

# States vs. FDA

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## ABSTRACT

*In the United States, food and drug safety is regulated in two ways: a stringent ex ante, national regime led by the Food and Drug Administration (“FDA”) and a robust ex post system of state-law enforcement. This federalist structure of dual regulatory levels sets the stage for synergy and for conflict.*

*Two recent preemption lawsuits showcase a novel dimension of the dual structure: states competing with or complimenting the FDA as regulators of food and drug safety. In *Zogenix, Inc. v. Patrick*, a federal district court enjoined Massachusetts from enacting a statewide ban on Zohydro, an FDA-approved opioid analgesic drug, but upheld the state’s subsequent prescription and dispensation-related restrictions. In *Grocery Manufacturers Ass’n v. Sorrell*, food industry representatives challenged a Vermont law mandating labeling of genetically engineered food—labeling the FDA had not required.*

*Both cases explore how states can regulate drug and food safety without treading impermissibly upon the FDA’s turf. In doing so, they raise the issue of who should determine if state regulatory efforts advance or impede the federal regulatory scheme. Are courts or the regulating agencies the better arbiters? If the latter, when do their conclusions warrant judicial deference?*

*This Article advances two claims. First, courts, when facing implied obstacle preemption challenges to state regulations, should consider the FDA’s view on the matter—namely whether the agency considers the state-level regulation to conflict with its national regulatory agenda. In *Zogenix*, the court, strikingly, paid no attention to the FDA Commissioner’s support of Massachusetts’s proposed restrictions on the prescribing and dispensing of Zohydro. In *Sorrell*, the court had before it informal policy guidance from the FDA that suggested that the agency was somewhat open to state labeling mandates. Deference to the FDA’s position in each case would have readily resolved the preemption challenge.*

*Second, these cases reiterate and reinforce the key argument of the Administrative Conference of the United States (“ACUS”) 2010 Recommendation, *Agency Procedures for Considering Preemption of State Law*: if there will ever be a coherent body of case law and regulatory policy in the realm of food and drug laws, courts must probe the extent to which the FDA considered relevant state interests in the regulation enactment process. Rather than blindly deferring to the federal agency’s view, courts should evaluate whether that view resulted from a responsible process affording states the chance to*

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articulate how their own proposed state regulation fits with the federal regulatory scheme.

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## INTRODUCTION

Food and drugs are essential. But they pose serious health and safety risks. In the United States, these risks are addressed through a two-pronged approach: a stringent ex ante, centralized regulatory regime led by the Food and Drug Administration (“FDA”) and a robust ex post, decentralized system enforced primarily by private litigants.

The FDA regulates at the national level, while private litigants enforce (or attempt to enforce) state tort law protections.<sup>1</sup> Federal and state law, therefore, simultaneously regulate the health and safety risks posed by food and drugs. This federalist structure, operating on dual regulatory levels, sets the stage for both synergy and conflict.

The FDA and other federal regulatory agencies have promulgated rules and regulations that expressly claim to preempt—that is, to oust—conflicting state tort law.<sup>2</sup> Because these agency pronouncements of preemption bear heavily on state interests, agencies are required to consult directly with the states before enacting preemptive regulations.<sup>3</sup> The Administrative Conference of the United States (“ACUS”) has urged federal agencies to take this state consultation mandate seriously. Specifically, in 2010, ACUS issued an official recommendation (for which I served as Academic Consultant), entitled *Agency Procedures for Considering Preemption of State Law*,<sup>4</sup> which aimed to facilitate state representatives’ participation in the preemp-

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<sup>1</sup> While the FDA (and Congress) clearly exists to vindicate the relevant national interests, it is less clear who speaks for the relevant state regulatory interests, given the decentralized, private enforcement of state tort law. See Catherine M. Sharkey, *Inside Agency Preemption*, 110 MICH. L. REV. 521, 582–90 (2012) (proposing various reforms to expand the appropriate representatives of state regulatory interests, particularly in the context of consumer health and safety issues).

<sup>2</sup> See, e.g., Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601) (purporting to preempt conflicting state drug labeling laws). See generally Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007) (describing an emergent trend of federal agencies asserting preemption of state law in preambles to regulations); see also Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 NW. U. L. REV. 695, 695–98 (2008) (examining the tendency of federal agencies to claim that their regulations preempt state law). The Obama Administration has, to a degree, reined in federal agencies’ tendencies and abilities to preempt state tort law. See Sharkey, *supra* note 1, at 531 (“The May 2009 Presidential Memorandum on Preemption caught federal agencies’ attention and prompted serious internal review, at least for the majority of agencies surveyed.”); see also Gillian E. Metzger, *Federalism Under Obama*, 53 WM. & MARY L. REV. 567, 594–97 (2011) (assessing the Obama Administration’s record on agency preemption).

<sup>3</sup> Exec. Order No. 13,132, §§ 3(a), 4(d), 3 C.F.R. 209 (2000), *reprinted in* 5 U.S.C. § 601 app. at 807–09 (2012) (directing federal agencies to avoid infringing on states’ policymaking authority and to consult state-level authorities in developing policies that could restrict such authority). Such consultation is likewise consistent with the Obama Administration’s official position “that preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption.” Memorandum on Preemption for the Heads of Executive Departments and Agencies, 2009 DAILY COMP. PRES. DOC. 1 (May 20, 2009).

<sup>4</sup> ACUS Recommendation 2010-1, *Agency Procedures for Considering Preemption of State Law*, 76 Fed. Reg. 81 (Jan. 3, 2011).

tive rulemaking process.<sup>5</sup> Several federal agencies have abided by these recommendations.<sup>6</sup>

Two recent high-profile preemption lawsuits squarely address the role of states vis-à-vis the FDA in regulating food and drug safety. In *Zogenix, Inc. v. Patrick*,<sup>7</sup> a federal district court enjoined the Massachusetts government from enacting a statewide ban on Zohydro,<sup>8</sup> an FDA-approved opioid analgesic drug,<sup>9</sup> but upheld the state's subsequent prescription- and dispensation-related restrictions.<sup>10</sup> In *Grocery Manufacturers Association v. Sorrell*,<sup>11</sup> food industry representatives challenged a Vermont law mandating labeling of genetically engineered food—labeling that the FDA, to date, has not required.<sup>12</sup>

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<sup>5</sup> See *id.* at 82 (explaining the ACUS's decision to adopt recommendations designed to facilitate participation by state representatives in federal agencies' preemptive rulemakings); see also Sharkey, *supra* note 1, at 582–90 (setting forth specific measures that would improve consultation between states and federal agencies with regard to potentially preemptive rulemakings).

<sup>6</sup> The Department of Transportation (“DOT”), for example, has issued the following statement, entitled “Federalism”:

The DOT has internal procedures to ensure compliance with the preemption provisions of Executive Order 13132. Many of our procedures are modeled after Administrative Conference of the United States (ACUS) recommendations found in a December 9, 2010, Recommendation 2010–1 on “Agency Procedures for Considering Preemption of State Law.” For example, DOT encourages relationship building with State and local officials and reaching out to those officials when we consider rules that may have a preemptive effect. When done in the course of rulemaking proceedings, we disclose to the public when meetings take place by placing a memorandum in the rulemaking docket in accordance with our policies on ex parte communications.

*Federalism*, U.S. DEP'T OF TRANSP., <http://www.dot.gov/regulations/federalism> (last updated Feb. 5, 2015). Likewise, the Consumer Financial Protection Bureau entered into a memorandum of understanding with state banking officials, pursuant to which the regulators would adhere to an agreed upon framework intended to help these regulatory bodies coordinate and cooperate. See Miriam Seifter, *States as Interest Groups in the Administrative Process*, 100 VA. L. REV. 953, 976 (2014).

<sup>7</sup> *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696 (D. Mass. Apr. 15, 2014).

<sup>8</sup> *Id.* at \*2 (“If the Commonwealth were able to countermand the FDA's determinations and substitute its own requirements, it would undermine the FDA's ability to make drugs available to promote and protect the public health.”).

<sup>9</sup> An opioid—as defined by the FDA—is a powerful pain management drug that is effective when prescribed and used responsibly, but that can cause serious harm, including overdose and death, when abused. *Opioid Medications*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm> (last updated Apr. 1, 2015).

<sup>10</sup> *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 4273251, at \*1 (D. Mass. Aug. 28, 2014).

<sup>11</sup> *Grocery Mfrs. Ass'n v. Sorrell*, No. 5:14-cv-117, 2015 WL 1931142, at \*19 (D. Vt. Apr. 27, 2015), *appeal docketed*, No. 15-1504 (2d Cir. May 6, 2015).

<sup>12</sup> See Complaint for Declaratory & Injunctive Relief, *Sorrell*, 2015 WL 1931142. Connecticut and Maine recently enacted genetically modified organism (“GMO”) labeling bills with

Both cases explore the extent to which states can regulate drug and food safety without treading impermissibly upon the FDA's turf. In doing so, they raise the issue of who should determine if state regulatory efforts are in sync, or at odds, with the federal regulatory scheme. This issue in turn gives rise to important, unresolved questions: To what degree must administrative agencies consider states' interests in promulgating and enforcing federal regulations? Should this obligation apply only when agencies are initially developing regulations, or should agencies also be required to consider states' interests after the regulatory decisions in question have been finalized? And finally, in the absence of agencies' due consideration of state interests, when and to what extent may states take matters into their own hands by promulgating more stringent regulations of their own?

This Article examines these issues in the context of two compelling case studies, and ultimately advances two primary arguments. First, courts should consider and critically evaluate the relevant agency's perspective on potential state law conflicts, that is, whether the agency perceives state regulations to be in tension with its own federal regulatory goals. Second, courts should take heed of the degree to which the federal agency considered relevant state interests before acting, placing particular focus on the extent to which states had a meaningful opportunity to articulate their own views of the relationship between state regulations and the federal scheme.

## I. DRUG REGULATION IN A FEDERALISM FRAMEWORK

The process of bringing a pharmaceutical to market is a lengthy one and pharmaceutical companies repeatedly face dual levels of regulation along the way. In order to obtain FDA approval, a prescription drug must meet federal safety and efficacy standards<sup>13</sup> as well as federal labeling requirements.<sup>14</sup> But state tort law also regulates these areas through state-level product laws applicable to pharmaceutical drugs and devices, namely design defect claims for unreasonably dan-

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an intriguing additional feature—they are contingent on the enactment of similar measures in other states. This feature was proposed in order to prevent Connecticut and Maine from being “outliers” and to mitigate risk of litigation. *See* 56 H.R. Proceedings, pt. 26, 2013 Sess., at 9044 (Conn. 2013) (statement of Rep. Shaban) (addressing the possibility that the Connecticut bill could present “legal and market obstacles” absent this feature); S. 126–1160, 1st Sess., at 1174 (Me. 2013) (statement of Sen. Jackson) (explaining that the measure helped guard against the danger that the Maine legislation would effectively turn the state into “an outlier”).

<sup>13</sup> *See* Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 355(d)(1)–(4) (2012).

<sup>14</sup> *See* 21 C.F.R. §§ 201.1–.327 (2014).

gerous products and failure to warn claims for labeling deficiencies.<sup>15</sup> Several of the U.S. Supreme Court's high-profile preemption cases over the last decade have addressed whether and to what extent states can continue to enforce their own standards in defective design and/or failure to warn private tort lawsuits against pharmaceutical companies when the drug or device at issue has been approved by the FDA.<sup>16</sup>

There is another realm of potential regulatory overlap. While the FDA regulates the safety and efficacy of prescription drugs,<sup>17</sup> states regulate the practice of medicine, including the licensing of doctors and pharmacists.<sup>18</sup> As a general matter, the FDA has the power to

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<sup>15</sup> See, e.g., *Wyeth v. Levine*, 555 U.S. 555, 573–81 (2009) (holding that defendant brand-name drug manufacturer Wyeth was liable under state tort law for failure to warn, despite the drug label's compliance with applicable FDA regulations); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492–97 (1996) (ruling that defendant medical device manufacturer Medtronic could be held liable for negligent design under state law).

<sup>16</sup> Though preemption jurisprudence is notoriously “muddled,” several trends are evident. First, when express preemption is at issue (namely where there is an explicit statutory provision preempting state law), as is the case with provisions of the FDCA governing medical devices, the Court has tended toward a textualist approach. See generally Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 103 Nw. U. L. REV. 437 (2009). Second, in the realm of implied preemption (where, absent an explicit statutory provision, courts must discern preemption from the entire statutory and regulatory framework), the Court has increasingly shied away from determinations of implied *field* preemption, in which a federal scheme is so pervasive that the court will infer that Congress “left no room for state regulation of these matters.” *United States v. Locke*, 529 U.S. 89, 111 (2000). Third, in decisions finding implied *conflict* preemption, the Court has been more apt to embrace the narrower form of “impossibility” preemption over broader “obstacle” preemption. The more demanding impossibility preemption standard requires that it be “impossible for a private party to comply with both state and federal requirements.” *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 899 (2000) (Stevens, J., dissenting). Obstacle preemption can be found in a broader set of circumstances where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Id.*

The most recent pharmaceutical preemption cases fit these general trends. The Court's preemption determinations rest on impossibility preemption and emphasize in particular the inability of a generic drug manufacturer to comply unilaterally both with its federal duty of “sameness” vis-à-vis its brand-name counterpart as well as a state-law requirement to alter its design or add to its warning labeling. See, e.g., *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2478–80 (2013) (holding that FDA regulations preempted the plaintiff's state law design defect claim against defendant generic drug manufacturer); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577–79 (2011) (deferring to FDA's interpretation of its regulations in determining that such laws foreclosed the plaintiff's state law failure to warn claim against a generic drug manufacturer).

<sup>17</sup> 21 U.S.C. § 355(d)(1)–(4).

<sup>18</sup> See, e.g., INST. OF MED., LEADERSHIP COMMITMENTS TO IMPROVE VALUE IN HEALTHCARE 28–29, 242 (2009), <http://www.ncbi.nlm.nih.gov/books/NBK52854> (“The states directly regulate the practice of medicine and the healthcare workforce. . . . Because these duties are not assigned to the federal government by the Constitution, [the Tenth Amendment] provides the states the right to enact laws and regulations to protect the health and general welfare of their residents.”).

determine which prescription drugs and devices are safe and efficacious enough to be made available to the public, while states are responsible for determining how and under what conditions these products will be distributed within their jurisdiction.<sup>19</sup> Additionally, states are primarily responsible for regulating pharmacists' practices, including the dispensing of medication.<sup>20</sup>

The *Zogenix* case confronts both dimensions of this regulatory overlap. First, Massachusetts's ban on the sale of Zohydro raises the issue of whether the state can take a different position from that of the FDA on the safety and efficacy of an FDA-approved drug.<sup>21</sup> Second, although the state's subsequent restrictions on how the drug is to be prescribed and dispensed fall squarely within the state's domain of regulating the practice of medicine,<sup>22</sup> the question remains whether, in enforcing those regulations, Massachusetts obstructs the FDA's regulatory goals.<sup>23</sup>

## A. *Zogenix: Opioid Drug Preemption Case Study*

### 1. *FDA's Controversial Approval of Zohydro*

In October 2013, the FDA approved Zohydro ER,<sup>24</sup> a powerful, extended-release formulation of hydrocodone, an opioid analgesic

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<sup>19</sup> See *id.* at 242–43; see also, e.g., *Gonzales v. Oregon*, 546 U.S. 243, 269–72 (2006) (recognizing the primary authority of states in regulating “the medical profession”).

<sup>20</sup> See, e.g., *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52,716, 52,717 (Sept. 6, 2006) (“*State laws and State licensing bodies . . . collectively regulate the practice of medicine. In contrast, the scope of the [Controlled Substances Act] (and therefore role of [the Drug Enforcement Administration]) is much narrower. The CSA regulates only the segment of medical practice involving the use of controlled substances, and DEA is correspondingly responsible for ensuring that controlled substances are used in compliance with Federal law.*” (footnote omitted)).

<sup>21</sup> *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696, at \*2 (D. Mass. Apr. 15, 2014).

<sup>22</sup> See *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. at 52,717 (discussing the role of the states vis-à-vis the DEA in regulating medical practice and controlled substances); see also *INST. OF MED.*, *supra* note 18, at 29.

<sup>23</sup> See *Verified Second Amended Complaint* at 21–23, *Zogenix, Inc. v. Patrick*, No. 1:14-cv-11689-RWZ, 2014 WL 3339610 (D. Mass. July 8, 2014) (arguing that the states are bound to use their authority to regulate the practice of medicine in ways that do not undermine the FDA's power to approve prescription drugs, and that the Massachusetts regulations do not adhere to this requirement).

<sup>24</sup> See Press Release, U.S. Food & Drug Admin., *FDA Approves Extended-Release, Single-Entity Hydrocodone Product* (Oct. 25, 2013), <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm372287.htm>. Typically, the FDA reviews new drug applications using a review team, the members of which analyze the drug's clinical trials in order to determine whether the drug is effective for its proposed use, as well as whether the drug's benefits outweigh the apparent risks. See *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*,

prescription drug. The agency's controversial decision overrode vociferous objections from its own Anesthetic and Analgesic Drug Products Advisory Committee,<sup>25</sup> which voted 11-2 against approving the drug.<sup>26</sup> The advisory committee had taken the position that opioids like Zohydro, which are subject to misuse and abuse, should not be approved unless abuse-deterrent or similar risk-mitigation properties were imported into the drug.<sup>27</sup>

Furthermore, the committee's vote occurred in the wake of a public meeting regarding the risks and benefits of Zohydro, where citizens urged the committee to vote against the drug's approval in light of public health considerations.<sup>28</sup> Despite this public concern, the

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U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm> (last updated Nov. 6, 2014).

<sup>25</sup> FDA advisory committees are composed of outside experts and may be called upon to weigh in on uncertainties that the FDA review team has identified or to provide input on broader policy-related issues. See U.S. FOOD & DRUG ADMIN., FDA 101: ADVISORY COMMITTEES 1, <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm048045.pdf> (2010). According to the FDA, "For specific products, advisory committees consider the available evidence and provide scientific and medical advice on safety, effectiveness, and appropriate use. Committees might also advise the agency on broader regulatory and scientific issues." *Id.* See generally PHILIP MA ET AL., MCKINSEY CTR. FOR GOV'T, FDA ADVISORY COMMITTEE OUTCOMES (2013), [http://www.mckinsey.com/~media/McKinsey/dotcom/client\\_service/Public%20Sector/Regulatory%20excellence/FDA\\_advisory\\_committee\\_outcomes.ashx](http://www.mckinsey.com/~media/McKinsey/dotcom/client_service/Public%20Sector/Regulatory%20excellence/FDA_advisory_committee_outcomes.ashx) (analyzing FDA advisory committee meetings and their apparent influence on the agency's decisions).

<sup>26</sup> CTR. FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., RISK ASSESSMENT AND RISK MITIGATION REVIEW(S): ZOHYDRO ER (HYDROCODONE BITARTRATE) 3 (2013), [http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2013/202880Orig1s000RiskR.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/202880Orig1s000RiskR.pdf) (reporting the outcome of the advisory committee vote); see also Cathryn Jakobson Ramin, *Why Did the F.D.A. Approve a New Pain Drug?*, NEW YORKER, Dec. 2, 2013, <http://www.newyorker.com/business/currency/why-did-the-f-d-a-approve-a-new-pain-drug> (discussing the FDA's decision to approve Zohydro against the committee's recommendation).

The agency's decision to override the committee's recommendation was unusual. FDA drug approval decisions tend to be consistent with advisory committees' recommendations as to whether to approve a certain drug, whether such recommendations are positive or negative. See MA ET AL., *supra* note 25 (analyzing the consistency between FDA advisory committee recommendations and agency decision-making outcomes).

<sup>27</sup> CTR. FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., SUMMARY REVIEW FOR REGULATORY ACTION: ZOHYDRO ER 25 (2013), [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/202880Orig1s000SumR.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202880Orig1s000SumR.pdf) (summarizing the committee's position that prescription opioids such as Zohydro should not be approved unless they have features to discourage or prevent abuse).

<sup>28</sup> CTR. FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., TRANSCRIPT FOR THE DECEMBER 7, 2012 MEETING OF THE ANESTHETIC AND ANALGESIC DRUG PRODUCTS ADVISORY COMMITTEE 214-70 (2012). The FDA publishes notices of advisory committee meetings in the Federal Register at least fifteen calendar days in advance of a meeting. 41 C.F.R. § 102-3.150(a) (2014). An advisory committee calendar is also posted on the FDA's website. *Advisory Committee Calendar*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AdvisoryCommittees/Calendar> (last updated Sept. 9, 2015).



FDA, with its approval decision, stated that it had thoroughly assessed the underlying science of the proposed drug and concluded that, on balance, the potential benefits outweighed the risks.<sup>29</sup> Moreover, the FDA specifically declined to require manufacturers to incorporate abuse-deterrent features to protect against potential misuse and addiction, citing considerations such as the imperfect and underdeveloped nature of abuse-deterrent technology.<sup>30</sup>

## 2. State Law Ban Preempted

Five months after the FDA's approval of Zohydro, in March 2014, Massachusetts Governor Deval Patrick issued an emergency order banning the prescribing and dispensing of Zohydro within the state.<sup>31</sup> Zogenix, the manufacturer of Zohydro, filed a motion for a temporary restraining order and preliminary injunction against the ban on the ground that federal law preempted the state's action.<sup>32</sup> Zogenix argued that the FDA's determination that Zohydro was safe and effective preempted state laws that were implicitly based on contrary findings, such as the Massachusetts ban.<sup>33</sup>

In April 2014, a Massachusetts federal district court granted Zogenix's motion and enjoined the Commonwealth from enforcing the ban.<sup>34</sup> The court based its holding on implied obstacle preemption,<sup>35</sup> reasoning that the state "obstruct[ed] the FDA's Congressionally-given charge"<sup>36</sup> when the state had "interposed its own conclusion about Zohydro ER's safety and effectiveness by virtue of [the] emergency order."<sup>37</sup>

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<sup>29</sup> CTR. FOR DRUG EVALUATION & RESEARCH, *supra* note 27, at 29.

<sup>30</sup> *Id.* at 32 ("[T]he technology used to produce abuse-deterrent opioid formulations is still in the nascent stages . . . . [E]ven the currently available abuse-deterrent technologies only limit abuse by routes other than oral administration.").

<sup>31</sup> See Brian MacQuarrie, *Governor Declares an Emergency on Opiate Abuse*, BOSTON GLOBE (Mar. 27, 2014), <http://www.bostonglobe.com/metro/2014/03/27/with-heroin-overdoses-rise-gov-patrick-declares-public-health-emergency-mass/hOajTIJNKnSHKAnWjZ6wYL/story.html#>.

<sup>32</sup> Verified Complaint at 14–15, *Zogenix, Inc. v. Patrick*, No. 1:14-cv-11689-RWZ, 2014 WL 1454696 (D. Mass. Apr. 15, 2014). The complaint also alleged that the order violated the dormant Commerce Clause and the Contract Clause. *Id.* at 16–18.

<sup>33</sup> *Id.* at 15.

<sup>34</sup> *Zogenix*, 2014 WL 1454696, at \*3.

<sup>35</sup> See *supra* note 16.

<sup>36</sup> *Zogenix*, 2014 WL 1454696, at \*2. The "charge" in question is the FDA's responsibility to protect and promote public health by ensuring that "drugs are safe and effective." *Id.* (quoting the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 393(b)(2)(B) (2012)).

<sup>37</sup> *Id.* The court rejected the state's reliance on *Wyeth v. Levine*, 555 U.S. 555 (2009), a drug labeling case in which the Supreme Court determined the federal regulation at issue to be a

### 3. *State Law Restrictions Not Preempted*

In response to the injunction, Massachusetts changed tactics and instead targeted the practices of prescribing and dispensing medications—areas traditionally and squarely within the purview of state law.<sup>38</sup> The Commonwealth's Board of Registration in Medicine issued an emergency regulation restricting the prescription and dispensation of the hydrocodone-only extended-release drugs.<sup>39</sup> Two additional state regulatory bodies—the Board of Registration of Physician Assistants and Board of Registration in Pharmacy—promulgated additional restrictions on the prescription and dispensation, respectively, of Zohydro.<sup>40</sup>

Zogenix amended its complaint immediately after the Board of Registration in Medicine issued the initial emergency regulation.<sup>41</sup> In response to the subsequent prescription and dispensation restrictions (promulgated by the Physician Assistant and Pharmacy boards), Zogenix amended the complaint again, this time apparently anticipating and responding to the argument that the regulations were within the field of medicine, an area traditionally left to state control.<sup>42</sup> Al-

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floor—above which state law could impose additional requirements—rather than a floor and a ceiling (which would preempt additional state law requirements):

*Wyeth* assumed the availability of the drug at issue and analyzed whether stronger state labeling requirements obstructed the FDA's objectives. Here, the obstruction is clearer because the drug Massachusetts wants Zogenix to adopt—Zohydro ER with an “abuse-resistant formulation”—has not been approved by the FDA. To satisfy the Commonwealth, Zogenix would be required to return to the FDA and seek approval of a drug different from the one the FDA has already deemed safe.

*Zogenix*, 2014 WL 1454696, at \*2.

<sup>38</sup> See INST. OF MED., *supra* note 18, at 29.

<sup>39</sup> 243 MASS. CODE REGS. 2.07(25) (2014).

<sup>40</sup> 263 MASS. CODE REGS. 5.07(12) (2014) (Board of Registration of Physician Assistants regulation); 247 MASS. CODE REGS. 8.05(3) (2014) (Board of Registration in Pharmacy regulation); 247 MASS. CODE REGS. 9.04(8) (2014) (additional Board of Registration in Pharmacy regulation). Prior to issuing these restrictions, the Boards held hearings and public comment periods. See Memorandum in Support of Defendants' Motion to Dismiss Plaintiff's Verified Second Amended Complaint at 13, n.13, *Zogenix, Inc. v. Patrick*, No. 1:14-cv-11689-RWZ, 2014 WL 3339610 (D. Mass. July 8, 2014).

<sup>41</sup> The amended complaint claimed that the Board's regulations amounted to “an effective ban” and were unconstitutional. Verified Second Amended Complaint at 6, *Zogenix*, 2014 WL 3339610. Zogenix alleged that the regulatory action “represent[ed] an impermissible effort by Massachusetts to establish its own drug approval policy” and “specifically undermine[d] the FDA's assessment that Zohydro ER is a safe and effective product that may be distributed in all fifty states.” *Id.* at 34. The regulation, Zogenix argued, also posed an obstacle to “the FDA's comprehensive regulatory scheme for nationally-effective drug approvals.” *Id.* The amended complaint also maintained that the restrictions, like the initial ban, contravened the Contract Clause and dormant Commerce Clauses, and also violated the Equal Protection Clause. *Id.* at 9.

<sup>42</sup> Verified Second Amended Complaint, *supra* note 23, at 19–29.

though this revised complaint conceded that states have the power to regulate the practices of prescribing and dispensing medications, it argued that states were required to do so in a way that did not “interfere[ ] with FDA’s authority to approve drugs as safe and effective.”<sup>43</sup>

Massachusetts moved to dismiss, emphasizing that “state governments have not only concurrent, but primary, authority to regulate matters of health and safety, including the practices of health professionals.”<sup>44</sup> After requiring the state to go back to the drawing board and refine its restrictions,<sup>45</sup> the court subsequently granted the state’s motion to vacate the preliminary injunction, and upheld the revised regulations as valid and not preempted.<sup>46</sup> In doing so, the court re-

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<sup>43</sup> *Id.* at 23. Specifically, Zogenix alleged that state restrictions that “require indications for the drug that are inconsistent with the indication for which the drug was approved by FDA” are preempted by federal law. *Id.* Zogenix also advanced the same obstacle preemption arguments it had previously articulated. *See id.* at 34 (arguing that the regulations “specifically undermine[d] the FDA’s assessment that Zohydro ER is a safe and effective product that may be distributed in all fifty states” and thus “impeded the FDA’s Congressional mandate to approve a range of safe treatments to promote the public health”).

<sup>44</sup> Memorandum in Support of Defendants’ Motion to Dismiss Plaintiff’s Verified Second Amended Complaint, *supra* note 40, at 6.

<sup>45</sup> On July 8, 2014, the district court allowed in part Zogenix’s motion for a preliminary injunction against enforcement of the Massachusetts regulations. *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 3339610, at \*5 (D. Mass. July 8, 2014), *vacated in part*, No. 14-11689-RWZ, 2014 WL 4273251 (D. Mass. Aug. 28, 2014). The court concluded that one of the restrictions—which required doctors to certify that other pain-management treatments had failed when prescribing Zohydro—was ambiguous, and it reasoned that, as a result, the regulation could be enforced in a way that would “severely frustrate Zohydro’s availability” and thus “pose significant constitutional concerns.” *Id.* at \*4. The court advised the state defendants that if they “provide adequate and constitutional guidance to physicians regarding the prerequisites for prescribing Zohydro in compliance with the regulation, then they may thereafter move to lift the injunction.” *Id.* at \*5.

Following the court’s direction, Massachusetts amended the regulations. First, the regulations no longer require that alternative pain management treatment options have “failed,” but only that alternative options be “inadequate.” *Zogenix*, 2014 WL 4273251, at \*2 (D. Mass. Aug. 28, 2014). Second, doctors no longer have to reference failed treatments in the letters of medical necessity that they are required to send when prescribing the drug. *See id.* at \*3.

<sup>46</sup> *Zogenix*, 2014 WL 4273251, at \*3. In response to the district court’s decision, Zogenix filed a third amended complaint, maintaining that the revised regulations still constituted an “effective ban” that was “inconsistent with the federal regulatory scheme governing the approval of prescription drugs.” Verified Third Amended Complaint at 7, *Zogenix, Inc. v. Baker*, No. 14-11689-RWZ, 2015 WL 1206354 (D. Mass. Mar. 17, 2015). Zogenix launched the familiar assault on the Boards’ regulations, arguing the restrictions were obstacle preempted because the Commonwealth’s power to regulate pharmaceutical practices “must not be exercised in a manner that interferes with FDA’s authority to approve drugs as safe and effective.” *Id.* at 26. Zogenix also relied heavily on the argument that the intent of the government had been to impose an effective ban on the drug. *Id.* at 34–37. The company also maintained its Equal Protection, Contract Clause, and dormant Commerce Clause claims, which had not been substantively addressed in any of the district court decisions. *Id.* at 11.

jected Zogenix's preemption argument and concluded that the state law restrictions did not conflict with federal law.<sup>47</sup>

*B. A Framework for Preemption: The Road Not Taken*

With its series of decisions in the *Zogenix* case, the Massachusetts federal district court ostensibly reached a sound conclusion as to how the state could best vindicate its regulatory goals without infringing on the FDA's turf. In making its preemption determinations, however, the court ignored two fundamental considerations: the FDA's own view on the tension between state and federal regulatory goals and the degree to which the FDA had considered Massachusetts's articulation of the relevant competing (or complementary) state interests.

With respect to the preemption dispute regarding the state-level restrictions on the prescribing and dispensing of Zohydro, the court missed an opportunity to resolve the matter in a way that gave due consideration to the FDA's publicly stated position that such state regulatory efforts were not only consistent with, but conducive to, federal regulatory goals. Given that the critical legal inquiry for implied obstacle preemption is the extent to which the state regulation impedes or frustrates the purposes and objectives of the federal regulatory scheme,<sup>48</sup> it seems almost inconceivable that the court did not take heed of the view of the FDA—the regulator with delegated authority to administer the national drug regulation regime. While input from the relevant regulator is increasingly a factor relied upon by

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The district court, construing Zogenix's complaint to challenge only the final "pharmacist only" regulation promulgated by the Board of Registration in Pharmacy, denied the Commonwealth's motion to dismiss on the ground that:

Zogenix may be able to show, through survey evidence or third-party discovery from pharmacies and physicians, that Massachusetts pharmacies are not stocking its drug because of handling difficulties caused by the regulations and that their failures to stock the drug are affecting physicians' prescribing practices. Zogenix has alleged such facts in its Complaint, and I must take those allegations as true at this stage. That the defendants are skeptical that the evidence will support those allegations is immaterial, because, if the allegations are proven, Zogenix will be entitled to relief.

*Zogenix*, 2015 WL 1206354, at \*4.

In April, 2015, a company called Pernix bought Zohydro ER from Zogenix, and indicated that it intended to intervene in the action. In May, 2015, the parties filed a joint motion to stay the proceedings "pending FDA final action on requested new labeling for Zohydro ER," which apparently is expected to happen toward the end of 2015. Joint Motion to Stay Proceedings, *Zogenix v. Baker*, No. 1:14-cv-11689 (D. Mass. May 22, 2015). The district court judge granted the motion and stayed the proceedings as per the parties' request. Order, *Zogenix v. Baker*, No. 1:14-cv-11689 (D. Mass. May 26, 2015).

<sup>47</sup> *Zogenix*, 2014 WL 4273251, at \*3.

<sup>48</sup> See *supra* note 16.

courts in preemption disputes,<sup>49</sup> it has yet to be ensconced as part of an established framework for preemption determinations.

It is a closer call whether such an agency-regarding approach would have led the court to void Massachusetts's original ban of the opioid drug on preemption grounds. Two features distinguish the ban from the subsequently enacted restrictions. First, the FDA did not take an official position on whether the ban thwarted its regulatory mission. Second—even assuming that, if asked, the FDA would have objected to the ban—Massachusetts's action raises the corollary issue of the extent to which the FDA's view has taken into consideration the competing regulatory interests asserted by the state. The preemption framework should condition deference to the FDA on some degree of meaningful consideration or engagement with contrary state regulatory interests.

In the case of Zohydro's journey from manufacture to marketplace, the FDA did actually try to engage with state interests. It provided Massachusetts (and, indeed, all states) an opportunity to participate in the regulatory drug approval process. Even though Massachusetts's officials declined the invitation, the FDA gave due consideration to the precise health and safety risks that gave rise to the state's objection. Under these circumstances, Massachusetts's ban on the drug, in the wake of the FDA's approval, has the specter of unwarranted defiance of federal authority, whereby it effectively substituted its own drug approval process for that of the FDA.

### 1. *The FDA's Position*

While the FDA has primary authority to oversee and monitor risks associated with opioid drugs, the agency also contemplates a significant role for state regulation. Both the FDA and the states play roles in guarding against potential dangers of abuse and addiction: the FDA through the drug approval process, and the states through regulations on the practice of medicine and the prescribing and dispensing of drugs.<sup>50</sup> The FDA has expressly recognized that the agency works in tandem with the states to achieve public health goals.<sup>51</sup> This collaborative federal-state scheme, however, could be further extended. For

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<sup>49</sup> See generally Sharkey, *supra* note 1.

<sup>50</sup> See *supra* notes 17–20 and accompanying text.

<sup>51</sup> See Margaret A. Hamburg, *The Way Forward on Opioid Abuse: A Call to Action for Science-Based, Comprehensive Strategies*, FDA VOICE (Apr. 29, 2014), <http://blogs.fda.gov/fda/voice/index.php/2014/04/the-way-forward-on-opioid-abuse-a-call-to-action-for-science-based-comprehensive-strategies-2>.

example, states could play an enhanced role in the post-approval risk surveillance phase of the drug regulatory process. States might be particularly well suited to observe at close range the efficacy and safety of a particular drug and to collect relevant data and report back to the FDA.<sup>52</sup>

The FDA welcomed states' efforts—like those of Massachusetts—to impose restrictions (as opposed to a ban) on the prescribing and dispensing of opioid drugs. On April 29, 2014—after Massachusetts's Board of Registration in Medicine issued its regulations on the prescribing and dispensing of Zohydro in response to the district court's ruling that the total ban was preempted<sup>53</sup>—Dr. Margaret Hamburg, FDA Commissioner, published a post on the FDA's official blog, responding in part to the steps Massachusetts had taken to regulate the drug within the state.<sup>54</sup> Commissioner Hamburg took the position that the promulgation of restrictions on prescribing and dispensing of Zohydro and similar drugs was an appropriate exercise of state regulatory authority: “As the entities with responsibility for overseeing the practice of medicine, the states have an important role to play in addressing a critical driver of opioid abuse—inappropriate prescribing practice.”<sup>55</sup> She further described the Massachusetts restrictions as “consistent with the essential tenets of numerous medical society guidelines on appropriate pain management,” and as “precisely what responsible physicians should be doing.”<sup>56</sup>

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<sup>52</sup> Consider in this regard the letter five New England governors sent to the Department of Health and Human Services (“HHS”) in the wake of the FDA's approval of Zohydro. The Governors, while asking HHS to overrule the FDA's Zohydro approval decision, also highlighted states' responsibility in responding to the opioid abuse crisis and outlined specific steps they were prepared to take:

We know that this crisis is about more than one drug and that a multifaceted action plan is necessary. That is why we have agreed to jointly explore a number of potential tools to address this epidemic. These include: regional data sharing among our prescription monitoring programs, regional prevention campaigns directed to the public, regional prescribing guidelines and educational campaigns to ensure safe opioid prescribing, expansion of treatment options across the region including medication assisted therapy, and increased and better coordinated law enforcement efforts.

Letter from Dannel P. Malloy, Governor of Conn., et al., to Hon. Sylvia Matthews Burwell, Sec'y, U.S. Dep't of Health & Human Servs. 1–2 (Aug. 28, 2014), [http://votesmart.org/public-statement/916887/letter-to-sylvia-matthews-burwell-secretary-of-health-and-human-services-rejecting-zohydro-extended-release#.VOkJAvnF\\_4s](http://votesmart.org/public-statement/916887/letter-to-sylvia-matthews-burwell-secretary-of-health-and-human-services-rejecting-zohydro-extended-release#.VOkJAvnF_4s).

<sup>53</sup> See *supra* notes 34–39 and accompanying text.

<sup>54</sup> Hamburg, *supra* note 51.

<sup>55</sup> *Id.*

<sup>56</sup> *Id.* Indeed, Commissioner Hamburg advocated extending the restrictions beyond Zohydro to apply to the entire class of opioid drugs. *Id.* Zogenix attached a hard copy of Com-

Commissioner Hamburg also encouraged ongoing state participation in the drug regulation process: “We urge those states with active prescription drug monitoring programs, as well as insurers and pharmacy benefit managers, to help identify and halt inappropriate prescribing. And we urge all states to consider requiring common sense, responsible pain management prescribing practices for all opioids.”<sup>57</sup>

Commissioner Hamburg thus envisioned a regulatory framework where state and federal actors played complementary roles in ensuring the safe, legal, and effective use of prescription drugs. Moreover, her special mention of the Massachusetts restrictions confirmed that the FDA viewed those efforts to be consistent with its own regulatory mission and goals.

The district court nonetheless found—in its first ruling on the restrictions—that the state restrictions had the potential to “severely frustrate Zohydro’s availability,” which the court concluded would “pose significant constitutional concerns.”<sup>58</sup> Although Commissioner Hamburg had referred approvingly to the regulation requiring doctors to certify that other pain management treatments had failed before prescribing Zohydro,<sup>59</sup> the district court—which was concerned about that particular requirement above all others—took no notice of Commissioner Hamburg’s statements. The court took no notice even though those statements were brought to its attention in the Commonwealth’s briefs, which argued that “[c]learly, the FDA does not regard the Boards’ emergency regulations as an obstacle to its new-drug-approval process.”<sup>60</sup> Instead, the court, while acknowledging states’ authority to regulate in this area, held that states must do so in

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missioner Hamburg’s blog post as Exhibit D in its June 6, 2014 memorandum opposing Massachusetts’s motion to dismiss. Memorandum of Law in Opposition to Defendants’ Motion to Dismiss, *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 3339610 (D. Mass. July 8, 2014). In the memo itself, Zogenix quoted selectively from the blog post, in which Commissioner Hamburg indicated that the states’ regulations would be more appropriate were they broadly tailored to opioids as a class, rather than applicable to Zohydro alone. *Id.* at 4–5.

<sup>57</sup> Hamburg, *supra* note 51. The Massachusetts government, in its motion to dismiss Zohydro’s second amended complaint, brought the FDA Commissioner’s statements to the court’s attention by asserting that the FDA “has long acknowledged state authority to regulate how medical practitioners prescribe and pharmacists dispense prescription drugs.” Memorandum in Support of Defendants’ Motion to Dismiss Plaintiff’s Verified Second Amended Complaint, *supra* note 40, at 7–9.

<sup>58</sup> *Zogenix*, 2014 WL 3339610, at \*4.

<sup>59</sup> Commissioner Hamburg specifically mentioned that the regulations would obligate physicians to “take certain steps such as screening for abuse risk and documenting medical need before prescribing the opioid Zohydro ER.” Hamburg, *supra* note 51.

<sup>60</sup> Memorandum in Support of Defendants’ Motion to Dismiss Plaintiff’s Verified Second Amended Complaint, *supra* note 40, at 8.

a manner not “inconsistent with federal law,” such that they “prevent the accomplishment of the [Food, Drug, and Cosmetic Act]’s objective that safe and effective drugs be available to the public.”<sup>61</sup> Nor did the court address the FDA’s position when it subsequently ruled, after the state’s further revisions to the regulations, to lift the injunction.<sup>62</sup>

The court’s disregard of the FDA’s position was a significant error as a matter of obstacle preemption analysis and, given the clarity of the FDA’s stated position, the court overlooked a prime opportunity to undertake that analysis in a manner that would have woven together the two levels of opioid regulation in a coherent way. The FDA is the agency with congressionally-delegated authority to manage and oversee the drug approval process. Its views on whether state restrictions on the prescribing and dispensing of drugs impede its regulatory mission should have been, and should always be, a significant factor in a court’s framework for assessing obstacle preemption.<sup>63</sup> Such an approach would have been consistent with the “agency reference” theory of preemption, by which a court addressing a preemption dispute should look to the relevant federal agency, which is uniquely well positioned to provide insight on the matter, for its views about the impact that the state law would have on the operation of the federal regulatory scheme.<sup>64</sup>

However, this is not to say that a court should reflexively defer to such views either. It should do so only where the agency’s position is supported by persuasive data or factual determinations.<sup>65</sup> Moreover, part of the court’s consideration of the agency’s position should entail scrutiny of the extent to which the agency considered competing state regulatory interests that might be at stake.

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<sup>61</sup> *Zogenix*, 2014 WL 3339610, at \*4.

<sup>62</sup> See *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 4273251 (D. Mass. Aug. 28, 2014).

<sup>63</sup> See Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 471–77 (2008). And in *Zogenix*, Massachusetts so argued. See Memorandum in Support of Defendants’ Motion to Dismiss Plaintiff’s Verified Second Amended Complaint, *supra* note 40, at 8 (“[O]f course, ‘the agency’s own views should make a difference.’” (quoting *Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323, 335 (2011); and *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000))).

<sup>64</sup> See Catherine M. Sharkey, *Federalism Accountability: “Agency-Forcing” Measures*, 58 DUKE L.J. 2125, 2129 (2009); see also Sharkey, *supra* note 63, at 477–502.

<sup>65</sup> See Sharkey, *supra* note 64, at 2185–91.



## 2. *State Interests*

Judicial deference to the FDA's position is only proper where the FDA can show that it invited states an opportunity to express health and safety concerns during the approval process.

### a. *State Participation in the Federal Regulatory Process*

The ACUS project promoting state representatives' participation in the preemptive rulemaking process<sup>66</sup> was designed to enhance and encourage cooperation between federal and state officials.<sup>67</sup> In its recommendation on preemption, ACUS proposed that regulations with federalism implications—i.e., those affecting the balance of power and interests between states and the federal government—be developed in consultation with generalist groups within the “Big Seven,”<sup>68</sup> and through direct channels of communication between federal and state agencies.<sup>69</sup> This process would facilitate federal agency collaboration with “generalist” collections of state-level elected officials as well as “specialist” bodies composed of “subject-focused” state administrators.<sup>70</sup> Ensuring that federal agencies establish adequate mechanisms to facilitate state participation, however, is only a partial solution.

Even if the FDA, for example, were to invite feedback from state health administrators or attorney general (“AG”) office staff on a particular drug application, a mechanism is still required to ensure that such an invitation is accepted. ACUS did not explore how states might be motivated to participate in the FDA regulatory process and thus left wide open the question of what incentives could prompt them to do so.<sup>71</sup>

The *Zogenix* case is illustrative of the incentives problem. The FDA offered state officials the opportunity to attend or send representatives to its public drug advisory committee meetings regarding Zohydro and even to register ahead of time in order to make com-

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<sup>66</sup> See *supra* notes 4–5 and accompanying text.

<sup>67</sup> See ACUS Recommendation 2010-1, Agency Procedures for Considering Preemption of State Law, 76 Fed. Reg. 81, 81–82 (Jan. 3, 2011).

<sup>68</sup> See *id.* at 83. The Big Seven, a group of non-profit organizations composed of state and local officials, includes the Council of State Governments, the National Governors Association, the National Conference of State Legislatures, the National League of Cities, the U.S. Conference of Mayors, the National Association of Counties, and the International City/County Management Association. *Id.* at 82 n.19.

<sup>69</sup> *Id.* at 82–83.

<sup>70</sup> Seifter, *supra* note 6, at 968–69.

<sup>71</sup> States, for example, could establish roles or divisions within their AG offices to handle relationships with federal regulators, or perhaps develop a process for monitoring and responding to notifications in the Federal Register.

ments at these events.<sup>72</sup> But not a single state official or state representative spoke or even attended the advisory committee's public meeting.<sup>73</sup>

To what extent should the state's failure to participate when given the opportunity have borne on the court's decisionmaking in the *Zogenix* case? More generally, how, if at all, should courts deciding preemption cases—and in particular those courts that are assessing the appropriate level of deference to accord an agency's view regarding a regulation's preemptive effect—consider whether the states could have participated in the regulatory process, but chose not to? The question is most vexing in the context of drug approval decisions. Although states ostensibly were given opportunity to participate, it is unclear how meaningful state participation in the drug approval process would or could have been.<sup>74</sup> But the fact remains that there was an opportunity for the state to put before the FDA its own critical and competing views and evidence, an opportunity the state failed to seize.

*b. States Taking Matters into Their Own Hands*

Notwithstanding their self-imposed absence from the approval process, state officials unleashed a firestorm of criticism after the FDA announced it had approved Zohydro.<sup>75</sup> More than two dozen state

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<sup>72</sup> Given that the media reported on the FDA's early consideration of the drug, states could have contacted the agency at that time to express their concerns. See Anna Edney, *Zogenix Painkiller Fails to Win Support of U.S. Advisers*, BLOOMBERG NEWS (Dec. 7, 2012, 6:24 PM), <http://www.bloomberg.com/news/articles/2012-12-07/zongenix-s-painkiller-fails-to-win-support-of-u-s-advisers>. Also, state representatives were subject to notice of the proceedings through the Federal Register, in which advisory committee meetings are announced. 41 C.F.R. § 102-3.150(a) (2014). Moreover, the fact that the story made immediate news indicates that at least some information about the drug application had been made available to the public at large. See, e.g., Edney, *supra*.

<sup>73</sup> CTR. FOR DRUG EVALUATION & RESEARCH, *supra* note 28, at 214-70.

<sup>74</sup> While the advisory committee holds public hearings and entertains comments, the committee typically votes immediately after public comments are made. See, e.g., *id.* at 214-332, 388 (reporting on the vote regarding Zohydro, which followed extensive public comments and a relatively brief committee discussion, with the entire process lasting less than four hours). Moreover, drug advisory committee members are typically scientists and statisticians, namely professionals within technical fields who might not fully appreciate the political or policy-driven nuances of state officials' positions. See U.S. FOOD & DRUG ADMIN., *supra* note 25, at 1; see also OFFICE OF THE COMM'R, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR THE PUBLIC, FDA ADVISORY COMMITTEE MEMBERS, AND FDA STAFF: THE OPEN PUBLIC HEARING AT FDA ADVISORY COMMITTEE MEETINGS 1-2 (2013), <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM236144.pdf> (explaining that the advisory committee system is designed to "provide independent expert advice and recommendations to the [FDA] on scientific, technical, and policy matters related to FDA-regulated products" and discussing the open public hearing sessions).

<sup>75</sup> See, e.g., Ed Silverman, *Governors to HHS: Rescind FDA Approval of the Zohydro*

AGs urged the agency to reconsider its approval, or at least to wait to make its final decision until Zogenix implemented abuse-deterrent technology.<sup>76</sup> Other state officials raised similar concerns about the national epidemic of opioid abuse and addiction in urging the FDA to reconsider its position.<sup>77</sup> The FDA declined to do so and defended its decision to approve the drug.<sup>78</sup>

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*Painkiller*, WALL ST. J. (Sept. 4, 2014, 9:02 AM), <http://blogs.wsj.com/pharmalot/2014/09/04/governors-to-hhs-rescind-fda-approval-of-the-zohydro-painkiller> (describing a letter sent by the governors of five New England states urging HHS to overturn the FDA's approval of Zohydro); Bill Trott, *State AGs Urge FDA to Rethink Approval of Painkiller Zohydro*, REUTERS (Dec. 12, 2013, 5:33 PM), <http://www.reuters.com/article/2013/12/12/us-usa-fda-zohydro-idUSBRE9BB1AQ20131212> (reporting on a letter sent by twenty-eight state AGs to the FDA, urging the agency to reconsider the approval of Zohydro based on the drug's potential for abuse).

<sup>76</sup> Letter from Pamela Jo Bondi, Fla. Attorney Gen., et al., to Margaret Hamburg, M.D., FDA Comm'r (Dec. 10, 2013), <http://www.oag.state.md.us/Press/Zohydro.pdf>. According to the state AGs, allowing onto the market painkiller drugs without abuse-deterrent properties "created an environment whereby our nation witnessed a vicious cycle of overzealous pharmaceutical sales, doctors over-prescribing the narcotics, and patients tampering with these drugs, ultimately resulting in a nationwide prescription drug epidemic claiming thousands of lives." *Id.*

Patient advocacy groups have advanced similar arguments. *See, e.g.*, Laura Sullivan, *Critics Question FDA's Approval of Zohydro*, NPR (Feb. 26, 2014 5:00 AM), <http://www.npr.org/2014/02/26/282836473/critics-question-fdas-approval-of-zohydro> (covering an interview with representatives from patient advocacy groups, law enforcement officers, and the chief medical officer of Zogenix); Letter from The FED Up! Coalition Steering Comm. to Margaret A. Hamburg, M.D., FDA Comm'r (Feb. 26, 2014), <http://www.citizen.org/documents/2185.pdf> ("In the midst of a severe drug addiction epidemic fueled by overprescribing of opioids, the very last thing the country needs is a new, dangerous, high-dose opioid."). *See generally* Roni Caryn Rabin, *New Painkiller Rekindles Addiction Concerns*, N.Y. TIMES (Apr. 21, 2014, 4:50 PM), <http://nyti.ms/1eXL3t9> (providing an overview of the positions taken by the FDA and its critics with respect to the agency's decision to approve Zohydro).

<sup>77</sup> *See, e.g.*, Letter from Kirsten E. Gillibrand, U.S. Senator, et al., to Margaret Hamburg, M.D., FDA Comm'r (Dec. 6, 2013), [http://www.manchin.senate.gov/public/index.cfm/files/serve?File\\_id=a4ba49fd-9bde-4ff7-a834-2dcf0a470c38&SK=5622C75FC16231198083213DE70C2C3F](http://www.manchin.senate.gov/public/index.cfm/files/serve?File_id=a4ba49fd-9bde-4ff7-a834-2dcf0a470c38&SK=5622C75FC16231198083213DE70C2C3F) (citing statistics on opioid abuse and overdose rates); Letter from Greg Zoeller, Ind. Attorney Gen., et al., to Hon. Kathleen Sebelius, Sec., U.S. Dep't of Health & Human Servs. (Mar. 25, 2014), [http://ag.ky.gov/pdf\\_news/zohydro-letter.pdf](http://ag.ky.gov/pdf_news/zohydro-letter.pdf).

<sup>78</sup> FDA officials responded to critics by publishing an essay defending the agency's decision in the *Journal of the American Medical Association*. Christopher M. Jones et al., *Addressing Prescription Opioid Overdose: Data Support a Comprehensive Policy Approach*, 312 JAMA 1733 (2014). The officials suggested that policies like Massachusetts's—which in practice would affect only Zohydro, rather than the broader class of opiate drugs to which it belonged—were misguided. *Id.* at 1734. They likewise provided justifications for the agency's decision to defy the advisory committee's recommendation. *Id.* at 1733 (describing steps that the FDA took subsequent to its approval of Zohydro to increase the safety of opiate drugs as a class).

In the months following Zohydro's approval, Commissioner Hamburg also unequivocally defended the FDA's position and publicly made substantive counterarguments regarding the safety of the drug. *See* Margaret Hamburg, M.D., FDA Comm'r, *Address to the National Rx Abuse Summit: Regulating in an Era of Increasingly Sophisticated Medicines* (Apr. 22, 2014), <http://www.fda.gov/newsevents/speeches/ucm394400.htm>.

It was at that point that Massachusetts took matters into its own hands and enacted its statewide ban.<sup>79</sup> It cited health and safety concerns, namely the potential for abuse and addiction, as grounds for the ban<sup>80</sup>—the very considerations raised by the advisory committee and rejected by the FDA in approving Zohydro<sup>81</sup> in the course of the process that Massachusetts officials chose not to attend.<sup>82</sup> The state would thus have been hard-pressed to complain that it had been precluded from presenting its case to the FDA. Moreover, the FDA—having considered a contrary position, raised by the advisory committee and various public health experts, but in essence the same as that adopted by the states, along with evidence cited in support of that position—came to a different conclusion.<sup>83</sup>

Agency actions are more deserving of preemptive effect when those actions have taken state interests into account.<sup>84</sup> Though a close call, preemption was the right result in a case like this, where the state's decision to ban or effectively ban the drug was grounded in the very same concerns (and evidence) that were expressly considered and rejected by the FDA.<sup>85</sup> The FDA deliberated on the precise

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<sup>79</sup> See MacQuarrie, *supra* note 31.

<sup>80</sup> See *id.*

<sup>81</sup> CTR. FOR DRUG EVALUATION & RESEARCH, *supra* note 27, at 29.

<sup>82</sup> See *supra* note 73 and accompanying text.

<sup>83</sup> See CTR. FOR DRUG EVALUATION & RESEARCH, *supra* note 27, at 30–33 (recognizing the potential health and safety risks posed by opioid drugs like Zohydro, but finding these to be outweighed by the drug's benefits).

<sup>84</sup> Executive agencies are directed to consider the federalism implications of their preemptive regulations. See Exec. Order No. 13,132, § 4(d), 3 C.F.R. 209 (2000), *reprinted in* 5 U.S.C. § 601 app. at 807–09 (2012); Memorandum on Preemption for the Heads of Executive Departments and Agencies, 2009 DAILY COMP. PRES. DOC. 1 (May 20, 2009). ACUS's recommendations, moreover, aim to facilitate state participation in the regulatory process. See ACUS Recommendation 2010-1, Agency Procedures for Considering Preemption of State Law, 76 Fed. Reg. 81, 82 (Jan. 3, 2011).

<sup>85</sup> See CTR. FOR DRUG EVALUATION & RESEARCH, *supra* note 27, at 30–33. A more difficult case would arise whereby the state asserted a different type of purpose or interest—one that was not directly contrary to the FDA's health and safety determination. To take an admittedly extreme example, suppose that the state enacted a ban on a painkiller drug not due to health and safety concerns, but instead because it wanted to recognize and encourage its citizens' puritan-minded, "buck-up in the face of pain" mentality. In such a case, the purpose behind the federal regulations would be different from the state's motivation for action, and the FDA ostensibly would not have considered the state's (non-health and safety) related purposes when regulating. When federal and state actors regulate for different purposes, such that a federal agency is less likely to have considered a state's purported interests, the case for preemption is weaker.

The U.S. Supreme Court seemed to embrace just such a "purpose-based" test when drawing upon preemption principles to resolve a preclusion dispute in *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2238 (2014) ("The Lanham Act and the FDCA complement each other in major respects, for each has its own scope and purpose. . . . [T]he Lanham Act protects

health concerns that the state cited, and the agency's approval decision reflected a responsible risk-benefit analysis.<sup>86</sup> Massachusetts's subsequent ban thus undermined the FDA's conclusions and, as such, posed a formidable obstacle to the federal regulatory scheme.

The Massachusetts district court, therefore, reached the correct result with respect to preemption of the state's attempt to ban Zohydro outright, but based on a flawed analysis. A more careful preemption review—consistent with the spirit of the ACUS recommendations on federal-state consultation—would have examined the FDA approval process itself and the degree to which the state's interests were considered during that process.

## II. FOOD REGULATION IN A FEDERALISM FRAMEWORK

The FDA's food and food labeling regulations are far less comprehensive than those applicable to prescription drugs.<sup>87</sup> The agency's regulations do target certain foods, and nutritional claims about foods, with great specificity. But several public entities still accuse the FDA of being too lax, especially with respect to the safety of genetically engineered foods.<sup>88</sup> In the absence of FDA action, states have tried to introduce their own regulations, primarily in the realm of mandatory labeling. In the course of doing so, they have confronted preemption challenges premised on the theory that the FDA's decision not to act preempted states' efforts to fill the regulatory gap.

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commercial interests against unfair competition, while the FDCA protects public health and safety.”). Such an approach, however, raises difficult issues with respect to (1) whether a court should accept a state's rationale at face value, and (2) how a court should handle cases in which the effects, if not the purpose, of state regulations are antithetical to the purpose of federal regulations.

<sup>86</sup> See *CTR. FOR DRUG EVALUATION & RESEARCH*, *supra* note 27, at 30–33.

<sup>87</sup> See *POM Wonderful*, 134 S. Ct. at 2235 (noting that the FDA plays a less extensive role in the regulation of food than it does in the regulation of drugs).

As a general matter, there is a stronger argument for preemption where agency regulations are comprehensive, as these areas ostensibly have been subject to a greater degree of regulatory scrutiny and are more likely to reflect the agency's considered determinations as to the optimal rules or standards of care. Where agencies are less thorough and deliberate in making their regulatory decisions, such that the level of care required by federal regulations might be suboptimal, there ought to be more room for the operation of complementary state law. See, e.g., Catherine M. Sharkey, *Drug Advertising Claims: Preemption's New Frontier*, 41 *LOY. L.A. L. REV.* 1625, 1640–51 (2008) (applying this idea in evaluating the conflict-preemptive effects of FDA actions within the area of consumer fraud and drug advertising).

<sup>88</sup> See, e.g., Gregory Jaffe, *FDA Concludes Genetically Engineered Apple and Potato Are Safe*, *CTR. FOR SCI. PUB. INT.* (Mar. 20, 2015), <https://cspinet.org/new/201503201.html> (stating that the process for allowing new crops in which DNA has been manipulated “is badly flawed”).

### A. *Sorrell: Food Labeling Preemption Case Study*

In 2014, Vermont enacted a law requiring labeling of foods containing genetically engineered plants.<sup>89</sup> Various food manufacturers and industry groups challenged the law on preemption grounds.<sup>90</sup> They argued that it impermissibly interfered with the federal regulatory goals behind “(1) establishing nationally uniform food and ingredient labeling requirements, and (2) granting statutory authority to FDA . . . and other agencies to monitor the safety of plants and plant-based products based on sound science.”<sup>91</sup>

Vermont argued that the FDA’s informal policy statements regarding the safety risks of genetically engineered plants, as well as the agency’s correlated decision not to impose special labeling regulations for these products, did not preclude contrary state laws.<sup>92</sup> Vermont further argued that federal law’s silence about labeling designations for genetically engineered foods entitled states to regulate in this area.<sup>93</sup>

The federal district court sided with Vermont on preemption,<sup>94</sup> but missed an opportunity to take up the state’s entreaty to fashion a coherent framework for preemption by regulatory inaction.

#### 1. *FDA Food Labeling*

The FDA has issued policy statements regarding the health risks of genetically engineered food, yet has repeatedly declined to implement a mandatory system for the labeling of such foods.<sup>95</sup> Instead, the FDA has dealt with the issue using a system whereby developers of genetically engineered crops may voluntarily consult with the agency regarding the plants’ safety.<sup>96</sup>

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<sup>89</sup> VT. STAT. ANN. tit. 9, § 3403 (2014).

<sup>90</sup> See Complaint for Declaratory & Injunctive Relief, *supra* note 12.

<sup>91</sup> Plaintiffs’ Opposition to Motion to Dismiss at 24, *Grocery Mfrs. Ass’n v. Sorrell*, No. 5:14-cv-117, 2015 WL 1931142 (D. Vt. Apr. 27, 2015).

<sup>92</sup> Defendants’ Memorandum of Law in Support of Their Motion to Dismiss Plaintiffs’ Complaint at 35–36, *Sorrell*, 2015 WL 1931142 (citing *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 341 (3d Cir. 2009), for the proposition that FDA’s “non-action” with respect to genetically engineered food does not support a finding of preemption).

<sup>93</sup> *Id.* at 36.

<sup>94</sup> *Sorrell*, 2015 WL 1931142, at \*25.

<sup>95</sup> See, e.g., Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992) (explaining the agency’s decision not to require special labeling for GMO foods).

<sup>96</sup> *Id.* at 22,990–91.

a. *1992 Policy Statement: No GMO Labeling Required*

Under federal labeling law, a product's genetically modified organism ("GMO") status must be disclosed only in two instances, in which the absence of such labeling would be misleading: (1) if a product differs so drastically from its non-GMO counterparts that "the common or usual name [of the product] no longer applies to the new food," or (2) if "a safety or usage issue exists to which consumers must be alerted."<sup>97</sup>

Applying this standard, the FDA concluded in 1992 that there was insufficient evidence to support the conclusion that GMO foods were materially different from their non-GMO counterparts:

The agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding.<sup>98</sup>

The following year, having received several comments in response to its 1992 policy statement, the FDA published a notice in the Federal Register soliciting "additional data and factual information relative to the labeling of foods derived from 'genetically engineered' plants."<sup>99</sup> The FDA provided no further guidance on the issue, however, until eight years later.

b. *2001 Policy Statement: Voluntary GMO Labeling Guidance*

In 2001, after a series of public meetings held in 1999, the FDA published guidance on GMO labeling.<sup>100</sup> Emphasizing that the guidelines were for *voluntary* GMO labeling, the FDA provided examples of how manufacturers could include GMO-related information on product labels without rendering the labels misleading.<sup>101</sup> The FDA

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<sup>97</sup> See *id.* at 22,991.

<sup>98</sup> *Id.*

<sup>99</sup> Food Labeling: Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837, 25,838 (Apr. 28, 1993).

<sup>100</sup> U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DEVELOPED USING BIOENGINEERING; DRAFT GUIDANCE (2001), <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm059098.htm>.

<sup>101</sup> See *id.* To the extent that consumers exhibit a preference regarding genetically modified status as such, this preference seems to favor GMO-free rather than genetically engineered foods. See Annie Gasparro, *The GMO Fight Ripples Down the Food Chain*, WALL ST. J. (Aug. 7, 2014, 10:38 PM), <http://www.wsj.com/articles/the-gmo-fight-ripples-down-the-food-chain-1407465378>.

expressly declined to impose a mandatory labeling scheme, again pointing to lack of evidence that bioengineered foods differ materially from non-bioengineered foods or “have adverse health effects.”<sup>102</sup>

*c. 2013 Consumer Update*

In a 2013 consumer update, the FDA reaffirmed its decision not to impose mandatory labeling requirements for GMO foods.<sup>103</sup> The FDA explained that it provided support and guidance for voluntary labeling practices, but, to date, had not gone further: “The agency has received two citizen petitions . . . request[ing] that FDA change its position on [GMO] labeling. . . . The agency is currently reviewing those petitions and considering the issues presented.”<sup>104</sup> In 2014, Commissioner Hamburg testified before a House subcommittee that the FDA had no intention of imposing a mandatory labeling scheme specific to GMO foods.<sup>105</sup> Commissioner Hamburg reportedly told the subcommittee (which has authority over the FDA’s budget) that the “FDA will soon re-assert that it’s unnecessary to mandate labels for foods that contain genetically engineered ingredients.”<sup>106</sup>

*2. State Labeling Law Not Preempted*

In May 2014, Vermont enacted Act 120,<sup>107</sup> a statute that imposed requirements on the labeling and advertising of foods made from genetically engineered crops.<sup>108</sup> According to the state legislature:

Because both the FDA and the U.S. Congress do not require the labeling of food produced with genetic engineering, the State should require food produced with genetic engineering to be labeled as such in order to serve the interests of the State, notwithstanding limited exceptions, to prevent inadvertent consumer deception, prevent potential risks to

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<sup>102</sup> U.S. FOOD & DRUG ADMIN., *supra* note 100.

<sup>103</sup> U.S. FOOD & DRUG ADMIN., FDA’S ROLE IN REGULATING SAFETY OF GE FOODS 3 (2013), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM352193.pdf>.

<sup>104</sup> *Id.*

<sup>105</sup> See Tarini Parti, *Hamburg Reaffirms FDA GMO-Labeling Position*, POLITICO (Mar. 28, 2014, 10:00 AM), <http://www.politico.com/morningagriculture/0314/morningagriculture13440.html>.

<sup>106</sup> *Id.*

<sup>107</sup> VT. STAT. ANN. tit. 9, §§ 3041–48 (2014).

<sup>108</sup> Act 120, which goes into effect July 1, 2016, requires the manufacturers of foods containing genetically modified ingredients to label such products as “produced with genetic engineering” or, if applicable, “may be produced with genetic engineering,” or “partially produced with genetic engineering.” *Id.* § 3043(b)(2)–(3). The statute also forbids manufacturers from labeling such products as “natural.” *Id.* § 3043(c).



human health, protect religious practices, and protect the environment.<sup>109</sup>

Various trade associations representing food producers and manufacturers sued to enjoin enforcement and to invalidate the Act, raising implied preemption claims (among others).<sup>110</sup> Plaintiffs' impossibility conflict preemption argument rested on the notion that, because the FDA, which regulates claims about nutritional composition—did not require labeling of genetically engineered products, a state law that did require GMO labeling as though it were related to a product's nutrition or composition essentially required labeling that was misleading and would therefore be deemed misbranded under the Food, Drug, and Cosmetic Act ("FDCA").<sup>111</sup> Plaintiffs argued further that the labels required by Act 120 were barred because they "legitimate some individuals' opinion that foods produced with ingredients from genetically engineered crops are not as safe as other foods. . . . By implying there may be validity to those opinions . . . . Act 120's labels are misleading and in conflict with federal law."<sup>112</sup>

Scoping out a broader obstacle preemption argument—one that in fact somewhat resembled a field preemption argument<sup>113</sup>—the plaintiffs asserted that the comprehensive federal oversight of food labeling would be undermined by state-level regulation.<sup>114</sup> Plaintiffs relied on this "coordinated framework" to argue that there exists an "overarching federal overlay that governs in this area," of the kind

<sup>109</sup> No. 120, § 1(6), 2014 Vt. Acts & Resolves 348 (to be codified at VT. STAT. ANN. tit. 9, §§ 3041–48 (2014)).

<sup>110</sup> Memorandum of Points & Authorities in Support of Plaintiffs' Motion for a Preliminary Injunction at 1–2, *Grocery Mfrs. Ass'n v. Sorrell*, No. 5:14-cv-117, 2015 WL 1931142 (D. Vt. Apr. 27, 2015).

<sup>111</sup> *Id.* at 51–52.

<sup>112</sup> *Id.* at 52 (emphasis omitted).

<sup>113</sup> A court will find field preemption if the federal regulatory scheme is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). See *supra* note 16.

<sup>114</sup> Plaintiffs claimed:

Long-standing federal policy requires [federal] agencies . . . to regulate genetically engineered plants and plant products primarily through the frameworks established [by several federal] statutes . . . . The agencies coordinate and sequence review at each stage, so that "[b]y the time a genetically engineered product is ready for commercialization, it will have undergone substantial review and testing during the research phase, and thus, information regarding its safety should be available."

Memorandum of Points & Authorities in Support of Plaintiffs' Motion for a Preliminary Injunction, *supra* note 110, at 4–5 (quoting Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986)).

that would give rise to obstacle preemption.<sup>115</sup> They argued that Act 120 was “premised on a finding” that this oversight framework had been insufficient.<sup>116</sup> Moreover, they claimed, a system that allowed for state-by-state regulation would “undermine” the federal framework’s “guarantees of regulatory certainty and uniformity,” and would impose substantial burdens on the use of genetically engineered ingredients.<sup>117</sup>

The Vermont federal district court, noting that impossibility preemption “is a demanding defense,”<sup>118</sup> rejected plaintiffs’ impossibility argument with dispatch: “Not only does the FDA allow for voluntary [genetic engineering (“GE”)] disclosures, but, for illustrative purposes, the State has proffered a product label that demonstrates how dual compliance may be achieved.”<sup>119</sup> The court likewise rejected plaintiffs’ obstacle preemption argument. It conceded that this was “[p]laintiffs’ strongest conflict preemption argument”—namely that interests in “national uniformity” in certain aspects of food labeling would be thwarted by state-by-state regulation.<sup>120</sup> But, according to the court, “[w]hile [p]laintiffs’ plea for GE labeling uniformity reflects economic sense, and perhaps common sense as well, it runs afoul of the presumption against preemption . . . .”<sup>121</sup> Moreover, “[r]egulation of food and beverages is an area in which Congress has long expressed its awareness of state legislation and has consistently tolerated the states’ competing interests and regulatory control.”<sup>122</sup>

The Vermont court took a formalist position, adverting at numerous junctures to the necessity for Congress to answer preemption questions, invoking the traditional (if frequently disparaged) “pre-

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<sup>115</sup> Transcript of Hearing on Motions to Dismiss, Preliminary Injunction & Requests for Judicial Notice at 74, *Sorrell*, 2015 WL 1931142.

<sup>116</sup> Memorandum of Points & Authorities in Support of Plaintiffs’ Motion for a Preliminary Injunction, *supra* note 110, at 53.

<sup>117</sup> *Id.* at 54.

<sup>118</sup> *Sorrell*, 2015 WL 1931142, at \*19 (quoting *Wyeth v. Levine*, 555 U.S. 555, 572 (2009)).

<sup>119</sup> *Id.* at \*20.

<sup>120</sup> *Id.* at \*21.

<sup>121</sup> *Id.* The presumption against preemption is a “cornerstone” of federal preemption analysis, by which courts will presume that the federal regulations do not preempt state law in areas that have traditionally been occupied by the states unless “the clear and manifest purpose of Congress” appears to the contrary. See *Wyeth*, 555 U.S. at 565. The *Sorrell* court agreed with the Vermont defendants who claimed that food and beverage labeling is one such (traditionally state-occupied) area. See Defendants’ Memorandum of Law in Support of Their Motion to Dismiss Plaintiffs’ Complaint, *supra* note 92, at 32 (“Health and safety issues have traditionally fallen within the province of state regulation. This is true of the regulation of food and beverage labeling.” (quoting *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334 (3d Cir. 2009))).

<sup>122</sup> *Sorrell*, 2015 WL 1931142, at \*21.

sumption against preemption” canon, and evincing skepticism regarding federal administrative preemption.<sup>123</sup> It therefore missed an opportunity to set forth a framework for thinking about a thorny area of administrative preemption: preemption by regulatory inaction.

### B. *A Framework for Preemption by Regulatory Inaction*

The *Sorrell* case implicates the question whether and when regulatory silence or inaction may be deemed preemptive. It also raises difficult questions about the appropriate interpretation of the FDA’s position when the agency has taken no specific, determinate stance on the validity of state regulation, as is the case with state-imposed GMO labeling.<sup>124</sup> Two factors weigh against conflict preemption in this particular situation. First, the FDA’s informal policy statements regarding genetically modified foods do not squarely reject mandatory labeling. Second, given that the FDA countenances—and, indeed, offers guidance upon—voluntary labeling by manufacturers who want to include GMO-related information on their labels, it would be a stretch to suggest that the FDA has made a determinative decision that mandatory GMO labeling would in fact pose a health and safety risk.<sup>125</sup>

#### 1. *No Field Preemption: States Take Matters into Their Own Hands to Fill Regulatory Void*

As the federal district court noted, the plaintiffs in *Sorrell* did not expressly allege—“nor could they reasonably [have] allege[d]”—field

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<sup>123</sup> The court refused to give “preemptive effect” to the “coordinated framework”—albeit without any extended analysis of the level of deference to accord to agency guidance documents. *See id.* (quoting *Holk*, 575 F.3d at 341, in which the Third Circuit had “observ[ed] that the ‘FDA’s policy statement’ [was] ‘not entitled to preemptive effect’”). The court added: “There is also no basis for finding the [Office of Science and Technology Policy’s] Coordinated Framework reflects Congress’s objectives with regard to the labeling of GE foods.” *Id.*

<sup>124</sup> When California previously proposed mandatory GMO labeling with Proposition 37, commentators noted the FDA’s silence on this issue. *See, e.g.,* Lisa Baertlein & Carey Gillam, *California GMO Measure May Fail After Food Industry Fights Back*, REUTERS (Nov. 5, 2012, 7:00 AM), <http://www.reuters.com/article/2012/11/05/california-gmo-idUSL1E8M2DGD20121105> (stating that FDA “had no position on” Proposition 37, California’s proposed GMO labeling law); Claire Trageser, *Supporters of GMO Labeling Call “No On 37” Campaign Mailers “Criminal,”* KPBS PUB. BROADCASTING (Oct. 19, 2012), <http://www.kpbs.org/news/2012/oct/19/supporters-prop-37-call-nos-campaign-mailers-gmo> (reporting on FDA’s refusal to comment on Proposition 37).

<sup>125</sup> *See Sorrell*, 2015 WL 1931142, at \*17 (“Plaintiffs further concede that the FDA provides guidance for the voluntary disclosure of GE ingredients. This clearly implies that, at least from the FDA’s perspective, GE ingredient information may be provided without violating federal law or misbranding a food product.”).

preemption, “which would require the court to find that Congress has regulated so comprehensively, and the federal interest is so dominant, in the field of food and beverage labeling that Congress ‘left no room for state regulation of these matters.’”<sup>126</sup> But plaintiffs’ obstacle preemption argument was so broad that it approximated a field preemption argument. Under their theory, state regulation would be stymied even in the face of regulatory inaction.<sup>127</sup>

While the U.S. Supreme Court has not weighed in on this specific preemption-by-inaction issue, its decision in *POM Wonderful LLC v. Coca-Cola Co.*,<sup>128</sup> which addresses the displacement of one federal law by another federal law, is nonetheless enlightening.<sup>129</sup> In that case, the Ninth Circuit Court of Appeals held that FDA regulations barred the plaintiff’s federal Lanham Act (trademark) claim regarding an allegedly misleading label on a juice beverage.<sup>130</sup> In so ruling, the Ninth Circuit remarked that the FDCA “comprehensively regulates food and beverage labeling.”<sup>131</sup> Moreover, the court reasoned, “for a court to act when the FDA has not—despite regulating extensively in this area—would risk undercutting the FDA’s expert judgments and authority.”<sup>132</sup> In essence, the Ninth Circuit embraced a field preemption view, which, applied to a state law challenge, would hold that even a lack of action on the part of the FDA would preclude states from taking any action to fill the void.

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<sup>126</sup> *Id.* at \*16 (quoting *United States v. Locke*, 529 U.S. 89, 111 (2000)).

<sup>127</sup> Here, there is a striking correspondence to dormant Commerce Clause arguments. For elaboration, see Catherine M. Sharkey, *Against Freewheeling, Extratextual Obstacle Preemption: Is Justice Clarence Thomas the Lone Principled Federalist?*, 5 N.Y.U. J.L. & LIBERTY 63, 79 (2010) (“For the striking down of state regulation on the grounds of the dormant Commerce Clause is, for all intents and purposes, akin to preemption by Congressional silence.”); See also *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 615 (1997) (Thomas, J., dissenting) (characterizing invalidation under the dormant Commerce Clause as “preemption-by-silence”).

<sup>128</sup> *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014).

<sup>129</sup> “Although the Court’s pre-emption precedent does not govern preclusion analysis in this case, its principles are instructive insofar as they are designed to assess the interaction of laws that bear on the same subject.” *Id.* at 2236.

<sup>130</sup> See *POM Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1174, 1177 (9th Cir. 2012). The plaintiff’s Lanham Act claim involved several aspects of the product’s label. The label bore the phrases “Pomegranate Blueberry” and “Flavored Blend of 5 Juices,” with the former presented above and in “larger, more conspicuous type” than the latter. *Id.* at 1177. The plaintiff contended that the name of the product was misleading (because the beverage contained only a tiny percentage of pomegranate juice) and that the font size and display of the labeling was likewise misleading. *Id.*

<sup>131</sup> *Id.* at 1175.

<sup>132</sup> *Id.* at 1177.

The Supreme Court emphatically rejected the Ninth Circuit's decision and its determination that the FDA had sole regulatory authority over the field of juice beverage labeling.<sup>133</sup> Before the Court, the Solicitor General (representing the United States and the FDA) argued that "nothing in the FDCA, the . . . FDA's regulations, or the preambles to those regulations suggests that FDA has marked the metes and bounds of all possible misleading material on juice labels, or that its authority must be deemed exclusive even as to matters the agency has never specifically addressed."<sup>134</sup> Moreover, the Solicitor General highlighted that "[s]uch reasoning could reach even the many foods that FDA's regulations do not specifically address at all."<sup>135</sup> In the face of this incomplete federal regulatory scheme, the Court rejected Coca-Cola's counterargument that allowing Lanham Act claims would "undermine the pre-emption provision's goal of ensuring that food and beverage manufacturers can market nationally without the burden of complying with a patchwork of requirements."<sup>136</sup>

Coca-Cola's arguments parallel those made by the food industry in *Sorrell*.<sup>137</sup> Vermont's response essentially claims that where the FDA has declined to regulate, states can step in and fill the regulatory void with laws of their own.

Extending its reasoning by analogy to *POM Wonderful*, the Supreme Court would likely find that field preemption does not override state-based labeling in light of the regulatory void created by the FDA's failure to mandate such labeling in the context of genetically engineered foods.<sup>138</sup>

## 2. Conflict Preemption: Scrutinizing the FDA's Position

*POM Wonderful* also sheds light on the issue of deference to the FDA's position. While the Court did embrace the government's position regarding field preemption, it did not follow its direction on conflict preemption. Careful analysis of the government's position and its

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<sup>133</sup> See *POM Wonderful*, 134 S. Ct. at 2241–42.

<sup>134</sup> Brief for the United States as Amicus Curiae at 11–12, *POM Wonderful*, 134 S. Ct. 2228 (No. 12-761).

<sup>135</sup> *Id.* at 12.

<sup>136</sup> See *POM Wonderful*, 134 S. Ct. at 2239–40.

<sup>137</sup> See *supra* notes 110–17 and accompanying text.

<sup>138</sup> Indeed, the *POM Wonderful* Court arrived at its conclusion without applying the "presumption against preemption," which—at least in some regulatory areas—weighs against a finding of federal preemption of state law, but which is irrelevant to preclusion analysis. In the preemption context, where the federal-state balance is at stake and the presumption against preemption is potentially applicable, the Court would ostensibly be still more reluctant to find preemption of state law. See generally *supra* note 121.

rejection by the Court, however, does not support the view that the Court has cast a dark cloud on deference to the FDA on such matters. Instead, it reveals the outlines of a coherent preemption framework—equally necessary in the case of preemption by regulatory inaction—namely, rigorous scrutiny of the FDA’s position.

While the government rejected the field preemption view of the Ninth Circuit, it nonetheless embraced a more narrow conflict preemption view—one that distinguished between the different Lanham Act claims on the basis of whether the FDA had enacted a specific regulation on point that, it argued, should take priority.<sup>139</sup> The Solicitor General argued that the FDA regulations did clearly authorize defendant to describe its product as a “Pomegranate Blueberry Flavored Blend of 5 Juices,” and that the portion of the Lanham Act claim challenging the name should thus be precluded.<sup>140</sup> According to the Solicitor General, the FDA’s regulation reflected the agency’s “considered determination that compliant names would not be misleading,” based on a “weigh[ing of] the competing interests relevant to the particular requirement in question.”<sup>141</sup> Thus, according to the Solicitor General, a Lanham Act claim based on the product’s name “would directly contravene FDA’s judgment by declaring misleading what FDA determined to be nonmisleading.”<sup>142</sup>

The Supreme Court rejected this analysis with words that suggested, at the least, ambivalence regarding administrative preemption and perhaps hostility toward agency deference: “Even if agency regulations with the force of law that purport to bar other legal remedies may do so, it is a bridge too far to accept an agency’s after-the-fact statement to justify that result here. An agency may not reorder federal statutory rights without congressional authorization.”<sup>143</sup> But, before reaching this conclusion, the Court scrutinized the basis for the government’s position that the FDA’s juice-naming regulation reflected the determinative outcome of a weighing of competing interests, and thus should operate as both a floor and ceiling for regulating this particular aspect of the label. According to the Court, the FDA’s “rulemaking does not discuss or even cite the Lanham Act, and the Government cites no other statement in the rulemaking suggesting

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<sup>139</sup> See Brief for the United States as Amicus Curiae, *supra* note 134, at 17–19.

<sup>140</sup> *Id.* at 17.

<sup>141</sup> Brief for the United States as Amicus Curiae Supporting Neither Party at 9, 19, *POM Wonderful*, 134 S. Ct. 2228 (No. 12-761), <http://www.justice.gov/sites/default/files/osg/briefs/2013/01/01/2012-0761.mer.ami.pdf>.

<sup>142</sup> *Id.* at 9.

<sup>143</sup> *POM Wonderful*, 134 S. Ct. at 2241 (citations omitted).

that the FDA considered the full scope of the interests the Lanham Act protects.”<sup>144</sup> It was on this basis that the Court refused to accept the government’s argument that FDA regulations regarding misleading labeling effectively operated as both a “floor” and a “ceiling,” concluding instead that they served only as a floor, above which other laws—specifically, the Lanham Act—could operate.

The Court’s reasoning points to two related inquiries that should be part and parcel of the conflict preemption framework: (1) when does an agency speak with the “force of law” necessary to preempt state law, and (2) has the agency fully considered and balanced the relevant interests at hand to reach its determinative conclusion that a particular federal standard should operate not as a minimum, but instead as an optimal standard? Taken together, these principles suggest that competing state regulations should be preempted only when it would countermand a deliberate determination by the agency with delegated (explicit or implicit) authority to act.

Had the *Sorrell* court followed the Supreme Court’s lead, it would have had a stronger foundation for its rejection of obstacle preemption—as opposed to its nearly exclusive reliance on the “presumption against preemption”—and it could have defined a coherent framework for consideration of preemption by regulatory inaction.<sup>145</sup>

In *Sorrell*, plaintiffs pointed to FDA statements, policy statements, and guidance documents to make the case that the FDA had explicitly taken a position antithetical to mandatory GMO labeling.<sup>146</sup>

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<sup>144</sup> *Id.*

<sup>145</sup> The Third Circuit had a similar opportunity in *Holk v. Snapple Beverage Corp.*, a case involving a consumer’s claim that Snapple’s use of the term “all natural” on its product labels was misleading. *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 332 (3d Cir. 2009). The FDA had not formally defined the term “natural,” but it had previously issued a policy statement regarding the use of the term in a notice of proposed rulemaking in the Federal Register. *Id.* at 340 (citing Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (Nov. 27, 1991)). Snapple argued that the requirements the plaintiff’s suit would impose with respect to the term “natural” would be inconsistent with the definition set forth in the policy statement, and that the plaintiff’s claim thus was conflict preempted. *Id.* at 339. The Third Circuit concluded that the FDA’s policy statement was not entitled to preemptive effect and rejected Snapple’s argument. *Id.* at 340–41. In the absence of a legally binding definition of “natural,” the court concluded, conflict preemption could not exist. *Id.* at 342. In a subsequent regulatory action, the FDA had explained that it chose not to engage in rulemaking to establish a definition for the term due to “resource limitations and other agency priorities,” and the court reasoned that such a policy position could not support a finding of preemption. *Id.* at 341 (citing Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2,302, 2,397 (Jan. 6, 1993)).

<sup>146</sup> See generally Complaint for Declaratory & Injunctive Relief, *supra* note 12.

Specifically, the plaintiffs referenced Commissioner Hamburg's statements at the House subcommittee hearings, the FDA's 1992 policy statement, and the FDA's 2001 draft guidance document.<sup>147</sup>

Previous FDA actions, however, strongly indicated that the agency had not absolutely rejected the possibility of mandatory GMO labeling.<sup>148</sup> The FDA's determination that manufacturers could voluntarily provide GMO-related information on their labels would tend to undercut any argument that the FDA's refusal to implement mandatory labeling laws could be construed as preemptive silence.

This result fits within a framework by which a judicial finding of federal preemption—consistent with the argument in Part I regarding agencies' positions on preemption questions—should hinge on an agency's ability to show that it has acted deliberately and on the basis of a body of evidence that takes into meaningful account all relevant considerations, including states' interests.

#### CONCLUSION

This Article advances two primary claims. First, courts, when facing implied obstacle preemption challenges, should consider what the FDA's view on the matter is—namely whether the agency itself considers the state-level regulation to be in tension with its national regulatory agenda. In *Zogenix*, it is striking that the court paid no attention to the FDA Commissioner's overt support of Massachusetts's proposed restrictions on the prescribing and dispensing of Zohydro. In *Sorrell*, the court had before it informal policy guidance from the FDA that suggested that the agency was somewhat open to state labeling mandates. Deference to the FDA's position in each case would have provided much clearer resolution of the preemption challenge.

Second, these cases reiterate and reinforce an argument that was at the heart of the ACUS Recommendation: if there is ever to be a coherent body of case law and regulatory policy in the realm of food and drug laws, courts should take heed of the degree to which the FDA gave due regard to relevant state interests before acting.<sup>149</sup> Rather than blindly deferring to the federal agency's view, courts should evaluate whether that view was adopted in a context that war-

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<sup>147</sup> *Id.* at 8–9.

<sup>148</sup> See *supra* notes 95–106 and accompanying text.

<sup>149</sup> See Sharkey, *supra* note 63, at 477 (proposing a novel “agency reference” model for judicial review in the field of products liability preemption); see also Sharkey, *supra* note 64, at 2125 (elaborating on the federalism dimension of this judicial model).



rants deference; and in the interest of encouraging responsible agency action and protecting states' interests in the regulatory process, this evaluation should consider the extent to which states had a meaningful opportunity to put forth their view of how the state regulation fits with the federal regulatory scheme.