

# Public Participation and the Transatlantic Trade and Investment Partnership

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## ABSTRACT

*In the last several years, regulators in major industrialized states have increasingly focused on achieving greater integration between international regulatory regimes and eliminating unnecessary regulatory divergences that create barriers to trade. So-called international regulatory cooperation, which the Administrative Conference of the United States ("ACUS") first advocated in a 1991 recommendation and again embraced in a 2011 recommendation, has been formally endorsed in an Obama Administration executive order and represents a major component of several free trade agreements that the United States is currently negotiating. Notwithstanding its increasing prominence, international regulatory cooperation has been and largely remains a relatively low priority for administrative agencies.*

*This article seeks to alter that dynamic by highlighting elements of international regulatory cooperation that advance agencies' regulatory missions. In particular, it focuses upon public participation, examining how the Transatlantic Trade and Investment Partnership, a free trade agreement currently being negotiated between the United States and European Union, might enhance agency decisionmaking by expanding opportunities for stakeholder input on both sides of the Atlantic. It compares the primary mechanisms for public participation in the United States and European Union, identifies the primary goals each side seeks to achieve, and highlights possible reforms that might improve participatory processes on both sides.*

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## INTRODUCTION

In the 2005 best-seller *The World is Flat*, journalist Thomas Friedman catalogued the rise of globalization in the business world, a process which had begun decades earlier and had rapidly accelerated with advances in communications technology toward the end of the twentieth century.<sup>1</sup> Friedman's overarching thesis concerning the vastly expanded interconnection between developed and developing nations would probably not have been terribly shocking to the titans of industry discussed in his work: businesses had begun marketing products and offshoring production decades earlier, and many large companies had evolved into multinational conglomerates with increasingly attenuated ties to any one geographic locale.<sup>2</sup> Interestingly, although a globalist mindset has become increasingly imperative to survival in the

<sup>1</sup> THOMAS L. FRIEDMAN, *THE WORLD IS FLAT: A BRIEF HISTORY OF THE TWENTY-FIRST CENTURY* (2005).

<sup>2</sup> See, e.g., Steven Pearlstein, *Outsourcing: What's the True Impact? Counting Jobs Is Only Part of the Answer*, WASH. POST (July 1, 2012), [http://www.washingtonpost.com/business/economy/outsourcings-net-effect-on-us-jobs-still-an-open-ended-question/2012/07/01/gJQAs1szGW\\_story.html](http://www.washingtonpost.com/business/economy/outsourcings-net-effect-on-us-jobs-still-an-open-ended-question/2012/07/01/gJQAs1szGW_story.html).

modern business world, governmental regulators have largely remained balkanized and provincial in focus, training their attention on international issues only insofar as they affect their domestic missions.<sup>3</sup>

Nevertheless, in the last three to four years, regulators have awoken to the realities of an increasingly interconnected, flattened world. Though somewhat late to the party, regulatory authorities in developed nations have recently embraced the concept of international regulatory cooperation with zeal, initiating a series of highly ambitious trade agreements that seek to eliminate unnecessary regulatory divergences, which can serve as barriers to trade. For instance, in early 2011, the United States and Canada signed an agreement creating the Regulatory Cooperation Council, which aims to achieve increased regulatory convergence in both nations.<sup>4</sup> Also in 2011, the United States formally joined the Trans-Pacific Partnership (“TPP”), a free trade agreement currently being negotiated amongst several Pacific Rim nations that includes a chapter aimed at promoting regulatory cooperation.<sup>5</sup> In 2012, President Obama issued Executive Order (“EO”) 13,609, which directs executive branch agencies (and encourages independent regulatory agencies) to identify regulations with international impact and also to strive to eliminate unnecessary regulatory divergences.<sup>6</sup> In his 2013 State of the Union Address, President Obama announced the initiation of talks on the Transatlantic Trade and Investment Partnership (“TTIP”), a free trade agreement between the United States and European Union that largely focuses on achieving enhanced regulatory convergence across the Atlantic.<sup>7</sup>

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<sup>3</sup> See, e.g., Kenneth Feith et al., *America's Disconnect Between Domestic and Global Automotive Rulemaking: Time to Pull in the Same Direction*, 42 PRODUCT SAFETY & LIABILITY REP. 667, 667 (2014) (“The United States espouses international cooperation and a commitment to common rules. Its safety and environmental rulemaking, however, remains sealed within a domestic process largely adverse to open technical discussion, outside recommendations, and international cooperation prior to formal proposal. As a result, the U.S. has difficulty implementing the regulatory harmonization at home that it actively supports abroad.”).

<sup>4</sup> Press Release, Office of the Press Secretary, *Joint Statement by President Obama and Prime Minister Harper of Canada on Regulatory Cooperation*, THE WHITE HOUSE (Feb. 4, 2011), <http://www.whitehouse.gov/the-press-office/2011/02/04/joint-statement-president-obama-and-prime-minister-harper-canada-regul-0>.

<sup>5</sup> *Outlines of the Trans-Pacific Partnership Agreement*, OFF. U.S. TRADE REPRESENTATIVE (Nov. 12, 2011), <https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2011/november/outlines-trans-pacific-partnership-agreement>.

<sup>6</sup> Exec. Order No. 13,609, 3 C.F.R. § 255 (2013), *reprinted as amended in* 5 U.S.C. § 601 app. at 819 (2012).

<sup>7</sup> President Barack Obama, *Remarks by the President in the State of the Union Address* (Feb. 12, 2013), THE WHITE HOUSE, <http://www.whitehouse.gov/the-press-office/2013/02/12/re>

Interestingly, the Administrative Conference of the United States (“ACUS”), a small federal agency focused on issuing recommendations designed to improve administrative procedure,<sup>8</sup> heralded the importance of international regulatory cooperation long before it became fashionable to do so. In 1991, on the cusp of the rapid commercial globalization that would proceed over the course of the 1990s, ACUS urged every U.S. agency to “inform itself of the existence of foreign . . . regulatory bodies whose activities may relate to the mission of that agency” and to pursue appropriate opportunities for regulatory cooperation.<sup>9</sup> In 2011, shortly after reopening its doors following a fifteen-year hiatus,<sup>10</sup> ACUS again addressed this salient topic, prompting agencies to “consider strategies for regulatory cooperation with relevant foreign authorities when appropriate to further the agencies’ missions or to promote trade and competitiveness when doing so does not detract from their missions.”<sup>11</sup> The 2011 recommendation helped raise the profile of the issue and was partly responsible for the issuance of EO 13,609, which was announced at an Implementation Summit of the Administrative Conference and the U.S. Chamber of Commerce.<sup>12</sup>

In studying international regulatory cooperation in connection with the 2011 recommendation, ACUS identified an issue that will be critical not only to domestic directives such as EO 13,609, but also to international agreements such as TTIP and TPP: absent “buy-in” from the relevant regulators and stakeholder communities, any such effort is likely doomed to fail.<sup>13</sup> In surveying U.S. agencies, ACUS found

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marks-president-state-union-address; see also Adam C. Schlosser & Reeve T. Bull, *Regulatory Cooperation in the TTIP*, REG BLOG (Aug. 27, 2013), <http://www.regblog.org/2013/08/27-schlosser-reeve-ttip.html> (discussing initial negotiations between the United States and European Union regarding the TTIP).

<sup>8</sup> See 5 U.S.C. § 591(1) (2012) (“The purposes of this subchapter are . . . to provide suitable arrangements through which Federal agencies . . . may . . . develop recommendations for action by proper authorities to the end that private rights may be fully protected and regulatory activities and other Federal responsibilities may be carried out expeditiously in the public interest . . .”).

<sup>9</sup> ACUS Recommendation 91-1, Federal Agency Cooperation with Foreign Government Regulators, 1 C.F.R. § 305.91-1 (1993) (footnote omitted).

<sup>10</sup> *A Brief History of the Administrative Conference*, ADMIN. CONFERENCE OF THE U.S., <http://www.acus.gov/history> (last visited Sept. 18, 2015).

<sup>11</sup> ACUS Recommendation 2011-6, International Regulatory Cooperation, 77 Fed. Reg. 2259, 2260 (Jan. 17, 2012).

<sup>12</sup> Megan Kindelan, *Executive Order Signed Based on Administrative Conference Recommendation*, ADMIN. CONFERENCE OF THE U.S. (May 9, 2012, 11:18 AM), <http://www.acus.gov/newsroom/news/executive-order-signed-based-administrative-conference-recommendation>.

<sup>13</sup> See MICHAEL T. MCCARTHY, INTERNATIONAL REGULATORY COOPERATION, 20 YEARS LATER: UPDATING ACUS RECOMMENDATION 91-1, 1-2 (Oct. 19, 2011), <http://www.acus.gov/>

that some agencies, such as the Food and Drug Administration and Securities and Exchange Commission, have developed close ties with foreign counterparts.<sup>14</sup> Others, however, not only assign a low priority to such efforts, but also even question whether they are legally capable of pursuing them, given that their authorizing statutes focus solely on domestic regulatory missions.<sup>15</sup> Though an international agreement explicitly directing U.S. regulators to engage with foreign counterparts would resolve any uncertainty concerning their legal authority to do so, agencies already struggling to marshal the resources to successfully discharge their domestic regulatory missions may be somewhat reluctant to devote much time or effort to such endeavors.<sup>16</sup>

Thus, in order for such an agreement to succeed, ensuring that agencies possess adequate resources and that regulators internalize the norms of international cooperation is imperative. An absolutely crucial element of promoting those twin goals is guaranteeing robust public participation in the regulatory process: stakeholders can both provide information that government regulators lack, thereby allowing regulatory agencies to preserve resources by leveraging expertise residing in the private sector, and hold agency officials accountable for honoring their commitment to international cooperation. In that light, this Article will explore the optimal mechanisms for achieving enhanced public participation in the framework of the TTIP, the trade agreement that focuses most closely on promoting regulatory convergence.<sup>17</sup>

Part I of this Article begins by exploring the existing regulatory frameworks in both the United States and European Union, highlighting opportunities for public participation and contrasting the two systems. Part II of this Article will then examine the stated aims of both regulatory regimes and enumerate a series of desiderata that regulators on both sides seek when soliciting and considering public input. Finally, Part III of this Article will suggest various reforms that might be considered in connection with the TTIP negotiations, drawing

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sites/default/files/documents/COR-IRC-report-10-19-11.pdf (noting the need for agencies to focus on international coordination and the need to include relevant businesses in discussions).

<sup>14</sup> *Id.* at 40–43.

<sup>15</sup> *Id.* at 19.

<sup>16</sup> *See id.* at 21, 26 (discussing limited resources as an obstacle to developing international cooperation).

<sup>17</sup> Although this Article focuses exclusively on regulatory cooperation amongst the United States and European Union, similar principles animate efforts to promote regulatory convergence in the TPP and any other such international agreement.

upon best practices under both regimes as well as proposals in the scholarly literature and ACUS recommendations.

If executed properly, the TTIP represents not merely an opportunity for crosspollination between U.S. and EU regulators, but also a forum for fundamentally rethinking the balkanized regulatory regimes of an earlier era and recognizing that, in an interconnected world, virtually all regulations reverberate across political boundaries.

#### I. A BRIEF OVERVIEW OF PUBLIC PARTICIPATION IN THE UNITED STATES AND EUROPEAN UNION

A comprehensive analysis of the U.S. and EU regulatory regimes would require multiple volumes and is well beyond the scope of this Article. Rather, this Part offers a very broad overview of the primary modes of public participation in both systems, identifying the key avenues for stakeholder input while necessarily eliding many of the nuances of both regimes. Even at the highest level of generality, however, certain fundamental differences between the U.S. and EU regulatory states are discernible. In keeping with traditional stereotypes concerning the alacrity with which Americans and Europeans embrace the principles of classical liberalism,<sup>18</sup> the U.S. system can be characterized as more “market-based” than its EU counterpart: it relies upon a notice-and-comment process that is available to any interested party,<sup>19</sup> sorts the comments on the basis of merit (with especially relevant comments entitled to close consideration and comments deemed irrelevant effectively ignored),<sup>20</sup> and empowers regulated entities to challenge governmental action deemed to be unlawful or arbitrary.<sup>21</sup> The EU regulatory system, by contrast, is more “communitarian,” with a less inclusive participatory process but greater emphasis on achieving some level of balance amongst the stakeholders who provide input and ensuring the authority of regulators to act even in the face of opposition from regulated entities.<sup>22</sup>

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18 See PETER BALDWIN, *THE NARCISSISM OF MINOR DIFFERENCES: HOW AMERICA AND EUROPE ARE ALIKE: AN ESSAY IN NUMBERS* 1 (2009); OLAF GERSEMAN, *COWBOY CAPITALISM: EUROPEAN MYTHS, AMERICAN REALITY* 2 (2004).

19 See 5 U.S.C. § 553(c) (2012).

20 Specifically, under the Administrative Procedure Act, an agency is legally bound to consider the “relevant matter presented” in comments received. *Id.* To the extent that a comment presents no germane information, the agency is under no obligation to consider or respond to it. *Safari Aviation Inc. v. Garvey*, 300 F.3d 1144, 1151 (9th Cir. 2002); JEFFREY S. LUBBERS, *A GUIDE TO FEDERAL AGENCY RULEMAKING* 343 (5th ed. 2012).

21 5 U.S.C. §§ 704, 706 (2012).

22 PETER L. STRAUSS ET AL., *ADMINISTRATIVE LAW OF THE EUROPEAN UNION: RULEMAKING* 83–84 (George A. Bermann et al. eds., 2008).

### A. *The United States: Notice-and-Comment Rulemaking*

In contrast to the European Union, wherein the various Directorates-General of the Commission<sup>23</sup> ply their specialized expertise to develop rather detailed regulations and directives prior to the Commission's transmitting such draft legislation to the Council and Parliament,<sup>24</sup> the U.S. Congress—which initiates all legislation—often promulgates exceedingly vague statutes that largely delegate the primary decisionmaking function to administrative agencies.<sup>25</sup> Though any citizen (including any corporate “person”) is free to seek to influence members of Congress, which can range from simply penning a letter to one's local representative to spending millions of dollars to hire sophisticated “K Street” lobbyists, Congress is under no legal obligation to consider public input.<sup>26</sup> Thus, some scholars have contended that administrative agencies, which are overwhelmingly staffed by bureaucrats insulated from the political process, are actually much more accountable to members of the public than Congress,<sup>27</sup> given the

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<sup>23</sup> Though there is no precise analog for the European Commission in the United States, it is roughly comparable to the entire Executive Branch of the federal government, including the President, the Executive Office of the President, and the various federal agencies. *Id.* at 5. The Commission is divided into a series of Directorates-General, which, like federal agencies, focus on specific regulatory subject matters (e.g., DG-Environment or DG-Trade), though they are generally less independent of the central executive than are United States agencies. *See id.* at 20; *see also About the European Commission*, EUR. COMMISSION, [http://ec.europa.eu/about/index\\_en.htm#directorates](http://ec.europa.eu/about/index_en.htm#directorates) (last visited Sept. 17, 2015) (explaining that, although the Directorates-General draft laws, the proposals cannot become official unless adopted by the College of Commissioners).

<sup>24</sup> *See* STRAUSS ET AL., *supra* note 22, at 58, 83–86.

<sup>25</sup> *See* *Mistretta v. United States*, 488 U.S. 361, 372 (1989) (“So long as Congress ‘shall lay down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform, such legislative action is not a forbidden delegation of legislative power.’”) (quoting *J. W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)); DAVID SCHOENBROD, *POWER WITHOUT RESPONSIBILITY: HOW CONGRESS ABUSES THE PEOPLE THROUGH DELEGATION* 183–84 (1993) (describing the differences between statutes that “state[ ] a law rather than delegate[ ] the power to make laws” to an administrative agency).

<sup>26</sup> Of course, consistently flouting public opinion might materially diminish a politician's chances of reelection. Equally importantly, candidates who fail to reward campaign contributions provided by various special interest groups will probably be unlikely to enjoy continued support in subsequent election cycles. *Cf.* LAWRENCE LESSIG, *ONE WAY FORWARD: THE OUTSIDER'S GUIDE TO FIXING THE REPUBLIC* ch. 5 (2012) (ebook) (“So long as congressmen spend between 30 and 70 percent of their time raising money, they will be responsive to their funders.”).

<sup>27</sup> *See* Peter H. Schuck, *Delegation and Democracy: Comments on David Schoenbrod*, 20 CARDOZO L. REV. 775, 781–82 (1999) (“[T]he agency is often the site in which public participation is most effective. . . . [T]he agency is where the public can best educate the government about the true nature of the problem that Congress has tried to address.”).

explicit requirement that agencies conducting rulemakings seek out and consider public comments (the so-called “notice-and-comment” requirement).<sup>28</sup>

The notice-and-comment process used by U.S. agencies in informal rulemaking is designed to be maximally participatory: any member of the public, no matter how unsophisticated or inexperienced in the agency’s work, can submit a comment regarding a particular agency rulemaking.<sup>29</sup> This not only lends greater “democratic legitimacy” to the work of the agencies by preserving a role for citizen participation,<sup>30</sup> but also provides a mechanism whereby agencies can exploit the expertise residing in the general public, which is especially relevant in determining how regulations will affect regulated industries and in minimizing any unforeseen consequences.<sup>31</sup>

After the notice-and-comment process has occurred and the agency has promulgated a final rule, stakeholders can still influence the decisionmaking process by seeking judicial review of the regulation.<sup>32</sup> The agency is required to consider the “relevant matter presented” in public comments,<sup>33</sup> and a party that filed a comment can challenge the agency’s ultimate determination if it feels that the agency has not adequately grappled with the information identified in the comment.<sup>34</sup> The period spanning the initial issuance of a notice of proposed rulemaking and a rule’s surviving any challenges pursued by aggrieved stakeholders can run for multiple years, leading some to argue that the regulatory process has become excessively “ossified” and

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<sup>28</sup> 5 U.S.C. § 553(c) (2012).

<sup>29</sup> With the advent of regulations.gov, the process of submitting comments has become even simpler (at least for individuals with Internet access): an interested party merely need log onto the website and fill out an electronic form to file his or her comment. See REGULATIONS.GOV, <http://www.regulations.gov/#!home> (last visited Sept. 18, 2015).

<sup>30</sup> See, e.g., David Fontana, *Reforming the Administrative Procedure Act: Democracy Index Rulemaking*, 74 FORDHAM L. REV. 81, 82 (2005) (advocating increased deference for rulemakings involving significant public participation); Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342, 440 (2004) (contending that enhancing public participation lends increased democratic legitimacy to agency rulemakings).

<sup>31</sup> See LUBBERS, *supra* note 20, at 271–72 & n.7.

<sup>32</sup> 5 U.S.C. §§ 704, 706 (2012).

<sup>33</sup> *Id.* § 553(c).

<sup>34</sup> *Liliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1312, 1314 (D.C. Cir. 2014) (holding that “[a]n agency’s failure to respond to relevant and significant public comments” indicates the agency did not consider the relevant factors and warranted remand for further consideration).



that U.S. agencies cannot regulate effectively, at least in controversial areas likely to draw an organized response by regulated parties.<sup>35</sup>

*B. The European Union: Stakeholder Consultation*

In the European Union, the Commission, which is most closely analogous to the entire executive branch of the U.S. government (i.e., the President and all administrative agencies), is responsible for initiating legislation.<sup>36</sup> The Commission most commonly initiates legislation pursuant to the co-decision process, wherein one of the various Directorates-General will undertake the initial analysis necessary to devise a regulation or directive, and the full Commission will then amend the proposal as necessary and then forward it to the Council and Parliament for consideration.<sup>37</sup> Thus, EU regulations and directives are often more technical (and arguably more sophisticated) than statutes promulgated by the U.S. Congress.<sup>38</sup> After the Council and Parliament have approved a regulation or directive, the Commission often has additional responsibilities for clarifying how the legislation will be enforced through issuing implementing and delegated acts,<sup>39</sup> which are roughly analogous to agency rulemakings in the United States.

Perhaps in part because public input occurs much earlier in the lawmaking process (at the “legislative” rather than the “rulemaking” stage, to use American terminology), stakeholder consultation is less formalized in the European Union. In some cases, the Commission prepares green and white papers<sup>40</sup> and informally consults with Member State experts and other stakeholders prior to drafting a proposed regulation or directive.<sup>41</sup> The Commission also announces many pro-

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<sup>35</sup> Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 DUKE L.J. 1385, 1400–03, 1410–26 (1992); Paul R. Verkuil, *Comment: Rulemaking Ossification—A Modest Proposal*, 47 ADMIN. L. REV. 453, 453 (1995).

<sup>36</sup> STRAUSS ET AL., *supra* note 22, at 5.

<sup>37</sup> *Id.* at 20–21.

<sup>38</sup> *Id.* at 20 n.26.

<sup>39</sup> Consolidated Version of the Treaty on the Functioning of the European Union arts. 290–91, May 9, 2008, 2008 O.J. (C 115) 172–73 [hereinafter TFEU].

<sup>40</sup> Green papers identify an area in which the EU is contemplating action and solicit input from stakeholders. *Green Paper*, EUR-LEX, [http://eur-lex.europa.eu/summary/glossary/green\\_paper.html](http://eur-lex.europa.eu/summary/glossary/green_paper.html) (last visited Sept. 17, 2015). If the Commission ultimately decides to proceed with legislation following issuance of a green paper, it will then issue a white paper that describes the legislative proposal in greater detail. *White Paper*, EUR-LEX, [http://eur-lex.europa.eu/summary/glossary/white\\_paper.html](http://eur-lex.europa.eu/summary/glossary/white_paper.html) (last visited Sept. 17, 2015).

<sup>41</sup> STRAUSS ET AL., *supra* note 22, at 59–60.

posed initiatives on the “Your Voice in Europe” website,<sup>42</sup> which allows any interested member of the public to provide comments.<sup>43</sup> Unlike U.S. agencies, which typically leave comment solicitations open-ended and allow participants to comment on essentially any aspect of a proposed rulemaking, the Commission generally structures the inquiry by requesting information on specific issues.<sup>44</sup> Finally, the Commission will, in some instances, conduct opinion polls to determine how the regulated public might react to a particular policy proposal.<sup>45</sup> As a general matter, the Commission is far more likely to collect public input in drafting regulations or directives than in issuing delegated or implementing acts designed to execute such laws,<sup>46</sup> even though the Commission has increasingly solicited stakeholder input in connection with the latter set of functions.<sup>47</sup> The Commission is not legally bound to undertake the various stakeholder consultation initiatives described above, and the extent to which it does so therefore varies from case to case.<sup>48</sup>

Once the EU has promulgated a regulation, directive, delegated act, or implementing act, the opportunities for disaffected stakeholders to challenge the ultimate outcome are far more limited than in the United States. The EU regulatory framework does not include any comprehensive mechanism for regulated parties to seek judicial review of final laws (though they may challenge certain laws in limited instances).<sup>49</sup> This potentially undermines the accountability of EU

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<sup>42</sup> *Your Voice in Europe*, EUR. COMMISSION, [http://ec.europa.eu/yourvoice/index\\_en.htm](http://ec.europa.eu/yourvoice/index_en.htm) (last updated Feb. 7, 2015).

<sup>43</sup> STRAUSS ET AL., *supra* note 22, at 71–72.

<sup>44</sup> *Id.* at 76–77.

<sup>45</sup> *Opinion Polls Capturing Images of the EU*, EUR. PARLIAMENTARY RES. SERV. (June 1, 2013), <http://epthinktank.eu/2013/06/01/opinion-polls-capturing-images-of-the-eu/> (explaining that Flash Eurobarometer are ad hoc surveys which capture “immediate feedback on a topical issue”).

<sup>46</sup> See *Stakeholder Consultation Guidelines 2014*, at 5 (2014), [http://ec.europa.eu/smart-regulation/impact/docs/scgl\\_pc\\_questionnaire\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/docs/scgl_pc_questionnaire_en.pdf) (explaining that consultations on delegated and implementing acts are done only when an impact assessment is necessary).

<sup>47</sup> See, e.g., *Delegated Act on the Detailed Rules for a Unique Identifier for Medicinal Products for Human Use, and Its Verification*, (Nov. 18, 2011), [http://ec.europa.eu/health/files/counterf\\_par\\_trade/safety\\_2011-11.pdf](http://ec.europa.eu/health/files/counterf_par_trade/safety_2011-11.pdf); *Implementing Act on a Common Logo for Legally-Operating Online Pharmacies/Retailers Offering Medicinal Products for Human Use for Sale at a Distance to the Public* (Oct. 17, 2012), [http://ec.europa.eu/health/files/falsified\\_medicines/common\\_logo\\_consult.pdf](http://ec.europa.eu/health/files/falsified_medicines/common_logo_consult.pdf).

<sup>48</sup> STRAUSS ET AL., *supra* note 22, at 74–75.

<sup>49</sup> See TFEU, *supra* note 39, art. 263 (limiting judicial review to acts that either are “addressed to” the challenging party or are “of direct and individual concern” to said party); STRAUSS ET AL., *supra* note 22, at 25–26 (discussing limited examples of situations where private parties would have standing to seek judicial review of European Commission legislative acts).

lawmakers insofar as any determination they reach is essentially final, but it also ensures that regulators can act with some level of dispatch.<sup>50</sup>

## II. QUALITIES OF EFFECTIVE PUBLIC PARTICIPATION

Although the policies undergirding the participatory mechanisms in both the United States and European Union are fundamentally similar, with both sides seeking to leverage the decentralized expertise residing in the private sector and to engender a sense of “invested-ness” by creating a pipeline for channeling stakeholder input to governmental decisionmakers,<sup>51</sup> the systems are sufficiently different that merely exporting concepts from one to the other is unlikely to prove especially productive. In addition, even though opportunities to increase public participation in *both* systems abound, any effort to do so must be mindful of the costs and benefits associated with additional outreach efforts. Though blithely seeking to maximize public participation out of a misguided effort to promote “democracy” is unlikely to be effective,<sup>52</sup> carefully targeted efforts to seek out *relevant* input can improve the quality of governmental decisionmaking, diminish burdens on regulated entities, and preserve agency resources.

In that vein, this Part explores the characteristics of effective public participation and considers how the U.S. and EU systems perform on each of these metrics. Given the disparities between the two systems outlined in the previous Part, any effort to achieve enhanced international coordination and improved stakeholder input must grapple with the following questions:

- At what point(s) in the lawmaking process should public input be solicited?
- Can any member of the public provide input, or is participation limited to a subset of stakeholders with a material interest in the outcome of a particular policy decision?

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<sup>50</sup> See Francesca E. Bignami, *The Democratic Deficit in European Community Rulemaking: A Call for Notice and Comment in Comitology*, 40 HARV. INT'L L.J. 451, 503–04 (1999) (recognizing that extensive judicial review procedures cause the United States' rulemaking process to move excessively slowly in the context of comparing United States rulemaking to that of the European Union).

<sup>51</sup> See *supra* Part I.

<sup>52</sup> Reeve T. Bull, *Making the Administrative State “Safe for Democracy”: A Theoretical and Practical Analysis of Citizen Participation in Agency Decisionmaking*, 65 ADMIN. L. REV. 611, 626 (2013) (noting that a focus on making the administrative state “more democratic” will “improperly exalt[] a style of governance that was viewed by neither the nation’s founders nor the creators of the administrative state as an end in and of itself”).

- Should stakeholders have access to some sort of enforcement mechanism (e.g., judicial review of regulatory decisions) to ensure that regulators respond to their input and integrate it into the decisionmaking calculus as appropriate?
- Should stakeholders have a role beyond merely providing information for the agency to consider?
- Is public input limited to prospective laws, or is it considered when governments reassess existing laws?

Each of these inquiries defies a simple answer. For instance, obtaining stakeholder input early in the process allows regulators to benefit from relevant information while they are still crafting regulations, but stakeholders may be unable to comment meaningfully on a proposal as it is still taking shape. Soliciting widespread public input ensures that the agency has maximum access to data that may be germane to its analysis, but it also increases the risk that the agency will be flooded by irrelevant comments.<sup>53</sup> Providing for judicial review of regulators' determinations promotes accountability, but it invites abuse of the process and contributes to "ossification."<sup>54</sup> Nevertheless, regulators on both sides of the Atlantic tend to identify common policy goals, such as promoting an inclusive process and gathering relevant information, when touting the benefits of widespread public participation.<sup>55</sup> In that light, this Part highlights the various desiderata that undergird the public participatory mechanisms in both the United States and European Union and explores the extent to which the two systems achieve those goals. Part III then examines possible reforms to both systems that might more effectively advance those policies while expanding opportunities for participation to a worldwide audience.

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<sup>53</sup> *Id.* at 631–32.

<sup>54</sup> See McGarity, *supra* note 35, at 1400–03, 1410–26 (discussing the pros and cons of judicial review, and noting examples of judicial overreaching, including where an agency explained the ossification of its rulemaking process was due to belief that “any faster action would simply invite reversal on judicial review”).

<sup>55</sup> See, e.g., Exec. Order No. 13,563, 3 C.F.R. § 215 (2012), *reprinted as amended in* 5 U.S.C. § 601 app. at 816 (2012) (promoting “public participation and an open exchange of ideas” as a mechanism to improve federal regulations); *Impact Assessment Board Report for 2011*, at 4, SEC (2012) 101 final (Feb. 1, 2012), [http://ec.europa.eu/smart-regulation/impact/key\\_docs/docs/sec\\_2012\\_0101\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/key_docs/docs/sec_2012_0101_en.pdf) (“[T]he Board recommends that services pay close attention to the transparent and comprehensive presentation of the different views of stakeholders throughout the [impact assessment] reports.”).

### A. *Inclusiveness*

According to the Condorcet jury theorem, if one assembles a group of amateur decisionmakers who are even slightly more capable of reaching a correct conclusion than random probability would dictate,<sup>56</sup> a sufficiently large group will always converge on the correct response.<sup>57</sup> Famed Austrian School economist F. A. Hayek applied these insights to decisionmaking in a free market, contending that decentralized, independent decisionmakers will reach better conclusions than government experts, especially in complicated scenarios wherein it would be quite difficult for any small coterie of bureaucrats to grasp the full complexity of the problem.<sup>58</sup> Thus, to the extent possible, societal resource allocations should be governed or informed by the input of large, decentralized groups.<sup>59</sup>

Unfortunately, the principles of the Condorcet jury theorem apply only when the members of a decisionmaking group are acting independently and the full range of existing perspectives is reflected in the input received (such that extreme views on either end can cancel each other out).<sup>60</sup> In the regulatory context, this precondition is unlikely to prevail, for the only individuals who have a sufficient incentive to participate are those who will experience some concentrated benefit or harm if the regulation issues, and their comments, which will almost certainly be overrepresented in the responses received, are likely to advocate only one narrow perspective.<sup>61</sup> Nevertheless, a

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<sup>56</sup> For instance, in a binary decision, these conditions hold so long as the probability that the group has reached a correct conclusion is greater than fifty percent (i.e., the likelihood of being correct if one hazarded a random guess).

<sup>57</sup> See Krishna K. Ladha & Gary Miller, *Political Discourse, Factions, and the General Will: Correlated Voting and Condorcet's Jury Theorem*, in *COLLECTIVE DECISION-MAKING: SOCIAL CHOICE AND POLITICAL ECONOMY* 393, 393–94 (Norman Schofield ed., 1996) (“[T]he majority will approach perfect accuracy in judgment as the size of the group increases.”).

<sup>58</sup> F. A. HAYEK, 2 *THE COLLECTED WORKS OF F.A. HAYEK: THE ROAD TO SERFDOM* DEFINITIVE EDITION 94–96 (Bruce Caldwell ed., 2007) (“It is only as the factors which have to be taken into account become so numerous that it is impossible to gain a synoptic view of them that decentralization becomes imperative.”).

<sup>59</sup> See *id.* at 95.

<sup>60</sup> See JAMES SUROWIECKI, *THE WISDOM OF CROWDS* 41 (First Anchor Books 2005) (noting that independence is important to intelligent decisionmaking because it “keeps the mistakes that people make from becoming correlated” and that “[t]he smartest groups . . . are made up of people with diverse perspectives who are able to stay independent of each other.”); see also Ladha & Miller, *supra* note 57, at 393–94 (“[W]ithout the assumption of independence, Condorcet has nothing to say about whether groups are more likely to be correct than their constituent members.”).

<sup>61</sup> WILLIAM N. ESKRIDGE, JR. ET AL., *CASES AND MATERIALS ON STATUTORY INTERPRETATION* 56–60 (2012). In addition to parties that are likely to be significantly affected by proposed regulations, commenters might include individuals who have invested very little time in

more modest version of the “wisdom of crowds” phenomenon might apply: widespread participation ensures that the government regulators have the broadest possible information base, and experts can sift through that information to identify considerations relevant to a proposed regulation.<sup>62</sup>

The United States essentially subscribes to this model of regulation, literally opening the commenting process to the entire world (including corporations and non-U.S. citizens), but empowering regulators to glean the proverbial wheat from the chaff in considering these comments.<sup>63</sup> To be effective, such an approach requires that two underlying assumptions be met: (1) though certain perspectives might be under-represented, the final data set includes at least one comment reflecting each relevant viewpoint and (2) regulators are capable of ferreting out the most germane information from the comments received. Unfortunately, these assumptions may not always hold. First, because certain stakeholders will have a stronger incentive to file comments or greater access to the financial resources required to submit sophisticated comments, regulators may receive public input that does not reflect the full panoply of relevant viewpoints.<sup>64</sup> Second, regulators may be so overwhelmed by the amount of information received and so fearful in the face of potential legal challenges that they place greater emphasis on information submitted by parties most likely to seek judicial review of the agency’s conclusions.<sup>65</sup>

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studying the problem at issue and file highly simplistic comments (e.g., merely expressing agreement or disagreement with the agency’s proposal). See Nina A. Mendelson, *Rulemaking, Democracy, and Torrents of E-Mail*, 79 GEO. WASH. L. REV. 1343, 1360–61 (2011). These comments are also of diminished value, for the commenters usually are not acting independently but instead have been encouraged to act by an organization advocating a particular viewpoint. See *id.* at 1361–62.

<sup>62</sup> See *id.* at 1380 (“We should strongly encourage agencies to engage comments on the value-laden questions more seriously, including the comments of lay persons submitted in large numbers.”). This is, in essence, the model utilized by Wikipedia, where peer production “mixes elements of hierarchy and self-organization and relies on meritocratic principles of organization.” See DON TAPSCOTT & ANTHONY D. WILLIAMS, *WIKINOMICS: HOW MASS COLLABORATION CHANGES EVERYTHING: EXPANDED EDITION* 67 (2008). Any member of the public can contribute to a Wikipedia article, but “the most skilled and experienced members of the community provide leadership and help integrate contributions from the community,” *id.*, and if an “edit war” breaks out, a Wikipedia staffer makes the final judgment. *Id.* at 73.

<sup>63</sup> See 5 U.S.C. § 553(c) (2012).

<sup>64</sup> See Fontana, *supra* note 30, at 85 (“[A]ll of the empirical research on public participation in agency rulemaking demonstrates that participation is minimal, of low quality, and dominated by powerful interests.”).

<sup>65</sup> See Mark Seidenfeld, *Demystifying Deossification: Rethinking Recent Proposals to Modify Judicial Review of Notice and Comment Rulemaking*, 75 TEX. L. REV. 483, 487 (1997) (discussing instances where “agencies have shied away from highly beneficial regulations because of

In this light, widespread participation creates numerous benefits, but it also presents a number of drawbacks that should give regulators pause when attempting to expand stakeholder input as broadly as possible.

### B. Representativeness

Because a widely inclusive system for public participation suffers from various flaws related to self-selection of commenters, regulators might undertake efforts to ensure that the group of entities offering input roughly reflects the demographic makeup of the larger society affected by a proposed regulation. The European Commission attempts to achieve such balance when formulating a policy proposal by reaching out to diverse stakeholder groups (including industry representatives, unions, civil society organizations, etc.).<sup>66</sup>

Striving to promote balance in selecting organizations to provide input theoretically corrects for the self-selection issue endemic to a system of completely open participation, but it generates countervailing problems. First, some authority must select the individuals or groups who will be invited to participate, which can prove enormously challenging given the difficulty of determining precisely whom to invite and how to ensure that one viewpoint does not improperly dominate the process.<sup>67</sup> Second, limiting the number of participating stakeholders increases the risk of explicit or tacit collusion amongst the chosen organizations, who might reach a mutually beneficial bar-

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a fear that the regulations will not pass judicial muster.”); Wendy E. Wagner, *Administrative Law, Filter Failure, and Information Capture*, 59 DUKE L.J. 1321, 1329 (2010) (“To win, a player need not convince his opponents of the merits of his case; he need only wear them down enough to cause them to throw in their towels and give in.”).

<sup>66</sup> See *Stakeholder Consultation Guidelines 2014*, *supra* note 46, at 29. Similarly, in some cases, U.S. agencies form advisory committees to receive input on specific policy proposals. See Kit Gage & Samuel S. Epstein, *The Federal Advisory Committee System: An Assessment*, 7 ENVTL. L. REP. 50,001, 50,001 (1977). The Federal Advisory Committee Act governs these groups, and it specifically requires representativeness by providing that any committee must reflect ideological balance amongst its members. 5 U.S.C. app. § 5(b)(2). Unlike the notice-and-comment requirement, which applies to *all* informal rulemakings, 5 U.S.C. § 553(c), agencies are seldom required to form advisory committees and generally need not place any particular reliance upon the determinations of such committees. See Gage & Epstein, *supra*, at 50,010.

<sup>67</sup> See REEVE T. BULL, THE FEDERAL ADVISORY COMMITTEE ACT: ISSUES AND PROPOSED REFORMS 23 (draft, Sept. 12, 2011), <http://www.acus.gov/sites/default/files/documents/COCG-Reeve-Bull-Draft-FACA-Report-9-12-11.pdf>. For instance, if a specific perspective represents an extreme minority position (e.g., climate change skepticism among legitimate scientists), should it nevertheless be represented on any advisory group in the interest of ensuring “balance”? Or does doing so improperly elevate its importance and thereby render the group “unbalanced”? See, e.g., *id.* at 24.

gain that undermines the interests of groups who were not party to the discussions.<sup>68</sup> Critics contend that the EU system suffers from these two flaws, such that EU regulators tend to seek input from a small coterie of repeat players (e.g., large EU corporations and unions) and that these stakeholders advocate policies that advance their own narrow goals without necessarily serving the broader public interest.<sup>69</sup>

Thus, representativeness is a noble goal in theory that often proves exceedingly elusive in practice, as efforts to achieve “balance” amongst competing viewpoints can raise insoluble issues and open the door to regulatory capture.

### C. Responsiveness

As public choice theory has famously posited, government officials, no less than other human decisionmakers, respond to traditional incentives and seek to advance their own interests.<sup>70</sup> The doctrine of separation of powers, first articulated by the Baron de Montesquieu<sup>71</sup> and fundamental to the design of the U.S. Constitution,<sup>72</sup> represents one approach to combating this inherent flaw of human nature, intentionally dividing governmental power between rival branches such that the self-interest of actors in one branch can serve as a check upon the others. As the American administrative state vastly expanded over the course of the 20th century, lawmakers sought to curtail the power of federal agencies by applying this classical wisdom, empowering other branches of government and even private actors to exercise

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<sup>68</sup> PETER STRAUSS ET AL., EU RULEMAKING, AM. B. ASS'N 59, <http://www.americanbar.org/content/dam/aba/migrated/adminlaw/eu/RulemakingFinal31008.authcheckdam.pdf>.

<sup>69</sup> See Shawn Donnan, *US Pushes for Greater Transparency in EU Business Regulation*, FIN. TIMES (Feb. 23, 2014), <http://www.ft.com/intl/cms/s/0/6e9b7190-9a65-11e3-8e06-00144feab7de.html#axzz38mJgpnx2> (“US companies also complain that they are often shut out of the regulatory process in Europe because the EU system can depend on closed consultations with local industry groups that make it difficult for outsiders to register their concerns.”).

<sup>70</sup> Gary S. Becker, *A Theory of Competition Among Pressure Groups for Political Influence*, 98 Q. J. ECON. 371, 373–74 (1983) (“The basic assumption of the analysis is that taxes, subsidies, regulations, and other political instruments are used to raise the welfare of more influential pressure groups.”); see also MANCUR OLSON, *THE RISE AND DECLINE OF NATIONS: ECONOMIC GROWTH, STAGFLATION, AND SOCIAL RIGIDITIES* 47 (1982).

<sup>71</sup> See BARON DE MONTESQUIEU, *THE SPIRIT OF LAWS* 151–52 (Thomas Nugent trans., The Colonial Press 1899) (1748).

<sup>72</sup> THE FEDERALIST NO. 47, at 324 (James Madison) (Jacob E. Cooke ed., 1961) (“The accumulation of all powers, legislative, executive and judiciary, in the same hands, whether of one, a few or many, and whether hereditary, self-appointed, or elective, may justly be pronounced the very definition of tyranny.”).



oversight over agencies' decisionmaking.<sup>73</sup> Perhaps the most potent mechanism for ensuring regulator accountability is the process of judicial review: private actors are empowered to challenge final agency decisions in court, and federal judges scrutinize regulators' determinations to ensure that they have behaved lawfully and rationally.<sup>74</sup> Thus, U.S. regulators ignore relevant stakeholder input at their own peril, for agencies are legally bound to consider public comments and justify their final determination in light of the information received.<sup>75</sup>

Nevertheless, achieving enhanced accountability and responsiveness is not a costless endeavor, and the robust system of judicial review has contributed to "ossification" and made it exceedingly difficult for U.S. regulators to act with dispatch.<sup>76</sup> The EU has therefore been understandably reluctant to impose legal obligations upon the Commission such as requiring consultation with stakeholders and empowering private sector entities to hold regulators accountable if they feel their concerns are not adequately addressed.<sup>77</sup> Absent any enforcement mechanism for ensuring that regulators solicit and consider public input, however, the system ultimately relies upon an underlying faith that bureaucrats will act in an enlightened manner, seeking input from outsiders when appropriate and taking proper account of the information received. If public choice theory carries any persuasive power, this faith is perhaps misplaced.<sup>78</sup>

In short, ensuring responsiveness to public input requires a delicate balance: regulators freed from any public accountability begin to resemble the mandarins of Imperial China, yet promoting excessive responsiveness essentially reduces government regulators to handmaidens of industry groups and other well-financed private entities. The U.S. and EU systems represent neither extreme, yet the two regimes reflect fundamentally different visions of the appropriate role of stakeholders and courts for promoting regulatory accountability.

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<sup>73</sup> Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1669, 1678–81 (1975).

<sup>74</sup> 5 U.S.C. §§ 704, 706 (2012); Stewart, *supra* note 73, at 1679–80.

<sup>75</sup> 5 U.S.C. § 553(c) (2012).

<sup>76</sup> McGarity, *supra* note 35, at 1400–03, 1410–26.

<sup>77</sup> STRAUSS ET AL., *supra* note 22, at 72 ("Such an over-legalistic approach would be incompatible with the need for timely delivery of policy, and with the expectations of the citizens that the European Institutions should deliver on substance rather than concentrating on procedures.").

<sup>78</sup> See *supra* note 70 and accompanying text.

#### D. Relevance

Stakeholder input might be relevant to an agency on at least two separate dimensions: (1) private parties might possess technical information to which the agency does not otherwise have access<sup>79</sup> and (2) citizens might express agreement or disagreement with the policies of the agency, and accounting for the public's preferences may accord some measure of "democratic legitimacy" to the agency's decision-making.<sup>80</sup> Traditionally, neither the United States nor the European Union has carefully attempted to disambiguate these two functions when seeking public input, though the European Union is likely somewhat more advanced than the United States in carving out separate spheres for technical and policy input.

In U.S. notice-and-comment rulemaking, an agency merely issues a solicitation for public comments and permits interested parties to comment on any aspect of a proposed rule.<sup>81</sup> Not surprisingly, the content and quality of comments received vary substantially: some commenters may furnish detailed information to which the agency lacks access, whereas others may simply express summary approval of or disagreement with the agency's proposed course of action.<sup>82</sup> Agencies are under no legal obligation to adopt the policy favored by a majority of commenters,<sup>83</sup> and, as a general matter, agencies do not attempt to glean public policy preferences from comments, instead focusing solely on relevant technical information they may contain.<sup>84</sup>

In the EU, whenever the Commission solicits public input, it typically publishes a relatively structured inquiry seeking rather specific information on certain relevant subjects.<sup>85</sup> If the Commission wishes to ascertain public policy preferences, it will typically undertake an opinion poll targeted at a demographically representative group of participants (including pollees from all member states).<sup>86</sup> The EU re-

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<sup>79</sup> Under the so-called "transmission belt" model, the mission of administrative agencies is purely technocratic, filling in the details of broad policy pronouncements promulgated by Congress. See Stewart, *supra* note 73, at 1675, 1684. Under this vision, the sole relevance of stakeholder input would derive from any technical information it might contain.

<sup>80</sup> Mendelson, *supra* note 61, at 1349–52.

<sup>81</sup> *A Guide to the Rulemaking Process*, OFF. FED. REG., [https://www.federalregister.gov/uploads/2011/01/the\\_rulemaking\\_process.pdf](https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf) (last visited Sept. 17, 2015).

<sup>82</sup> Mendelson, *supra* note 61, at 1358, 1360–61.

<sup>83</sup> See *U.S. Cellular Corp. v. FCC*, 254 F.3d 78, 87 (D.C. Cir. 2001); *Nat. Res. Def. Council v. EPA*, 822 F.2d 104, 122 n.17 (D.C. Cir. 1987).

<sup>84</sup> Mendelson, *supra* note 61, at 1346, 1362–63.

<sup>85</sup> STRAUSS ET AL., *supra* note 22, at 76–77.

<sup>86</sup> See *Flash Eurobarometer Reports*, EUR. COMMISSION, [http://ec.europa.eu/public\\_opinion/archives/flash\\_arch\\_390\\_375\\_en.htm](http://ec.europa.eu/public_opinion/archives/flash_arch_390_375_en.htm) (last updated Oct. 23, 2014).

gime is perhaps more rational than its U.S. counterpart insofar as it tailors its public input procedures in light of the type of information being sought (rather than relying exclusively on an open-ended comment process), but the Commission's methodology for weighing the outside input (technical and policy-oriented) against information developed by internal governmental experts and rendering a final decision is rather abstruse.<sup>87</sup> Moreover, since the European Union lacks any comprehensive system of judicial review, stakeholders have little recourse if governmental decisionmakers discount or ignore their input.<sup>88</sup>

### *E. Iterativeness*

In recent years, administrative law scholars and advocates of governmental reform have increasingly emphasized the problem of regulatory accretion: though any individual regulation may make eminent sense when initially adopted, the cumulative burden of regulations promulgated by various governmental authorities has grown increasingly ponderous over time and potentially stifles the market dynamism and creativity required to maintain a robust economy.<sup>89</sup> In this light, both U.S. and EU officials have implemented "regulatory look-back" initiatives designed to reassess existing regulations and determine whether they should be eliminated, modified, or strengthened in light of new information concerning their efficacy and burdensomeness. Specifically, in the United States, President Barack Obama has issued three executive orders directing executive branch agencies (and encouraging independent regulatory agencies) to adopt plans for periodically reevaluating existing regulation and implementing appropriate changes.<sup>90</sup> The EU Commission has adopted a program of

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<sup>87</sup> See Yves Mény, *Can Europe Be Democratic? Is It Feasible? Is It Necessary? Is the Present Situation Sustainable?*, 34 *FORDHAM INT'L L.J.* 1287, 1295 (2011).

<sup>88</sup> See STRAUSS ET AL., *supra* note 22, at 25–27.

<sup>89</sup> See, e.g., Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation*, in *NEW PERSPECTIVES ON REGULATION* 113, 113–14 (David Moss & John Cisternino eds., 2009); Sam Batkins & Ike Brannon, *The Need for Retrospective Review of Regulations*, *REGULATION*, Summer 2013, at 3, 3; Reeve T. Bull, *Building a Framework for Governance: Retrospective Review & Rulemaking Petitions*, 67 *ADMIN. L. REV.* 265 (2015); Cary Coglianese, *Moving Forward with Regulatory Lookback*, 30 *YALE J. ON REG. ONLINE* 57, 65 (2013); MICHAEL MANDEL & DIANA G. CAREW, *REGULATORY IMPROVEMENT COMMISSION: A POLITICALLY-VIABLE APPROACH TO U.S. REGULATORY REFORM* 1 (May 2013), <http://www.progressivepolicy.org/issues/economy/regulatory-improvement-commission-a-politically-viable-approach-to-u-s-regulatory-reform/>.

<sup>90</sup> Exec. Order No. 13,610, 3 C.F.R. § 258 (2013), *reprinted as amended* in 5 U.S.C. § 601 app. at 820 (2012); Exec. Order No. 13,579, 3 C.F.R. § 256 (2012), *reprinted as amended* in 5

“evaluation,” which entails reassessment of existing government programs with an eye toward making them “more effective, coherent, useful, relevant and efficient.”<sup>91</sup>

Given the decentralized expertise residing in the private sector, one would expect governmental decisionmakers to solicit and rely upon public input in connection with such retrospective review efforts. The Obama Administration executive orders on retrospective review create at least a limited role for public input, directing agencies to invite “public suggestions about regulations in need of retrospective review and about appropriate modifications to such regulations,”<sup>92</sup> but they do not mandate that agencies take any action in response to such input—unlike the notice-and-comment provisions of the Administrative Procedure Act (“APA”).<sup>93</sup> The EU Evaluation Standards provide that “[e]valuation results must be communicated effectively to all relevant decision-makers and other interested stakeholders/parties,”<sup>94</sup> but they do not require the relevant Directorates-General to solicit or consider input from private parties when conducting evaluation.<sup>95</sup>

In short, it appears that both the United States and European Union under-exploit public input in the “regulatory lookback” process and make much more extensive efforts to solicit feedback when adopting a new regulation than when reassessing an existing one. In that light, both systems might be made more iterative, opening new avenues for public participation and perhaps even creating new levers by which stakeholder groups can hold government regulators to account.

### III. OPPORTUNITIES FOR IMPROVEMENT THROUGH THE TTIP

As demonstrated in Part II, neither the U.S. nor the EU system has erected an ideal model for public participation in regulatory deci-

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U.S.C. § 601 app. at 817 (2012); Exec. Order No. 13,563, 3 C.F.R. § 215 (2012), *reprinted as amended in* 5 U.S.C. § 601 app. at 816 (2012).

<sup>91</sup> *Commission Communication on Evaluation Standards and Good Practice*, at 1, COM (2002) 5267 final (Dec. 23, 2002), [http://ec.europa.eu/smart-regulation/evaluation/docs/standards\\_c\\_2002\\_5267\\_final\\_en.pdf](http://ec.europa.eu/smart-regulation/evaluation/docs/standards_c_2002_5267_final_en.pdf).

<sup>92</sup> Exec. Order No. 13,610, § 2, 3 C.F.R. § 259.

<sup>93</sup> *Cf.* 5 U.S.C. § 553(c) (2012). Alternatively, members of the public could file a rulemaking petition requesting a change to existing regulations, which would require a response from the relevant agency. *See* 5 U.S.C. §§ 553(e), 555(e). *See generally* Bull, *supra* note 89 (proposing expanded use of petitions for rulemaking as a device for minimizing regulatory burdens while preserving the strong public welfare protections).

<sup>94</sup> *Commission Communication on Evaluation Standards and Good Practice*, *supra* note 91, at 5.

<sup>95</sup> *See id.* at 1.

sionmaking. In some instances, the two regimes have balanced the competing tradeoffs somewhat differently (e.g., the United States has adopted a more robust system of judicial review, rendering it more accountable to stakeholders but also more subject to “ossification”).<sup>96</sup> In other instances, neither side has fully captured the benefits that arise from robust public input (e.g., in the “regulatory lookback” context).<sup>97</sup> Thus, the TTIP negotiations represent an ideal opportunity for both sides to implement necessary improvements and to share insights arising from decades of experience in the regulatory arena.

Any effort to transpose the model prevailing in one system to the other, in addition to fueling objections of “imperialism,”<sup>98</sup> is unlikely to prove successful, given that the U.S. and EU regulatory models are sufficiently different that a public participation regimen designed for one system is unlikely to function effectively if grafted onto the other. At the other extreme, merely injecting international considerations into the preexisting regimes<sup>99</sup> is unlikely to work any sea change in the regulatory landscape absent any sustained effort to promote “buy-in” from both regulators and members of the public. If regulators have not internalized norms of public participation and fail to perceive the value that public input can provide, no amount of reform designed to increase or diversify such input will prove especially productive.<sup>100</sup> Members of the public, in turn, will grow dispirited and cease to participate if they do not feel that their input has any material effect on the regulatory decisionmaking process.<sup>101</sup>

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<sup>96</sup> See *supra* notes 32–35, 49 and accompanying text.

<sup>97</sup> See *supra* notes 92–94 and accompanying text.

<sup>98</sup> See, e.g., Jean-Luc Mélenchon, *The Giddiness of the Moment: On Facts and Words*, UNITED FOR PEACE OF PIERCE COUNTY. (May 24, 2013), <http://www.ufppc.org/us-a-world-news-mainmenu-35/11481-translation-melenchon-attacks-ttip-defends-casse-cul-rhetoric.html> (referring to the TTIP as “the annexation by the USA of our already smashed-up democracies”).

<sup>99</sup> The highest level U.S. commitment to international regulatory cooperation to date, President Obama’s Executive Order 13,609, does precisely this, urging agencies to take account of international considerations and tasking a working group with raising the profile of international issues but stopping short of creating any enforcement mechanism by which the President, the courts, or stakeholders can hold agencies accountable. See Exec. Order No. 13,609, 3 C.F.R. § 255 (2013), *reprinted as amended in* 5 U.S.C. § 601 app. at 819 (2012); see also EUROPEAN COMMISSION-UNITED STATES HIGH-LEVEL REGULATORY COOPERATION FORUM: REPORT OF THE 9TH MEETING 11 (Dec. 16, 2010), [https://www.whitehouse.gov/sites/default/files/omb/oir/irc/hlrcf\\_summary\\_report\\_december\\_2010.pdf](https://www.whitehouse.gov/sites/default/files/omb/oir/irc/hlrcf_summary_report_december_2010.pdf) (recognizing that the United States and the EU have different approaches and agreeing that international considerations are important, but not proposing any changes).

<sup>100</sup> See Stuart Minor Benjamin, *Evaluating E-Rulemaking: Public Participation and Political Institutions*, 55 DUKE L.J. 893, 912–13 (2006) (concluding that agencies will be disinclined to take public views into account).

<sup>101</sup> See *id.* at 921.

This Part sets forth various reform proposals designed to enhance public participation on both sides of the Atlantic. It examines the existing systems in light of the desiderata articulated in the previous Part, identifies where one or both regimes fall short, and then highlights relatively modest changes designed to promote more effective and valuable public participation. If executed properly, such reforms hold the potential not only to create new avenues for public input and to facilitate greater coordination between U.S. and EU regulators but also to decrease the burden on governmental decisionmakers by allowing them to more effectively leverage the expertise residing outside of government. This is imperative in obtaining the necessary “buy-in” on the part of regulators, who might otherwise view international regulatory cooperation and enhanced stakeholder input as an additional burden and drain of resources.

A. *U.S. agencies should remove unnecessary restrictions on early stakeholder input*

The EU Commission solicits stakeholder input quite early in the regulatory process, prior to formulating a draft regulation or directive.<sup>102</sup> In the United States, by contrast, the agency need not technically seek out public comments until the issuance of a notice of proposed rulemaking (“NPRM”).<sup>103</sup> U.S. agencies can (and do) obtain input from interested persons prior to the initiation of the formal notice-and-comment period,<sup>104</sup> but the process is far less inclusive and comprehensive than that provided under the APA. Early input is exceedingly valuable for both regulators and stakeholders because agency decisionmakers are more likely to be influenced by information furnished by outside parties prior to having completed a draft rule, at which point viewpoints may have become entrenched and officials may be less likely to entertain alternatives offered by stakeholders.<sup>105</sup>

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<sup>102</sup> STRAUSS ET AL., *supra* note 22, at 76. Notwithstanding its early solicitation of public input, the EU Commission may not be sufficiently accountable to stakeholders in integrating relevant information received into its decisionmaking process, as a subsequent subsection will address.

<sup>103</sup> 5 U.S.C. § 553(c) (2012).

<sup>104</sup> See, e.g., *Sierra Club v. Costle*, 657 F.2d 298, 400–01 (D.C. Cir. 1981). See also Paul R. Verkuil, *The Emerging Concept of Administrative Procedure*, 78 COLUM. L. REV. 258, 290 (1978).

<sup>105</sup> E. Donald Elliott, *Re-Inventing Rulemaking*, 41 DUKE L.J. 1490, 1494–95 (1992); Mark Seidenfeld, *A Civic Republican Justification for the Bureaucratic State*, 105 HARV. L. REV. 1511, 1560 (1992); see also Philip J. Harter, *Negotiating Regulations: A Cure for Malaise*, 71 GEO. L.J. 1, 25–26 (1982) (cataloguing agency efforts to obtain early stakeholder input); Jim Rossi, *Bar-gaining in the Shadow of Administrative Procedure: The Public Interest in Rulemaking Settlement*,

Thus, reforms to the U.S. system designed to promote pre-NPRM public input would further the goal of greater inclusiveness while ensuring that agencies receive relevant information at a time when it can maximally influence the decisionmaking process. The APA places no limit upon an agency's ability to procure outside input prior to the issuance of an NPRM.<sup>106</sup> Unfortunately, U.S. agencies have imposed certain supplemental restrictions and have perhaps interpreted potential legal restraints on outside consultation too broadly. First, several agencies have adopted limitations on *ex parte* contacts prior to issuance of an NPRM.<sup>107</sup> Second, a cursory reading of the Federal Advisory Committee Act ("FACA") might suggest that agencies cannot convene groups of stakeholders to provide input on questions of policymaking without complying with the strictures of the Act,<sup>108</sup> including chartering a committee (a process that can take several months)<sup>109</sup> and providing advance notice of all meetings.<sup>110</sup> As a general matter, merely obtaining input from interested stakeholders should not run afoul of FACA so long as the agency does not formally convene an advisory group designed to debate policy questions and offer overall group (rather than individualized) recommendations to the agency,<sup>111</sup> but agencies may avoid seeking external advice from any group of stakeholders out of an abundance of caution.

From this perspective, one potential goal of TTIP might be to eliminate unnecessary restrictions on early stakeholder consultation by U.S. agencies. Though U.S. agencies should not be required to solicit outside input prior to drafting a proposed rule, regulators should

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51 DUKE L.J. 1015, 1022 (2001) (praising negotiated rulemaking insofar as it provides an opportunity for public input prior to the official notice-and-comment period).

<sup>106</sup> *Costle*, 657 F.2d at 401–02.

<sup>107</sup> ESA L. SFERRA-BONISTALLI, *EX PARTE COMMUNICATIONS IN INFORMAL RULEMAKING* 39 (drft. Feb. 2014), <https://www.acus.gov/sites/default/files/documents/First%20Draft%20Ex%20Parte%20Report%20%5B2-20-14%5D.pdf> ("Agency practice seems to occur on a spectrum: some agencies permit or even welcome *ex parte* communications; other agencies discourage or refuse them.").

<sup>108</sup> 5 U.S.C. app. 2 § 3(2) (applying to any advisory committee convened for purposes of "obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government" and including at least one non-federal employee).

<sup>109</sup> *Id.* § 9(c); Bull, *supra* note 67, at 47–48.

<sup>110</sup> 5 U.S.C. app. 2 § 10(a)(2).

<sup>111</sup> *Ass'n of Am. Physicians & Surgeons, Inc. v. Clinton*, 997 F.2d 898, 913 (D.C. Cir. 1993) ("[A] group is a FACA advisory committee when it is asked to render advice or recommendations, *as a group*, and not as a collection of individuals."); *see also* *Judicial Watch, Inc. v. Clinton*, 76 F.3d 1232, 1233 (D.C. Cir. 1996) (noting that FACA does not apply to groups merely providing facts or information rather than policy advice, and "that [The Federal Advisory Committee Act] is only intended to reach committees that offer policy advice").

be made aware of the lack of any statutory restrictions and should be encouraged to seek out such input from stakeholders worldwide where it would be relevant and beneficial to the decisionmaking calculus (as the Administrative Conference has recommended).<sup>112</sup> This might occur in connection with an advance notice of proposed rulemaking<sup>113</sup> or may simply involve informal contacts between agency officials and private parties wishing to offer input. Finally, as will be explored more thoroughly in the following Subpart, when the agency reaches out to specific groups to provide input, it should seek a diversity of perspectives from a representative set of stakeholders (including foreign entities likely to be affected by a proposed rule).

*B. U.S. agencies should strive to achieve greater representativeness, whereas the EU Commission should promote wider inclusiveness*

Mindful of the risk of overgeneralization and the fact that the circumstances of individual regulatory actions will vary from case to case, the U.S. system is widely inclusive but not terribly representative,<sup>114</sup> whereas the EU system is perhaps more representative but not especially inclusive.<sup>115</sup> As explored in Part II, each system is susceptible to a significant risk of regulatory capture: well-financed parties tend to dominate the U.S. notice-and-comment process, whereas the collaborative EU process runs the risk of domination by repeat players who may reach mutually amenable bargains that ignore the views of unrepresented groups.<sup>116</sup> Moreover, neither system is necessarily ideal in yielding useful information: U.S. agencies are often flooded with a deluge of repetitive or unhelpful comments,<sup>117</sup> and the EU system may foreclose participation by groups with information that is

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<sup>112</sup> See ACUS Recommendation 2014-4, “Ex Parte” Communications in Informal Rulemaking, 79 Fed. Reg. 35,993, 35,995 (June 25, 2014) (“Agencies should not impose restrictions on ex parte communications before an NPRM is issued.”).

<sup>113</sup> See LUBBERS, *supra* note 20, at 188–90 (describing the circumstances in which agencies use advance notices of proposed rulemaking).

<sup>114</sup> See *id.* at 271–84 (discussing public participation in the rulemaking process); Fontana, *supra* note 30, at 85 (detailing the low level of public participation and representation in the rulemaking process); see also REGULATIONS.GOV, *supra* note 29 (publicly-facing website allowing for the submission of comments from any person).

<sup>115</sup> See STRAUSS ET AL., *supra* note 22, at 59–60, 74–75 (discussing the EU notice process “to inform those [the Directorates General] *determine to be stakeholders*.” (emphasis added)).

<sup>116</sup> See Fontana, *supra* note 30, at 85 (“[P]ublic participation in [U.S.] agency rulemaking. . . is . . . dominated by powerful interests” and “repeat player interest groups.”); STRAUSS ET AL., *supra* note 22, at 76–77 (discussing the difference between the American and European rulemaking processes).

<sup>117</sup> Cary Coglianese, *Citizen Participation in Rulemaking: Past, Present, and Future*, 55



quite relevant to the Commission's decisionmaking (particularly those located outside of the European Union).<sup>118</sup>

Ultimately, the likelihood that either the United States or European Union will fundamentally overhaul its primary system for procuring public input is small, given the fact that regulators and stakeholders have grown accustomed to the prevailing regimes and would likely oppose any overhaul.<sup>119</sup> Nevertheless, both the United States and European Union might supplement their predominant public participation mechanisms to achieve greater representativeness (in the United States) and inclusiveness (in the European Union). Specifically, in the United States, where a rulemaking is likely to affect a diverse group of stakeholders, only some of whom possess the resources to participate, the proposing agency might consider directly contacting representatives of underrepresented groups or forming an advisory committee including a diverse set of participants. In the European Union, the Directorate-General formulating a proposed regulation or directive might consider soliciting general public comments in addition to consulting with major stakeholder groups, which is unlikely to prove especially costly and may ultimately uncover relevant information that the more limited consultative process would have overlooked.<sup>120</sup>

In a select set of circumstances, wherein a proposed regulation is likely to affect a relatively discrete set of interests, both U.S. agencies and EU Directorates-General might consider undertaking a process similar to negotiated rulemaking.<sup>121</sup> Though negotiated rulemaking it-

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DUKE L.J. 943, 958–59 (2006); Mariano-Florentino Cuéllar, *Rethinking Regulatory Democracy*, 57 ADMIN. L. REV. 411, 486 (2005); Wagner, *supra* note 65, at 1334–35.

<sup>118</sup> See STRAUSS ET AL., *supra* note 22, at 80 (discussing European preference to deal with “established partners” and to “act in the general European interest”).

<sup>119</sup> In addition to the fact that parties that benefit from the existing state of affairs will lobby vociferously for its retention, as a result of the so-called endowment effect, individuals will, absent overwhelming evidence favoring a change, tend to prefer the status quo to any proposed alternative. DANIEL KAHNEMAN, THINKING, FAST AND SLOW 289–99 (2011).

<sup>120</sup> Earlier this year, the European Commission took a significant step in this direction with the release of its “Better Regulation” package. *Better Regulation for Better Results: An EU Agenda*, COM (2015) 215 final (May 19, 2015), [http://ec.europa.eu/smart-regulation/better-regulation/documents/com\\_2015\\_215\\_en.pdf](http://ec.europa.eu/smart-regulation/better-regulation/documents/com_2015_215_en.pdf). Among other things, the EU Commission has committed to providing an opportunity for stakeholder consultation both when undertaking new initiatives and after the Commission has produced draft text for new delegated acts and many implementing acts. *Id.* at 5.

<sup>121</sup> 5 U.S.C. §§ 561–70 (2012); ACUS Recommendation 85-5, 1 C.F.R. § 305.85-5 (1993); ACUS Recommendation 82-4, 1 C.F.R. § 305.82-4 (1993); C. Boyden Gray, *Upgrading Existing Regulatory Mechanisms for Transatlantic Regulatory Cooperation*, 78 LAW & CONTEMP. PROBS. (forthcoming 2015).

self has fallen into relative disuse in recent years,<sup>122</sup> the fundamental principles upon which it is based, including early input from stakeholders, responsiveness to private sector concerns, and balancing of regulatory tradeoffs,<sup>123</sup> remain quite salient, especially in the international regulatory context.<sup>124</sup> Thus, when a U.S. agency or EU Directorate-General is considering a regulation that might affect a discrete group of interests whose input is relevant to the drafting process and whose “buy-in” is critical to the success of the ultimate regulation, it may consider forming a committee including representatives from the key international stakeholders to discuss the relevant considerations and examine potential regulatory alternatives. Though tasking those stakeholders with preparing a draft rule, as in negotiated rulemaking,<sup>125</sup> may not prove viable,<sup>126</sup> undertaking some form of consultative process would both promote public-private collaboration and ensure that regulators consider the international impacts of potential regulations very early in the process.

*C. U.S. and EU regulators should more forthrightly state the role of public input in regulatory policymaking*

Though the administrative law literature has occasionally heralded public participation as an opportunity for “democratizing” the regulatory process and bringing accountability to unelected bureaucrats,<sup>127</sup> neither legal scholars nor regulators have fully reconciled the “technocratic” role of agencies with the pervasive sentiment that citizen input, even if effectively irrelevant to the technical function of

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<sup>122</sup> Jeffrey S. Lubbers, *Achieving Policymaking Consensus: The (Unfortunate) Waning of Negotiated Rulemaking*, 49 S. TEX. L. REV. 987, 996–1005 (2008) (citing various potential explanations for the decline of negotiated rulemaking in the United States).

<sup>123</sup> See DAVID M. PRITZKER & DEBORAH S. DALTON, NEGOTIATED RULEMAKING SOURCEBOOK 2–7 (1995); Harter, *supra* note 105, at 7.

<sup>124</sup> See, e.g., Marie Boyd, *Unequal Protection Under the Law: Why FDA Should Use Negotiated Rulemaking to Reform the Regulation of Generic Drugs*, 35 CARDOZO L. REV. 1525, 1566–67 (2014).

<sup>125</sup> 5 U.S.C. § 563(a) (2012).

<sup>126</sup> Professor Jeffrey Lubbers has catalogued various reasons for the decline of negotiated rulemaking in recent years (e.g., complications related to convening negotiated rulemaking committees in full compliance with FACA), and these challenges would generally remain applicable in the international context. Lubbers, *supra* note 122, at 996–1005.

<sup>127</sup> See, e.g., Michael Asimow, *On Pressing McNollgast to the Limits: The Problem of Regulatory Costs*, 57 LAW & CONTEMP. PROBS. 127, 129 (1994); Jacob E. Gersen & Anne Joseph O’Connell, *Deadlines in Administrative Law*, 156 U. PA. L. REV. 923, 972 (2008); Amanda Leiter, *Substance or Illusion? The Dangers of Imposing a Standing Threshold*, 97 GEO. L.J. 391, 415 (2009); Nina A. Mendelson, *Agency Burrowing: Entrenching Policies and Personnel Before a New President Arrives*, 78 N.Y.U. L. REV. 557, 664 (2003); Beth Simone Noveck, *The Electronic Revolution in Rulemaking*, 53 EMORY L.J. 433, 517 (2004).

agency decisionmakers, should somehow influence the decisionmaking process. As discussed in Part II, U.S. agencies typically ignore policy-focused comments that contain no relevant technical information; the EU Commission occasionally attempts to ascertain public policy preferences, but it has not been terribly transparent in articulating how it weighs those views along with the relevant technical considerations in reaching an ultimate determination.

Addressing the relevance of citizen policy preferences to the regulatory decisionmaking process is well beyond the scope of this Article.<sup>128</sup> In the same light, the TTIP negotiations are an unlikely forum for rethinking the precise role of the public in influencing U.S. or EU regulatory policymaking. Nevertheless, regulators may consider offering a clearer description of the downstream effects of public input on both technical issues and policy questions. Such a clarification is particularly appropriate in light of increased opportunities for international stakeholder participation: an EU entity filing a comment in connection with a U.S. agency rulemaking or a U.S. organization seeking to participate in a stakeholder consultation undertaken by the EU Commission may be largely unaware of how the regulator intends to utilize the information solicited, which may dissuade potential participants and frustrate those who feel that the regulatory decisionmaker improperly overlooked comments that they supplied.

In the United States, agencies should state forthrightly that public comments expressing assent or disagreement with a proposed course of action are irrelevant and that the agency reviews comments solely to glean information germane to the technical aspects of a regulatory problem.<sup>129</sup> United States agencies might borrow from the practices of the EU Commission, providing a structured set of inquiries in a request for comments indicating the precise questions on which the

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128 The author has, however, grappled with this issue in other articles. See generally Reeve T. Bull, *Developing a Domestic Framework for International Regulatory Cooperation*, 78 LAW & CONTEMP. PROBS. (forthcoming 2015), <http://ssrn.com/abstract=2636550>; Bull, *supra* note 52.

129 See, e.g., ADMIN. CONF. OF THE U.S., PUBLIC COMMENT POLICY 2, <http://www.acus.gov/sites/default/files/documents/Public%20Comment%20Policy.pdf> (“The comment process is not a vote. The Conference attempts to formulate the best policy, which is not necessarily the most popular policy.”); A Guide to the Rulemaking Process, *supra* note 81 (“The notice-and-comment process . . . is not like a ballot initiative or an up-or-down vote in a legislature. An agency is not permitted to base its final rule on the number of comments in support of the rule over those in opposition to it.”). If agencies actually wish to obtain policy-oriented input from the general public, administrative law scholars have offered a number of alternative approaches that are far superior to tabulating the comments received and selecting the option favored by a majority of participants. See generally, e.g., David J. Arkush, *Direct Republicanism in the Administrative Process*, 81 GEO. WASH. L. REV. 1458 (2013); Bull, *supra* note 52; Mendelson, *supra* note 61.

agency seeks input,<sup>130</sup> which should both promote more relevant comments and manage the expectations of stakeholders. In the European Union, the Commission should consider promulgating a document that provides an overview of its process for integrating technical and policy-oriented public input into the drafting of proposed regulations, directives, and delegated and implementing acts. Thereafter, once the Commission has promulgated a draft law, it should consider providing a brief explanation for its chosen course of action and a summary of how any public input received affected that determination, much as U.S. agencies do in preambles to final rules.<sup>131</sup> Though relatively modest, these reforms would help stakeholders navigate the regulatory process (something of particular value as U.S. stakeholders attempt to participate in the EU process and vice versa) and quell unrealistic expectations concerning the role of public input in regulatory decisionmaking.

*D. The EU Commission should expand opportunities for public input beyond the earliest policymaking stages and provide some explanation for how such input affects its ultimate decisionmaking*

Though judicial review of the sort practiced by U.S. federal courts arguably results in “ossification” of the regulatory process,<sup>132</sup> the lack of any mechanism by which EU stakeholders can hold regulators accountable for considering and responding to relevant input likely contributes to the inconsistent efforts of EU regulators to seek outside information.<sup>133</sup> In this light, the European Union may wish to consider creating additional levers for promoting regulatory accountability. Of course, as discussed in Part I.B, the Commission does not control the final form of a regulation, directive, or delegated act, given the role of the Parliament and Council in approving such legal instruments, but it could expand opportunities for dialogue between the Commission and stakeholders during the drafting of such laws.

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<sup>130</sup> STRAUSS ET AL., *supra* note 22, at 76–77.

<sup>131</sup> 5 U.S.C. § 553(c) (2012) (“[T]he agency shall incorporate in the rules adopted a concise general statement of their basis and purpose.”). Unfortunately, agency statements of basis and purpose have become anything but “concise” or “general” in recent years, yet this prolixity is largely a function of the agency’s attempts to ward off any challenge on judicial review. *See* LUBBERS, *supra* note 20, at 337–41. Given the lack of any similarly robust system of judicial review in the EU, the risk that such explanations will become excessively unwieldy seems to be considerably diminished.

<sup>132</sup> McGarity, *supra* note 35, at 1400–03, 1410–26.

<sup>133</sup> *See supra* notes 45–50 and accompanying text.

At present, the opportunity for stakeholder input is primarily limited to the early stages of the regulatory process, when a Directorate-General publishes a green paper setting forth a general outline of a potential regulation or directive.<sup>134</sup> Though this opportunity for early input is exceedingly valuable, as explored above, the proposal often changes significantly as it proceeds through the Commission, and stakeholders have limited opportunities to respond to any changes or comment on the document that ultimately goes to the Parliament or Council.<sup>135</sup> Thus, the Commission should consider expanding the opportunities for citizen participation to extend throughout the process, soliciting stakeholder input when considering regulating in a specific area (as it presently does) and also when it has settled upon draft text of a proposed lawmaking instrument.<sup>136</sup>

The Commission also should consider erecting some mechanism whereby a party that believes that information it has furnished has not been adequately addressed can seek an explanation for the decision reached.<sup>137</sup> Whether the challenging party can ultimately obtain judicial review if it feels that the Commission has not properly responded to its input requires a delicate balance between the need to ensure regulatory accountability and the risk of promoting excessive litigiousness and kneecapping regulators' efforts to act expeditiously. Nevertheless, merely expanding the opportunities for citizen input, even absent the ultimate threat of judicial review, should bring greater accountability and enhance the Commission's ability to leverage private sector expertise.

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<sup>134</sup> STRAUSS ET AL., *supra* note 22, at 59; Donnan, *supra* note 69 ("Both European and American business want to provide meaningful analysis for proposed EU legislation and regulation, but to do this we need to see and comment on the actual text that is being considered"). For delegated acts and implementing acts, the Commission is much less likely to solicit public input, though it has recently undertaken efforts to expand opportunities for stakeholder participation. *Report on European Governance (2003-2004)*, at 4-6, SEC (2004) 1153 (Sept. 22, 2004), [http://www.partizipation.at/fileadmin/media\\_data/Downloads/themen/report\\_governance\\_2003\\_2004\\_en.pdf](http://www.partizipation.at/fileadmin/media_data/Downloads/themen/report_governance_2003_2004_en.pdf) (Commission staff working document).

<sup>135</sup> See Donnan, *supra* note 69.

<sup>136</sup> See, e.g., Bignami, *supra* note 50, at 506-13 (proposing a notice-and-comment process to supplement existing comitology procedures in the EU). As previously noted, the European Commission now does solicit stakeholder input on many proposed pieces of secondary legislation (i.e., delegated and implementing acts), see *supra* note 120, though stakeholders that feel that the Commission has ignored their input still have few, if any, remedies.

<sup>137</sup> The author has proposed such a system in the U.S. international regulatory cooperation context, advocating a program whereby stakeholders who question either an agency's resolution of scientific issues or its decision on a matter of policy can file a petition requesting that the agency justify its position. See generally Bull, *supra* note 128. The European Commission might consider adopting a similar reform, regardless of whether stakeholders ultimately have an opportunity to challenge the regulatory action in court.

*E. Both U.S. and EU regulators should seek targeted opportunities for public input in retrospective review of existing laws*

As explored in Part II, though the United States and European Union have both undertaken “regulatory lookback” initiatives in recent years, the opportunities for public input are relatively modest in both systems, particularly in comparison to the public participation mechanisms available in connection with prospective regulation.<sup>138</sup> On one hand, this is perhaps appropriate: fully opening the doors to stakeholder challenges of existing regulations would potentially precipitate trench warfare between regulators and industry groups seeking to challenge any costly regulation (regardless of the economic and social benefits the regulation provides).<sup>139</sup> On the other hand, stakeholder input is especially relevant in the retrospective review context insofar as regulators lack the incentives (because they are deeply invested in existing regulations), expertise (because they may not realize how their regulations interact with those of other entities), and resources to carefully scrutinize their existing corpus of regulations.<sup>140</sup> Both the United States and European Union could benefit from expanded public participation in the “regulatory lookback” context, but they must balance this goal against the need for stability and the risks of regulatory paralysis and industry capture associated with excessive accountability.<sup>141</sup>

The author has proposed the expanded use of rulemaking petitions in U.S. retrospective review initiatives, urging agencies to allow regulated entities to file petitions proposing private sector-driven alternatives to traditional regulations.<sup>142</sup> Short of erecting a system by which regulated entities can petition for regulatory reform (which would be a rather novel innovation in the top-down oriented EU regime), governmental policymakers should attempt to leverage information residing in the private sector to the greatest extent practicable. For instance, following the recent efforts of U.S. agencies to design a more comprehensive framework for retrospective review in response to the Obama Administration Executive Orders, various think tanks and academic institutions have submitted public comments designed to highlight additional considerations agencies may have overlooked

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<sup>138</sup> See *supra* notes 90–95 and accompanying text.

<sup>139</sup> Bull, *supra* note 89, at 23.

<sup>140</sup> See *id.* at 16–20.

<sup>141</sup> See *id.* at 23.

<sup>142</sup> See generally *id.* at 29–37.

in crafting their retrospective review plans.<sup>143</sup> ACUS's recent recommendation on retrospective review urges U.S. agencies to make appropriate use of such outside expertise.<sup>144</sup> More ambitiously, a research team associated with PayPal has proposed using data analytics techniques to compile information concerning the effectiveness of existing programs and elucidate possible alternative approaches,<sup>145</sup> a functionality that would be exceedingly difficult for government agencies to develop in-house.

The extent to which U.S. and EU regulators actually empower regulated entities to challenge agency retrospective review plans for failure to consider relevant information submitted by private sector entities is an exceedingly delicate issue that is beyond the scope of the instant Article, but regulators should in all cases cast as wide an informational net as possible so as to make optimal use of outside expertise. This may involve solicitation of public comments, creation of advisory committees with representatives from key stakeholders, and any number of alternative mechanisms for soliciting relevant information.

### CONCLUSION

The TTIP represents an unprecedented opportunity not only to enhance trade flows between the United States and European Union but also to move beyond the parochial, domestically-focused mindset that has heretofore prevailed in the regulatory arena and create a robust, enduring framework for international regulatory cooperation. In order to achieve that goal, both parties must rethink the fundamental assumptions underlying their regulatory systems and consider reforms designed to retool national regulatory regimes to function in a globalized world. Focusing specifically on the benefits of public par-

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<sup>143</sup> JOSEPH E. ALDY, *LEARNING FROM EXPERIENCE: AN ASSESSMENT OF THE RETROSPECTIVE REVIEWS OF AGENCY RULES AND THE EVIDENCE FOR IMPROVING THE DESIGN AND IMPLEMENTATION OF REGULATORY POLICY* 25–26 (Nov. 17, 2014), <https://www.acus.gov/sites/default/files/documents/ALdy%2520Retro%2520Review%2520Draft%252011-17-2014.pdf>.

<sup>144</sup> ACUS Recommendation 2014-5, *Retrospective Review of Agency Rules*, 79 Fed. Reg. 75,114, 75,117 (Dec. 17, 2014); *see also* ALDY, *supra* note 143, at 7, 70.

<sup>145</sup> PAYPAL, INC., *21ST CENTURY REGULATION: PUTTING INNOVATION AT THE HEART OF PAYMENTS REGULATION* 14, 17, <http://www.ebaymainstreet.com/sites/default/files/PayPal-Payment-Regulations-Booklet-US.pdf> (“To address the shortcomings of the current landscape, regulators and policymakers need to emulate the best practices of the markets that they regulate. In the modern digital age, this means creating regulation that is collaborative and iterative; regulation that is outcome-focused and is not attached to any one technology, business model or operating model; and regulation that utilizes data analytics techniques to make regulatory decisions that keep pace with the rate that the market is developing.”).

ticipation, this Article has articulated a series of goals that should animate those reforms and offered a set of proposals to advance those policies. If executed properly, such reforms promise not only to promote greater convergence between U.S. and EU regulations but also to serve as a model for successful intergovernmental collaboration that can ideally be expanded worldwide as more and more nations come to realize the benefits of international regulatory cooperation.