most of the unit.⁹⁸ Lastly, the Board feared that allowing graduate assistants to collectively bargain would force the Board to adjudicate disputes regarding “traditional academic freedoms,” such as how tests are administered.⁹⁹ After an about-face in four years between the Clinton Board’s *New York University* and the Bush Board’s *Brown* decisions, no new cases involving student workers arose for another twelve years, when the Obama Board asserted jurisdiction.

3. Columbia II and Re-Embracing the Common-Law Approach

In *Trustees of Columbia University* (“*Columbia II*”), the Board under President Obama asserted jurisdiction over a group of graduate—and notably, undergraduate—student assistants.¹⁰⁰ The Board

the compensation requirement was satisfied where the company issued flat fees labeled as reimbursements).

⁹³ See N.Y. Univ., 332 N.L.R.B. at 1206.

⁹⁴ 342 N.L.R.B. 483, 487 (2004).

⁹⁵ *Id.* at 487; see also *supra* Section I.B.2.

⁹⁶ See *Brown Univ.*, 342 N.L.R.B. at 494 (citing *NLRB v. Yeshiva Univ.*, 444 U.S. 672, 680–81 (1980)).

⁹⁷ See *id.* at 487.

⁹⁸ See *id.* at 488.

⁹⁹ *Id.* at 490.

¹⁰⁰ 364 N.L.R.B. 1080, 1080 (2016).

returned to its previous common-law analysis, applying the right to control test to find that the assistants were statutory employees.¹⁰¹ It reasoned that where statutory text is clear, and statutory or policy considerations do not outweigh the Act's purpose in promoting effective labor relations, common-law employees must also qualify as employees under the Act.¹⁰² Recognizing the student assistants as statutory employees promoted the aims of the Act, the Board reasoned, because doing so allowed them to collectively bargain for enhanced working conditions.¹⁰³ To address concern that forming an economic relationship with the school while enrolled as a student could create tension, the Board noted that the assistants performed substantive teaching duties.¹⁰⁴ Because other students paid tuition to avail themselves of these services, the Board found that an economic relationship already existed.¹⁰⁵

Furthermore, *Columbia II* rejected the *Brown* Board's concern that allowing students to collectively bargain would constitute a threat to "academic freedoms."¹⁰⁶ It determined, for example, that neither the parties nor the *Brown* Board empirically demonstrated that collective bargaining would in any way infringe on the students' right to free speech in the classroom.¹⁰⁷ The Board also rejected the school's claim that allowing students to unionize would negatively affect students' education, as allowing collective bargaining in similar situations had not led to such dire results.¹⁰⁸

Since being declared statutory employees, many more student workers have sought to collectively bargain with their colleges and universities.¹⁰⁹ Approximately 20,000 student workers at both public and private colleges and universities joined unions between 2013 and 2019, with most of this growth occurring in the years following *Columbia II*.¹¹⁰ In fact, many of these groups did not petition the Board, but

¹⁰¹ *See id.*

¹⁰² *See id.* at 6 (citing *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 261 (1993)).

¹⁰³ *See id.* at 7.

¹⁰⁴ *See id.* at 16.

¹⁰⁵ *See id.* at 16.

¹⁰⁶ *Id.* at 6–8.

¹⁰⁷ *See id.* at 7–8.

¹⁰⁸ *See id.* at 11 (discussing the lack of negative consequences after medical residential house staff unionized).

¹⁰⁹ *See, e.g.*, David W. Chen, *Columbia Graduate Students Walk Out Over Union Fight*, N.Y. TIMES (Apr. 24, 2018), <https://www.nytimes.com/2018/04/24/nyregion/columbia-graduate-students-strike-union-walkout.html> [<https://perma.cc/QYN2-VMJT>].

¹¹⁰ *See* Dan Papsun, *Spike in Grad Student Union Petitions Likely with NLRB Changes*, BLOOMBERG L. (July 28, 2021, 9:42 AM).

rather requested their schools to recognize them voluntarily.¹¹¹ Many public schools have honored these requests,¹¹² some likely due to the precedent of *Columbia II*, whereas private schools have largely resisted.¹¹³ Commentators have noted that the trend of student workers joining unions historically unrelated to student affairs indicates greater flexibility in terms of the Act applying to non-factory-like settings and longstanding unions adapting to prevailing labor trends.¹¹⁴

Thus, the Board's most recent assertion of jurisdiction over a group of student workers at a private college serves as the current test for determining whether students qualify as statutory employees.¹¹⁵ If a group of students satisfies the broad language of the Act,¹¹⁶ and no enumerated exceptions apply,¹¹⁷ the Board will look for compelling reasons to decline jurisdiction.¹¹⁸ Because operating private colleges and universities has a substantial impact on interstate commerce,¹¹⁹ and the Board found in *Columbia II* that unsubstantiated threats to academic freedom do not suffice as a compelling justification for the

¹¹¹ See Colleen Flaherty, *Realities of Trump-Era NLRB*, INSIDE HIGHER ED (Feb. 15, 2018).

¹¹² See, e.g., Kelly Hunter-Lynch, *6000 Strong: Student Labor and Community Organizing with the UAW Local 4121*, THE DAILY (Aug. 26, 2021), https://www.dailyuw.com/special_sections/welcome2021/power/article_56a04746-05f1-11ec-832d-9bd3bb1212cb.html [https://perma.cc/KDY8-WPB4] (University of Washington); *About UAW 2865*, UNITED AUTO WORKERS 2865, <https://uaw2865.org/about-our-union/> [https://perma.cc/VUV5-67AR] (University of California schools); *Wins from the Last Contract*, UNIV. OF CONN. GRADUATE EMP. UNION, <http://uconngradunion.org/wins-from-the-last-contract/> [https://perma.cc/3XE4-TG3E] (University of Connecticut).

¹¹³ See Flaherty, *supra* note 111 (describing the unlikelihood of voluntary recognition at Yale University, the University of Chicago, and Boston College).

¹¹⁴ See Barry Eidlin, *A New Force in American Labor: Academe*, THE CHRON. OF HIGHER EDUC. (Nov. 29, 2021) (reporting that student workers constitute about one-fifth of United Auto Workers, one of the most prominent unions in the country).

¹¹⁵ The Trump Board attempted to pass a rulemaking categorically excluding student works from statutory protection. Jurisdiction—Nonemployee Status of University and College Students Working in Connection With Their Studies, 84 Fed. Reg. 49691, 49691 (proposed Sept. 23, 2019) (to be codified at 29 C.F.R. pt. 103), *withdrawn* by 86 Fed. Reg. 14297, 14297 (Mar. 15, 2021). However, the Biden Board swiftly withdrew the proposed rulemaking. *Id.*

¹¹⁶ See 29 U.S.C. § 152(3).

¹¹⁷ See Trs. of Columbia Univ., 364 N.L.R.B. 1080, 1084 (2016).

¹¹⁸ *Id.* at 1087.

¹¹⁹ See NAT'L CTR. FOR EDUC. STAT., POSTSECONDARY INSTITUTION REVENUES, (2022), <https://nces.ed.gov/programs/coe/indicator/cud#:~:text=IN%202018%E2%80%939319%2C%20total%20revenues,at%20private%20for%2Dprofit%20institutions> [https://perma.cc/K6KS-7Q7D] (finding that revenues at American colleges and universities totaled \$695 billion in 2019–20, a long way away from the nature of such schools in 1951); see also Andrew Rossi, *How American Universities Turned into Corporations*, TIME (May 22, 2014, 12:01 AM) (reporting that the cost of college increased from 1978 to 2014 by 1,120 percent).

Board to decline jurisdiction,¹²⁰ it will continue to assert jurisdiction unless political winds shift in the other direction.

C. *NLRB's Jurisdiction in the Wide World of Sports*

The move towards organized labor in professional sports dates back to the nineteenth century.¹²¹ In 1968, the owners of the National Football League (“NFL”) recognized a union composed of players.¹²² The Board has consistently asserted jurisdiction over professional leagues since 1970, when it first recognized this union comprising players: the NFL Players Association (“NFLPA”).¹²³ In a recent momentous development, Major League Baseball (“MLB”) announced that it will voluntarily recognize a union representative for minor league players, after more than a century of MLB’s refusal to do so.¹²⁴

NCAA and school officials have based their policies on those of professional leagues in some aspects,¹²⁵ but they have not yet recognized unions comprising players.¹²⁶ One major difference between professional and collegiate sports is that the Act enumerates workers at public universities and colleges as exceptions to statutory coverage.¹²⁷ In fact, only seventeen of about 130 total Football Bowl Subdivision (“FBS”) teams—and roughly one-third of Division I men’s basketball teams¹²⁸—play for private schools.¹²⁹ Although no FBS

¹²⁰ 364 N.L.R.B. at 1086.

¹²¹ See, e.g., *Phila. Ball Club, Ltd. v. Hallman*, 8 Pa. C. 57 (C.P., Phila. Cnty. 1890).

¹²² See Kevin Jackman, *NFL Lockout: An In-Depth Look at Past Labor Disputes in Sports; Current NFL Issue*, BLEACHER REP. (June 5, 2011), <https://bleacherreport.com/articles/724433-nfl-lockout-an-in-depth-look-at-past-labor-disputes-in-sports-current-nfl-issue> [http://perma.cc/243R-JCDL].

¹²³ See *id.* Professional leagues include the National Football League (“NFL”), Major League Baseball (“MLB”), National Basketball Association (“NBA”), and National Hockey League (“NHL”).

¹²⁴ See James Wagner, *M.L.B. Will Voluntarily Recognize Minor League Union*, N.Y. TIMES (Sept. 9, 2022), <https://www.nytimes.com/2022/09/09/sports/baseball/minor-league-union.html> [https://perma.cc/YJ4B-9529].

¹²⁵ See, e.g., Billy Witz, *Doctors Enter College Football's Politics, but Maybe Just for Show*, N.Y. TIMES (Sept. 17, 2020), <https://www.nytimes.com/2020/08/23/sports/ncaafootball/college-football-myocarditis-coronavirus.html> [https://perma.cc/X2MM-YSD7] (reporting that schools looked to professional leagues in deciding how to handle COVID-19 risk).

¹²⁶ See *Northwestern Univ.*, 362 N.L.R.B. 1350, 1350 (2015).

¹²⁷ See *id.* at 1354.

¹²⁸ See *Your Complete List of Men's Division I Basketball Colleges*, NEXT COLL. STUD. ATHLETE, <https://www.ncsasports.org/mens-basketball/division-1-colleges> [https://perma.cc/N7A9-XD7F].

¹²⁹ See *Northwestern*, 362 N.L.R.B. at 1354. The FBS is one of two subdivisions of Division I football. See *Understanding the Different College Football Divisions*, VERIFIED ATHLETICS, <https://www.verifiedathletics.com/athlete-resources/2018/12/4/understand-the-different-college-football-divisions> [https://perma.cc/WZB9-TKYZ].

conference currently has a majority of private schools, the Board has previously asserted jurisdiction over employees on a conference-wide basis.¹³⁰

The Board has not ruled whether one college or university in a conference can unionize at a time.¹³¹ In *Northwestern University*, the Board declined to assert jurisdiction over a unit of grant-in-aid¹³² football players at the sole private university in the FBS Big Ten Conference; the Board therefore did not decide whether the players qualified as statutory employees.¹³³ The Board stated that no extant analytical framework clearly applied to recognizing a unit consisting of an individual college team.¹³⁴ Because the Act did not extend to the team's public school competitors, the Board reasoned, Northwestern might have a recruiting advantage if only their team could benefit from collective bargaining.¹³⁵ For that reason, the Board argued that asserting jurisdiction would lead to an inequitable result in terms of competitive balance and labor relations.¹³⁶

Although it did not reach a decision, the Board implied that the group of players could theoretically qualify as employees.¹³⁷ Before the case reached the Board, in fact, the Regional Director came to this conclusion, noting that several aspects of collegiate athletics resemble professional sports.¹³⁸ For example, players receive compensation including tuition, lodging, and incidental reimbursements; spend more than forty hours each week on football activities; and must comply with the rules imposed by the school, conference, and NCAA.¹³⁹ In addition, the Board itself noted that college football teams have an

¹³⁰ See *Northwestern*, 362 N.L.R.B. at 1352 n.9 (citing Big E. Conf., 282 N.L.R.B. 335 (1986)).

¹³¹ See *id.* at 1354 n.16.

¹³² A "grant-in-aid" scholarship covers the cost of an athlete's expenses while on the team. See *id.* at 1351. In this case, players' scholarships had a value of about \$61,000 per year for each eligible player, calculated to address the costs of "tuition, fees, room, board, and books." *Id.*

¹³³ *Id.* at 1350, 1352.

¹³⁴ *Id.* at 1351–52.

¹³⁵ See *id.* at 1352–54. In fact, states such as Ohio and Michigan specifically exclude scholarship athletes in the definition of "employee" in state labor law. *Id.* On the other hand, Iowa is considering legislation that would include college athletes as statutory employees. Dennis Dodd, *Iowa State Bill Aims to Reclassify College Athletes as Employees Due Compensation by Universities*, CBS SPORTS (Jan. 27, 2022, 11:51 AM), <https://www.cbssports.com/college-football/news/iowa-state-bill-aims-to-reclassify-college-athletes-as-employees-due-compensation-by-universities/> [<https://perma.cc/AD6S-JMFX>] (discussing IA H.F. 2055).

¹³⁶ See *Northwestern*, 362 N.L.R.B. at 1352.

¹³⁷ See *id.* at 1353 n.13.

¹³⁸ See *id.* at 1350–51.

¹³⁹ See *id.* at 1351, 1358–59.

effect on commerce so substantial that declining jurisdiction on that basis would not be feasible.¹⁴⁰ Sure enough, Division I sports brought in about \$18 billion total in 2019 alone,¹⁴¹ and March Madness—college basketball’s flagship playoff event—brings in more than \$1 billion each year by itself.¹⁴² Despite these factors, the Board declined jurisdiction, and did not indicate whether the “primarily students” or right to control test would apply to collegiate players in the future.¹⁴³

D. Challenging the Concept of Amateurism in Collegiate Sports

In 2017, President Obama’s appointed NLRB General Counsel Richard F. Griffin, Jr. set forth his position that the Northwestern grant-in-kind athletes qualified as statutory employees under the Act.¹⁴⁴ Griffin argued that by declining to assert jurisdiction, the Board left perilously unanswered the question of whether collegiate players could take part in concerted activities subject to Board protection.¹⁴⁵ Griffin advocated for applying the right to control test, opining that the *Columbia II* Board correctly applied the test to student workers.¹⁴⁶

In applying the two prongs of the test to scholarship collegiate football players, Griffin maintained that (1) the players perform services for their school under the school’s right to control, and (2) the players do so in exchange for compensation.¹⁴⁷ He asserted that schools demonstrate a right to control because they regulate minute details such as how often players workout and practice.¹⁴⁸ Griffin argued that the second prong—compensation in exchange for work—was also satisfied because grant-in-aid players receive up to \$75,000 in scholarships per year, and all players received reimbursements for

¹⁴⁰ See *id.* at 1353.

¹⁴¹ Billy Witz, *N.C.A.A. Reorganizes Around New Constitution That Shifts Power to Universities*, N.Y. TIMES (Jan. 20, 2022), <https://www.nytimes.com/2022/01/20/sports/ncaafootball/ncaa-constitution-transgender-athletes.html> [<https://perma.cc/B9BR-WS7R>].

¹⁴² Nat’l Collegiate Athletic Ass’n v. Alston, 141 S. Ct. 2141, 2150 (2021).

¹⁴³ *Northwestern*, 362 N.L.R.B. at 1353. Since the Board’s nondecision, no groups of collegiate players have attempted to organize in earnest. See Taylor Brinkman & Tatianna Witter, *From “Student-Athletes” to “Players”: A Review of the 2021 Legal Developments Shaping a New Reality of College Sports*, JDSUPRA (Jan. 6, 2022), <https://www.jdsupra.com/legalnews/from-student-athletes-to-players-a-6189761/> [<https://perma.cc/55KK-GEMN>].

¹⁴⁴ Memorandum from Richard F. Griffin, Jr., Gen. Couns., NLRB, to All Reg’l Dirs., Officers-in-Charge, & Resident Officers 20 (Jan. 31, 2017) (withdrawn Dec. 1, 2017), <https://apps.nlr.gov/link/document.aspx/09031d4582342bfc> [<https://perma.cc/3ABH-MWAN>].

¹⁴⁵ See *id.* at 17.

¹⁴⁶ See *id.* at 10–13.

¹⁴⁷ *Id.* at 19.

¹⁴⁸ *Id.*

travel and childcare expenses.¹⁴⁹ True to the NLRB's history of political fluctuation, Peter B. Robb, the General Counsel appointed by President Trump, rescinded Griffin's memorandum without comment.¹⁵⁰

In 2021, however, President Biden's appointed General Counsel Jennifer A. Abruzzo emphatically echoed Griffin's contention that grant-in-aid players are statutory employees based on the right to control test.¹⁵¹ Abruzzo has encouraged Division I football and basketball teams at private colleges and universities to unionize, implying that the Board's jurisdictional concerns in 2015 are no longer an impediment.¹⁵² Further, she suggested that players could potentially organize in a conference- or Division-wide capacity under a theory of joint employment.¹⁵³

Perhaps contrary to popular belief, the concept of amateurism in college sports is a relatively recent phenomenon.¹⁵⁴ In fact, the NCAA created the term "student-athlete" in the 1950s as a litigation defense.¹⁵⁵ Critics point out that the NCAA has wielded the language of amateurism to prevent players from asserting their rights to organize and demand payment for their work.¹⁵⁶ In addition, these critics posit that the disparity between schools' revenue and players' lack of finan-

¹⁴⁹ *Id.* at 19 n.118.

¹⁵⁰ Memorandum from Peter B. Robb, Gen. Couns., NLRB, to All Reg'l Dirs., Officers-in-Charge, & Resident Officers 4–5 (Dec. 1, 2017), <https://apps.nlr.gov/link/document.aspx/09031d458262a31c> [<https://perma.cc/DK8J-ZG2X>].

¹⁵¹ Abruzzo, *supra* note 19, at 4.

¹⁵² *See id.* at 7–9.

¹⁵³ *See id.* at 4, 9 n.34. Joint employment exists in the common law where multiple employers simultaneously possess the right to control employees' work performance. *See* *Browning-Ferris Indus. of Cal., Inc. v. NLRB*, 911 F.3d 1195, 1200–01 (D.C. Cir. 2018). In fact, the NLRB has proposed a rulemaking that will codify the common-law joint employment standard; that is, such a relationship will exist where two employers "share[] or codetermine[] those matters governing at least one of the employees' essential terms and conditions of employment." Standard for Determining Joint-Employer Status, 87 Fed. Reg. 54641, 54645 (Sept. 7, 2022) (to be codified at 29 C.F.R. pt. 103).

¹⁵⁴ *See generally* RONALD A. SMITH, *THE MYTH OF THE AMATEUR* (2021) (detailing the professionalized nature of college sports well into the twentieth century).

¹⁵⁵ *See* Jay D. Lonick, Note, *Bargaining with the Real Boss: How the Joint Employer Doctrine Can Expand Student-Athlete Unionization to the NCAA as an Employer*, 15 VA. SPORTS & ENT. L.J. 135, 140 (2015) (tracing the NCAA's use of the term "student-athlete" to *Univ. of Denver v. Nemeth*, 257 P.2d 423 (Colo. 1953), where an injured player argued that he was entitled to worker's compensation).

¹⁵⁶ *See* Jeffrey L. Kessler & David L. Greenspan, *The NIL in Amateurism's Coffin: How the NCAA's Policy Reversal Shows Once Again that Compensating Student-Athletes Won't Hurt College Sports*, HARV. J. SPORTS & ENT. L. (2020) (arguing that amateurism is a tool wielded by the NCAA to "control their costs and maximize their profits").

cial benefits perpetuates race-based disparities.¹⁵⁷ Further, because the NCAA has failed to abide by a consistent definition of “amateurism,” it has entangled courts in a convoluted guessing game, likely leading to extensive and costly litigation.¹⁵⁸

Recent years have seen a higher incidence of NCAA-related litigation than ever before, each attacking the core idea of amateurism.¹⁵⁹ For example, in *Alston*, the Supreme Court unanimously held that NCAA rules restricting education-related benefits violate antitrust law.¹⁶⁰ The Court clarified that the decision centered around whether the district court’s finding was reasonable, and not whether the overall amateur athletic model passed muster.¹⁶¹ In Justice Kavanaugh’s concurrence, however, he directly challenged collegiate players to take part in collective bargaining so they could collect a fair portion of revenue.¹⁶²

NCAA-related litigation is also prevalent in the lower courts. One such case deals with the issue of whether collegiate athletes qualify as employees under the Fair Labor Standards Act (“FLSA”), and are therefore entitled to minimum wage.¹⁶³ Meanwhile, collegiate players filed a complaint in 2021 at an NLRB regional office alleging that schools and the NCAA are committing an unfair labor practice by misclassifying players as student-athletes, thereby violating the NLRA.¹⁶⁴ Partly in response to these channels of litigation, the NCAA Board of Directors has agreed on an updated, less extensive constitution that will shift power to individual conferences and away from the NCAA as a central governing body.¹⁶⁵ This coincides with a flurry of changes in conference composition, as schools seek advantageous financial positions.¹⁶⁶

¹⁵⁷ See RAMOGI HUMA & ELLEN J. STAUROWSKY, NAT’L COLL. PLAYERS ASS’N, *HOW THE NCAA’S EMPIRE ROBS PREDOMINANTLY BLACK ATHLETES OF BILLIONS IN GENERATIONAL WEALTH* (2020).

¹⁵⁸ See Nat’l Collegiate Athletic Ass’n v. *Alston*, 141 S. Ct. 2141, 2170–71 (2021).

¹⁵⁹ See, e.g., *Berger v. Nat’l Collegiate Athletic Ass’n*, 843 F.3d 285, 294 (7th Cir. 2016) (Hamilton, J., concurring) (pointing out the disparity between players’ lack of salary and the NCAA’s billions in yearly revenue).

¹⁶⁰ *Alston*, 141 S. Ct. at 2145.

¹⁶¹ See *id.* at 2153, 2161.

¹⁶² See *id.* at 2168 (Kavanaugh, J., concurring).

¹⁶³ See *Johnson v. Nat’l Collegiate Athletic Ass’n*, No. 19-5230, 2021 U.S. Dist. LEXIS 246324, at *3 (E.D. Pa. Dec. 28, 2021) (motion for interlocutory appeal granted on issue of whether players qualify as statutory employees under FLSA).

¹⁶⁴ The Nat’l Collegiate Athletic Ass’n, Case 25-CA-286101 (filed Nov. 10, 2021).

¹⁶⁵ See Witz, *supra* note 141 (reporting that the updated constitution was approved, effective August of 2022).

¹⁶⁶ See Tony Moss, *College Basketball Realignment Tracker: Keeping Track of NCAA Divi-*

Finally, collegiate athletes are now permitted to profit off of their names, images, and likenesses (“NIL”).¹⁶⁷ After decades of prohibition, California became the first state to allow college athletes to monetize their likeness; this triggered a rush of other states to follow suit.¹⁶⁸ After many states drafted similar laws, the NCAA repealed its prohibitions on profiting from NIL.¹⁶⁹ In the wake of this momentous change, the NCAA’s concern that allowing players to earn money would dwindle fan interest has not occurred to this point.¹⁷⁰

II. LEVELING THE PLAYING FIELD WITH THE RIGHT TO CONTROL TEST

The Board’s refusal to assert jurisdiction over a particularly vulnerable group of workers like collegiate athletes runs counter to the Act’s broad goal of promoting peaceful labor relations to limit disruptions to interstate commerce.¹⁷¹ In addition, the right to control test is much more administrable in practice than the muddled abstractions inherent in the *Brown* test.¹⁷² Applying the right to control test to collegiate players will also be consistent with precedent regarding collegiate workers and professional athletes.¹⁷³ Lastly, the concept of collegiate players as amateurs has proven untenable in the modern world, and denying them statutory protection is therefore inconsistent with prevailing attitudes.¹⁷⁴

sion I Conference Changes, ESPN (July 12, 2022), https://www.espn.com/mens-college-basketball/story/_/id/32855347/college-basketball-realignment-tracker-keeping-track-ncaa-division-conference-changes [https://perma.cc/L8ST-L9SW] (reporting that in 2021–22 alone, nineteen of thirty-two Division I basketball conferences added or subtracted teams).

¹⁶⁷ See Caroline K. Hicks, Note, *How Pay to Play Legislation Has a Bolstering Effect on the Argument that Student Athletes Should Be Compensated as Employees and How the NCAA Should Respond*, 15 CHARLESTON L. REV. 491, 492 (2021).

¹⁶⁸ See Alan Blinder, *After California Law, Statehouses Push to Expand Rights of College Athletes*, N.Y. TIMES (Jan. 13, 2020), <https://www.nytimes.com/2020/01/13/sports/ncaa-athletes-pay-california.html> [https://perma.cc/8M7M-HR83].

¹⁶⁹ See Hicks, *supra* note 167, at 492.

¹⁷⁰ See Dennis Dodd, *With the NCAA Backed into a Corner, the Age of Paying College Athletes Is Officially Upon Us*, CBS SPORTS (Jan. 20, 2022, 2:47 PM), <https://www.cbssports.com/college-football/news/with-the-ncaa-backed-into-a-corner-the-age-of-paying-college-athletes-is-officially-upon-us/> [https://perma.cc/5BXT-DXVH].

¹⁷¹ See *supra* Section I.A.

¹⁷² See *infra* Section II.B.

¹⁷³ See *infra* Section II.B.

¹⁷⁴ See *infra* Section II.C.

A. *Declining Jurisdiction Impedes the Purpose of the NLRA*

The Act's broad language enumerates only a few exceptions to the definition of "employee," none of which apply to collegiate athletes.¹⁷⁵ Because the statute enumerates certain exceptions, the negative-implication canon of statutory construction presumes that unenumerated categories of workers qualify as employees.¹⁷⁶ In addition, because the Board exists to further the goals of the Act, it has authority to define "employee" broadly.¹⁷⁷ It therefore stands to reason that collegiate athletes definitionally qualify as employees according to a plain reading of the Act's text.¹⁷⁸

The Board's declining jurisdiction over collegiate athletes is harmful to the goals of the NLRA because it leaves open labor-related questions that could have been resolved years ago.¹⁷⁹ Since the Board declined to assert jurisdiction in 2015, no college athletes have attempted to unionize in earnest, and entire additional generations of players have been unable to negotiate effectively to mitigate the inherent dangers of contact sports.¹⁸⁰ Meanwhile, in the years immediately after the Board asserted jurisdiction over student workers in *Columbia II*, more than 20,000 similarly situated public school student workers joined labor unions across the country—whereas far fewer of their private school counterparts did the same, fearing that a Republican-majority Board would overturn *Columbia II*.¹⁸¹ The disparity between unionization at public and private schools indicates that the Board's political fluctuations have discouraged unknown numbers of would-be employees from asserting their statutory rights.¹⁸²

The *Northwestern* Board's concerns over how the assertion of jurisdiction over players at private schools would give those schools an unfair recruiting advantage can be mitigated. If players seek to organize conference- or Division-wide through a theory of joint employment, then the Board could ensure that no disparities in bargained-for

¹⁷⁵ See 29 U.S.C. § 152(3); *supra* text accompanying notes 37–38.

¹⁷⁶ See *NLRB v. Town & Country Elec., Inc.* 516 U.S. 85, 90–91 (1995); *see also* SCALIA & GARNER, *supra* note 39, at 107–11.

¹⁷⁷ See *Town & Country Elec.*, 516 U.S. at 89–90.

¹⁷⁸ See 29 U.S.C. § 152(3).

¹⁷⁹ See Marc Edelman, *The Future of College Athlete Players Unions: Lessons Learned from Northwestern University and Potential Next Steps in the College Athletes' Rights Movement*, 38 CARDOZO L. REV. 1627, 1640–42 (2017).

¹⁸⁰ See Brinkman & Witter, *supra* note 143.

¹⁸¹ See Papsun, *supra* note 110; Flaherty, *supra* note 111.

¹⁸² See *supra* notes 112–13.

rights exist between similarly situated teams.¹⁸³ In fact, General Counsel Abruzzo has supported the idea that the Board could potentially assert jurisdiction over a unit including public school players under a theory of joint employment by their school and their conference or the NCAA.¹⁸⁴ Such a theory appears plausible in light of recent jurisprudence.¹⁸⁵

Lastly, the Act prompts the Board to assert jurisdiction over labor disputes with substantial effects on commerce unless compelling considerations outweigh such effects.¹⁸⁶ The Board conceded in *Northwestern* that Division I football has a significant impact on commerce.¹⁸⁷ Collegiate athletes on “revenue-generating” teams¹⁸⁸—mostly football and basketball—bring substantial streams of money to their schools.¹⁸⁹ The Board’s jurisdictional standard covers private colleges and universities with yearly revenue exceeding \$1 million,¹⁹⁰ a threshold eclipsed roughly fifty times over by each football program in the Big Ten conference alone.¹⁹¹ As demonstrated by their tremendous revenues, Division I sports have a massive impact on interstate commerce and the Board should only decline jurisdiction over players through a substantially compelling justification.¹⁹² The Board claimed it had such a justification in *Northwestern*, citing the possible competitive imbalance that could result from one team unionizing at a time.¹⁹³ However, players could assuage this concern by joining together in conference- or division-wide bargaining units—drawing influence from professional sports’ models.¹⁹⁴ Alternatively, the decentralized nature of the NCAA’s new constitution allows conferences to realign more easily.¹⁹⁵ As a result, conferences could continue to realign¹⁹⁶

¹⁸³ See Abruzzo, *supra* note 19.

¹⁸⁴ *Id.* at 9 n.34.

¹⁸⁵ See *supra* note 153 and accompanying text.

¹⁸⁶ See 29 U.S.C. § 164(c); see also Trs. of Columbia Univ., 364 N.L.R.B. 1080, 1081 (2016).

¹⁸⁷ See *Northwestern Univ.*, 362 N.L.R.B. 1350, 1353 (2015).

¹⁸⁸ In most schools, only two or three sports generate more money than they cost. See Patrick Rishe, *College Football Profiteering a Necessary Evil for Financing Athletics, Long-Term Branding*, FORBES (Sept. 21, 2011, 2:10 PM), <https://www.forbes.com/sites/prishe/2011/09/21/college-football-profiteering-a-necessary-evil-for-financing-athletics-long-term-branding/?sh=9396d1e52fd3> [<https://perma.cc/3FVG-8JNX>].

¹⁸⁹ See Witz, *supra* note 141.

¹⁹⁰ 29 C.F.R. § 103.1.

¹⁹¹ See Berkowitz, *supra* note 14.

¹⁹² See Trs. of Columbia Univ., 364 N.L.R.B. 1080, 1084 (2016).

¹⁹³ See *Northwestern Univ.*, 362 N.L.R.B. 1350, 1352 (2015).

¹⁹⁴ See *supra* notes 122–25 and accompanying text.

¹⁹⁵ See Witz, *supra* note 165.

¹⁹⁶ See Moss, *supra* note 166.

and even form a conference containing a majority of private colleges and universities, in which case the Board would be hard-pressed to find a compelling justification to decline jurisdiction.¹⁹⁷

B. The Common-Law Test Is More Administrable Than the “Primarily Students” Approach

When the *Columbia II* Board rejected the *Brown* Board’s “primarily students” analysis,¹⁹⁸ it moved from an arbitrary and abstract standard to one that promotes clarity and reliability.¹⁹⁹ The Board has a history of moving from abstract dividing lines to more workable bright line coverage of entire classes of workers, such as when it rejected the *Columbia I* dividing line between commercial and noncommercial activities in favor of a general jurisdiction approach.²⁰⁰ Similar to the line between commercial and noncommercial activities, the line between “primarily students” and “primarily workers” is nebulous and therefore unpredictable in its analysis.²⁰¹ Moreover, the idea that a school’s *only* purpose is to educate students—as advanced in *Columbia I* more than seventy years ago²⁰²—is no longer persuasive; private colleges’ and universities’ revenues have exploded and far outpaced the rate of inflation, demonstrating their commercial nature.²⁰³ Furthermore, even though students have an educational relationship with their school, such a distinction hardly merits forcing student workers to experience oppressive labor practices.²⁰⁴

Because the *Brown* test²⁰⁵ is vague, applying it to collegiate assistants and extending it to players would lead to uncertainty for schools, students, and unions. The test is vague because it implies a quantitative metric by which a worker could shift from primarily a student to primarily a worker, but fails to define such a metric.²⁰⁶ The *Brown* Board held that graduate assistants were primarily students because they spent more hours per week on their own studies than on assistant work, but did not clarify how the calculus would change if the oppo-

¹⁹⁷ See Big E. Conf., 282 N.L.R.B. 335, 341–42 (1986).

¹⁹⁸ See Trs. of Columbia Univ., 364 N.L.R.B. 1080, 1082–83 (Aug. 23, 2016).

¹⁹⁹ See *id.* at 1085.

²⁰⁰ See *supra* text accompanying notes 72–75.

²⁰¹ See *Columbia*, 364 N.L.R.B. at 1086.

²⁰² See Trs. of Columbia Univ., 97 N.L.R.B. 424, 425 (1951).

²⁰³ See *supra* note 119.

²⁰⁴ See *Columbia*, 364 N.L.R.B. at 1086.

²⁰⁵ See *supra* Section II.B.2.

²⁰⁶ See *Brown Univ.*, 342 N.L.R.B. 483, 488–89 (2004). The “primarily students” test bears a strong resemblance to the NCAA’s use of the term “student-athlete,” strategically ordering the terms to imply that the former outweighs the latter. See Lonick, *supra* note 155.

site were true.²⁰⁷ In the case of collegiate athletes, the opposite is in fact true; throughout the season players consistently devote more than forty hours per week to their sport.²⁰⁸ In addition, whereas teaching was required for most students in *Brown* to earn a degree,²⁰⁹ participating in college sports is not necessary to graduate. Therefore, although the *Brown* Board found that graduate assistants were primarily students based on allocation of time and the integrality of teaching to their roles as students, such analysis cannot withstand the more complex nature of collegiate sports.²¹⁰

Applying the right to control test to Division I athletes better aligns with precedent set by the Supreme Court in other types of employee determinations.²¹¹ In fact, the Supreme Court has held that it should rely on the common-law approach for determining whether a worker qualifies as an employee absent explicit Congressional indication to the contrary.²¹² The Court's rationale is that the common-law right to control test—providing compensation for work plus retaining the right to control how that work is accomplished—is much more administrable in practice than alternatives.²¹³

Acknowledging the Board's preference for tests embodying "simplicity and ease of application"²¹⁴—thereby promoting consistency and reliability—it follows that the Board should favor the right to control test. To illustrate, consider the clarity with which General Counsel Griffin was able to apply the test to the facts of *Northwestern*.²¹⁵ The first prong of the right to control test—the employer's right to control—is easily satisfied because players perform grueling work on behalf of the NCAA, conferences, and colleges and universities.²¹⁶ All three manifest the right to control players' work by regulating how

²⁰⁷ See *Brown*, 342 N.L.R.B. at 488.

²⁰⁸ See, e.g., *Northwestern Univ.*, 362 N.L.R.B. 1350, 1358 (2015).

²⁰⁹ See *Brown*, 342 N.L.R.B. at 488.

²¹⁰ See *id.* at 488–89.

²¹¹ See, e.g., *Cnty. for Creative Non-Violence v. Reid*, 490 U.S. 730, 751 (1989).

²¹² See *Nationwide Mut. Ins. Co. v. Darden*, 503 U.S. 318, 322–23 (1992).

²¹³ See *id.*

²¹⁴ Other Rules, 35 Fed. Reg. 18370, 18371 (Dec. 3, 1970) (to be codified at 29 C.F.R. § 103.1).

²¹⁵ See Griffin, *supra* note 144.

²¹⁶ See *Northwestern Univ.*, 362 N.L.R.B. 1350, 1351 (2015). Although it may be tempting to discredit players' labor because football is a game, players such as Kain Colter demonstrate the significant toll such games consistently impose. See *supra* notes 3–5 and accompanying text.

often players work out and practice²¹⁷ and conditioning scholarships on players' strict rule compliance.²¹⁸

Likewise, the facts of *Northwestern* satisfy the test's second prong—requiring compensation in exchange for performing work.²¹⁹ Not only do grant-in-aid players receive up to \$75,000 each year to cover academic expenses, but all players regardless of scholarship status receive reimbursements for travel and childcare expenses.²²⁰ Because compensation does not necessarily denote a formal paycheck, but can take the form of other types of reimbursements, this type of remuneration satisfies the second element of the test.²²¹ As a result, applying the right to control test to men's and women's Division I players will likely find that they also qualify as statutory employees.²²²

If clarity is the goal,²²³ then the *Brown* test is woefully lacking. Because of its vagueness, applying it will lead to confusion for players, colleges and universities, and unions—a risk that the Board has historically sought to avoid.²²⁴ Even if the *Brown* test were to ultimately result in players being considered employees, the uncertainty before such a finding would have the unfortunate consequence of discouraging players from asserting their rights.²²⁵

C. *The Amateur Status of Collegiate Athletes Has Proven Untenable*

Because collegiate sports are highly similar to professional sports, collegiate players should receive the same level of statutory protection afforded to professional athletes.²²⁶ In 2011 the NFLPA collectively bargained for contact limits in practices, a rule that led to a sharp decline in concussions suffered;²²⁷ harrowingly, college football players, with no leverage to negotiate for similar contact limits, experience a much higher incidence of concussions suffered during practice.²²⁸ Al-

²¹⁷ Griffin, *supra* note 144.

²¹⁸ See *Northwestern*, 362 N.L.R.B. at 1351–58.

²¹⁹ See *N.Y. Univ.*, 332 N.L.R.B. 1205, 1206 (2000).

²²⁰ Griffin, *supra* note 144.

²²¹ See *Seattle Opera v. NLRB*, 292 F.3d 757, 762 (D.C. Cir. 2002).

²²² Abruzzo, *supra* note 19.

²²³ Other Rules, 35 Fed. Reg. 18370, 18371 (Dec. 3, 1970) (to be codified at 29 C.F.R. § 103.1).

²²⁴ See *id.*

²²⁵ See *Trs. of Columbia Univ.*, 364 N.L.R.B. 1080 (2016).

²²⁶ See *Northwestern Univ.*, 362 N.L.R.B. 1350, 1353 (2015).

²²⁷ See George, *supra* note 6.

²²⁸ See *id.* (indicating that more than seventy percent of college players' concussions occur during practice, compared to just eighteen percent for NFL players).

though football inherently includes risk to players' health and safety, NFL players have a platform to mitigate these risks, where their collegiate counterparts do not.²²⁹

Although the Board posited that Division I athletes' requirement to be enrolled as students meaningfully distinguishes them from professionals—therefore providing justification for declining jurisdiction²³⁰—such logic falls flat given that the Board asserted jurisdiction over enrolled student workers in *Columbia II*.²³¹ Just as teaching assistants benefit their school through teaching and assisting academically,²³² players' performance on the field leads to greater revenue to the school, increased enrollment numbers, and more generous alumni donations.²³³ In addition, the Board cited as a justification for its nondecision in *Northwestern* that collegiate athletes “are prohibited by NCAA regulations from engaging in many of the types of activities that professional athletes are free to engage in, such as profiting from the use of their names or likenesses.”²³⁴ In the time since, however, the NCAA has rewritten its rules to allow players to profit off of their NIL, thereby invalidating this crucial distinction.²³⁵

The NCAA's impact on interstate commerce rivals that of professional leagues. In 2021, a pandemic-plagued year, the television advertisement earnings of college basketball's March Madness totaled more than \$850 million.²³⁶ March Madness routinely earns more than the NFL playoffs, and more than the National Basketball Association (“NBA”), NHL, and MLB playoffs *combined*.²³⁷ Even with NIL reform, collegiate players still benefit far less from participating in big

²²⁹ See Strauss, *supra* note 6.

²³⁰ See *Northwestern*, 362 N.L.R.B. at 1353–54.

²³¹ See Trs. of Columbia Univ., 364 N.L.R.B. 1080, 1080 (2016).

²³² See *id.*

²³³ See Nat'l Collegiate Athletic Ass'n v. Alston, 141 S. Ct. 2141, 2149 (2021).

²³⁴ *Northwestern*, 362 N.L.R.B. at 1353.

²³⁵ See Michelle Brutlag Hosick, *NCAA Adopts Interim Name, Image and Likeness Policy*, NCAA (June 30, 2021, 4:20 PM), <https://www.ncaa.org/about/resources/media-center/news/ncaa-adopts-interim-name-image-and-likeness-policy> [https://perma.cc/98SD-SNUE].

²³⁶ Jason Breslow, *March Madness is an NCAA Gold Mine. This Year, Players Can Finally Cash in Too*, NPR (Mar. 16, 2022, 2:35 PM), [npr.org/2022/03/16/1085906019/march-madness-ncaa-tournament-student-athletes-nil-paid-endorsement](https://www.npr.org/2022/03/16/1085906019/march-madness-ncaa-tournament-student-athletes-nil-paid-endorsement) [https://perma.cc/DNE8-ZBYC].

²³⁷ Zak Cheney-Rice, *Here's How Many Billions College Players Will Make During March Madness this Year*, MIC (Mar. 19, 2014), <https://www.mic.com/articles/85763/here-s-how-many-billions-college-players-will-make-during-march-madness-this-year> [https://perma.cc/5VY9-K7C8] (answering the question posed in the title with a resounding “zero”); see also Kris Rhim & Jesus Jiménez, *Big Ten Players Wonder Where They Fit into a \$1 Billion TV Deal*, N.Y. TIMES (Aug. 19, 2022), <https://www.nytimes.com/2022/08/19/sports/ncaafotball/big-ten-tv-deal-student-athletes.html> [http://perma.cc/NZU9-QL47].

money athletics than do professional athletes.²³⁸ Minor league baseball players—with a relatively meager impact on commerce²³⁹—will soon join a union after more than a hundred years of stifled attempts,²⁴⁰ thus making the NCAA’s arguments against collegiate athletes’ unionizing appear even less persuasive.

Although the Board punted the issue of whether collegiate players qualify as statutory employees in 2015, the cracks in the amateur sports model make it impossible to avoid the NCAA’s labor implications.²⁴¹ The Supreme Court has expressed frustration with the shifting concept of “amateurism” that the NCAA tends to define on a case-by-case basis.²⁴² For the first time ever, a Supreme Court Justice openly endorsed players’ organizing.²⁴³ Meanwhile, shockwaves of activism have rippled throughout collegiate sports in recent years.²⁴⁴ The net result of the proliferation of litigation and activism is that the Board will need to clarify its position, and soon.²⁴⁵

III. THE NLRB SHOULD APPLY *COLUMBIA II* TO DIVISION I ATHLETES

The Board should apply its *Columbia II* approach in asserting jurisdiction over Division I athletes. Because asserting jurisdiction using the right to control test is necessary to further the goals of the Act and more administrable than the *Brown* “primarily student” test, and because the concept of amateurism in college athletics is losing persuasiveness, this is the optimal approach to answering the questions left unaddressed by the Board’s declining of jurisdiction in *Northwestern*.²⁴⁶ Alternatively, if no petitions arise, the Board should publish a rule²⁴⁷ guaranteeing that it will assert jurisdiction over players. Doing so can clarify the Board’s position while withstanding politically motivated fluctuations that have characterized the Board’s past adjudications.²⁴⁸

²³⁸ See HUMA & STAUROWSKY, *supra* note 157, at 3.

²³⁹ See *supra* note 237 and accompanying text.

²⁴⁰ See Wagner, *supra* note 124.

²⁴¹ See *supra* Section I.D.

²⁴² See Nat’l Collegiate Athletic Ass’n v. Alston, 141 S. Ct. 2141, 2152 (2021).

²⁴³ See *id.* at 2168 (Kavanaugh, J., concurring).

²⁴⁴ See BUFFALANO ET AL., *supra* note 45.

²⁴⁵ See *supra* notes 163–65.

²⁴⁶ See *supra* Section II.C.

²⁴⁷ See 5 U.S.C. §§ 551–59.

²⁴⁸ See *supra* Section II.B.

Players have multiple plausible avenues to unionizing. One option is for players at a single private college or university to seek recognition, as was the case in *Northwestern*.²⁴⁹ The benefit of this approach is the relative ease of organizing in-house, pushing the Board to clarify its jurisdictional standards so other teams could then follow suit.²⁵⁰ The downside, however, is that the Board could potentially decline jurisdiction again—sensible or not—leaving another generation of players in flux.²⁵¹ Players may thus prefer the approach of creating a conference- or Division-wide players' association based on the professional sports model, as suggested by football players in the fall of 2020²⁵² and endorsed by General Counsel Abruzzo.²⁵³ Although this approach requires a high degree of cooperation among players and a sizable administrative burden, it more easily fits within extant framework regarding athletes unionizing.²⁵⁴ As this approach would theoretically include teams at public schools, too, it also has the dual advantages of protecting more players without relying on state-by-state legislative changes²⁵⁵ and allaying the Board's competitive balance concerns.²⁵⁶

Establishing a clear jurisdictional standard consistent with *Columbia II* would lead to the conclusion that Division I athletes qualify as statutory employees, and therefore could engage in collective bargaining.²⁵⁷ As a result, players would be able to negotiate over terms and conditions of employment such as receiving shares of revenue, improving travel accommodations,²⁵⁸ and setting more extensive health and safety standards.²⁵⁹ In addition, being declared statutory employees would allow players to participate in concerted activities that the NCAA has not allowed in the past, such as the right to strike for better working conditions.²⁶⁰

²⁴⁹ See *Northwestern Univ.*, 362 N.L.R.B. 1350, 1352 (2015).

²⁵⁰ See Edelman, *supra* note 179, at 1643.

²⁵¹ See *supra* Section III.A.

²⁵² See Blinder & Witz, *supra* note 23.

²⁵³ See Abruzzo, *supra* note 19.

²⁵⁴ See *Northwestern*, 362 N.L.R.B. at 1352–53.

²⁵⁵ See, e.g., Dodd, *supra* note 135 (discussing Iowa's push to pass legislation that would make public school college athletes employees).

²⁵⁶ See Edelman, *supra* note 179, at 1660 n.174.

²⁵⁷ See *supra* Section II.B.

²⁵⁸ See BUFFALANO ET AL., *supra* note 45.

²⁵⁹ See *About the NPCA: Mission & Goals*, NAT'L COLLEGIATE PLAYERS ASS'N, <https://www.ncpanow.org/about-us> [<https://perma.cc/VR4Y-HU5K>].

²⁶⁰ See 29 U.S.C. § 157.

Based on collective bargaining conducted by student assistants through their union representatives, student workers have demonstrated that they are invested in establishing lasting changes that benefit workers years down the line.²⁶¹ Potential concern that collegiate athletes only play for four or five years and thus have insufficient incentivization to collectively bargain is therefore misplaced. As a point of comparison, an average NFL career lasts only about three years.²⁶² This reality does not prevent NFL players from making an impact via their union, nor does it preclude representation during their careers and afterwards.²⁶³ In addition, establishing unions that are specifically catered to Division I players could create professional opportunities for former players, such as the position of union representative,²⁶⁴ thereby benefiting both current and former players. Moreover, just as in professional leagues, collegiate players could bargain for benefits—such as establishing a trust for graduating players—that would also benefit former players even after their playing days.²⁶⁵

Concerns that allowing players to unionize would lead to dwindling fan interest are lessened by the fact that no such trend has occurred following the repeal of prohibitions on players earning generous NIL deals.²⁶⁶ Although other critics may express concern that unionization could have unintended consequences such as recruiting complications,²⁶⁷ the reality is that the Act is meant to allow

²⁶¹ See, e.g., *Frequently Asked Questions*, GWC-UAW LOCAL 2110: THE UNION FOR RSCH. & TEACHING ASSISTANTS AT COLUM. UNIV., <https://columbiagradunion.org/faq/> [<https://perma.cc/2EZG-EDM9>].

²⁶² See John Keim, *With Average NFL Career 3.3 Years, Players Motivated to Complete MBA Program*, ESPN: NFL NATION (Jul. 29, 2016), https://www.espn.com/blog/nflnation/post/_/id/207780/current-and-former-nfl-players-in-the-drivers-seat-after-completing-mba-program [<https://perma.cc/2FSP-NL4U>]. For a look at the average career lengths of players in other leagues, see Travis Sawchik, *How Much Do MLB Players Really Make?*, FIVETHIRTYEIGHT (June 5, 2020, 7:00 AM), <https://fivethirtyeight.com/features/how-much-money-do-mlb-players-really-make/> [<https://perma.cc/5KT6-44CK>] (3.71 years for MLB players); Mona Chalabi, *The Kobe Bryant Outlier: How His Career Compares to the NBA Average*, THE GUARDIAN (Nov. 30, 2015, 5:59 PM), <https://www.theguardian.com/sport/2015/nov/30/the-kobe-bryant-outlier-how-his-career-compares-to-the-nba-average> [<https://perma.cc/RZ33-3JA8>] (4.9 years for NBA players).

²⁶³ See *How the NFLPA Works*, *supra* note 11.

²⁶⁴ See Nadkarni, *supra* note 4 (reporting that Ramogi Huma, a former college football player, as the leader of the College Athletes Players Association, represented the Northwestern team in their push to organize).

²⁶⁵ See Strauss, *supra* note 6.

²⁶⁶ See Dodd, *supra* note 170.

²⁶⁷ See Todd A. Cherry, Note, *Declining Jurisdiction: Why Unionization Should Not Be the Ultimate Goal for Collegiate Athletes*, U. ILL. L. REV. 1937, 1968–80 (2016).

workers the freedom to organize.²⁶⁸ If the players choose to organize, the Board should not act paternalistically in preventing them from making that choice.²⁶⁹ Moreover, the NCAA has adjusted to countless changes since its inception,²⁷⁰ including extensive conference realignment in 2021–22 alone.²⁷¹ Amid these changes and a sea of litigation challenging the nature of amateur sports,²⁷² the Board could lend clarity by asserting its jurisdiction over collegiate players for good.

If the trend since *Northwestern* holds and no groups of players seek to unionize in the near future,²⁷³ the Board should use its rulemaking authority to establish a clear jurisdictional standard, which it identified to be within its statutory authorization in *Cornell*.²⁷⁴ Doing so would solidify *Columbia II* as the analysis to be used regarding student workers and Division I collegiate athletes. Regarding the content of such a rulemaking, this Note suggests amending the extant jurisdictional standard as follows:

The Board will assert its jurisdiction in any proceeding arising under sections 8, 9, and 10 of the Act—including *proceedings pertaining to employees also enrolled as students*—involving any private nonprofit college or university which has a gross annual revenue from all sources . . . of not less than \$1 million.²⁷⁵

This amended language will actualize General Counsel Abruzzo's implication that the jurisdictional concerns that sank *Northwestern* will no longer impede unionization efforts.²⁷⁶

As asserting jurisdiction over collegiate players has a substantial impact on commerce, it is important that the Board seeks a course of action that can withstand the Board's characteristic political fluctuations.²⁷⁷ If not, the statutory protection afforded to players could be just as inconsistent as the path graduate and undergraduate student assistants have experienced in the past two decades alone.²⁷⁸ To avoid this level of uncertainty and to further the purposes of the Act, the Board should establish a strong position that can stand the test of

²⁶⁸ See Trs. of Columbia Univ., 364 N.L.R.B. 1080, 1085 (2016).

²⁶⁹ See *id.*

²⁷⁰ See generally SMITH, *supra* note 154.

²⁷¹ See Moss, *supra* note 166.

²⁷² See *supra* Section I.D.

²⁷³ See *supra* Section II.C.

²⁷⁴ See 183 N.L.R.B. 329, 334 (1970); 29 C.F.R. § 103.1 (2019).

²⁷⁵ 29 C.F.R. § 103.1(a) (proposed language in italics).

²⁷⁶ See Abruzzo, *supra* note 19.

²⁷⁷ See *supra* Section I.B.

²⁷⁸ See *supra* Section I.B.

time, just as its jurisdictional standard over private colleges and universities has survived since 1970.²⁷⁹ Indeed, because *Northwestern* fell short,²⁸⁰ it is unclear whether a group of similarly situated players will want to petition a Democrat-majority, union-favoring Board. Although rulemaking is inherently more complex and intensive than waiting for parties to bring disputes one at a time, the Board should take advantage of prevailing trends to make such a change.²⁸¹

CONCLUSION

This Note urges the NLRB to adopt and apply the common-law right to control test to collegiate athletes. Alternatively, the Board should adopt a new rule automatically asserting jurisdiction over all labor disputes and attempts to organize by Division I athletes. Looking to the Board's treatment of student assistants, a right to control test will find that collegiate athletes qualify as statutory employees and therefore are entitled to employment-based protections. Adopting a rule will serve to further the purposes of the NLRA—the guiding mission of the NLRB—because unionized collegiate players could engage in concerted activities such as collective bargaining. Going through the rulemaking process will also mitigate the NLRB's tendency to fluctuate wildly along with shifts in political control.

Asserting jurisdiction over collegiate players, and finding that they qualify for statutory protection, will make the Board's treatment of collegiate players consistent with its treatment of student workers and professional athletes. Players such as Kain Colter could benefit from collective bargaining because it could provide a platform from which they could negotiate for improved health protocols, greater financial support, and the ability to engage in concerted activities. The time is now for the NLRB to act: like a quarterback scanning the field as his line breaks down around him, the Board's situation is urgent yet potentially momentous. With the game on the line and attacks on the collegiate amateur model coming from all directions, colleges and universities, players, unions, and the legal community all watch from the sideline with bated breath.

²⁷⁹ See 29 C.F.R. § 103.1.

²⁸⁰ See Edelman, *supra* note 179, at 1640–42.

²⁸¹ See Noah, *supra* note 55.

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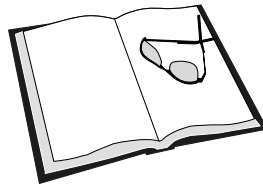
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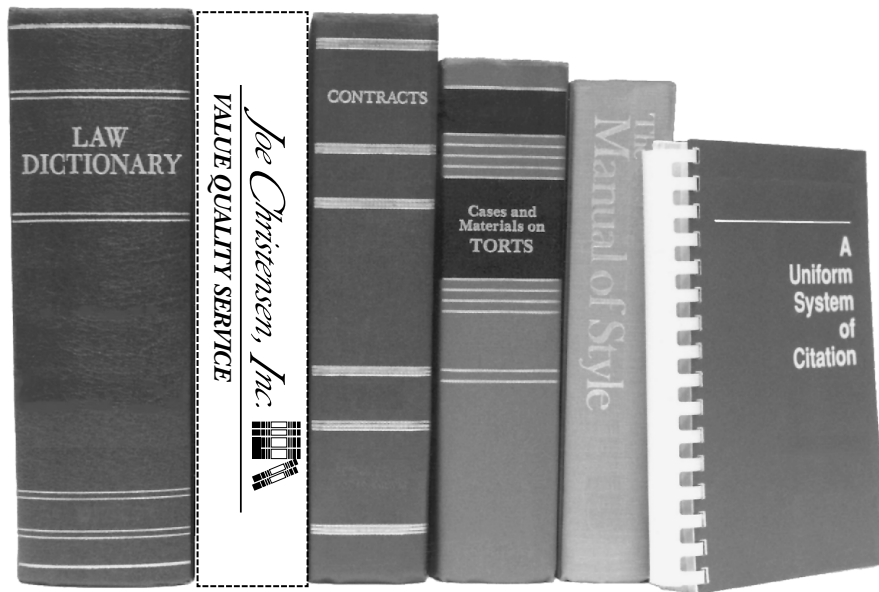
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