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## *ARTICLES*

### HOW LITIGATION IMPORTS FOREIGN REGULATION

*Diego A. Zambrano\**

*Foreign regulators exert a powerful and deeply underestimated influence on American complex litigation. From the French Ministry of Health and the United Kingdom's National Health Services, to the Japanese Fair Trade Commission and the European Commission, foreign agencies have participated in some of the most important cases in the last two decades. The intersections between American litigation and foreign regulation range from plaintiff discovery requests of documents produced by or to foreign regulators, to coattail class actions against multinationals triggered by enforcement penalties abroad, all the way to foreign agency letters submitted to U.S. courts expressing an interest in a case. Indeed, dozens upon dozens of the most important multidistrict cases in the country—covering over 100,000 claims—have been influenced by foreign regulatory documents or enforcement actions. In this manner, litigation is importing foreign regulatory zeal to the United States. Yet few American legal actors*

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*know that foreign regulation affects domestic cases and even judges are unsure whether this practice is appropriate.*

*This Article presents a systematic study of the new relationship between foreign regulation and American litigation. The cross-border spread of litigation ideas sits at the center of broader debates about complex litigation, the regulatory role of multidistrict litigation, the recent trend of litigation isolationism, and the expanding role of discovery. The Article argues that litigation can import and domesticate foreign regulations, allowing private litigants to audit the work of captured domestic agencies. For instance, litigators can measure the work of the FDA against health regulators in France, or the work of the FTC against regulators in Germany. Litigation can also push U.S. law to match foreign regulation, promoting a rough harmonization across borders, coherence, and convergence. While the litigation-led use of foreign regulation promises a wealth of benefits for U.S. law, it has not been sufficiently recognized, nudged forward, or appreciated. The Article thus seeks to provide a solid theoretical footing for the incorporation of foreign regulations and argues that an understanding of litigation-led globalization clarifies scholarly debates in a variety of literatures. After this analysis, the Article also argues that courts should invite American regulators to help them decide whether to welcome or reject this foreign influence.*

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INTRODUCTION

In 2015, hundreds of pregnant mothers sued the pharmaceutical giant GlaxoSmithKline (“GSK”) in courts throughout the United States, alleging that the drug Zofran caused severe birth defects.<sup>1</sup> After the cases were consolidated into a massive multidistrict litigation, GSK argued there was no evidence that the drug caused birth defects and that even the Food and Drug Administration (“FDA”) had repeatedly rejected that

<sup>1</sup> In re Zofran (Ondansetron) Prods. Liab. Litig., 368 F. Supp. 3d 94, 98 (D. Mass. 2019).

link.<sup>2</sup> Lacking sufficient evidence and facing the prospect of an adverse summary judgment, the plaintiffs' case looked weak. But their claims came to hinge on a new source of evidence—discovered documents that defendants had produced in the 1990s to the Japanese Ministry of Health and Welfare, including a series of animal studies showing potential birth defects that defendants had “performed specifically to satisfy Japanese regulatory requirements.”<sup>3</sup> The use of discovery to uncover these communications allowed plaintiffs to defeat a motion for summary judgment, pegging their case to the content and application of Japanese regulations.<sup>4</sup>

Switching to a different context, in a series of spring press releases in 2017, Mexican antitrust regulators announced an investigation into seven banks, including three U.S. entities, for “price fixing and collusion in the government bond intermediation market.”<sup>5</sup> That announcement triggered a piggyback antitrust lawsuit in the United States against the three American banks: J.P. Morgan, Citibank, and Bank of America. All three defendants moved to dismiss the claim, arguing that plaintiffs' complaint did not meet *Twombly*'s pleading standard because there was no plausible allegation of a conspiracy.<sup>6</sup> Plaintiffs, among other things, responded that the Mexican investigation—and all of its potential documents—were a “plus factor” that makes their allegations more plausible.<sup>7</sup> Due to settlement negotiations and dismissal on other grounds, Judge Oetken ultimately did not decide whether the existence of a foreign investigation can nudge a plaintiff's claims beyond the plausibility requirement.<sup>8</sup>

*In re Zofran* and *In re Mexican Government Bonds* are just two of thousands of claims in the United States that have been heavily shaped by

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<sup>2</sup> *Id.*

<sup>3</sup> *Id.* at 108 (internal quotation marks omitted).

<sup>4</sup> *Id.* at 99.

<sup>5</sup> *In re Mexican Gov't Bonds Antitrust Litig.*, 412 F. Supp. 3d 380, 383–84 (S.D.N.Y. 2019) (internal quotation marks omitted).

<sup>6</sup> *Id.* at 387; *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545–46 (2007); Defendants' Memorandum of Law in Support of Their Joint Motion to Dismiss for Failure to State a Claim at 7–18, *In re Mexican Gov't Bonds*, 412 F. Supp. 3d 380 (No. 1:18-cv-02830).

<sup>7</sup> Plaintiffs' Memorandum of Law in Opposition to Defendant's Joint Motion to Dismiss the Consolidated Class Action Complaint for Failure to State a Claim at 18, *In re Mexican Gov't Bonds*, 412 F. Supp. 3d 380 (No. 1:18-cv-02830).

<sup>8</sup> *In re Mexican Gov't Bonds Antitrust Litig.*, No. 18-cv-2830, 2020 WL 7046837, at \*4 (S.D.N.Y. Nov. 30, 2020) (granting motion to dismiss on other grounds); *In re Mexican Gov't Bonds Antitrust Litig.*, No. 18-cv-02830, 2020 WL 7398747, at \*1 (S.D.N.Y. Dec. 16, 2020) (approving proposed settlement).

foreign regulations.<sup>9</sup> Indeed, foreign regulators have come to exert a powerful and underestimated influence on American litigation. From the French Ministry of Health and the United Kingdom's National Health Service, to the Japanese Fair Trade Commission and the European Commission, foreign agencies have shaped some of the most important cases in the last decade, ranging from antitrust claims, technology and privacy class actions, all the way to mass torts litigation.<sup>10</sup> The intersections between American litigation and foreign regulation include American discovery of documents produced to foreign regulators, coattail U.S. class actions against multinationals triggered by enforcement penalties abroad, and foreign agency letters submitted to U.S. district courts expressing an interest in a pending case.<sup>11</sup> Sometimes the relationship is more informal—American litigators draw on foreign case theories, strategies, and findings.

In this manner, litigation is discreetly importing foreign regulatory zeal to the United States. Yet few American legal actors know that foreign regulation is impacting American cases, and even judges are unsure whether this practice is appropriate.

This Article presents the first systematic study of the relationship between foreign regulation and American litigation. It lays out the wide array of intersections between these two legal institutions, showing that this is an important, extensive, and understudied phenomenon. Scholars have long debated the role of foreign law in a handful of U.S. cases dealing with the alien tort statute, constitutional interpretation, or sovereign immunity, among others.<sup>12</sup> But the literature has mostly

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<sup>9</sup> See *infra* Part I.

<sup>10</sup> See *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, No. 2:18-md-2846, 2019 WL 341909, at \*1 (S.D. Ohio Jan. 28, 2019) (National Health Services); *Eve v. Sandoz Pharm. Corp.*, No. 98-1429, 2001 U.S. Dist. LEXIS 4531, at \*71 (S.D. Ind. Mar. 7, 2001) (French Health Ministry); Plaintiffs' Reply in Support of Their Motions to Compel re: RFP No. 33 and Interrogatory No. 35 at 1, *In re Capacitors Antitrust Litig.*, 106 F. Supp. 3d 1051 (N.D. Cal. July 18, 2014) (No. 3:14-cv-03264) (Japanese and Korean Fair Trade Commissions); Special Master's Order Denying Motion of Direct Purchaser Class Plaintiffs to Compel Hitachi to Produce Foreign Regulatory Documents at 4, *In re TFT-LCD (Flat Panel) Antitrust Litig.*, 599 F. Supp. 2d 1179 (N.D. Cal. Apr. 26, 2011) (No. 3:07-md-01827) (European Commission).

<sup>11</sup> See *infra* Part I.

<sup>12</sup> See, e.g., *Roper v. Simmons*, 543 U.S. 551, 575–78 (2005) (constitutional interpretation); Hannah L. Buxbaum, *Transnational Regulatory Litigation*, 46 *Va. J. Int'l L.* 251, 253–54 (2006) (one hundred foreign-cubed securities suits); Cortelyou C. Kenney, *Measuring Transnational Human Rights*, 84 *Fordham L. Rev.* 1053, 1060 (2015) (sovereign immunity).

overlooked how *thousands* of domestic law claims rely extensively on foreign regulations.

More generally, the dominant view within the judiciary, led by the Supreme Court, has switched to skepticism of foreign law and foreign cases in U.S. courts.<sup>13</sup> And this view often transcends partisan lines. Addressing questions about the potential approval of a coronavirus vaccine in the United Kingdom, Speaker Pelosi recently argued that Americans could not rely on foreign regulators who were not “on par” with the U.S. Food and Drug Administration:

We have very stringent rules about the Food and Drug Administration here about clinical trials, timing, number of people etc[.], so that when a drug is approved by the FDA that it’s safe and efficacious, then it has the trust of the American people. . . . *My concern is that the UK’s system for that kind of judgment is not on par with ours.* So if Boris Johnson decides he’s going to approve a drug and this president embraces that, that’s the concern I have.<sup>14</sup>

Yet, despite this aversion to the importation of foreign law, American litigants routinely rely on foreign regulations to shape thousands of claims every year—even when foreign regulators disagree with U.S. regulators.<sup>15</sup> This Article highlights the hidden but powerful role that foreign regulations have occupied in complex litigation, a fact which should inform assumptions in an array of related literatures.<sup>16</sup>

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<sup>13</sup> See, e.g., *Animal Sci. Prods., Inc. v. Hebei Welcome Pharm. Co.*, 138 S. Ct. 1865, 1869 (2018) (declining to grant “conclusive effect” to a foreign government’s interpretation of its own law); *Bodum USA, Inc. v. La Cafetière, Inc.*, 621 F.3d 624, 628–29 (7th Cir. 2010); Pamela K. Bookman, *Litigation Isolationism*, 67 *Stan. L. Rev.* 1081, 1084–85 (2015); David J. Seipp, *Our Law, Their Law, History, and the Citation of Foreign Law*, 86 *B.U. L. Rev.* 1417, 1417 (2006); cf. *Kiobel v. Royal Dutch Petroleum Co.*, 569 U.S. 108, 124–25 (2013) (declining to apply the Alien Tort Statute extraterritorially). See also Maggie Gardner, “Foreignness”, 69 *DePaul L. Rev.* 469 (2020) (exploring what counts as a “foreign” case).

<sup>14</sup> Peter Beaumont & Sarah Boseley, *US Won’t Rely on UK for Covid Vaccine Safety Tests, Says Nancy Pelosi*, *Guardian* (Oct. 9, 2020, 1:28 PM), <https://www.theguardian.com/society/2020/oct/09/us-wont-rely-on-uk-for-covid-vaccine-safety-tests-says-nancy-pelosi> [<https://perma.cc/LQ3M-HRBZ>] (emphasis added).

<sup>15</sup> See, e.g., *Bodum*, 621 F.3d at 628, 630–31.

<sup>16</sup> See Gregory Shaffer, *Globalization and Social Protection: The Impact of EU and International Rules in the Ratcheting Up of U.S. Privacy Standards*, 25 *Yale J. Int’l L.* 1, 74–75 (2000) (suggesting that U.S. businesses’ wariness to EU regulation is partially rooted in “businesses’ experience with U.S. legal culture”); David P. Graham & Jacqueline M. Moen, *Discovery of Regulatory Information for Use in Private Products Liability Litigation: Getting Past the Road Blocks*, 27 *Wm. Mitchell L. Rev.* 653, 655 (2000) (discussing cross-border discovery).

Part I of the Article begins by outlining three major channels through which foreign regulation is creeping into complex litigation cases. One common channel involves cases with American plaintiffs against multinational defendants in which plaintiffs request in discovery *any documents that defendant produced to or received from foreign regulators*. The kicker is that often, plaintiffs are interested in these documents because some foreign regulators impose higher burdens of production than domestic ones. In this manner, plaintiffs can take advantage of more burdensome safety and efficacy requirements imposed by, say, France or Japan. These cases cover dozens of the most important multidistrict litigation suits (“MDL”), including hundreds of thousands of products liability claims over faulty blood filters,<sup>17</sup> anti-psychotic medications linked to diabetes,<sup>18</sup> contraceptives,<sup>19</sup> a drug that allegedly caused birth defects,<sup>20</sup> surgical mesh products,<sup>21</sup> talcum powder,<sup>22</sup> and a blood anticoagulant.<sup>23</sup> Importantly, through discovery in these cases, plaintiffs benefit from foreign regulations that exceed FDA requirements and effectively subject defendants to foreign regulations in U.S. courts.<sup>24</sup>

Section I.B outlines a second channel involving American plaintiffs riding on the coattails of foreign agency findings or enforcement. These cases arise when agencies in countries like France or Germany either file successful claims in their own courts against multinationals or publicize the results of a new investigation or study. These public filings prompt American plaintiffs to file analogous claims in the United States under domestic law, transforming foreign regulatory actions into U.S.

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<sup>17</sup> In re Bard IVC Filters Prods. Liab. Litig., 2020 WL 1166224, at \*1–2 (D. Ariz. Mar. 6, 2020).

<sup>18</sup> In re Seroquel Prods. Liab. Litig., 447 F. Supp. 2d 1376, 1378 (J.P.M.L. 2006).

<sup>19</sup> In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig., No. 3:09-md-02100, 2011 WL 6733952, at \*1 (S.D. Ill. Dec. 16, 2011).

<sup>20</sup> In re Zofran (Ondansetron) Prods. Liab. Litig., 368 F. Supp. 3d 94, 94–95, 107–08 (D. Mass. 2019).

<sup>21</sup> In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., 299 F.R.D. 502, 509 (S.D. Va. 2014).

<sup>22</sup> In re Johnson & Johnson Talcum Powder Prods., Mktg., Sales Prac. & Prods. Liab. Litig., No. 3:16-md-02738, 2017 WL 5196741, at \*1–2 (D.N.J. Nov. 6, 2017).

<sup>23</sup> In re Xarelto (Rivaroxaban) Prods. Liab. Litig., 65 F. Supp. 3d 1402, 1404 (J.P.M.L. 2014).

<sup>24</sup> This phenomenon is the reverse of cases in which foreign litigants seek to use our broad discovery system in aid of foreign cases. See Yanbai Andrea Wang, *Exporting American Discovery*, 87 U. Chi. L. Rev. 2089, 2092–93 (2020).

litigation.<sup>25</sup> For instance, a 2015 World Health Organization study, which found that glyphosate was likely a human carcinogen, triggered a massive and ongoing case against Monsanto over the glyphosate-based weed killer Roundup.<sup>26</sup> This WHO study was not only the spark for the case, but it has also shaped the entire path of the litigation, including complaints, media coverage, discovery, trial, and an ongoing battle of foreign regulators, in which both plaintiffs and defendant have submitted studies and evidence on foreign regulatory findings from dozens of countries.<sup>27</sup> Similarly, plaintiffs have filed an array of cases against tech companies over privacy violations, citing European data protection laws and enforcement actions. These privacy related claims may represent what one survey of general counsels calls “the next wave of class actions.”<sup>28</sup> These cases present a remarkable expansion of foreign regulatory influence on American litigation.<sup>29</sup>

The final channel discussed in Section I.C. is when foreign regulators file letters of interest in ongoing cases, primarily in the antitrust context. These cases also involve discovery of documents produced to foreign antitrust regulators. But, unlike the cases above, a foreign agency then files a letter with U.S. courts objecting to the alleged violation of sovereignty and requesting that the information be kept confidential. For instance, just in the past decade, plaintiffs have filed class action claims alleging price-fixing by multinational corporations in an array of industries like vitamins,<sup>30</sup> air freight,<sup>31</sup> metals,<sup>32</sup> credit cards,<sup>33</sup> and TV

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<sup>25</sup> It is worth noting that claims filed in the United States that do involve foreign law often become entangled with foreign regulatory agencies. See, e.g., *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241, 246 (2004).

<sup>26</sup> See Complaint at 2, 11–12, *Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037 (N.D. Cal. 2016) (No. 4:16-cv-00525), 2016 WL 11574934.

<sup>27</sup> Indeed, in the midst of these cases, dozens of foreign regulators have banned glyphosate. See *Where Is Glyphosate Banned?*, Baum Hedlund Aristei & Goldman PC, <https://www.baumhedlundlaw.com/toxic-tort-law/monsanto-roundup-lawsuit/where-is-glyphosate-banned/> [<https://perma.cc/XFA4-HG2T>] (last visited July 18, 2020).

<sup>28</sup> 2019 Carlton Fields Class Action Survey: Best Practices in Reducing Cost and Managing Risk in Class Action Litigation 4 (2019).

<sup>29</sup> See *infra* Parts I & II.

<sup>30</sup> *Animal Sci. Prods., Inc. v. Hebei Welcome Pharm. Co. Ltd.*, 138 S. Ct. 1865, 1867 (2018).

<sup>31</sup> *In re Air Cargo Shipping Servs. Antitrust Litig.*, No. 06-md-1175, 2014 WL 7882100, at \*1 (E.D.N.Y. Oct. 15, 2014).

<sup>32</sup> *In re Capacitors Antitrust Litig.*, 106 F. Supp. 3d 1051, 1058 (N.D. Cal. 2015).

<sup>33</sup> *In re Payment Card Interchange Fee & Merch. Disc. Antitrust Litig.*, 986 F. Supp. 2d 207, 213 (E.D.N.Y. 2013).

panels.<sup>34</sup> These cases prompted the Chinese Ministry of Commerce, the European Commission, the Korea Fair Trade Commission, and the Japanese Fair Trade Commission to write letters arguing that the disclosure of documents would weaken their antitrust laws.<sup>35</sup> In this manner, foreign regulators influence American law.<sup>36</sup>

These three channels show how U.S. litigants are taking advantage of foreign regulations to shape cases in U.S. courts. Most of the time it is plaintiffs that seek foreign input to counter the strategy of multinational companies that selectively reveal information to some regulators but not others. But defendants can also present foreign regulatory approvals as exculpatory, pushing against liability in U.S. court. On the whole, U.S. litigants are importing regulatory *information* and not necessarily legal standards. But this information is only generated due to different legal requirements and is inevitably tied to a set of foreign institutions set up to produce and enforce law. This interaction is therefore not solely epistemic. As I argue below, foreign regulatory information can have a substantive effect on U.S. law.

After documenting these channels, Part II of the Article explores the consequences of this litigation and foreign regulation interaction, with specific focus on the role of foreign law in U.S. court, multidistrict litigation, regulatory harmonization, and the so-called Brussels Effect. Scholars and courts have long wrestled with the influence of foreign law on American litigation,<sup>37</sup> and the rise of cross-border agency networks

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<sup>34</sup> In re TFT-LCD (Flat Panel) Antitrust Litig., 599 F. Supp. 2d 1179, 1183 (N.D. Cal. 2009).

<sup>35</sup> See *infra* notes 165, 169, 171 and accompanying text. This phenomenon represents one of myriad challenges posed by globalizing markets and the proliferation of antitrust law worldwide. See *F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 165 (2004).

<sup>36</sup> There is an older literature on the reverse phenomenon—the application of U.S. antitrust law abroad. See Jonathan T. Schmidt, Note, Keeping U.S. Courts Open to Foreign Antitrust Plaintiffs: A Hybrid Approach to the Effective Deterrence of International Cartels, 31 *Yale J. Int'l L.* 211, 221–22 (2006); Wolfgang Wurmnest, Foreign Private Plaintiffs, Global Conspiracies, and the Extraterritorial Application of U.S. Antitrust Law, 28 *Hastings Int'l & Comp. L. Rev.* 205 (2005).

<sup>37</sup> *Roper v. Simmons*, 543 U.S. 551, 578 (2005); Vicki C. Jackson, Constitutional Comparisons: Convergence, Resistance, Engagement, 119 *Harv. L. Rev.* 109, 116–24 (2005); Daniel J. Frank, Note, Constitutional Interpretation Revisited: The Effects of a Delicate Supreme Court Balance on the Inclusion of Foreign Law in American Jurisprudence, 92 *Iowa L. Rev.* 1037, 1064–69 (2007). For broader debates about foreign law in U.S. litigation, see, e.g., Jenny S. Martinez, Who's Afraid of International and Foreign Law?, 104 *Calif. L. Rev.* 1579 (2016) [hereinafter, Martinez, Who's Afraid?]; Ganesh Sitaraman, The Use and Abuse of Foreign Law in Constitutional Interpretation, 32 *Harv. J.L. & Pub. Pol'y* 653 (2009). In the most closely related work to date, David Noll argued that U.S. courts have promoted a policy

that promote regulatory convergence.<sup>38</sup> But these debates have not considered the ways in which American litigation can import foreign regulation. The Article argues that while this phenomenon promises a wealth of benefits for U.S. institutions, it has not been sufficiently recognized, appreciated, or nudged forward. The Article argues that litigation-led globalization clarifies debates in three areas:

In Section II.A, the Article provides a normative appraisal, arguing that litigation can borrow foreign regulatory information, a process that promises benefits and corrects the conventional wisdom about foreign law in U.S. courts.<sup>39</sup> One benefit is that private claims that draw on foreign regulators can serve as a “failsafe” when domestic regulators are captured. In that sense, this kind of litigation can improve and audit (or replace) the work of domestic regulators. For instance, litigators can measure the work of the FDA against health regulators in France, or the work of the FTC against regulators in Europe. This failsafe role is particularly important given that research shows the staggering amount of lobbying that takes place in the United States as compared to some European countries.<sup>40</sup> Moreover, these cases can also allow domestic regulators to draw on foreign expertise and improve domestic rules. For instance, in *In re Zofran*—involving agencies in the United Kingdom, Canada, and Japan—the judge personally submitted a comment to the FDA disclosing the facts of the case and urging the FDA to engage in rule-making “as expeditiously as possible.”<sup>41</sup> The use of foreign regulations to inform both

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whereby “U.S. regulatory systems are disabled in favor of regulation by other legal systems.” David L. Noll, *The New Conflicts Law*, 2 *Stan. J. Complex Litig.* 41, 44 (2014) [hereinafter Noll, *Conflicts*]. In this Article, however, I highlight how lower courts have allowed foreign regulation to *complement* domestic private enforcement.

<sup>38</sup> Paul Schiff Berman, *Global Legal Pluralism*, 80 *S. Cal. L. Rev.* 1155, 1224–25 (2007); Eric C. Chaffee, *The Internationalization of Securities Regulation: The United States Government’s Role in Regulating the Global Capital Markets*, 5 *J. Bus. & Tech. L.* 187, 193–95 (2010).

<sup>39</sup> See, e.g., Jackson, *supra* note 37, 116–18; Stephen C. Yeazell, *When and How U.S. Courts Should Cite Foreign Law*, 26 *Const. Comment.* 59, 67 (2009) [hereinafter Yeazell, *Foreign Law*]; Eugene Volokh, *Foreign Law in American Courts*, 66 *Okla. L. Rev.* 219, 227 (2014). The Article contributes to a literature examining the relationship between foreign and domestic regulation. See, e.g., Jason Marisam, *The Internationalization of Agency Actions*, 83 *Fordham L. Rev.* 1909 (2015); Buxbaum, *supra* note 12.

<sup>40</sup> Anu Bradford, *The Brussels Effect: How the European Union Rules the World* 251 (2019) [hereinafter Bradford, *Brussels Effect Book*].

<sup>41</sup> Letter from F. Dennis Saylor, IV, C.J. D. Mass., to Stacy Cline Amin, Chief Counsel, FDA (Dec. 13, 2019).

tort liability and rulemaking exemplifies how litigation can domesticate the fruits of foreign regulations.

A sustained focus on litigation as an agent of globalization also highlights the understudied interaction between multidistrict litigation and foreign law.<sup>42</sup> The federal multidistrict statute, 28 U.S.C. § 1407, allows a panel of federal judges to consolidate thousands of related cases.<sup>43</sup> Most of the literature has focused on the domestic impact of this consolidation.<sup>44</sup> But it appears that foreign regulations have been at the core of some of the most important multidistrict litigation cases in the past decade, raising questions about the inner workings of MDLs and discovery. By uncovering and breaking down this process, the Article urges scholars to further explore the interaction between MDLs and foreign law.<sup>45</sup>

Section II.B of the Article then shows that litigation can be a surprising vehicle for regulatory harmonization, borrowing from and contributing to a literature on global administrative law.<sup>46</sup> Recent works have explored

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<sup>42</sup> The one explicit comment about this phenomenon notes that evidentiary rulings usually exclude foreign regulatory evidence but fails to recognize that earlier *discovery* rulings typically allow it. See Mark Herrmann & David B. Alden, *Drug & Device Product Liability Litigation Strategy* 383 (2012).

<sup>43</sup> 28 U.S.C. § 1407 (2018); see, e.g., Nora Freeman Engstrom, *The Lessons of Lone Pine*, 129 *Yale L.J.* 2, 7 (2019) (discussing the literature) [hereinafter Engstrom, *Lone Pine*].

<sup>44</sup> See Engstrom, *Lone Pine*, *supra* note 43; Elizabeth Chamblee Burch, *Remanding Multidistrict Litigation*, 75 *La. L. Rev.* 399 (2014); Elizabeth Chamblee Burch & Margaret S. Williams, *Judicial Adjuncts in Multidistrict Litigation*, 120 *Colum. L. Rev.* 2129 (2020); Andrew D. Bradt, *The Long Arm of Multidistrict Litigation*, 59 *Wm. & Mary L. Rev.* 1165 (2018).

<sup>45</sup> For samples of the existing literature on this relationship, see, e.g., Cassandra Burke Robertson, *Transnational Litigation and Institutional Choice*, 51 *B.C. L. Rev.* 1081 (2010).

<sup>46</sup> See generally Daniel W. Drezner, *Globalization, Harmonization, and Competition: The Different Pathways to Policy Convergence*, 12 *J. Eur. Pub. Pol'y* 841 (2005) (considering the role of agencies in enhancing international regulatory harmonization); Beth Simmons, *The International Politics of Harmonization: The Case of Capital Market Regulation*, in *Dynamics of Regulatory Change: How Globalization Affects National Regulatory Policies* 42, 50–52 (David Vogel & Robert A. Kagan eds., 2004) (outlining challenges in regulating international capital markets); Jean Galbraith & David Zaring, *Soft Law as Foreign Relations Law*, 99 *Cornell L. Rev.* 735 (2014) [hereinafter Galbraith & Zaring, *Soft Law*] (recharacterizing “soft law” as the intersection of administrative and foreign relations law); Gabriella Blum, *Bilateralism, Multilateralism, and the Architecture of International Law*, 49 *Harv. Int'l L.J.* 323 (2008) (discussing the role of bureaucracies in shaping international treaty law); Anne-Marie Slaughter, *Sovereignty and Power in a Networked World Order*, 40 *Stan. J. Int'l L.* 283 (2004) (arguing that international cooperation enhances, rather than diminishes, state sovereignty); Lawrence L.C. Lee, *The Basle Accords as Soft Law: Strengthening International Banking Supervision*, 39 *Va. J. Int'l L.* 1 (1998) (recounting international movements against financial regulation and considering novel sources of international governance).

the ways in which regulators develop transnational links that translate into common domestic regulatory agendas.<sup>47</sup> This is especially true during global events like the 2008 financial crisis, in which the Federal Reserve coordinated its response with European agencies.<sup>48</sup> But this Article argues that, because U.S. litigation often assumes the role of regulation, we should also expect litigation to serve as a vehicle of regulatory harmonization.<sup>49</sup> And, as I show below, litigation may already be playing that role.<sup>50</sup>

This litigation-led harmonization also challenges traditional views about U.S. adversarial legalism, as compared to European bureaucratic legalism.<sup>51</sup> While much has been made of the differences between *ex post* private enforcement and *ex ante* regulation, the cases discussed here show that there can be substantial overlap and dialogue between the two systems.<sup>52</sup> This straightforward finding may have implications for political theory and congressional choices.

Finally, Section II.C. joins a growing scholarly literature that aims to rethink the scope of global, cross-border regulation, with specific focus on the so-called Brussels Effect.<sup>53</sup> Some recent works argue that the European Union successfully exports its regulations to the rest of the world in a variety of ways.<sup>54</sup> While that literature sets private litigation

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<sup>47</sup> See generally Bradford, *Brussels Effect Book*, *supra* note 40 (chronicling this phenomenon).

<sup>48</sup> See Galbraith & Zaring, *Soft Law*, *supra* note 46, at 737.

<sup>49</sup> See *infra* Subsection II.B.1.

<sup>50</sup> See *infra* Subsection II.B.2.

<sup>51</sup> See, e.g., Robert A. Kagan, *Adversarial Legalism: The American Way of Law* 3–4 (2001); Sean Farhang, *The Litigation State: Public Regulation and Private Lawsuits in the U.S.* (2010); William M. Landes & Richard A. Posner, *The Private Enforcement of Law*, 4 *J. Legal Stud.* 1 (1975).

<sup>52</sup> See *infra* Subsection II.A.2.

<sup>53</sup> See generally Anu Bradford, *The Brussels Effect*, 107 *Nw. U. L. Rev.* 1, 51–52 (2012) [hereinafter Bradford, *Brussels Effect Article*] (arguing that the European Union has exercised an outside influence on global regulatory agendas by effectively exporting EU regulation to the rest of the world); Paul M. Schwartz, *The EU-U.S. Privacy Collision: A Turn to Institutions and Procedures*, 126 *Harv. L. Rev.* 1966 (2013) (arguing that Internet law has emerged as an area of significant cross-border regulation); Stephen J. Choi & Andrew T. Guzman, *Portable Reciprocity: Rethinking the International Reach of Securities Regulation*, 71 *S. Cal. L. Rev.* 903 (1998) (arguing in favor of international regulatory competition in securities law); Carla L. Reyes, Note, *The U.S. Discovery-EU Privacy Directive Conflict: Constructing a Three-Tiered Compliance Strategy*, 19 *Duke J. Comp. & Int'l L.* 357 (2009) (discussing the challenges of incongruent regulatory schemes governing discovery in transnational litigation between U.S. and EU litigants).

<sup>54</sup> Bradford, *Brussels Effect Article*, *supra* note 53, at 5–6.

aside, this Article shows that the Brussels Effect may be both larger and narrower than previously understood. On the one hand, when litigants request documents produced to European regulators, including in data protection cases, those regulators are de facto exporting their agendas to the American legal system. This influence strengthens the scope and impact of the Brussels Effect. On the other hand, perhaps a better way to view this phenomenon is that American courts and litigants are voluntarily importing foreign regulations through complex litigation, giving judges and litigants a large role in determining the reach of the Brussels Effect.

Foreign regulations, in short, can have an array of legal, economic, and political effects on U.S. law and institutions. This sustained focus on foreign regulations is timely. The weakening of multilateralism and the U.S. administrative state calls for new avenues of cross-border legal interaction.<sup>55</sup> The Article demonstrates the power and promise of litigation-led harmonization.

After analyzing the implications of litigation as a tool for importing foreign regulation, Part III of the Article focuses on prescriptions, arguing that courts should invite domestic agencies to submit letters in these cases. Much of the literature frames the influence of foreign law on American courts as an either-or phenomenon: the internationalists encourage U.S. courts to use foreign law,<sup>56</sup> while the nationalists decry the legitimacy of such an exercise.<sup>57</sup> But this has always been, and continues to be, a false dichotomy in the context of litigation. We cannot decide ex ante that it is universally proper or improper to draw on foreign regulations. Rather, we should create better procedures to channel and control foreign regulatory input. The Article argues that domestic agencies can help courts understand—through the submission of letters or amicus briefs—the use and implications of foreign regulations in litigation.

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<sup>55</sup> These developments have prompted a substantial body of literature that has called for such interaction in a variety of contexts. See, e.g., Harold James, *International Order after the Financial Crisis*, 1 Penn. St. J.L. & Int'l Affs. 275, 283–84 (2012) (calling for cross-border collaboration in the economic regulation context); Paul M. Schwartz & Karl-Nikolaus Peifer, *Transatlantic Data Privacy Law*, 106 Geo. L.J. 115, 179 (2017) (calling for cross-border collaboration in the data privacy context).

<sup>56</sup> See Martinez, *Who's Afraid?*, supra note 37, at 1583; Harold Hongju Koh, *Is International Law Really State Law?*, 111 Harv. L. Rev. 1824, 1824 (1998).

<sup>57</sup> See, e.g., Curtis A. Bradley, *International Delegations, the Structural Constitution, and Non-Self-Execution*, 55 Stan. L. Rev. 1557, 1560 (2003).

Lastly, a word about this Article's methodology is appropriate. I draw unique insights here from an in-depth examination of hundreds of MDL cases, dozens of foreign regulatory enforcement actions, a review of legal documents citing foreign regulation or regulators, and unstructured correspondence and interviews with plaintiffs' attorneys who appeared in the relevant cases. The Article further explains the specific methods applied in each section below.

The Article proceeds in three parts. Part I discusses the three channels of interaction between U.S. litigation and foreign regulation. Part II argues that these interactions have a wide array of effects on U.S. law, courts, and institutions. Finally, Part III argues that courts should invite domestic agency input in these cases.

#### I. IDENTIFYING THE INTERSECTIONS: FOREIGN REGULATORS IN AMERICAN LITIGATION

This Part outlines the three major channels of foreign regulatory interaction with domestic complex litigation: Section I.A on discovery of foreign regulatory documents, Section I.B on coattail claims and emulation of foreign regulatory actions, and Section I.C on foreign letters of interest. All three channels raise questions about the appropriate role of foreign regulators in U.S. litigation, the uniquely powerful role of complex litigation in shaping American law and institutions, and the supposed distinctions between regulation and litigation. Although I divide the phenomenon into three channels, ultimately, they cover the same activity: U.S. litigants borrowing information from foreign regulators.

Before those three Sections, let me briefly discuss why foreign regulation can be a unique source of information that is worthy of sustained legal focus; and then, the project's limitations.

There are at least three reasons why we should care about foreign regulatory actions. First, foreign government officials and agencies have "moral" and "normative authority" that private entities lack.<sup>58</sup> When government officials enforce the law, they carry the coercive power of a sovereign, with all its attendant consequences for foreign affairs, democracy, and the domestic law on foreign relations. For example, corporate documents produced to foreign regulators often reflect specific requests made by those regulators. Those requests are, in turn, made possible by specific legal provisions, foreign agency budgets,

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<sup>58</sup> Volokh, *supra* note 39, at 224.

enforcement powers, staffing, statutory authorization, and regulatory priorities. Thus, documents produced to foreign regulators would not be generated *but for* an edifice of foreign law and its coercive power. Moreover, when a foreign government regulates conduct, its decisions carry weight that may be persuasive for U.S. juries or judges. We should thus treat the influence of foreign regulators as a distinct phenomenon with normative implications.

Second, foreign regulatory actions reflect the political preferences of foreign governments and citizens that may be at odds with decisions of U.S. domestic regulators. When French or German agencies enforce claims against a particular industry—like technology companies—those actions reflect public choices informed by their political economy, the structure of their administrative states, lobbying, and other domestic events.<sup>59</sup> Europeans, for instance, may be biased or protectionist against American tech companies.

Third, domestic litigation involving foreign regulators implicates many fields, including civil procedure, evidence, and foreign relations law. This clash generates difficult questions. Suppose, for instance, that French regulations require that any pharmaceutical manufacturer go through an extended three-year process with multiple studies for reliability. Suppose too that the American FDA only requires a one-year process and a single study. Suppose plaintiffs file a claim against a multinational defendant that involves defendants' knowledge of a drug's potential harm—known *only* through multiple studies—and request all documents produced to the French regulator. In those circumstances, the FDA standards lose relevance, and the key torts question—whether the defendant “knew or had reason to know” that their product was defective—will hinge on information created pursuant to French law. Issues like this simply do not arise when other information (not involving foreign regulation) is at stake.

With that said, a few points of clarification are in order. As an initial matter, the three channels I discuss are not the exclusive means by which foreign regulation influences American civil cases. Below I explain the methods by which I constructed each channel, but I note that the project's main goal was to identify the most salient ways by which foreign regulation impacts and becomes a part of U.S. cases. Methodologically, I engaged in an iterative review of legal documents that cite either to foreign regulation or regulators. I then followed this with correspondence

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<sup>59</sup> See Bradford, Brussels Effect Article, *supra* note 53, at 3–4.

and calls with plaintiffs' attorneys involved in the relevant cases. Still, the project did not seek to comprehensively map the overlap of foreign regulation and litigation.

The channels do, however, represent a hidden influence that is entirely distinct from existing ways by which foreign law enters U.S. court. Scholars have explored how Supreme Court Justices sometimes construe the Constitution through analogies to foreign decisions,<sup>60</sup> how U.S. courts must apply foreign law due to a choice-of-law or conflicts of law analysis, or even when a treaty or statute explicitly refers to foreign law.<sup>61</sup> Below, however, I focus instead on domestic cases where the only foreign element is that defendants are companies subject to multiple regulatory regimes. In these cases, foreign regulation can influence case outcomes. And, numerically, the cases below cover hundreds of thousands of claims incorporating foreign regulations *en masse*. The three channels that I discuss illuminate the effect that foreign regulation can exert on domestic litigation.

#### *A. Discovery of Foreign Regulatory Documents*

One common channel of interaction involves cases with American plaintiffs against multinational defendants in which plaintiffs request foreign regulatory documents. In these cases, plaintiffs survive an early motion to dismiss, get swept into a multidistrict litigation, and then, during discovery, seek as much information as possible about defendants' alleged misdeeds. Using discovery rules that allow broad requests for any potentially relevant documents, plaintiffs often seek *any documents that defendant previously produced to foreign regulators*, including materials prepared and produced *solely for the purpose of complying with foreign regulations*.<sup>62</sup> The interesting twist is that plaintiffs often take advantage of foreign regulations that are more burdensome than American regulations, thereby circumventing the comparatively light hand of America's regulatory state. As discussed below, these cases tend to involve products liability claims and foreign pharmaceutical regulations that sometimes exceed FDA requirements.

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<sup>60</sup> See *supra* note 37.

<sup>61</sup> Restatement (Second) of Conflict of Laws § 2 cmt. a (Am. L. Inst. 1971); Yeazell, *supra* note 39, at 60–61; Volokh, *supra* note 39, at 227–31; Noll, Conflicts, *supra* note 37.

<sup>62</sup> See, e.g., *In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 181 F. Supp. 3d 278, 306–07 (E.D. Pa. 2016); *In re Seroquel Prods. Liab. Litig.*, 601 F. Supp. 2d 1313, 1318–19 (M.D. Fla. 2009).

Over the last few decades, courts have expanded discovery's transnational reach, usually dismissing arguments about burden, scope, or relevancy. Indeed, American discovery has grown truly global despite many efforts by reformers to regulate or limit cross-border information flows.<sup>63</sup> Today, during a run-of-the-mill case in U.S. court, plaintiffs can request discovery of defendants' documents anywhere in the world.<sup>64</sup> Transnational discovery requests must seek material that is (1) "relevant to any party's claim or defense,"<sup>65</sup> (2) "proportional to the needs of the case,"<sup>66</sup> and (3) in the possession, custody, or control of the defendant.<sup>67</sup> Typically, defendants argue either that the materials are not "relevant," are unlikely to yield admissible evidence, or that it would be overly burdensome to find and produce documents that are located abroad.

Given the requirements of the discovery rules, foreign regulatory materials have been particularly relevant in litigation of medical products liability claims.<sup>68</sup> Although there is substantial FDA preemption in this context, state tort law generally governs these drug or products liability claims.<sup>69</sup> In such cases, questions of notice and causation tend to be central issues that can resolve failure to warn, negligent manufacturing, or strict liability causes of action. Moreover, the United States' distinctive *ex post* approach to products liability frees plaintiffs to file their claims even if foreign agencies or the FDA already regulate a given product.<sup>70</sup>

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<sup>63</sup> Diego Zambrano, *A Comity of Errors: The Rise, Fall, and Return of International Comity in Transnational Discovery*, 34 *Berkeley J. Int'l L.* 157, 198–99 (2016) [hereinafter Zambrano, Comity]. See also Wang, *supra* note 24, at 2154–55 (calling for cross-border information sharing). Much of this may also be influenced by the specifics of e-discovery which makes it easier to access information stored abroad. Cf. Seth Katsuya Endo, *Discovery Hydraulics*, 52 *U.C. Davis L. Rev.* 1317 (2019) (discussing the unexpected consequences of e-discovery).

<sup>64</sup> See Zambrano, Comity, *supra* note 63, at 167 (citing *First City, Tex.-Hous., N.A. v. Rafidain Bank*, 281 F.3d 48, 54 (2d Cir. 2002)).

<sup>65</sup> Fed. R. Civ. P. 26(b)(1).

<sup>66</sup> *Id.*

<sup>67</sup> Zambrano, Comity, *supra* note 63, at 164–65.

<sup>68</sup> Others have noted that this area of law involves constant procedural experimentation. See, e.g., Engstrom, *Lone Pine*, *supra* note 43, at 9–10; Elizabeth Chamblee Burch, *Nudges and Norms in Multidistrict Litigation: A Response to Engstrom*, *Yale L.J.F.* 64, 67 (2019), <https://www.yalelawjournal.org/forum/nudges-and-norms-in-multidistrict-litigation> [<https://perma.cc/TNJ7-53EL>].

<sup>69</sup> State tort law provides an interesting and useful avenue for "fraud-on-the-FDA" claims that would normally be preempted. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

<sup>70</sup> See, e.g., Mathias Reimann, *Liability for Defective Products at the Beginning of the Twenty-First Century: Emergence of a Worldwide Standard?*, 51 *Am. J. Comp. L.* 751, 810 (2003).

And, because these are common law tort claims, judges have substantial flexibility to innovate, embrace new sources of information, and guide the law to new frontiers.<sup>71</sup>

For these reasons, information produced to foreign regulators can be highly relevant—potentially revealing “what Defendants knew about the potential risks of the products at issue here, when Defendants knew about those potential risks, what follow-up investigations Defendants did to learn more about those potential risks, and other facts . . . .”<sup>72</sup> Indeed, over forty MDL cases in the past fifteen years have involved significant requests for documents produced to foreign regulators.<sup>73</sup> Notable cases include roughly eight thousand claims over faulty blood filters,<sup>74</sup> eight thousand claims over anti-psychotic medications that allegedly caused diabetes,<sup>75</sup> twelve thousand claims over contraceptives that allegedly contributed to cardiovascular events,<sup>76</sup> forty-thousand claims over complications related to surgical mesh products,<sup>77</sup> thousands of claims

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<sup>71</sup> Of course, there is a distinction between information generated internally by the company and information generated only to satisfy foreign regulatory requirements. For information that exists regardless of foreign regulation, the policy question discussed in Part II is whether (i) we welcome any information that increases the likelihood that courts will make fully informed decisions or (ii) mindful of the costs and benefits of such laws, we want to confine litigation to that which can be sustained by the ingenuity of the plaintiffs themselves, even at the expense of reducing punishment for bad acts. I thank Doug Melamed for some of the details here.

<sup>72</sup> *Hardy v. Pharmacia Corp.*, No. 4:09-cv-119, 2011 WL 2118983, at \*3 (M.D. Ga. May 27, 2011).

<sup>73</sup> See Apps. I–II.

<sup>74</sup> *In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02651, 2020 WL 1166224, at \*1 (D. Ariz. Mar. 6, 2020).

<sup>75</sup> *In re Seroquel Prods. Liab. Litig.*, 447 F. Supp. 2d 1376, 1378 (J.P.M.L. 2006); U.S. Jud. Panel on Multidistrict Litig., *Multidistrict Litigation Terminated Through September 30, 2020*, [https://www.jpml.uscourts.gov/sites/jpml/files/Cumulative%20Terminated%202020\\_0.pdf](https://www.jpml.uscourts.gov/sites/jpml/files/Cumulative%20Terminated%202020_0.pdf) (last visited Apr. 18, 2021) [<https://perma.cc/3BT4-PPP8>].

<sup>76</sup> *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practs. & Prods. Liab. Litig.*, No. 09-20021, 2011 WL 6733952, at \*1 (S.D. Ill. Dec. 16, 2011); U.S. Jud. Panel on Multidistrict Litig., *supra* note 75.

<sup>77</sup> *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 299 F.R.D. 502, 508–09 (S.D. W. Va. 2014); U.S. Jud. Panel on Multidistrict Litig., *MDL Statistics Report—Distribution of Pending MDL Dockets by Actions Pending*, [https://www.jpml.uscourts.gov/sites/jpml/files/Pending\\_MDL\\_Dockets\\_By\\_Actions\\_Pending-March-15-2021.pdf](https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_Actions_Pending-March-15-2021.pdf) (last visited Apr. 18, 2021) [<https://perma.cc/3ZX9-YALU>].

over allegedly cancerous talcum powder,<sup>78</sup> and thirty-one thousand claims over an anti-coagulant that allegedly led to excessive bleeding.<sup>79</sup>

Plaintiffs' requests have sought information produced to agencies in the United Kingdom, Canada, France, the Netherlands, Germany, Japan, Australia, South Korea, New Zealand, Sweden, Denmark, Ireland, Jordan, Lebanon, and Mexico.<sup>80</sup> Plaintiffs argued that information produced to foreign agencies would demonstrate defendants' knowledge of their products' dangers.<sup>81</sup> Requests ranged from open-ended productions of "all communications" between defendants and "foreign regulatory authorities"<sup>82</sup> to the much narrower "official regulatory file containing the communications and submissions between Defendants' implicated subsidiary or affiliate and the regulatory authority at issue."<sup>83</sup>

Procedurally, requesting documents specifically produced to foreign regulators is a discovery thermonuclear device—the requests are likely to be granted for several reasons. First, plaintiffs can argue that their requests are narrowly tailored and relevant because they identify specific documents that were produced in the past to specific regulators. Moreover, the fact that they have been produced to foreign regulators is a strong signal that the documents are likely relevant to a products liability claim. Second, plaintiffs can also argue that production should not be burdensome because defendants have already assembled and produced the documents. Finally, plaintiffs can argue that the documents should not be privileged because they have already been produced to third-party foreign regulators.<sup>84</sup> In this manner, plaintiffs pack a compelling demand: a narrowly tailored and relevant request that covers documents that might not be privileged.

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<sup>78</sup> *In re Johnson & Johnson Talcum Powder Prods., Mktg., Sales Prac. & Prods. Liab. Litig.*, No. 3:16-md-02738, 2017 WL 5196741, at \*1 (D.N.J. Nov. 6, 2017).

<sup>79</sup> *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 65 F. Supp. 3d 1402, 1403–04 (J.P.M.L. 2014); U.S. Jud. Panel on Multidistrict Litig., *supra* note 77.

<sup>80</sup> See Apps. I–II.

<sup>81</sup> *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prods. Liab. Litig.*, 181 F. Supp. 3d 278, 307 (E.D. Pa. 2016).

<sup>82</sup> *In re Bard IVC Filters Prods. Liab. Litig.*, 317 F.R.D. 562, 566 (D. Ariz. 2016).

<sup>83</sup> *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, No. 2:18-md-2846, 2019 WL 341909, at \*1 (S.D. Ohio Jan. 28, 2019) (internal citation omitted).

<sup>84</sup> Yet, foreign privilege law can differ from U.S. law. For a discussion of selective waiver, see *In re Pac. Pictures Corp.*, 679 F.3d 1121, 1127 (9th Cir. 2012). Confidentiality agreements and statutory provisions could also change this calculus. See 12 U.S.C. § 1828(x) (2018); *Saito v. McKesson HBOC, Inc.*, No. CIV.A. 18553, 2002 WL 31657622, at \*3 (Del. Ch. Nov. 13, 2002).

Substantively, plaintiffs in these cases sought information submitted to foreign agencies with more stringent requirements than the FDA in their particular cases. Although most of the time the FDA imposes some of the most burdensome requirements in the world,<sup>85</sup> in these cases, foreign countries imposed onerous label or disclosure requirements that the FDA rejected. While many still consider the FDA as the “gold standard” regulator of the world, the fact that so many cases draw on foreign regulators raises questions about this view. Indeed, this highlights areas where the FDA is under-regulating compared to other jurisdictions.<sup>86</sup>

In general, parties tend to request three types of materials: (a) documents prepared by defendants and produced to foreign regulators (including studies on the safety or effectiveness of a drug),<sup>87</sup> (b) materials created for the express purpose of complying with foreign regulation (including labels prepared with the direct input of foreign regulators),<sup>88</sup> and (c) all communications with foreign regulators (emails, documents, and other electronic information covering any exchange).<sup>89</sup> Below is a graphical representation of these three types of claims:

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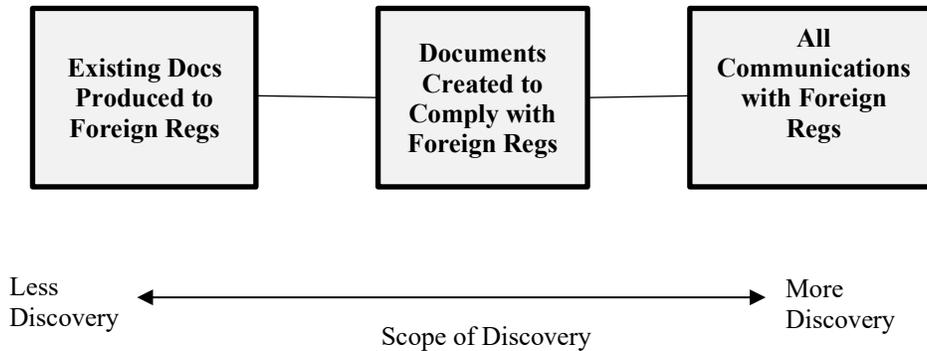
<sup>85</sup> See Joseph W. Cormier, *Advancing FDA’s Regulatory Science Through Weight of Evidence Evaluations*, 28 *J. Contemp. Health L. & Pol’y* 1, 1–2 (2011).

<sup>86</sup> Cf. Catherine M. Sharkey, *The Opioid Litigation: The FDA Is MIA*, 124 *Dick. L. Rev.* 669, 671 (2020) (discussing the regulatory shortcomings of the American FDA in light of the opioid epidemic) [hereinafter Sharkey, *Opioid Litigation*].

<sup>87</sup> See, e.g., *Brunston v. Bayer Healthcare Pharm., Inc.*, No. EDCV 13-1904, 2014 WL 12587032, at \*1–2 (C.D. Cal. May 16, 2014).

<sup>88</sup> See, e.g., *Hardy v. Pharmacia Corp.*, No. 4:09-cv-119, 2011 WL 2118983, at \*3 (M.D. Ga. May 27, 2011).

<sup>89</sup> *Kubicki v. Medtronic*, 307 F.R.D. 291, 294 (D.D.C. 2014).

**Figure 1**

In most cases, defendants pushed back against the propriety of introducing foreign regulatory evidence into the case without the fuller context of foreign regulation.<sup>90</sup> Without an understanding of the broader regulatory framework, isolated communications with foreign regulators may be misleading, especially when those regulators require more evidence of safety or efficacy.<sup>91</sup> But in most cases, plaintiffs successfully argued that, regardless of current FDA standards or the regulatory context abroad, foreign documents were relevant to the question of knowledge of risks related to defendants' products.<sup>92</sup> Plaintiffs sometimes introduced the evidence through expert testimony.<sup>93</sup> Defendants' arguments often focused on three other objections: that foreign regulatory evidence was irrelevant in the United States, that such evidence was not admissible at trial, and that foreign law prevented its disclosure.<sup>94</sup>

<sup>90</sup> See, e.g., *In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 181 F. Supp. 3d 278, 306–07 (E.D. Pa. 2016); *In re Seroquel Prods. Liab. Litig.*, 601 F. Supp. 2d 1313, 1316, 1318–19 (M.D. Fla. 2009).

<sup>91</sup> Cf. *In re Trasyol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1336 (S.D. Fla. 2010) (declining to admit expert testimony in part because it “merely summarizes and restates the findings of the foreign Inspection Reports” without broader context).

<sup>92</sup> See *In re Tylenol*, 181 F. Supp. 3d at 306–08.

<sup>93</sup> See *Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429, 2001 U.S. Dist. LEXIS 4531, at \*60–63, \*69–71 (S.D. Ind. Mar. 7, 2001).

<sup>94</sup> See, e.g., *Hodges v. Pfizer, Inc.*, No. 14-4855, 2016 WL 1222229, at \*2–3 (D. Minn. Mar. 28, 2016) (considering the arguments that foreign regulatory evidence is irrelevant or inadmissible); *In re Cathode Ray Tube (CRT) Antitrust Litig.*, No. C-07-5944, 2014 WL 5462496, at \*4–7 (N.D. Cal. Oct. 23, 2014) (considering and rejecting the argument that a discovery request should be denied because disclosure could raise a conflict with foreign law).

In the face of broad requests for foreign documents, courts have mostly granted discovery of foreign regulatory evidence, but have been more conflicted about the admissibility of these documents at trial.<sup>95</sup> Out of a sample of forty-two MDL cases, courts granted plaintiffs' requests around half of the time.<sup>96</sup> But, interestingly, in a subset of only discovery decisions (and not evidentiary admissions at trial), courts granted requests around two-thirds of the time.<sup>97</sup> Judges reasoned that the material was either highly relevant to the case or could lead to admissible evidence over whether "[d]efendants' warnings . . . were adequate and reasonable,"<sup>98</sup> or was apposite because "notice of the risks of [a medical product] could conceivably originate from any country."<sup>99</sup> As discussed above, the defendants' knowledge tended to be the key reason that foreign evidence would be relevant. Some courts also emphasized that materials submitted by the defendants to foreign regulators pertaining to *identical* products to those sold in the United States would be probative to plaintiffs' claims or defenses.<sup>100</sup> Most courts—with some exceptions—have also batted away complaints about proportionality or burden, mostly because defendants have often been large corporations that can easily find and produce these documents. Crucially, courts have rejected claims that discovery of foreign evidence would be duplicative of documents produced to American regulators, mostly because plaintiffs could show that regulatory requirements were different in most countries.<sup>101</sup>

To be clear, usually plaintiffs sought the information to argue that defendants violated U.S. law, not to import the foreign legal conclusions. The foreign information provided additional facts and information—it usually did not set the relevant legal standard.

The few courts that have refused to grant discovery of foreign regulatory documents have done so for a variety of reasons. In some

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<sup>95</sup> *Hodges*, 2016 WL 1222229, at \*3. Compare *St. Jude Med. S.C., Inc. v. Sorin CRM USA, Inc.*, No. 14-cv-00119, 2014 WL 1056526, at \*4 (D. Colo. Mar. 19, 2014) (granting plaintiff's request), with *In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769, 2008 WL 508391, at \*2 (M.D. Fla. Feb. 21, 2008) (dismissing such a request).

<sup>96</sup> See *Apps. I–II*.

<sup>97</sup> See *App. I*.

<sup>98</sup> *Hardy v. Pharmacia Corp.*, No. 4:09-cv-119, 2011 WL 2118983, at \*3 (M.D. Ga. May 27, 2011).

<sup>99</sup> *Hodges*, 2016 WL 1222229 at \*3.

<sup>100</sup> Pretrial Order at 4, *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327 (S.D. W. Va. Sept. 18, 2013) (Pretrial order #68 granting plaintiff's motion to compel and denying defendant's motion for protective order).

<sup>101</sup> *Id.* at 4–7.

cases, courts concluded that such discovery would be too burdensome, was out of the possession or control of the companies, and likely covered irrelevant documents. For instance, courts have been more willing to strike down exorbitant requests; such as asking for all communications with foreign regulators over the past thirteen years.<sup>102</sup> In other cases, courts worried that products sold abroad were not always the same as those sold at home, rendering foreign regulatory material somewhat beside the point.<sup>103</sup> Importantly, in a handful of cases courts balked at this kind of discovery because of comity concerns, reasoning that respect for foreign law and sovereignty counseled against discovery of regulatory information.<sup>104</sup>

The two case examples discussed below capture the basic mechanics of this channel of interaction between foreign regulators and American law:

In *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation*, thousands of plaintiffs filed claims against a medical device manufacturer over the failure of a mesh product implanted by surgeons to treat hernias.<sup>105</sup> Plaintiffs' main allegation was that defendant knew about their defective product and its potential complications but failed to warn consumers and physicians.<sup>106</sup> After the judicial panel on multidistrict litigation consolidated the cases into a single multidistrict litigation, plaintiffs requested in discovery all “communications relating to the safety and labeling of polypropylene

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<sup>102</sup> *In re Bard IVC Filters Prods. Liab. Litig.*, 317 F.R.D. 562, 566 (D. Ariz. Sep. 16, 2016). See also *SmithKline Beecham Corp. v. Apotex Corp.*, No. 98 C 3952, 1999 WL 311697, at \*7 (N.D. Ill. Mar. 13, 1999) (allowing discovery of only a portion of the documents that plaintiff requested from a prior Canadian suit); *Kubicki v. Medtronic*, 307 F.R.D. 291, 296–97 (D.D.C. 2014) (refusing to grant plaintiffs request for “all documents exchanged with foreign and domestic regulators for 15 years”).

<sup>103</sup> *SmithKline Beecham Corp. v. Apotex Corp.*, No. 98 C 3952, 1999 WL 311697, at \*6 (N.D. Ill. May 13, 1999) (declining a discovery request that would require defendants to “embark on a fishing expedition in pursuit of . . . products that will never reach the United States”).

<sup>104</sup> See, e.g., *In re Yasmin & Yaz: (Drospirenone) Mktg., Sales Prac. & Relevant Prods. Liab. Litig.*, No. 3:09-md-02100, 2011 WL 3759699, at \*4 (S.D. Ill. Aug. 18, 2011); *In re Payment Card Interchange Fee & Merch. Disc. Antitrust Litig.*, 2010 WL 3420517, at \*6–7 (E.D.N.Y. Aug. 27, 2010); *Campbell v. Facebook Inc.*, No. 13-cv-05996, 2015 WL 4463809, at \*4–5 (N.D. Cal. July 21, 2015).

<sup>105</sup> *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, No. 2:18-md-2846, 2019 WL 341909, at \*1 (S.D. Ohio Jan. 28, 2019); U.S. Jud. Panel on Multidistrict Litig., *supra* note 77.

<sup>106</sup> *In re Davol*, 2019 WL 341909, at \*2.

surgical mesh products’ between Defendants and a limited number of foreign regulatory authorities,” including the “Scientific Committees of the European Commission; the Medicines and Healthcare Products Regulatory Agency (MHRA), including Scotland’s Health Facilities Scotland (HFS) and the National Health Services (NHS) (United Kingdom); the Federal Institute for Drugs and Medical Devices (BfArM) (Germany); Health Canada; the Therapeutic Goods Administration (TGA) (Australia); and the Pharmaceuticals & Medical Devices Agency (PMDA) (Japan).”<sup>107</sup> The court ordered defendants to produce the information because the regulatory materials would show “what Defendants knew about the potential risks of the products at issue here.”<sup>108</sup> In response to defendant’s argument that the FDA had approved their product, the court noted that “[r]egardless of the country in which Defendants . . . operate, [they] are obligated to notify regulatory authorities of potential health and safety risks,” which could be relevant to the case.<sup>109</sup>

By contrast, in *In re Bard IVC Filters Product Liability Litigation*, the court rejected a similar request for foreign regulatory documents. The case involved negligence claims consolidated in a multidistrict litigation covering eight thousand plaintiffs against a blood filter manufacturer.<sup>110</sup> As in similar cases, plaintiffs requested “communications between [defendant’s] foreign entities and foreign regulatory bodies regarding the IVC filters at issue in this case.”<sup>111</sup> Interestingly, however, the plaintiffs claimed to seek the information “to determine if any of those communications have been inconsistent with Defendants’ communications with American regulators.”<sup>112</sup> Despite its similarity to other cases, the opinion rejected the discovery request because it was not “proportional to the needs of the case” under Rule 26.<sup>113</sup> The court reasoned that discovery was too costly and burdensome—covering all information produced to eighteen foreign regulators over thirteen years—and only marginally relevant.<sup>114</sup> As I discuss below, the court likely got

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<sup>107</sup> *Id.* at \*1.

<sup>108</sup> *Id.* at \*2.

<sup>109</sup> *Id.* at \*2.

<sup>110</sup> *In re Bard IVC Filters Prods. Liab. Litig.*, 317 F.R.D. 562, 563 (D. Ariz. Sept. 16, 2016); U.S. Jud. Panel on Multidistrict Litig., *supra* note 77.

<sup>111</sup> *In re Bard IVC Filters*, 317 F.R.D. at 563.

<sup>112</sup> *Id.* at 566.

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

this decision wrong because it is probably not burdensome for defendants to produce information that they have already compiled, reviewed, and produced to foreign agencies.

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To sum up: discovery can be a powerful device that connects domestic cases with foreign regulations. Plaintiffs are taking advantage of different regulatory burdens imposed in other countries to advance mass torts claims in the United States. Another upshot of the story is that judges are facing difficult and unresolved questions about the use of foreign regulatory materials. In these cases, judges are balancing conflicting values, including the use of foreign materials to shed light on the knowledge and conduct of the defendant, the potential role of foreign law as a standard for what counts as a violation under U.S. law, and the interaction between these cases and FDA regulation. Part III addresses in full these doctrinal and theoretical complexities.

### *B. Transnational Piggybacking on Foreign Regulators*

Litigation also imports foreign regulations when American plaintiffs ride on the coattails of foreign agency findings or enforcement actions. The cases discussed below arise when foreign agencies file successful claims against large multinationals, announce a settlement or penalty, or publicize new studies warning about the dangers of a product. These actions then trigger cases in the United States—even in areas that have slipped through the cracks of U.S. regulators—transforming foreign regulatory acts into domestic litigation. The American legal claims are not based on foreign law directly. Rather, plaintiffs’ attorneys use domestic claims as vehicles for presenting the foreign violations to a U.S. court. Below, I discuss cases involving both the European General Data Protection Regulation (“GDPR”) and claims in various contexts.

#### *1. Following a Foreign Lead*

Foreign regulatory findings can trigger American cases or support arguments in existing litigation. Public findings, or new studies that detail wrongdoing by a company or entity, can often provide the basis for tort or breach of contract claims. In this way, foreign regulators prompt American plaintiffs to file cases and, by publicizing and critiquing company actions, can also influence American litigation by shaping the background assumptions of juries and judges.

Sometimes foreign regulatory investigations serve as direct triggers for American cases. For example, in *In re European Government Bonds Antitrust Litigation*, plaintiffs alleged a conspiracy by several American and foreign banks to fix prices for European sovereign bonds in violation of U.S. antitrust laws.<sup>115</sup> In addressing a motion to dismiss the claim, the district court explicitly recognized that “[a]lthough this conspiracy allegedly ended before 2013, Plaintiffs allege that they learned of it only after the European Commission issued a Statement of Objections on January 31, 2019.”<sup>116</sup> Plaintiffs left no doubt in their complaint that “they remained ignorant of the conspiracy’s existence until the European Commission’s Statement of Objections put them on notice.”<sup>117</sup>

Cases drawing on foreign regulation can also make extensive use of those findings in complaints. Take, for instance, *Brenner v. Procter & Gamble Co.*, where a putative class brought claims of fraudulent marketing of baby wipes that contained “an unnatural and potentially harmful ingredient called phenoxyethanol.”<sup>118</sup> Paragraph five of the plaintiffs’ complaint cites a report from the French National Agency for Medicines and Health “recommending that phenoxyethanol should be ‘avoid[ed] . . . in cosmetic Wipes intended for the nappy area’ for ‘infants under the age of three years’ due to concerns of reproductive and developmental toxicity.”<sup>119</sup> Crucially, in deciding a motion to dismiss the claim, the court specifically cited this report as evidence that the plaintiffs’ claim was plausible, noting that “[i]n this case—given the FTC enforcement actions, FDA and *French government advisories*, and Natural Clean brand packaging—Plaintiff raises a plausible inference that the ‘Natural Clean’ label is misleading.”<sup>120</sup>

Although in *Brenner* the FDA agreed with the French Health authority, there are cases where plaintiffs use foreign agency findings that conflict with U.S. regulators. For example, in *Rotondo v. Amylin Pharmaceuticals*, plaintiffs alleged that defendant failed to warn of cancer risks associated with a diabetes drug. In support of their claim, plaintiffs

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<sup>115</sup> *In re Eur. Gov’t Bonds Antitrust Litig.*, No. 19 CIV. 2601, 2020 WL 4273811, at \*2–4 (S.D.N.Y. July 23, 2020).

<sup>116</sup> *Id.*

<sup>117</sup> *Id.* at \*10.

<sup>118</sup> *Brenner v. Procter & Gamble Co.*, No. SACV 16-1093, 2016 WL 8192946, at \*1 (C.D. Cal. Oct. 20, 2016) (internal citation omitted).

<sup>119</sup> Class Action Complaint at 2, *Brenner v. Procter & Gamble Co.*, 2016 WL 8192946 (C.D. Cal. June 13, 2016) (No. 8:16-cv-1093).

<sup>120</sup> *Brenner*, 2016 WL 8192946, at \*6 (emphasis added).

cited extensively to a report from Health Canada, which they argued uncovered “new safety information” that the FDA failed to consider.<sup>121</sup> These cases show how plaintiffs can piggyback on foreign regulatory findings or enforcement actions to discipline corporate conduct that would otherwise go unnoticed in the U.S.

There is even the possibility that district court judges *can* look to the existence of foreign regulatory actions to evaluate whether a complaint is plausible. Normally, “ongoing government investigations” are not sufficient by themselves to nudge a complaint from possibility to plausibility.<sup>122</sup> However, coupled with other allegations, some courts have found that “government investigations may be used to bolster the plausibility of . . . claims.”<sup>123</sup> One potential complication is the distinction between, on the one hand, pleading the fact that there is an ongoing investigation in another country and, on the other hand, drawing on facts unearthed by that investigation.

In a series of cases, plaintiffs have made the argument that foreign government investigations should count as a “plus” factor in a plausibility analysis. Interestingly, a few courts have accepted this argument. For example, in *Barry's Cut Rate Stores Inc. v. Visa, Inc.*, the district court denied a motion to dismiss an antitrust claim because, among other things, “[d]efendants’ conduct has been investigated, litigated, and regulated in many jurisdictions around the world” supporting allegations of a conspiracy.<sup>124</sup> The court acknowledged actions by the European Court of Justice, the European Parliament, and the Australian central bank.<sup>125</sup> By contrast, some courts have rejected this argument, finding that foreign investigations are inapposite because “foreign laws may prohibit behavior that is lawful” under U.S. law.<sup>126</sup> Despite this, plaintiffs continue to make

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<sup>121</sup> *Rotondo v. Amylin Pharm., Inc.*, No. B275314, 2018 WL 5800780, at \*4 (Cal. Ct. App. Nov. 6, 2018).

<sup>122</sup> *In re Commodity Exch., Inc.*, 213 F. Supp. 3d 631, 661 (S.D.N.Y. 2016).

<sup>123</sup> *Hinds Cnty., Miss. v. Wachovia Bank N.A.*, 790 F. Supp. 2d 106, 115 (S.D.N.Y. 2011); see, e.g., *Starr v. Sony BMG Music Ent.*, 592 F.3d 314, 323–24 (2d. Cir. 2010). But see *In re Graphics Processing Units Antitrust Litig.*, 527 F. Supp. 2d 1011, 1024 (N.D. Cal. 2007) (investigation itself “carries no weight”); *In re Commodity Exch.*, 213 F. Supp. 3d at 662 (same).

<sup>124</sup> *Barry's Cut Rate Stores Inc. v. Visa, Inc.*, No. 05-md-1720, 2019 WL 7584728, at \*32 (E.D.N.Y. Nov. 20, 2019).

<sup>125</sup> *Id.*

<sup>126</sup> *Jones v. Micron Tech. Inc.*, 400 F. Supp. 3d 897, 921 (N.D. Cal. 2019).

the argument in pending cases.<sup>127</sup> Either way, at minimum, plaintiffs will continue to draw on facts unearthed by foreign investigations.

Beyond complaints, foreign regulators can alter the entire trajectory of a case. This phenomenon has been on dramatic display in the ongoing litigation against Monsanto over its development of glyphosate, which it marketed and sold as a weed killer called Roundup. Both the EPA and the State of California approved Roundup for sale, finding that the product would not “generally cause unreasonable adverse effects on the environment.”<sup>128</sup> In 2015, the International Agency for Research on Cancer (“IARC”), which is based in France and part of the World Health Organization, announced that glyphosate was likely a human carcinogen.<sup>129</sup> This finding triggered simultaneous regulatory investigations in European countries and U.S. litigation against Monsanto.<sup>130</sup> But this foreign finding was not only the trigger for the case. It has also shaped the entire path of the case, including complaints, media coverage, discovery, and trial.<sup>131</sup>

At one point in the *Roundup* case, the parties were locked in a battle of regulators, both using foreign regulatory findings to bolster their cases. After citing to IARC findings in the complaint, plaintiffs made them the centerpiece of their case, arguing that the “international community is coming down on [Monsanto and glyphosate].”<sup>132</sup> Defendants met these arguments by pointing out that not only had the EPA approved glyphosate, but foreign regulators had also found glyphosate to be safe.<sup>133</sup> This battle of the regulators lasted the entire case, culminating in trial arguments about the respective regulators in front of a jury. During a motion for judgment as a matter of law, the judge highlighted that “there is credible evidence on both sides of the scientific debate, and the repeated approvals of glyphosate by the EPA, the European Chemicals Agency, Health Canada, and other worldwide regulatory agencies, surely

<sup>127</sup> *In re Mexican Gov’t Bonds Antitrust Litig.*, 412 F. Supp. 3d 380, 390 (S.D.N.Y. 2019).

<sup>128</sup> Complaint at 6, *Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037 (N.D. Cal. 2016) (No. 4:16-cv-00525).

<sup>129</sup> See *id.* at 11–12.

<sup>130</sup> *Id.*

<sup>131</sup> See *In re Roundup Prods. Liab. Litig.*, 385 F. Supp. 3d 1042, 1047 (N.D. Cal. 2019). Indeed, in the midst of these cases, dozens of foreign regulators have banned glyphosate. See *Where Is Glyphosate Banned?*, *supra* note 27.

<sup>132</sup> Transcript of Proceedings of the Official Electronic Sound Recording 2:14 PM–3:01 PM at 9, *Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037 (N.D. Cal. argued May 3, 2016) (No. 3:16-cv-00525).

<sup>133</sup> See *In re Roundup*, 385 F. Supp. 3d at 1047.

diminish—to a degree—Monsanto’s culpability.”<sup>134</sup> Before trial, plaintiffs’ attorneys tried to exclude some of the foreign regulatory evidence from the jury, knowing that it could potentially impact deliberations.

There are many ways to understand the *Roundup* case. One is that the case is an example of piggybacking litigators taking advantage of foreign regulatory acts and actions. The case shows that defendants—not just plaintiffs—can strategically employ foreign regulatory actions as exculpatory in U.S. court, putting the judge in a difficult position. An alternative view is that *Roundup* is not about transnational piggybacking, but rather an extreme use of foreign regulatory evidence for arguably its most controversial purpose: taking the conclusions of foreign regulators and presenting them as evidence to persuade a U.S. court to conclude similarly. Like the discovery cases, *Roundup* provides an example of how a single piece of evidence can serve both controversial and uncontroversial purposes, and how difficult it can be to decouple those purposes.

## 2. *Emulating Foreign Enforcement: Data Protection and American Securities Laws*

In the past few years, plaintiffs have brought new kinds of securities claims based on foreign regulatory penalties. These cases can arise as coattail class action claims when a European agency penalizes a large technology company like Google for violating European Law. Thereafter, American plaintiffs file securities cases in the United States, arguing that the company defrauded investors by failing to disclose noncompliance with foreign law (which exposed the company to material adverse consequences abroad). To be sure, these securities cases are not a neat fit because American law punishes only a fraudulent misrepresentation or misleading omission, not actual non-compliance with foreign law. Still, this channel shows how foreign law can sometimes increase liability through a securities fraud claim.

Prior to diving into these cases, it’s important to understand the two relevant bodies of law: European data protection and U.S. securities law. A few years ago, the European Union adopted a set of guidelines—the GDPR—that governs the use of consumer data by large technology

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<sup>134</sup> *Id.*

companies.<sup>135</sup> The GDPR empowers European regulators and non-governmental organizations to aggressively protect consumer data and privacy rules through significant fines and litigation.<sup>136</sup> Compliance with the GDPR imposes enormous costs on regulated entities, requiring a host of new procedures and disclosures.<sup>137</sup> The GDPR thus represents a pathbreaking event in the history of privacy law and technology.

On the American side is the Securities and Exchange Act. Under domestic securities laws, investors can file claims against a company based on alleged misrepresentations made to the market.<sup>138</sup> Typically, plaintiffs sue after a company's share price drops due to the revelation that the company made material misrepresentations about itself. Investors file securities class actions under section 10(b) of the Securities Exchange Act of 1934, arguing that a company misled investors by releasing false information or failing to correct information about the state of the company.<sup>139</sup>

Before delving into the data protection cases, let's first examine more general securities cases that draw on foreign regulations. In the past ten years, plaintiffs have filed cases arguing that failure to disclose adverse foreign investigations constitutes securities fraud. These cases range from allegations that a company failed to disclose adverse regulatory findings in the pharmaceutical context,<sup>140</sup> general concerns raised by foreign regulators,<sup>141</sup> or misled shareholders about the likelihood of a drug's approval by the European Medicines Agency.<sup>142</sup> In some of these cases, plaintiffs allege that defendants knew that foreign penalties were possible or even likely but did not disclose these facts in their public filings. For instance, in a recent securities case against Facebook, plaintiffs emphasize that the company was aware that European regulators would investigate its lax data privacy standards, and, indeed, plaintiffs

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<sup>135</sup> W. Gregory Voss & Kimberly A. Houser, *Personal Data and the GDPR: Providing a Competitive Advantage for U.S. Companies*, 56 *Am. Bus. L.J.* 287, 288 (2019).

<sup>136</sup> Paul W. Schwartz, *Global Data Privacy: The EU Way*, 94 *N.Y.U. L. Rev.* 771, 776 (2019).

<sup>137</sup> Bradford, *Brussels Effect Book*, *supra* note 40, at 237.

<sup>138</sup> *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 263 (2014).

<sup>139</sup> See, e.g., *id.* at 263–64.

<sup>140</sup> *Flynn v. Sientra, Inc.*, No. CV 15-07548, 2016 WL 3360676, at \*1–2 (C.D. Cal. June 9, 2016).

<sup>141</sup> *Jasin v. Vivus, Inc.*, No. 14-cv-03263, 2016 WL 1570164, at \*1 (N.D. Cal. Apr. 19, 2016), *aff'd*, *Jasin v. Vivus, Inc.*, 721 F. App'x 665 (9th Cir. 2018).

<sup>142</sup> *Vallabhaneni v. Endocyte, Inc.*, No. 1:14-cv-01048, 2016 WL 51260, at \*1, \*16 (S.D. Ind. Jan. 4, 2016).

highlighted that French regulators fined Facebook at least once because of its privacy violations.<sup>143</sup>

Another emerging area involves claims against Chinese companies listed in U.S. securities markets. A recent complaint against the Chinese company Baidu alleges that it failed to disclose that its feed services were not in compliance with Chinese regulatory standards.<sup>144</sup> Given the regulatory and cultural context for Chinese companies listed in U.S. markets, this kind of claim may become increasingly common.

With these cases in mind, let's now consider a new batch of cases that take advantage of the open-ended nature of securities claims to argue that companies have failed to disclose how compliance with the GDPR would affect their bottom line. In the most aggressive cases, plaintiffs file a claim after a GDPR penalty, arguing that defendant misled the market when it failed to disclose noncompliance with foreign law.<sup>145</sup> Applying a different theory, a series of recent class action cases against Nielsen argue that the company failed to disclose how GDPR compliance would affect its income and services. Plaintiffs alleged that “[Nielsen] recklessly disregarded its readiness for and the true risks of privacy related regulations and policies, including the GDPR, on its current and future financial and growth prospects.”<sup>146</sup> Plaintiffs also alleged that the defendant misrepresented the extent to which it depended on third-party “data set providers” like Facebook in the lead-up to the GDPR, thus blindsiding shareholders when revenues declined in light of those third-party entities’ non-compliance.<sup>147</sup>

In a few other cases, plaintiffs are arguing that defendants failed to disclose internal problems revealed while preparing for the GDPR. For instance, in *In re Alphabet, Inc. Securities Litigation*, an extensive complaint alleges that Google misrepresented the occurrence and extent of a security breach on Google+. Even though the breach was not directly related to the GDPR, plaintiffs allege that defendants repeatedly emphasized their preparedness for the GDPR, demonstrating that they understood the importance of data privacy to regulators. Although this

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<sup>143</sup> Class Action Complaint for Violation of the Federal Securities Laws at 9–10, Yuan v. Facebook, Inc., No. 5:18-cv-01725 (N.D. Cal. Mar. 20, 2018).

<sup>144</sup> Class Action Complaint at 7, Ikeda v. Baidu, No. 3:20-cv-02768 (N.D. Cal. Apr. 21, 2020).

<sup>145</sup> See, e.g., *In re Facebook, Inc. Sec. Litig.*, 405 F. Supp. 3d 809, 846 (N.D. Cal. 2019).

<sup>146</sup> Complaint for Violation of the Federal Securities Laws at 4, Gordon v. Nielsen Holdings PLC, No. 1:18-cv-07143 (S.D.N.Y. Aug. 8, 2018).

<sup>147</sup> See *id.* at 3–4.

emphasis on data privacy provided a venue for Google to disclose the Google+ breach to shareholders, the company failed to do so.<sup>148</sup> Another complaint against Google highlights that German and Irish regulators were already scrutinizing Google's lax compliance standards, suggesting that the company failed to disclose its internal non-compliance to shareholders.<sup>149</sup>

Similarly, in litigation against Facebook, plaintiffs alleged that Facebook materially misled shareholders by downplaying the anticipated effect of the GDPR on business. "Plaintiffs rely on a fraud by hindsight pleading—they allege that GDPR compliance statements must have been false because user growth declined slightly once . . . [GDPR] had been fully implemented."<sup>150</sup>

On the whole, these claims attempt to hold companies liable in the United States for regulatory non-compliance abroad. To be sure, because the vehicle is a securities fraud claim, companies could avoid liability by just disclosing non-compliance or at least not representing compliance with foreign law. In this sense, a securities fraud claim is not "importing" foreign law and, arguably, it will not increase deterrence or change the behavior of a multinational company. These caveats weaken the apparent effect of this channel. Nonetheless, the phenomenon still shows how transnational actors, by their very nature, are subject to *both* a wide range of regulatory schemes capable of imposing monetary sanctions *and* securities laws in the United States that can punish them for representing compliance with foreign law. This appears to be an example of how litigation can hinge on the existence or compliance with foreign regulation.

### *C. Foreign Regulators' Letters of Interest*

Recently, foreign regulators have filed dozens of letters in U.S. courts expressing an interest in a pending case. In doing so, they joined a longer tradition of foreign sovereigns filing amicus briefs in front of the Supreme Court. In this Section, I consider how this channel of foreign intervention into American litigation has come to play a larger role in two main types

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<sup>148</sup> Consolidated Amended Complaint for Violations of the Federal Securities Laws at 13–14, 16–17, *In re Alphabet Securities Litigation*, 4:18-cv-06245 (N.D. Cal. Apr. 26, 2019).

<sup>149</sup> [Unredacted] Verified Stockholder Derivative Complaint for Violation of Securities Law, Breach of Fiduciary Duty, Waste of Corporate Assets, and Unjust Enrichment at 2, 37, *Green et al. v. Page et al.*, No. 5:19-cv-01165 (N.D. Cal. Mar. 22, 2019).

<sup>150</sup> See *In re Facebook*, 405 F. Supp. 3d at 847.

of cases: domestic antitrust claims and claims applying foreign law. In the antitrust cases, foreign regulators request that foreign regulatory information be kept confidential rather than revealed in U.S. litigation. In doing so, foreign regulators use the litigation process to influence American litigation.

It's worth noting that I am particularly interested in cases in which foreign regulators, not sovereigns, directly file letters in U.S. court. While foreign amicus participation is by now recognized and policed,<sup>151</sup> we currently lack an understanding and vocabulary for when complex litigation claims incorporate input from foreign regulators.

### *1. Antitrust Claims and Foreign Regulators*

Antitrust cases have had multinational ramifications since the early 20<sup>th</sup> century, when American officials began to apply antitrust statutes extraterritorially.<sup>152</sup> So began an era of aggressive U.S. antitrust enforcement against international shipping cartels, oil companies, Swiss watchmakers, metal exporters, and others, involving documents spread all over the world.<sup>153</sup> The emergence of truly global companies at that time, paired with American willingness to enforce U.S. antitrust laws extraterritorially, heightened conflicts between overlapping antitrust regulatory authorities.<sup>154</sup> A wave of European countries responded by enacting anti-U.S. discovery laws—so-called “blocking statutes”—which punished the production of European-based documents to American authorities.<sup>155</sup> Conflict of laws issues thus became a common feature of the modern antitrust landscape.<sup>156</sup>

Given antitrust law's international nature, it is no surprise that foreign regulation has made its way into American antitrust cases. As discussed above, there is a growing set of piggyback claims where American plaintiffs copy theories or facts developed by foreign regulators, including

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<sup>151</sup> See *Animal Sci. Prods., Inc. v. Hebei Welcome Pharm. Co. Ltd.*, 138 S. Ct. 1865, 1873–74 (2018) (discussing the role of foreign regulators but only in interpreting foreign law).

<sup>152</sup> Andrew T. Guzman, *Is International Antitrust Possible?*, 73 N.Y.U. L. Rev. 1501, 1536 (1998).

<sup>153</sup> *Id.* at 1507 n.14.

<sup>154</sup> See, e.g., Brief for the Japan External Trade Organization as Amicus Curiae, *Sumitomo Shoji Am., Inc. v. Avigliano*, 457 U.S. 176 (1982) (Nos. 80-2070, 81-24), 1982 WL 608724, at \*2, \*7.

<sup>155</sup> See Zambrano, Comity, *supra* note 63, at 170.

<sup>156</sup> William S. Dodge, *Extraterritoriality and Conflict-of-Laws Theory: An Argument for Judicial Unilateralism*, 39 Harv. Int'l L.J. 101 (1998).

the European Commission and Mexican authorities.<sup>157</sup> But, in addition, because American antitrust statutes have private rights of action, many cases initiated by private plaintiffs run into conflicts of laws issues. For example, just in the past decade, plaintiffs have filed class action claims seeking to represent millions of claimants alleging price-fixing in industries like vitamins,<sup>158</sup> air freight,<sup>159</sup> aluminum and other metals,<sup>160</sup> credit cards,<sup>161</sup> rubber,<sup>162</sup> and TV panels.<sup>163</sup> Take for instance, *Animal Science Products v. Hebei Welcome Pharmacy Co.*, a case that reached the U.S. Supreme Court. There, U.S. class action plaintiffs filed an antitrust suit against Chinese vitamin manufacturers, alleging price fixing.<sup>164</sup> It was a run-of-the-mill case until the Ministry of Commerce of the People's Republic of China filed an amicus brief, explaining that the price regime was obligatory under Chinese law.<sup>165</sup> This intervention raised a difficult question: what deference is due to foreign sovereign opinions of their own law? The Supreme Court ultimately held that a federal court determining foreign law “should accord respectful consideration to a foreign government’s submission, but is not bound to accord conclusive effect to the . . . statements.”<sup>166</sup>

Interestingly, in many antitrust cases, plaintiffs explicitly seek documents produced to foreign regulators, running headlong into foreign anti-discovery laws. Requests can range from documents disclosed to investigators at the Korea Fair Trade Commission,<sup>167</sup> to “all communications and documents” exchanged with the European

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<sup>157</sup> See *supra* Subsection I.B.1.

<sup>158</sup> *Animal Sci. Prods., Inc. v. Hebei Welcome Pharm. Co. Ltd.*, 138 S. Ct. 1865, 1870 (2018).

<sup>159</sup> *In re Air Cargo Shipping Servs. Antitrust Litig.*, No. 06-md-1175, 2014 WL 7882100, at \*1 (E.D.N.Y. Oct. 15, 2014).

<sup>160</sup> *In re Capacitors Antitrust Litig.*, 106 F. Supp. 3d 1051, 1058 (N.D. Cal. 2015).

<sup>161</sup> *In re Payment Interchange Fee & Merch. Disc. Antitrust Litig.*, 986 F. Supp. 2d 207, 213 (E.D.N.Y. 2013).

<sup>162</sup> *In re Rubber Chems. Antitrust Litig.*, 232 F.R.D. 346, 348 (N.D. Cal. 2005).

<sup>163</sup> *In re TFT-LCD (Flat Panel) Antitrust Litig.*, 599 F. Supp. 2d 1179, 1183 (N.D. Cal. 2009).

<sup>164</sup> *Animal Sci. Prods., Inc. v. Hebei Welcome Pharm. Co. Ltd.*, 138 S. Ct. 1865, 1870–71 (2018).

<sup>165</sup> *Id.*

<sup>166</sup> *Id.* at 1869.

<sup>167</sup> Memorandum Order Granting Plaintiffs’ Motion to Compel Discovery of Korea Fair Trade Commission Materials at 1–2, *In re Air Cargo Shipping Services Antitrust Litigation*, 1:06-md-01775 (E.D.N.Y. Jan. 6, 2011).

Commission and the Japan Fair Trade Commission.<sup>168</sup> As in *Animal Science Products*, foreign regulators have filed letters objecting to the production of antitrust documents. The European Commission has submitted letters or amicus briefs in at least half a dozen cases, involving the rubber industry, flat TV panels, Microsoft, and credit card payments.<sup>169</sup> The EC's letters have shaped many of these cases and have been cited by some district courts.<sup>170</sup> The Korean Fair Trade Commission has also filed several amicus briefs, and Japanese regulators have intervened in a variety of cases.<sup>171</sup>

The regulators made three principal arguments. First, that disclosing regulatory documents to an American court would “pose a serious impediment” to ongoing antitrust investigations in the home country.<sup>172</sup> The Japanese regulators worried, for example, that their “on-going cartel investigation” would be affected.<sup>173</sup> The European Commission has complained that American discovery would reveal “business secrets and other confidential information, including information that the Commission regards as confidential to safeguard the integrity of its investigations.”<sup>174</sup> This may include files that “could reveal the Commission’s investigating strategy and the names of the undertakings under investigation.”<sup>175</sup> Second, regulators expressed concern that

<sup>168</sup> In re TFT-LCD (Flat Panel) Antitrust Litig., No. 07-cv-01827, 2011 WL 13147214, at \*1 (N.D. Cal. Apr. 26, 2011).

<sup>169</sup> See, e.g., Brief of the European Commission on Behalf of the European Union as Amicus Curiae in Support of Neither Party, *United States v. Microsoft Corp.*, 138 S. Ct. 1186 (2018) (No. 17-2); Letter from European Commission in Response to Special Master’s December 22, 2010 Order, In re TFT-LCD (Flat Panel) Antitrust Litig., No. 3:07-md-01827 (Feb. 15, 2011) [hereinafter European Commission Letter]; In re Rubber Chems. Antitrust Litig., 486 F. Supp. 2d 1078, 1081 (N.D. Cal. 2007); Defendant’s Opposition to Plaintiffs’ Motion to Compel Statement of Objections at 1, In re Payment Card Interchange Fee & Merchant Disc. Antitrust Litig., 1:05-md-01720 (E.D.N.Y. Jan. 8, 2010).

<sup>170</sup> See e.g., *In re Rubber Chems.*, 486 F. Supp. 2d at 1081–84; European Commission Letter, *supra* note 169, at 7–8 (citing several district court decisions). Interestingly, the European Court of Justice has allowed national courts to consider the discoverability of antitrust leniency agreements. See Case C-360/09, *Pfleiderer AG v. Bundeskartellamt*, 2011 E.C.R. I-5186, I-5199.

<sup>171</sup> See Wang, *supra* note 24, at 2149 (discussing other letters); Japan Fair Trade Commission Letter, In re TFT-LCD (Flat Panel) Antitrust Litigation, No. M: 07-1827 (Feb. 3, 2011).

<sup>172</sup> Japan Fair Trade Commission Letter at 3, In re TFT-LCD (Flat Panel) Antitrust Litig., No. 3:07-md-01827 (Feb. 3, 2011).

<sup>173</sup> *Id.*

<sup>174</sup> European Commission Letter, *supra* note 169, at 4.

<sup>175</sup> *Id.* at 5.

disclosure would weaken leniency programs. These programs encourage companies to disclose antitrust violations voluntarily in exchange for lenient penalties.<sup>176</sup> Regulators worried that if companies were routinely forced to disclose documents shared with foreign agencies, then companies would be disincentivized from sharing in the first place. For example, the European Commission called its program “the most effective tool . . . for the detection of cartels” and its “success is crucially dependent on the willingness of companies to provide comprehensive and candid information.”<sup>177</sup> In other words, American discovery may deter compliance with foreign regulations and leniency programs. Finally, regulators argued that document production would contravene their domestic laws, especially on questions of privacy.<sup>178</sup> They therefore asked U.S. courts to defer to foreign regulators’ preferences on disclosure.

In the face of regulatory concerns with American discovery, courts have given mixed deference to foreign letters.<sup>179</sup> In some cases, courts applied a traditional international comity weighing test before deciding that the documents should nonetheless be produced.<sup>180</sup> These courts defended production orders either because the foreign documents were already part of a public record or because plaintiffs were entitled to the documents under U.S. law. In one case, a court denied a request for foreign evidence, finding that “the marginal benefit of allowing discovery of the documents to be outweighed by the impact that disclosure will have on the EC’s and [Japan Fair Trade Commission’s] interest in the effective enforcement of their respective competition laws and their cooperation with the U.S. to enforce those laws internationally.”<sup>181</sup>

These cases highlight the new role of foreign regulators in antitrust cases: to supervise the use of documents stemming from their investigations. However, it remains unclear whether the antitrust-related

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<sup>176</sup> *Id.* at 6.

<sup>177</sup> *Id.*

<sup>178</sup> Brief of the European Commission on Behalf of the European Union as Amicus Curiae in Support of Neither Party, *United States v. Microsoft Corp.*, 138 S. Ct. 1186, 2–8 (2018) (No. 17-2).

<sup>179</sup> This partly confirms Noll’s point that “the new conflicts law privileges the regulatory preferences of actors operating across jurisdictional lines over the preferences of litigants seeking to enforce U.S. law.” Noll, *Conflicts*, supra note 37, at 65.

<sup>180</sup> See, e.g., *In re Cathode Ray Tube (CRT) Antitrust Litig.*, No. C-07-5944, 2014 WL 5462496, at \*4–7 (N.D. Cal. Oct. 23, 2014).

<sup>181</sup> Special Master’s Order Denying Motion of Direct Purchaser Class Plaintiffs to Compel Hitachi to Produce Foreign Regulatory Documents at 5-6, *In Re TFT (Flat Panel) Antitrust Litigation*, No. 3:07-md-01827 (N.D. Cal. Apr. 26, 2011).

materials in these cases are solely (i) documents that are otherwise discoverable and happen to have been disclosed to foreign regulators or also include (ii) documents that would not be discoverable if they had not been turned over to the foreign regulator but are arguably discoverable once produced to the foreign regulator. Arguably any concerns of the foreign regulator about disclosure are entitled to more deference in the latter category, especially if the documents produced to the foreign regulator in case (i) can be produced to plaintiffs in course of standard discovery. Below, in Part II, I discuss the wide array of implications of this channel.

## 2. *Foreign Law and Regulators*

Thousands of cases involving foreign law permeate the federal and state court systems, ranging from tort to contract law all the way to environmental claims. Whenever these cases arise—either because one of the parties is foreign or because a contract has a foreign choice of law clause—an American court is obligated to apply foreign law. In these cases, foreign countries often try to shape American courts' interpretation of foreign law. Recent literature has discussed how foreign sovereigns file amicus briefs in U.S. court, both to protect their own interests and to advocate in favor of one party.<sup>182</sup> Although most often it is the country's central legal authority that intervenes in U.S. court, recently, a crop of foreign regulators have independently filed letters to the court. For instance, in *Animal Science Products*, Chinese regulators tried to explain pricing regulations in China that would help defendants' arguments in the case.<sup>183</sup> Three years ago, the European Commission filed an amicus brief in *Microsoft v. United States*, urging the Court to consider the European law in its decision.<sup>184</sup> Even in an employment discrimination claim

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<sup>182</sup> Kristen E. Eichensehr, *Foreign Sovereigns as Friends of the Court*, 102 Va. L. Rev. 289 (2016); Daniel Fahrenthold, Note, *Respectful Consideration: Foreign Sovereign Amici in U.S. Courts*, 119 Colum. L. Rev. 1597 (2019).

<sup>183</sup> Brief of Amicus Curiae Ministry of Commerce of the People's Republic of China in Support of Respondents at 24–25, *Animal Sci. Prods., Inc. v. Hebei Welcome Pharm. Co.*, 138 S. Ct. 1865 (2018) (No. 16-1220).

<sup>184</sup> Brief of the European Commission on Behalf of the European Union as Amicus Curiae in Support of Neither Party at 3, *United States v. Microsoft Corp.*, 138 S. Ct. 1186 (2018) (No. 17-2).

against a Japanese company, the Japan External Trade Organization filed an amicus brief on treaty interpretation and Japanese investment.<sup>185</sup>

#### *D. Summing up the Channels*

These three major channels show that interaction between U.S. complex litigation and foreign regulation is common, varied, and impactful. Plaintiffs in domestic cases can use broad discovery rules, MDLs, class actions, and other procedural tools, to incorporate the work of foreign regulators, changing the factual universe in these cases. Importantly, and as discussed below, these channels show the different ways by which U.S. litigation can import foreign regulation, complementing and at times exceeding domestic regulations.

**Table 1: The Three Channels**

<b>Channel</b>	<b>Context</b>	<b>Influence</b>
1. Discovery of foreign regulatory documents	Mostly MDL cases involving pharmaceutical litigation	Plaintiffs use discovery to take advantage of more burdensome foreign regulations
2. Piggybacking on foreign regulators	Ranges from foreign studies on pharmaceuticals, to torts, privacy, and technology (GDPR) cases	Plaintiffs incorporate foreign regulatory findings or enforcement actions, allowing U.S. law to follow a foreign lead
3. Foreign letters of interest	Mostly cases involving foreign law or antitrust; key players include European Commission and other foreign antitrust regulators	Foreign regulators export their preferences to American litigation

<sup>185</sup> Brief for the Japan External Trade Organization as Amicus Curiae at 2, *Sumitomo Shoji Am., Inc. v. Avagliano*, 457 U.S. 176 (1982) (No. 80-2070), 1982 WL 608724.

Taking a broad view of the three channels, we can draw a few preliminary observations and conclusions:

*Importing Information Rather Than Legal Standards.* The three channels usually allow plaintiffs to import foreign regulatory information but not legal standards. This distinction is analogous to the traditional facts vs. law difference. In most cases, plaintiffs use foreign information in different ways: to pad complaints, to shed light on defendants' knowledge, or to argue that defendants violated U.S. law. Judges rely on foreign regulatory conclusions as relevant to compliance with U.S. law. But, ultimately, judges apply U.S. law. There are two ways of seeing this. On the one hand, this is fundamentally an epistemic interaction that is distinct from importing foreign legal standards. On the other hand, the information in these cases was generated pursuant to foreign law, and sometimes plaintiffs disclosed defendants' violations of foreign standards. Even if U.S. courts are not asked to apply those standards, the information is intimately linked with foreign regulators' legal conclusions. On this view, the channels represent more than just information-sharing; they import foreign law.

*Plaintiffs Usually Introduce Foreign Information, but Defendants Can Also Use Foreign Materials as Exculpatory Evidence.* All three channels implicate different actors: U.S. plaintiffs, multinational defendants, domestic agencies and judges, and foreign regulators. While these institutions play different roles in the litigation ecosystem, plaintiffs are usually the first movers. It is plaintiffs that issue discovery requests, draft complaints with foreign citations, or file motions. Of course, once plaintiffs initiate these interactions, they set in motion processes that bring U.S. judges and foreign regulators into the mix. It is important to understand the distinct roles of each actor because different consequences attach when the influence is exerted by foreign regulators rather than private entities.

Defendants can use foreign regulations, too. In the *Roundup* case, for instance, defendants highlighted glyphosate approvals from around the world. This opens up the possibility of defendants using foreign regulatory approvals as *exculpatory*. If so, this could potentially lead to strategic forum shopping and public choice problems. For instance, defendants might want to cozy up to foreign regulators so that they can use foreign approval in U.S. courts.

*The Three Channels Represent the Same Phenomenon.* While I highlighted distinctions among the three channels above, once we specify

that plaintiffs drive most of the interaction, the three channels begin to look alike. In channel one, plaintiff seeks to use in U.S. litigation documents defendant submitted to foreign regulators. In channel three, the same sequence occurs except that foreign agencies object. Channel two mostly consists of plaintiffs seeking to use in U.S. litigation a larger range of materials from foreign regulations.

Despite this similarity, the channels also bring different implications. For example, one key difference between discovery of foreign information and piggybacking on an investigation is that discovery gathers information that is otherwise secret, while piggybacking uses information that is already public to help build momentum for U.S. legal change. Indeed, piggybacking is not really about the information itself, but rather about the fact of foreign regulation—that the subject was important enough for foreign regulators to act so legal decisionmakers in the United States should also pay attention. I address all these difficulties more fully below.

One implication of these channels overturns the common wisdom on discovery. The usual narrative is that U.S. discovery is overly invasive and has implications for foreign legal systems. But this Article presents the opposite narrative: foreign regulatory discovery is often more invasive than American regulatory discovery.

*The Three Channels May Have Emerged Due to Recent Changes.* There may be historic reasons why the three channels have blossomed only recently. For instance, below I discuss why the emergence of multidistrict litigation has created a vehicle to import foreign regulation in the mass torts context.<sup>186</sup> I also discuss why structural changes to public antitrust enforcement—weakening in the 1980s—means that Europeans now have stricter enforcement priorities than U.S. authorities, pushing the cross-border interaction from regulator-to-regulator interactions to regulator-to-litigators overlap.<sup>187</sup>

*This Phenomenon Is Not Unidirectional.* It's worth highlighting that there is no reason to believe that this phenomenon is unidirectional. American litigation can also shape foreign regulatory agendas.<sup>188</sup> Indeed,

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<sup>186</sup> See *infra* Section II.A.

<sup>187</sup> See Anu Bradford, Adam Chilton, Katerina Linos & Alexander Weaver, *The Global Dominance of European Competition Law Over American Antitrust Law*, 16 *J. Empirical Legal Stud.* 731, 731–32 (2019).

<sup>188</sup> Cf. Wang, *supra* note 24, at 2142–46 (noting tensions that arise when discovery requests in the United States adversely affect litigation abroad); Deborah Hensler et al., RAND Institute

the series of class action and MDL cases against Volkswagen over its diesel scandal exemplify the reverse phenomenon. The scandal began in the United States when Volkswagen admitted it had rigged its emissions test to comply with U.S. environmental laws.<sup>189</sup> This admission triggered dozens of lawsuits in U.S. courts, which were eventually shepherded into class actions and multidistrict litigation.<sup>190</sup> But while U.S. litigation quickly centralized and moved towards settlement talks, German regulators moved slowly, refusing to penalize Volkswagen or allow broader private suits.<sup>191</sup> It was only after Volkswagen agreed to pay multibillion dollar settlements and compensation packages to U.S. consumers that German regulators began to respond and the German legislature adopted a broader collective litigation mechanism.<sup>192</sup> This case presented a dramatic example of how U.S. litigation can often lead the way and spur regulatory action in other countries.

## II. DOMESTICATING FOREIGN REGULATIONS: A NORMATIVE APPRAISAL

This Part provides a normative appraisal of the different ways that litigation involving foreign regulation can influence U.S. law, judges, litigants, and institutions. The section makes three arguments: Section II.A challenges current opposition to the use of foreign law in U.S. court, arguing that complex litigation (and MDLs) can draw significant benefits from foreign regulations, leading to a positive process by which foreign regulatory information is domesticated. Section II.B argues that litigation can lead to harmonization, promoting cross-border coherence and convergence that can benefit cross-border trade and regulated entities. Finally, Section III.C explores the interactions between domestic litigation and the so-called Brussels Effect, which is the

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for Civil Justice, *The Globalization of Mass Civil Litigation: Lessons from the Volkswagen “Clean Diesel” Case* 58–59 (Feb. 2021) (manuscript) (documenting how American litigation impacted litigation in Chile).

<sup>189</sup> Pamela K. Bookman, *The Unsung Virtues of Global Forum Shopping*, 92 *Notre Dame L. Rev.* 579, 580 (2016).

<sup>190</sup> *Id.* at 580–81, 619.

<sup>191</sup> See Andrea Thomas, *Germany Set to Allow Collective Lawsuits Following VW Scandal*, *Wall St. J.* (May 9, 2018), <https://www.wsj.com/articles/germany-set-to-allow-collective-lawsuits-following-vw-scandal-1525869967> [<https://perma.cc/M7YM-YFPV>].

<sup>192</sup> *Id.*; see also Pamela K. Bookman & David L. Noll, *Ad Hoc Procedure*, 92 *N.Y.U. L. Rev.* 767, 797–804 (2017) (detailing Germany’s slow adoption of consumer-initiated redress legislation).

phenomenon of European regulation that sets a global standard. I argue that litigation both enhances and limits the Brussels Effect.

### *A. Domesticating Foreign Law Through MDL*

Litigation offers a way by which foreign regulation is domesticated. This process fosters cross-pollination between U.S. courts and foreign regulators, allowing American courts to use foreign regulatory information in ways that avoid some of the major critiques of foreign law. Importantly, this process of domestication is possible because of MDLs, which dramatically expand the numbers of cases that are bound by pre-trial decisions like discovery or summary judgment. Below I argue that institutions can internalize foreign regulations and lead to a wealth of long-term benefits, including auditing the work of domestic agencies, operating as a failsafe to avoid regulatory capture, and increasing expertise and information-gathering.

#### *1. Internalizing Foreign Regulatory Information*

The intersections between American cases and foreign regulation show that litigation can absorb foreign law and practices, with consequences for domestic law, regulators, multinational companies, and courts. By this I mean that American institutions can internalize foreign law, shaping the legal landscape in the long run.

##### *a. Foreign Regulations' Effect on American Law and Litigators: Internalizing Foreign Expertise*

The most immediate effect of foreign regulation is on American legal claims. When litigation over products liability or securities fraud relies on foreign agency standards or practices, that reliance, in effect, makes foreign information an ingredient of a domestic legal claim. This process allows foreign information to shape U.S. litigation and legal outcomes, integrating with and nudging the development of our law.

Return, for instance, to the hypothetical discussed at the beginning of Part I: imagine that French regulations require pharmaceutical manufacturers to go through an extended three-year process involving multiple studies, while the American FDA only requires a one-year process and a single study. If plaintiffs can discover information produced to French regulators during their longer approval process, then FDA requirements become less relevant and the French requirements become

outcome determinative. The crucial tort question—whether the defendant “knew or had reason to know” about the dangers of its product—will hinge on information created due to French regulations. This may also be true in piggyback cases, where foreign investigations can inform courts’ plausibility analyses.

To be sure, in such a case, French regulations would not set the legal standard—they would only have an effect on the facts. But to see this only as epistemic input would be an overly formalist conception of what “foreign law” is—namely, doctrinal rules or principles. Instead of this limited view, one could conceive of foreign law more broadly as a foreign legal system, including a whole set of institutions set up to produce and enforce law, as well as the information/facts on which such law-production and regulation hinges. The actual information produced is only the last step of a process that involves foreign statutes, agency rules, staffing decisions, and enforcement priorities and strategies. This is especially true when the information would not exist *but for* foreign regulatory requirements, and foreign bureaucrats could reasonably anticipate that the information could result in liability. Return to the *In re Zofran* example involving Japanese regulators, GSK, and birth defect drugs. The relevant Japanese requirements may reflect a mountain of Japanese legal and political pressures: specific statutory provisions, agency budgets, number of regulators devoted to the case, experience with pharmaceutical companies, political pressures to supervise birth defect medications, and so on. This entire regulatory apparatus is what results in the specific studies in *Zofran*; not a mere corporate decision by GSK. If we define foreign law capaciously as embracing information generated pursuant to regulatory requirements and there are anticipated substantive effects, it appears that U.S. courts are indeed importing foreign law in these cases.<sup>193</sup>

Moreover, epistemic or not, foreign regulatory information can have a *de facto* effect on U.S. tort law, determining the outcome of a case. For instance, when U.S. substantive standards are based on what defendant knew—as tort law often is—foreign law can increase defendants’ knowledge and tort exposure. That would seem to further the purposes of U.S. law by protecting victims from harms defendant knew it should guard against. Not all cases have this effect. Some cases simply treat foreign enforcement as an event with a potential impact on U.S. firms or

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<sup>193</sup> I thank Amalia Kessler for this insight.

a convenient source for discovery.<sup>194</sup> In those cases, the influence of foreign regulations on the content and development of American law is attenuated. But many cases have a greater effect and present new inputs into our law.

We can observe the de facto effect of foreign regulation in some MDL cases. Take, for instance, *In re Tylenol*, a case involving claims against Johnson and Johnson (“J&J”) for selling a kind of Tylenol that allegedly caused liver damage.<sup>195</sup> Plaintiffs’ master complaint alleged, among other things, that J&J hid evidence that Tylenol was dangerous from the FDA, consumers, and the healthcare community.<sup>196</sup> Plaintiffs also argued that, at the same time as J&J misrepresented the safety of its product to the FDA, its foreign labels and regulatory compliance abroad recognized the risks of liver damage.<sup>197</sup> Defendant countered that “foreign regulatory processes . . . are so different from the FDA’s processes that information about foreign regulatory actions would be irrelevant.”<sup>198</sup> In the face of these arguments, the court accepted the foreign regulatory labeling evidence as probative of defendant’s knowledge at the time, but not as to the standard of care.<sup>199</sup>

It’s important to understand that accepting foreign evidence as relevant to the defendants’ knowledge nonetheless interacts with FDA requirements. Defendants argued that FDA regulators considered and approved labeling that did not warn of “potentially fatal hepatic necrosis.”<sup>200</sup> Canadian regulators, by contrast, adopted and released a set of labeling requirements that called for extensive disclosures of Tylenol’s effect on the liver.<sup>201</sup> By admitting evidence about these Canadian labels, the court allowed foreign law to alter the scope of defendants’ liability under U.S. law.<sup>202</sup>

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<sup>194</sup> See, e.g., *In re Facebook, Inc. Sec. Litig.*, 405 F. Supp. 3d 809, 847 (N.D. Cal. 2019).

<sup>195</sup> *In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 181 F. Supp. 3d 278, 283 (E.D. Pa. 2016).

<sup>196</sup> *Id.* at 284–93.

<sup>197</sup> *Id.* at 306–07.

<sup>198</sup> *Id.* at 307.

<sup>199</sup> *Id.*

<sup>200</sup> Defendants’ Motion In Limine Number 13 at 2, *In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 181 F. Supp. 3d 278 (E.D. Pa. 2016) (No. 2:12-cv-07263) (internal citation omitted).

<sup>201</sup> Health Canada, Revised Guidance Document: Acetaminophen Labelling Standard 6 (2016).

<sup>202</sup> *In re Tylenol*, 181 F. Supp. 3d at 307–08.

Similarly, in *In re Abilify (Aripiprazole) Products Liability Litigation*, an MDL case involving over 2,500 claims, plaintiffs alleged that Bristol-Myers Squibb (“BMS”) sold a prescription drug, Abilify, that caused compulsive behaviors, including gambling.<sup>203</sup> From the beginning, the complaint alleged (as early as paragraph five) that defendants’ pharmaceutical labeling in Europe and Canada warned “about the risk of ‘pathological gambling,’” while its American labeling never did.<sup>204</sup> But the only reason its Canadian and European labels were different is that the European Medicines Agency and Canadian regulators had concluded in 2015, after extensive analysis, that there was a “link between the use of [the medicine] and a possible risk of pathological gambling . . .”<sup>205</sup> The FDA, however, had not made a similar finding, allowing BMS to keep the warning off of its label until 2016.<sup>206</sup> For that reason, plaintiff requested that BMS produce all available foreign regulatory evidence. Surprisingly, not only did BMS agree to produce the information, but the court required that defendants certify that they had produced the full range of available foreign regulatory evidence, placing the burden entirely on defendants to comply with an extraordinarily broad request, covering regulatory information in “Europe, Canada, France, and Switzerland.”<sup>207</sup> Ultimately, the court denied defendants’ summary judgment motion, suggesting that plaintiffs had a solid case for trial. After that, BMS settled the case for an undisclosed amount.<sup>208</sup>

The key aspect of *In re Abilify* is that plaintiffs sued defendants for failure to warn during a period in 2015 when foreign regulators had increased disclosure standards on BMS but the FDA had not. By incorporating this foreign information, plaintiffs rendered BMS liable in tort for practices authorized by FDA regulations. Combined with the fact that it was an MDL involving thousands of claimants, the case created liability where otherwise there was none under U.S. law.<sup>209</sup>

<sup>203</sup> No. 3:16-md-2734, 2017 WL 4399198, at \*10 (N.D. Fla. Sept. 29, 2017).

<sup>204</sup> Complaint at 2, *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, No. 3:16-md-2734 (N.D. Fla. Dec. 2, 2016).

<sup>205</sup> *Id.* at 8 (internal quotation marks omitted).

<sup>206</sup> See *id.* at 2–3.

<sup>207</sup> Omnibus Order and Amended Case Management Schedule, *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, No. 3:16-md-2734, 2017 WL 4399198, at \*10 (N.D. Fla. Sept. 29, 2017).

<sup>208</sup> *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, No. 3:16-md-2734, 2019 WL 7859557, at \*3–4 (N.D. Fla. Dec. 6, 2019).

<sup>209</sup> See *id.* at \*4.

Judges seem aware in these cases that foreign information is influencing U.S. law. As I discuss below, judges often admit foreign materials for benign purposes—like shedding light on defendants’ knowledge—but, at the same time, judges refuse to admit it for other purposes—like setting the standard of care. Even though courts draw this distinction, they admit the *same information* and allow juries to see it.<sup>210</sup> So either way, foreign regulations influence case outcomes.

Finally, and more speculatively, foreign regulatory information may have a long-term effect on the development of U.S. law. We can understand this by imagining two scenarios. In the first scenario, courts unanimously hold that plaintiffs can discover any and all foreign regulatory information. In the second scenario, courts unanimously hold that such information is never discoverable. It is easy to see that after decades of living with these different discovery rules, tort law would look very different in the two scenarios. In scenario one, foreign regulatory standards and information would nudge the development of tort law, increasing liability and settlement rates. Scenario two would not see a similar effect. We might therefore expect a long run impact.

*b. Foreign Regulations’ Effect on American Regulators: The Failsafe, Backstop, and Auditing Benefits*

The incorporation of foreign regulations into American litigation harmonizes cross-border regulatory schemes and shapes the behavior of American regulators. By now, the costs and benefits of private and public redundant litigation are well known.<sup>211</sup> These are situations in which a private party sues a defendant after a government case, or, *vice versa*, the government sues a defendant after a private case. Proponents of these claims argue that private lawsuits following government enforcement can improve compensation for victims.<sup>212</sup> Private claims can also serve as a “failsafe” when government regulators are captured and fail to enforce

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<sup>210</sup> See, e.g., *Mahaney ex rel. Est. of Kyle v. Novartis Pharm. Corp.*, 835 F. Supp. 2d 299, 318 (W.D. Ky. 2011) (holding that a plaintiff may introduce evidence of foreign warning labels for the purpose of showing that defendant had knowledge of side effects, but plaintiff may not introduce them to suggest that defendant violated FDA regulations).

<sup>211</sup> See, e.g., David Freeman Engstrom, *Agencies as Litigation Gatekeepers*, 123 *Yale L.J.* 616 (2013) [hereinafter Engstrom, *Gatekeepers*]; Zachary D. Clopton, *Redundant Public-Private Enforcement*, 69 *Vand. L. Rev.* 285 (2016) [hereinafter Clopton, *Redundant*].

<sup>212</sup> See Margaret H. Lemos & Max Minzner, *For-Profit Public Enforcement*, 127 *Harv. L. Rev.* 853, 862–63 (2014) (arguing that public and private litigation “increasingly work together” to fulfill a common function: “compensating victims”).

the law.<sup>213</sup> In other words, private litigators can evade capture and enforce statutes in place of corrupt or ineffective regulators. While courts and scholars recognize these benefits, an array of opponents have worried about the costs of redundancy, including potential overdeterrence, wasted judicial resources, and the possibility of conflicting judgments.<sup>214</sup> Litigation can also impose extra costs that are unnecessary in regulatory regimes, undermining implementation of core statutory purposes.

Litigation involving foreign regulation, however, changes this debate by allowing private litigants to incorporate the work of foreign agencies and, in turn, influence U.S. regulators. Consider the following two potential paths from foreign regulation to American litigation (and sometimes to U.S. regulatory action):

- A foreign regulatory act or enforcement action triggers a private claim in the United States. That case then prompts the FDA to act.
- A group of plaintiffs files a private claim against a multinational company and draws on foreign regulation, either in its complaint or through discovery.

The first scenario occurs quite often in the domestic context, with the FDA openly considering rulemaking in response to ongoing litigation.<sup>215</sup> As discussed above, cases in the second scenario are also legion, and they de facto increase the burden on regulated entities in the United States, which then likely internalize the existing oversight of foreign regulators.<sup>216</sup> By consequence, target companies should theoretically increase compliance with domestic regulations.

If these two paths are possible—and there is evidence that they are occurring—then litigation is both improving and auditing the work of domestic regulators. For instance, litigators can measure the work of the FDA against health regulators in France, or the work of the FAA against

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<sup>213</sup> Engstrom, *Gatekeepers*, supra note 211, at 630.

<sup>214</sup> See John C. Coffee, Jr., *Rescuing the Private Attorney General: Why the Model of the Lawyer as Bounty Hunter Is Not Working*, 42 *Md. L. Rev.* 215, 228 (1983); William B. Rubenstein, *On What a “Private Attorney General” Is—And Why It Matters*, 57 *Vand. L. Rev.* 2129, 2151 (2004).

<sup>215</sup> There are many cases that nudge the FDA to consider rulemaking. See, e.g., Peter Shapiro, *All-Natural Class Action Suit in New York Federal Court Is Placed on Hold*, *Lewis Brisbois*, <https://lewisbrisbois.com/print/12131> [<https://perma.cc/U4Y8-ZBUA>] (last visited Apr. 18, 2021).

<sup>216</sup> See, e.g., *In re Tylenol (Acetaminophen) Mktg., Sales Practs. & Prods. Liab. Litig.*, 181 *F. Supp. 3d* 278, 307 (E.D. Pa. 2016).

aircraft regulators in Germany. We could call this a “backstop role” that can be particularly important when there is a danger of domestic regulatory capture.

Imagine, for instance, that a captured local regulator selectively underenforces rules against a multinational environmental polluter. Without an initial investigation by the government, it is difficult for private plaintiffs to have enough information for their own claims. But, imagine too, that Korean regulators pursue claims against the same polluter over very similar conduct. Now, private plaintiffs can ride the Korean regulators’ coattails through claims in the United States.

One example of this backstop role could have occurred in *In re Trasylol Products Liability Litigation*, a case involving claims against Bayer for an allegedly defective drug, Trasylol, used to prevent excessive bleeding during surgery.<sup>217</sup> During a *Daubert* hearing, plaintiffs proposed expert testimony on Bayer’s compliance with German health regulations “for the purpose of illuminating what Bayer . . . should have been disclosing to the FDA under FDA requirements and industry standards.”<sup>218</sup> Plaintiffs wanted to show at trial that while Bayer was disclosing known defects to its domestic German regulators—a relationship likely more valuable to Bayer—it was hiding this information from the FDA. By using information related to foreign regulation, in other words, plaintiffs wanted to double-check compliance with local FDA reporting requirements. Although the court excluded the testimony in that case,<sup>219</sup> courts can and should admit such information in similar cases, improving compliance with American regulations and turning foreign regulators into institutional fail-safes.<sup>220</sup>

Examples also occur in the series of piggyback cases that rely on foreign regulatory action. We see this in the ongoing antitrust case against seven large banks triggered by a Mexican government investigation rather than the FTC,<sup>221</sup> or *Brenner v. Procter & Gamble Co.*, where a putative

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<sup>217</sup> *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1323 (S.D. Fla. 2010).

<sup>218</sup> *Id.* at 1330.

<sup>219</sup> *Id.* at 1351.

<sup>220</sup> There are important limits to the failsafe argument. Under *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001), a piece of evidence cannot be admitted if it is going to be used to advance a fraud-on-the-FDA claim. See, e.g., *Mahaney ex rel. Est. of Kyle v. Novartis Pharms. Corp.*, 835 F. Supp. 2d 299, 317 (W.D. Ky. 2011). Because the Supreme Court has disallowed fraud-on-the-FDA claims, litigants have to defend the use of foreign information on alternative grounds.

<sup>221</sup> *In re Mex. Gov’t Bonds Antitrust Litig.*, 412 F. Supp. 3d 380, 382–84 (S.D.N.Y. 2019).

class relied on a report from the French National Agency for Medicines—not the FDA—to survive a motion to dismiss.<sup>222</sup> Another example is *Rotondo v. Amylin Pharmaceuticals, Inc.*, where plaintiffs sued a pharmaceutical company over cancer risks from a diabetes drug.<sup>223</sup> The case piggybacked on findings from Health Canada in the complaint, explicitly stating that Health Canada uncovered “new safety information” that the FDA failed to consider.<sup>224</sup>

Although there are examples of foreign standards both strengthening and weakening plaintiffs’ cases, on the whole, foreign regulation probably helps plaintiffs more often than not. We can expect that simply because foreign systems, like the European Union, are much more pro-regulation than the United States.<sup>225</sup> So plaintiffs will often be able to draw on foreign investigations or announcements that are pro-regulatory as compared to U.S. agencies.

Two potential downsides are worth discussing here. One is that multiple overlapping investigations of the same conduct could produce a bias toward false positives. Assume that both country A and country B share an identical substantive objective—i.e., ensure that drugs are safe and effective—embodied in different substantive rules or institutional contexts.<sup>226</sup> As discussed above, each country can “correct” a false negative by importing foreign legal information as a failsafe. But importantly, neither can easily correct the other’s false positive. So if the FDA misidentifies a problem in a particular drug but no other foreign regulator does, there is little recourse for a defendant *unless* it can use foreign regulations as exculpatory. This may mean that we should allow defendants to use foreign regulations as a shield.

Another potential downside worth discussing is the problem of administrative lassitude. Scholars have long noted that when private plaintiffs can substitute for public enforcement, agencies have an incentive to sit back and free-ride on private plaintiffs’ work.<sup>227</sup> Giving

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<sup>222</sup> *Brenner v. Procter & Gamble Co.*, No. SACV 16-1093, 2016 WL 8192946, at \*1 (C.D. Cal. Oct. 20, 2016).

<sup>223</sup> *Rotondo v. Amylin Pharm., Inc.*, No. B275314, 2018 WL 5800780, at \*1 (Cal. Ct. App. Nov. 6, 2018).

<sup>224</sup> *Id.* at \*4.

<sup>225</sup> See Bradford, *Brussels Effect Article*, *supra* note 53, at 14–16.

<sup>226</sup> I thank Doug Melamed for this insight.

<sup>227</sup> Cf. Olatunde C.A. Johnson, *Beyond the Private Attorney General: Equality Directives in American Law*, 87 N.Y.U. L. Rev. 1339, 1359–62 (2012) (discussing problems that plague public enforcement); Pamela S. Karlan, *Disarming the Private Attorney General*, 2003 U. Ill.

private parties the support of foreign agencies may make this problem worse—domestic regulators may be even more willing to sit back and let both private parties *and* foreign regulators do most of the work. While this is theoretically possible, it seems unlikely that foreign input would significantly change the status quo to such an extent.

*c. Foreign Regulations, Regulated Entities, and the Boeing 737 MAX Example*

As discussed above, a world in which litigation imports foreign standards should also change the behavior of regulated entities within the United States. Multinational companies cannot rely solely on compliance with American regulatory requirements. For purposes of liability in U.S. court, they now must also calculate whether they are complying with foreign requirements. In such a world, multinationals will know that anything they produce abroad—studies, documents, or any materials—may be discoverable in a future U.S. claim. This may force companies to standardize their compliance, knowing that liability depends on the most detailed information produced to any regulators. Indeed, in such a world, a company's initial interaction with foreign regulators gains importance. If a company foresees U.S. litigation, it may want to strategically focus on piling up foreign regulatory approvals that it can later use as exculpatory evidence in U.S. court.

The prospect that companies might change their behavior is not purely speculative: at least one large law firm has advised companies to “educat[e] foreign personnel” about the risks that documents produced to foreign regulators can pose “in U.S. litigation.”<sup>228</sup> One report written by two lawyers at that firm even suggests “simple training sessions” for employees and claims that “[c]ompanies are increasingly undertaking steps like this, and foreign company employees are becoming increasingly sophisticated about the risks of U.S. litigation.”<sup>229</sup>

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L. Rev. 183, 205 (2003) (noting that agencies like the EEOC can underenforce statutory rights).

<sup>228</sup> Michael X. Imbroscio & Paul W. Schmidt, *Border Control: Keeping Foreign Regulatory Evidence Out of U.S. Pharmaceutical Litigation*, Covington & Burling (2007), [https://www.cov.com/-/media/files/corporate/publications/2007/01/border\\_control\\_keeping\\_foreign\\_regulatory\\_evidence\\_out\\_of\\_the\\_us\\_pharmaceuti.pdf](https://www.cov.com/-/media/files/corporate/publications/2007/01/border_control_keeping_foreign_regulatory_evidence_out_of_the_us_pharmaceuti.pdf) [https://perma.cc/SLG9-NXRG].

<sup>229</sup> *Id.*

The consequences of company internalization could be extensive. Consider, for instance, ongoing litigation against Boeing over its 737 MAX crashes. It has been widely reported that Boeing had a close relationship with FAA regulators, allowing Boeing to skirt regulations and supervision of its plane certification process.<sup>230</sup> But Boeing lacks similar sway over foreign regulators. The European Union Aviation Safety Agency, for example, has aggressively pushed back against Boeing and the FAA's attempts to certify the 737 MAX.<sup>231</sup> Private plaintiffs—families of deceased plane crash victims—could rely on the work of European regulators to establish basic facts against Boeing, proving that Boeing knew that its planes were unsafe and yet chose to fly them anyway. If this is successful, it could even push Boeing to comply with foreign regulations more fully in the future.<sup>232</sup> Indeed, if the goal of regulation is to alter the behavior of regulated entities, the looming prospect of U.S. litigation that incorporates foreign regulation *is doing that*—without any input from U.S. agencies.

Companies could also engage in pre-emptive strategies to counter the effect of foreign regulations. For example, multinational companies could avoid some jurisdictions that have particularly intrusive approval standards. Seeking such foreign approval risks not only a negative decision abroad but also may increase a company's litigation risk in the United States if those same documents will then be deployed in U.S. litigation. So there might be some unintended effects that can be attributed to preemptive risk-mitigation strategies.

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<sup>230</sup> Andy Pasztor, Congressional Report Faults Boeing on MAX Design, FAA for Lax Oversight, *Wall St. J.* (Mar. 6, 2020) <https://www.wsj.com/articles/congressional-report-says-max-crashes-stemmed-from-boeings-design-failures-and-lax-faa-oversight-11583519145> [<https://perma.cc/3P8Z-HBVV>].

<sup>231</sup> Andy Pasztor & Andrew Tangel, European Air Regulators Break From FAA on 737 MAX Timeline, *Wall St. J.* (Oct. 21, 2019) <https://www.wsj.com/articles/european-air-regulators-break-from-faa-on-737-max-timeline-11571692941> [<https://perma.cc/D8Y3-2S82>].

<sup>232</sup> This may also be an outgrowth of the Brussels Effect. See Bradford, *Brussels Effect Article*, *supra* note 53, at 46–47 (hypothesizing that EU regulators may be motivated by a desire to “establish[] standards for universal conduct”). To be sure, the EUASA could itself be captured by Airbus.

## 2. *Domesticating Foreign Regulations: The Administrative Law and Epistemic Defenses*

Beyond internalizing foreign regulatory information, litigation fosters a conversation between litigants, the judiciary, and foreign law. While critics have long worried about the anti-democratic nature of foreign law in U.S. court, litigation involving foreign regulations shows that courts can acknowledge foreign law without running afoul of any constitutional or statutory constraints.<sup>233</sup> Below I discuss two ways to justify the use of foreign regulations: either an administrative law model or one that emphasizes the epistemic benefits of all these cases.

Scholars have long debated the influence of foreign law on U.S. legal policies and institutions. Some of the most heated debates have been over the influence of foreign law in American constitutional interpretation.<sup>234</sup> Other scholars have argued against the delegation of U.S. legal enforcement to international organizations because it devolves power away from elected domestic institutions to opaque, bureaucratized, and unconstrained foreign agents.<sup>235</sup> Most of these critics seem united in worrying that foreign law can frustrate U.S. democratic norms and self-governance.<sup>236</sup>

The use of foreign regulations in U.S. litigation interacts with these critiques but stands on robust and defensible grounds. The dialogue between domestic courts and foreign agencies can be justified on the same functional grounds that support the American administrative state.<sup>237</sup> Courts and scholars have long acknowledged that a robust bureaucracy can be defended on grounds of institutional competence and the promotion of social welfare.<sup>238</sup> We are willing to sacrifice some degree of popular control in exchange for expertise, efficiency, and the practical

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<sup>233</sup> See Kevin M. Clermont, *Degrees of Deference: Applying vs. Adopting Another Sovereign's Law*, 103 *Cornell L. Rev.* 243, 245–46 (2018).

<sup>234</sup> Volokh, *supra* note 39, at 220–27; Jackson, *supra* note 37, at 109–12.

<sup>235</sup> John O. McGinnis, *Medellin and the Future of International Delegation*, 118 *Yale L.J.* 1712, 1715–17 (2009) [hereinafter McGinnis, *Medellin*]. But see Alan O. Sykes, *Transnational Forum Shopping as a Trade and Investment Issue*, 37 *J. Legal Stud.* 339, 340 (2008) (arguing that American courts should adjudicate the disputes of foreigners only in certain cases).

<sup>236</sup> John O. McGinnis, *Foreign to Our Constitution*, 100 *Nw. U. L. Rev.* 303, 306–09 (2006).

<sup>237</sup> Even more broadly, literature on the virtues of “many minds” argues that increasing the number of eyes on a problem improves solutions to a problem. See Eric A. Posner & Cass R. Sunstein, *The Law of Other States*, 59 *Stan. L. Rev.* 131, 155 (2006).

<sup>238</sup> Jessica Bulman-Pozen, *Administrative States: Beyond Presidential Administration*, 98 *Tex. L. Rev.* 265, 285–86 (2019) (citing sources).

reality that a modern economy necessitates specialized bureaucratic management. The same argument could be made here: U.S. litigation can draw from foreign regulations because, in doing so, it brings a wealth of expertise, comparative competence, and efficiency benefits. In these cases, a foreign bureaucracy—in most cases from other industrialized countries—has already investigated the same question and has produced a treasure trove of relevant documents. By admitting these documents, courts take advantage of foreign information-gathering apparatuses and resources.

Moreover, as discussed below, the administrative state *itself* borrows extensive information from foreign regulators.<sup>239</sup> Domestic agencies have built a network of relationships with foreign agencies that involve widespread information-sharing.<sup>240</sup> But few question the legitimacy of that exercise. If such information sharing is appropriate for the administrative state, so it should be for the litigation state.

To be sure, administrative law scholars have built a deep literature that justifies the administrative state under both external accounts of political accountability as well as internal accounts of agency deliberation and rationalization.<sup>241</sup> Foreign agencies are not similarly subject to domestic political checks and may not have the same internal rules of procedure. We may worry that delegation to foreign agencies increases agency costs because international agents are diffused and distant from American interests.<sup>242</sup>

But these problems fail to hit the mark because in all the above cases foreign input is subject to both significant judicial gatekeeping and the limitations imposed by domestic law. U.S. judges have an arsenal of tools to limit discovery, dismiss complaints, or sanction parties. These powers allow judges to serve as robust gatekeepers, choosing which portions of foreign regulatory information are discoverable or admissible. Indeed, the cases discussed above indicate that judges examine foreign regulatory materials with a fine-toothed comb.<sup>243</sup> And, unlike some complaints about

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<sup>239</sup> See *infra* Section II.B.

<sup>240</sup> *Id.*

<sup>241</sup> Bulman-Pozen, *supra* note 238, at 285–87.

<sup>242</sup> McGinnis, *Medellin*, *supra* note 235, at 1738–39.

<sup>243</sup> See, e.g., *In re Trasyolol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1330 (S.D. Fla. 2010).

foreign litigants in U.S. court, almost all these cases involve only domestic litigants suing under U.S. law.<sup>244</sup>

Moreover, there is reason to believe that when Congress creates private rights of action, it accounts for, and confers, democratic legitimacy on creative litigation strategies.<sup>245</sup> This is also true of state common law claims. When Congress refuses to limit private tort actions in federal court—by rejecting legislation to pre-empt state tort law—it implicitly allows those claims to take place. Congress is well aware that private plaintiffs employ private rights of actions creatively, and when it wishes to give plaintiffs a short leash, Congress “resolves more policy issues in the legislature, elaborating substantive statutory law in greater detail, and leverages more administrative rulemaking expertise.”<sup>246</sup> Congress’s blessing of complex litigation not only mitigates democratic legitimacy concerns. It also means that when Congress gives litigants a long leash, it is implicitly inviting them to be creative, to act proactively, and to lead the development of statutory enforcement. Congress can always short-circuit this common law process by imposing limits on discovery or complaints, as it did in the Private Securities Litigation Reform Act.<sup>247</sup> But until Congress does that, private plaintiffs are allowed to use litigation creatively, including coattail claims and expansive discovery.

A second way to defend foreign input is that, in most cases, it provides solely an epistemic benefit. It thus avoids the democratic deficit, diffusion, and distance critiques and represents an innovative way to foster a dialogue between domestic and foreign law.<sup>248</sup> In all three channels of intersection between domestic litigation and foreign regulation, foreign law mostly *informs* plaintiffs (or defendants) and courts’ decisions but in no way binds or constrains them. Foreign law’s central contribution is to increase knowledge about the world, allowing

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<sup>244</sup> This is especially so because of the many procedural barriers that prevent foreign litigants from suing in American courts. See Bookman, *supra* note 13, at 1090–99.

<sup>245</sup> See Sean Farhang, *Legislating for Litigation: Delegation, Public Policy, and Democracy*, 106 *Calif. L. Rev.* 1529 (2018).

<sup>246</sup> *Id.* at 1534.

<sup>247</sup> See Private Securities Litigation Reform Act of 1995, Pub. L. 104-67, § 27(a), 109 Stat. 737, (1995).

<sup>248</sup> Cf. Peter M. Haas, *Introduction: Epistemic Communities and International Policy Coordination*, 46 *Int’l Org.* 1, 3 (1992) (setting forth a theory of “epistemic communities” among multinational bodies, focused on the sharing of knowledge for international coordination).

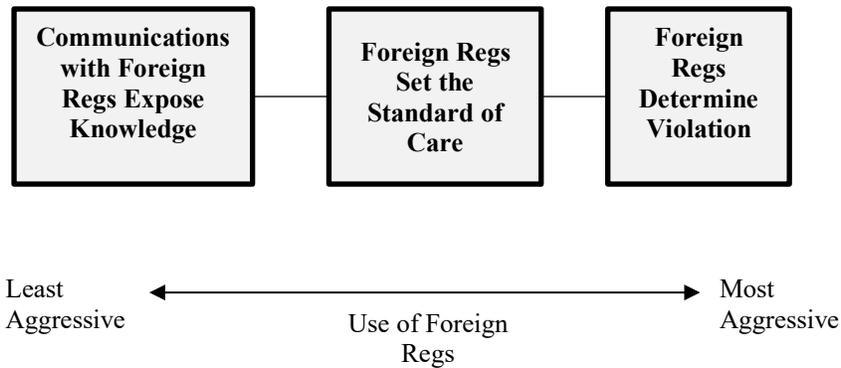
legal actors to enforce their rights, maximize deterrence, and increase compliance with statutes and the common law.

Under either model, the three channels provide lenient methods for domesticating foreign law. Consider a spectrum of foreign law's influence in U.S. courts:

- On one end of the spectrum is the controversial use of foreign law to determine a legal violation. For instance, plaintiffs could argue that a French penalty imposed on a drug manufacturer establishes a legal violation that should be remedied by U.S. tort law. Plaintiffs typically do not propose using foreign information in this manner.
- In the middle of the spectrum would be the use of foreign regulations to set the standard of care under U.S. law. Plaintiffs have repeatedly proposed this use but courts usually reject it.
- Finally, in its least controversial use, plaintiffs use communications with foreign regulators only to demonstrate that a defendant was aware that its products were dangerous. This last use seems to be the most popular and acceptable.

Below is a graphical representation of this spectrum:

**Figure 2**



If most cases are towards the least aggressive ends of the spectrum, it is easy to see that the administrative law and epistemic models both avoid

most existing concerns about foreign law.<sup>249</sup> Still, one might worry that a crafty plaintiffs' attorney could introduce foreign evidence to prove knowledge, but with the side benefit that it communicates to the jury, "Look, this foreign regulator found them liable, you should too." This may be an informal way to use foreign law for its most controversial purpose, including the possibility that it per se establishes evidence of a violation. Moreover, if this kind of use became widespread, the importation of foreign regulation would give plaintiffs and consumers regulation shopping incentives: they can both advocate for domestic regulation and, if that fails, take advantage of foreign regulation. These uses would nonetheless bring epistemic and innovation benefits but cannot entirely escape criticism.

### *3. MDL and Settlements as Vehicles for Internalizing Foreign Regulatory Information*

Multidistrict litigation and large-scale settlements allow litigation to internalize foreign regulations. If litigation-with-foreign-regulation is to have systemic effects, it must apply beyond individual parties and must involve areas where foreign regulators sometimes impose higher burdens than American regulators. MDLs meet these requirements in several ways:

First, while litigation is typically a case-by-case affair, MDLs can have systemic importance because they are akin to public administration.<sup>250</sup> The nature of the cases, procedures involved, and culture of MDL judges all push toward a regulatory role rather than a simple finding of liability.<sup>251</sup> MDL judges sometimes see themselves as quasi-regulators, attempting to resolve systemic issues of national importance.<sup>252</sup> There is the simple fact that while decisions in normal litigation are confined to

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<sup>249</sup> Yet, since most scholars and courts agree that the objections are weak, debates focus on how to determine the content of foreign law. See, e.g., *Bodum USA, Inc. v. La Cafetiere, Inc.*, 621 F.3d 624, 628–31 (7th Cir. 2010). To be sure, U.S. courts rarely cite foreign law. See, e.g., David Zaring, *The Use of Foreign Decisions by Federal Courts: An Empirical Analysis*, 3 *J. Empirical Legal Stud.* 297, 297 (2006).

<sup>250</sup> See, e.g., David L. Noll, *MDL as Public Administration*, 118 *Mich. L. Rev.* 403 (2019); Richard A. Nagareda, *Mass Torts in a World of Settlement* 57, 60, 70 (2007).

<sup>251</sup> See Andrew D. Bradt & D. Theodore Rave, *The Information-Forcing Role of the Judge in Multidistrict Litigation*, 105 *Calif. L. Rev.* 1259, 1262–64 (2017).

<sup>252</sup> See, e.g., Transcript of Proceedings at 4–6, *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-02804 (N.D. Ohio argued Jan. 9, 2018) (imploping the parties to reach a solution that would do something to "abate [the national opioid] crisis").

the parties, MDLs can be enormous. Moreover, procedural retrenchment and the expansion of arbitration have weakened class actions, mostly foreclosing that avenue of interaction.<sup>253</sup> But MDLs have stepped into this breach because, by their very nature, they aggregate large numbers of underlying claims with only a few common facts. Massive MDLs, especially in the mass torts context, can range from a few thousand claims to tens of thousands of plaintiffs. By allowing pre-trial decisions to affect thousands of cases at a time, MDL can have system-wide effects. And, in contrast to class action claims, which often settle pre- or post-certification and therefore before extensive discovery on the merits, there is no similar pre-discovery stage at which most MDLs die out.<sup>254</sup> That means that MDLs likely bring up discovery issues—and foreign regulations—much more directly than class actions do.

Second, discovery in MDLs is uniquely expansive. As discussed above, MDL discovery decisions have been a primary avenue for importing foreign health regulations from Europe, allowing pre-trial decisions to affect tens of thousands of plaintiffs.<sup>255</sup> But this is quite unusual. In the run-of-the-mill case, discovery requests for foreign regulatory information would face difficult objections on relevance, burden, and proportionality.<sup>256</sup> Discovery in an MDL case, however, avoids these problems. A request for regulatory information may not be proportional in an individual case, but it surely is when it involves thousands of plaintiffs. MDLs also expand the scope of relevance to thousands of cases with different legal claims.

Finally, the cases that get multidistrict treatment implicate multinational regulatory frameworks. Products liability and antitrust make up almost two-thirds of MDL cases.<sup>257</sup> These two areas have several

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<sup>253</sup> Brian T. Fitzpatrick, *The Conservative Case for Class Actions* 16 (2019).

<sup>254</sup> For a thorough discussion of MDL settlements, see D. Theodore Rave, *Closure Provisions in MDL Settlements*, 85 *Fordham L. Rev.* 2175 (2017). For a discussion of class action settlements, see Brian T. Fitzpatrick, *An Empirical Study of Class Action Settlements and Their Fee Awards*, 7 *J. Empirical Legal Stud.* 811, 819 (2010) (documenting that 68% of federal settlements from 2006 to 2007 were settlements of class actions). See also Andrew D. Bradt, *Something Less and Something More: MDL's Roots as a Class Action Alternative*, 165 *U. Pa. L. Rev.* 1711 (2017) (discussing the relationship between the two devices).

<sup>255</sup> See *supra* Subsection II.A.1.

<sup>256</sup> See, e.g., *In re Bard IVC Filters Prods. Liab. Litig.*, 317 F.R.D. 562, 566 (D. Ariz. 2016).

<sup>257</sup> Daniel S. Wittenberg, *Multidistrict Litigation: Dominating the Federal Docket*, *Am. Bar Ass'n* (Feb. 19, 2020), <https://www.americanbar.org/groups/litigation/publications/litigation-news/business-litigation/multidistrict-litigation-dominating-federal-docket/> [<https://perma.cc/7QZD-RKRC>].

unique qualities that make them amenable to internalizing foreign law. As Anu Bradford has argued, these areas are inelastic because regulated entities cannot easily circumvent regulation by moving jurisdictions, unlike tax or financial regulations.<sup>258</sup> As discussed above, antitrust has always been an international area of law, partly because over a hundred nations have antitrust laws and U.S. antitrust law can apply extraterritorially.<sup>259</sup> Similarly, products liability actions—especially in health and food—involve consumer markets that businesses cannot avoid by moving headquarters. That means that both areas involve transnational overlapping regulations.

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On the whole, the phenomenon of foreign regulation in American litigation seems to be leading to a domestication process, whereby American institutions internalize foreign laws and use them as a source of information. Few of the traditional concerns about foreign law in the American legal system seem to cash out here.

While we cannot make a strong claim about the optimal amount of information flow—this is not a net social welfare calculus—we can at least begin to appreciate the potential benefits of foreign input: auditing the work of domestic agencies, operating as a failsafe to avoid domestic regulatory capture, and increasing expertise and information-gathering. This leads to a qualified conclusion that courts should welcome foreign regulations, at least in some instances.

### *B. Harmonizing Regulation with Litigation*

This Section argues that when litigation nudges companies and regulators to domesticate foreign regulations, it also serves as a surprising vehicle for regulatory harmonization. When private plaintiffs incorporate foreign influences, they are unwittingly leading American law towards convergence with foreign law, promoting the broader goals of a burgeoning regulatory harmonization movement.<sup>260</sup> This harmonization effect runs against some of the literature in this area, which worries more

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<sup>258</sup> Bradford, Brussels Effect Article, *supra* note 53, at 16–17.

<sup>259</sup> See Subsection I.C.1.

<sup>260</sup> See Adam S. Zimmerman, The Global Convergence of Global Settlements, 65 U. Kan. L. Rev. 1053, 1057–58 (2017).

about existing conflicts between regulatory systems that sometimes disable U.S. law.<sup>261</sup>

*1. The Relationship Between Regulatory Harmonization and U.S. Litigation*

Countries have long recognized that an array of modern problems require global cooperation, whether the issues are related to commerce, national security, or environmental pollution. Solutions to these problems require cross-border cooperation between legislators and regulators.<sup>262</sup> Traditionally, this kind of harmonization took place through international conventions, bilateral treaties, and other formal or informal agreements. The global financial crisis, however, catalyzed a movement of direct regulator-to-regulator cooperation. Seizing the moment, the Obama administration issued an executive order that instructed “American regulators to coordinate with their foreign counterparts whenever possible.”<sup>263</sup> By then, the Federal Reserve, FBI, FDA, and other agencies were involved in coordinating actions with foreign counterparts, developing a rich network of cross-border relationships and promoting regulatory harmonization.<sup>264</sup> One particularly successful example has been the International Competition Network, where antitrust authorities from around the world communicate and cooperate with each other.<sup>265</sup>

Recent literature has explored the ways in which cross-border regulatory networks have unified domestic regulatory agendas.<sup>266</sup> Jean Galbraith and David Zaring have highlighted that this phenomenon has become “a strikingly important aspect of U.S. foreign policy,” and has mostly been operationalized through “soft law,” which they define as “agreements between executive branch actors in two or more countries that do not create legal obligations but which nonetheless contain

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<sup>261</sup> Noll, *Conflicts*, supra note 37, at 44–47 (discussing manners by which “U.S. regulatory systems are disabled in favor of regulation by other legal systems”).

<sup>262</sup> Curtis A. Bradley, *International Law in the U.S. Legal System* 75 (2013).

<sup>263</sup> Galbraith & Zaring, *Soft Law*, supra note 46, at 737 (citing Exec. Order No. 13,609, 77 Fed. Reg. 26, 413 (May 1, 2012)).

<sup>264</sup> *Id.* at 737–39.

<sup>265</sup> Press Release, U.S. and Foreign Antitrust Officials Launch International Competition Network, FTC (Oct. 25, 2001) <https://www.ftc.gov/news-events/press-releases/2001/10/us-and-foreign-antitrust-officials-launch-international> [<https://perma.cc/B9CX-8MTL>].

<sup>266</sup> See, e.g., Slaughter, supra note 46; Lawrence L.C. Lee, *The Basle Accords as Soft Law: Strengthening International Banking Supervision*, 39 Va. J. Int'l L. 1 (1998).

substantive commitments.”<sup>267</sup> The majority of this new soft-law is negotiated and implemented almost entirely by bureaucrats, translating into agreements between, for instance, “the Fed with the Bank of England and the FBI with Europol.”<sup>268</sup> This now means that U.S. agencies “have become international actors in order to fulfill their own domestic regulatory missions.”<sup>269</sup> Galbraith and Zaring argue that this new soft law is “promising” because it represents an “effort by the American government to address problems that cross borders with global solutions.”<sup>270</sup> Galbraith and Zaring defend this phenomenon on the constitutional basis that executive branch officials deserve leeway in the context of national security and foreign affairs.<sup>271</sup>

The phenomenon of litigation involving foreign regulation brings its own peculiarities in this context.<sup>272</sup> At the outset, we should understand that the distinction between regulation and litigation is often illusory. Although managed by different institutions—executive agencies as opposed to courts and plaintiffs—a rich literature has argued that in the United States, litigation often takes the role of regulation.<sup>273</sup> Never mind the distinction between a public regulator and a plaintiffs’ attorney. By empowering private plaintiffs to enforce statutes in a variety of contexts, Congress empowered litigants to behave like public regulators.<sup>274</sup> And we have reasons to believe that incentives for public regulators and private plaintiffs are comparable, leading to enforcement results that are more similar than one might expect.<sup>275</sup> The United States relies on ex post private enforcement much more than comparable countries, giving private litigation the power to shape a significant slice of our social norms, statutes, and laws. European regulatory standards may be more

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<sup>267</sup> Galbraith & Zaring, *Soft Law*, supra note 46, at 739–40.

<sup>268</sup> *Id.* at 740.

<sup>269</sup> *Id.*

<sup>270</sup> *Id.*

<sup>271</sup> *Id.* at 780.

<sup>272</sup> This resembles a literature on unusual transnational enforcement. See, e.g., Zachary D. Clopton, *Diagonal Public Enforcement*, 70 *Stan. L. Rev.* 1077, 1080–81 (2018); Anne-Marie Slaughter, *A New World Order* 3, 14 (2005).

<sup>273</sup> See, e.g., Robert A. Kagan, *Adversarial Legalism: The American Way of Law* 3 (2001); Sean Farhang, *The Litigation State: Public Regulation and Private Lawsuits in the U.S.* (2010); William M. Landes & Richard A. Posner, *The Private Enforcement of Law*, 4 *J. Legal Stud.* 1 (1975).

<sup>274</sup> See Diego A. Zambrano, *Discovery as Regulation*, 119 *Mich. L. Rev.* 71, 75 (2020) [hereinafter Zambrano, *Discovery*].

<sup>275</sup> *Id.* at 77.

burdensome than those of the U.S. in some contexts. But private rights of action in the U.S. are more prevalent and burdensome than in European law.

Once we understand that litigation is a form of regulation, we should expect litigation to play some role in regulatory harmonization. That, at least, is what we see in the three main channels of foreign regulatory influence on U.S. litigation. As discussed above, in channel one, plaintiffs generally request discovery of information that was not produced to the FDA, FTC, or SEC. In doing so, they move U.S. law closer to that of European counterparts and, crucially, reveal to domestic regulators the kinds of materials that they could be requesting. Moreover, plaintiffs open channels of information between domestic and foreign regulators, promoting regulatory convergence.

We may worry that there is no clear channel by which regulators can observe and incorporate innovations from litigation. But not only is there evidence that agencies track major litigation in their subject areas,<sup>276</sup> there is also evidence of a pro-harmonization connection between MDL cases and FDA rulemaking.

For instance, return to *In re Zofran*, in which plaintiffs filed claims over a medicine that allegedly caused birth defects. Plaintiffs requested the entire body of regulatory correspondence with agencies in the United Kingdom, Canada, and Japan, arguing that documents showed that regulators had cast doubt on the safety of Zofran and that defendants had in turn altered their foreign labels.<sup>277</sup> Plaintiffs also alleged that defendant disclosed to Japanese regulators a series of adverse studies that it then failed to disclose to the FDA.<sup>278</sup> While the case was taking place, the FDA simultaneously considered new rules that would alter labeling for that medicine. Surprisingly, the judge presiding over *In re Zofran* personally submitted a comment to the FDA—during the notice and comment period—disclosing the facts of *In re Zofran* and urging the FDA to “resolve the matter as expeditiously as possible, consistent with the agency’s statutory and regulatory duties, including its overarching duty

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<sup>276</sup> See Clopton, Redundant, *supra* note 211, at 297–300.

<sup>277</sup> Plaintiff’s Motion Addressing Production of Foreign Regulatory Files at 1–2, *In re Zofran* (Ondansetron) Prods. Liab. Litig., No. 1:15-md-02657 (D. Mass. July 27, 2017).

<sup>278</sup> Memorandum and Order on Defendant’s Motion for Summary Judgment Based on Federal Preemption at 18, *In re Zofran* (Ondansetron) Prods. Liab. Litig., No. 1:15-md-02657 (D. Mass. Feb. 5, 2019).

to protect the safety of the public.”<sup>279</sup> This connection between *In re Zofran* and FDA rulemaking exemplifies the potential for litigation to nudge American regulations closer to foreign standards. This suggests that the link between litigation involving foreign regulations and domestic rulemaking is not merely hypothetical—it already exists and may even be common.

The potential for litigation-led harmonization is even clearer in channel two, when American plaintiffs ride on the coattails of foreign agency findings or enforcement. This is a straightforward way for American law to align with foreign regulatory enforcement agendas. As discussed above, this harmonization could cover areas like technology and privacy, consumer rights, products liability, and antitrust. Cases related to the GDPR or Roundup mean that even if American regulators would otherwise prefer a more relaxed enforcement agenda, American litigators are narrowing the enforcement gap between the United States and Europe.

Further afield, there is some evidence of coordination (if not harmonization) in the third channel, when foreign agencies disclose ongoing foreign antitrust enforcement. For instance, in *Payment Card Interchange*, plaintiffs sought an extensive record of documents that defendants Visa and Mastercard had produced to the European Commission during an antitrust investigation.<sup>280</sup> In response, the Commission submitted an amicus brief that explained in detail its antitrust enforcement agenda and provided recent data about the efficacy of its leniency program.<sup>281</sup> The brief was so important that the Eastern District of New York recounted the European Union investigation extensively and cited the amicus brief, noting that “[t]he Commission has established that confidentiality plays a significant role in assisting the effective enforcement of European antitrust law.”<sup>282</sup> The key to this exchange was that by intervening in the case, foreign regulators pushed U.S. courts to

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<sup>279</sup> Letter from F. Dennis Saylor, IV, C.J. D. Mass., to Stacey Cline Amin, Chief Counsel, Food and Drug Administration, *In re Zofran (Ondansetron) Prods. Liab. Litig.*, No. 1:15-md-02657 (Dec. 13, 2019).

<sup>280</sup> Letter from Craig Wildfang, Robins, Kaplan, Miller, & Ciresi LLP, to James Orenstein, Mag. J. E.D.N.Y., *In re Payment Card Interchange Fee & Merch. Disc. Antitrust Litig.*, 1:05-md-01720 (Jan. 5, 2010).

<sup>281</sup> *In re Payment Card Interchange Fee & Merch. Disc. Antitrust Litig.*, No. 05-md-1720, 2010 WL 3420517, at \*9–10, (E.D.N.Y. Aug. 27, 2010).

<sup>282</sup> *Id.* at \*1, \*9.

defer to European leniency programs, promoting comity and avoiding conflicting approaches.<sup>283</sup>

Taking all of this together, it appears that litigation has the potential to standardize regulatory requirements across borders. By disseminating information about foreign regulations, that in turn can motivate U.S. regulators to pay attention to foreign regimes, litigation forces companies to deal with similar requirements across the world. As *In re Trasyolol Products Liability Litigation* shows, a German company like Bayer can no longer treat domestic German regulators better than it treats the FDA; nor can it produce more information abroad while keeping it from American regulators. And, vice versa, an American company like Boeing can no longer rely on a cozy relationship with the FAA (lest it pay larger tort damages). This pro-harmonization or standardization of regulation is a powerful effect.

## 2. *The Consequences of Litigation-Led Harmonization*

Litigation may at least sometimes push the United States to converge with European standards, but it is unclear whether this litigation-led harmonization is truly analogous to agency-led harmonization. Consider the following complications:

First, while regulator-to-regulator harmonization tends to increase the level of regulation, litigation can sometimes decrease it. Regulator-regulator cooperation is almost always in pursuit of a framework to address a new problem, be it a financial crisis, transnational crime, or environmental pollution. In all these cases, regulators reach out abroad with the goal of adopting new regulations. By contrast, the interaction between American litigation and foreign regulation can be either pro-regulatory or deregulatory. In channels one and two, cases that borrow from higher burdens imposed by foreign regulators are de facto increasing American litigation burdens. All GDPR-based cases in the United States would not exist without the GDPR. So too for discovery of information produced to Japanese or Canadian officials that increase the likelihood of liability for a defendant. So far, the analogy seems apt. But, in channel three, foreign regulators submit letters that prevent further discovery in an antitrust case. That kind of intervention effectively levels down or

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<sup>283</sup> To be sure, it may be unfair to call “harmonization” what in fact seem like instances of foreign frustration of American antitrust litigation. But I’m referring here to a kind of rough harmonization that promotes convergence.

weakens U.S. enforcement relative to what it would be if plaintiffs had access to foreign discovery. This limits the harmonizing effects of litigation.

Second, a litigation-led effect may not be comparable to regulations because it appears inefficiently in ad hoc litigation. Perhaps this litigation-led harmonization cannot possibly match the work of regulators who deal with system-wide problems through system-wide solutions. But even if litigation-led harmonization is marginal, it may be striking precisely at the relevant margin of cases that make a difference. There is evidence that sufficiently large cases can force companies to restructure their operations.<sup>284</sup> Moreover, in the context of antitrust, private claims significantly outnumber public enforcement in the United States, accounting for 90% of all actions between 1975 and 2012.<sup>285</sup> It only takes a dozen of these antitrust cases, with significant influence from foreign regulators, to have systemic effects. And given the historical laxity of American regulation, litigation is one remaining vehicle that can nudge the U.S. closer to global enforcement standards. (Although, to be sure, some of the historical laxity is itself rooted in judicial decisions).

Third, litigation may be so riddled with its own distortions that it is not consistently pro-harmonization.<sup>286</sup> Cases can follow *sui generis* paths that borrow or reject foreign law, or parties can settle early and confidentially, leaving no imprint on the law. But even if this is true, one important benefit of cross-border harmonization is consistency for regulated entities. It may be better for regulated multinationals that American litigation be influenced by European regulation because it leads to a more uniform set of standards across transnational markets.<sup>287</sup> Moreover, when U.S. litigation borrows from standards set by foreign regulators, there may be network efficiency gains, including reduced compliance and reporting costs for firms, and reduced information and enforcement costs

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<sup>284</sup> Brian T. Fitzpatrick, *Do Class Actions Deter Wrongdoing?*, in *The Class Action Effect* 197 (Catherine Piché ed., 2018).

<sup>285</sup> Brief of Antitrust Scholars as Amici Curiae in Support of Respondents at 12, *Apple Inc. v. Pepper*, 139 S. Ct. 1514 (2018) (No. 17-204).

<sup>286</sup> See Steven Shavell, *The Fundamental Divergence Between the Private and the Social Motive to Use the Legal System*, 26 *J. Legal Stud.* 575, 575 (1997); Steven Shavell, *The Level of Litigation: Private Versus Social Optimality of Suit and of Settlement*, 19 *Int'l Rev. L. & Econ.* 99, 99 (1999).

<sup>287</sup> Cf. George A. Bermann, *Regulatory Cooperation with Counterpart Agencies Abroad: The FAA's Aircraft Certification Experience*, 24 *Law & Pol'y Int'l Bus.* 669 (1993) (arguing for the superiority of transnational cooperation in aeronautical regulation).

for agencies.<sup>288</sup> From a political economy angle, U.S. companies are less likely to object to the use of foreign regulation in litigation if they already have market-based incentives to comply with a foreign standard across the board, as the Brussels Effect literature suggests.<sup>289</sup>

Fourth, one of the most important problems with litigation-led harmonization is that, as discussed above, it lacks the foreign affairs legitimacy of the executive branch.<sup>290</sup> Scholars have defended the growth of transnational regulatory networks by arguing that bureaucrats can draw from the President's Article II power.<sup>291</sup> Courts, by contrast, have crafted a set of doctrines that keep them away from foreign affairs.<sup>292</sup> One might also worry that Congress has not consented to these "unorthodox forms of international lawmaking."<sup>293</sup>

But it would stretch those doctrines to argue that courts have no role at all in cases involving foreign regulators. Courts host these cases only because they fall within existing limits on personal jurisdiction, venue, subject matter jurisdiction, and discovery. In other words, these cases are legitimate because they meet the same standards as every other case in front of U.S. court.<sup>294</sup> And the legitimacy of the phenomenon is enhanced by the fact that it is bi-directional: foreign regulators and private plaintiffs often borrow from U.S. litigants and regulators. It matters that the United States exports its regulations in a variety of ways, including aggressive assertions of extraterritorial jurisdiction, standard-setting in major industries, and market-based mechanisms. The phenomenon of regulatory convergence is thus borne out of an exchange of laws across borders.

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<sup>288</sup> See Marisam, *supra* note 39, at 1915–17.

<sup>289</sup> I thank Anu Bradford for this insight.

<sup>290</sup> Cf. Julian G. Ku, *International Delegations and the New World Court Order*, 81 Wash. L. Rev. 1, 5–8 (2006) (arguing that allowing U.S. courts to recognize international tribunal judgments would be constitutionally problematic, since that authority lies with the other two branches).

<sup>291</sup> Galbraith & Zaring, *Soft Law*, *supra* note 46, at 767–68.

<sup>292</sup> Ingrid Wuerth, *The Future of the Federal Common Law of Foreign Relations*, 106 Geo. L.J. 1825, 1830–33 (2018).

<sup>293</sup> See Timothy Meyer & Ganesh Sitaraman, *Trade and the Separation of Powers*, 107 Calif. L. Rev. 583, 662–66 (2019).

<sup>294</sup> One may also worry that litigation-led harmonization limits the ability of regulated entities to adjust compliance to each country.

*C. To Brussels Only When Americans Want It*

When domestic litigation imports foreign regulation, it strengthens the hand of foreign regulators who are already exporting their domestic regulations through other means. Foreign regulators gain an agenda-setting power because they can limit the scope of ongoing American litigation. However, this agenda power is limited, because U.S. courts need not comply with foreign regulatory letters of interest. In this sense, litigation both expands and constrains the influence of foreign regulations on U.S. law and domestic companies.

Recent literature on the so-called Brussels Effect argues that the European Union exports its regulations to the rest of the world in a variety of ways, both deliberately and unintentionally. Anu Bradford, for instance, has argued that the European Union exercises “unprecedented global power” by regulating multinationals and transnational markets, leading regulated entities to comply with EU standards worldwide.<sup>295</sup> Much of the mechanism is based on market forces which incentivize companies to standardize across the company conduct taken to comply with EU standards. When the EU shapes transnational markets, it effectively externalizes its regulatory frameworks to the rest of the world. The European Commission has explicitly recognized that the EU seeks to “inspire global standard setting” in contexts like product safety, securities and corporate governance, and the environment.<sup>296</sup> One prominent example is the worldwide effect of the European GDPR, which has nudged large technology companies to adopt new privacy policies in all markets, not just the EU.<sup>297</sup>

Yet another aspect of the Brussels Effect involves state and federal legislation that explicitly draws on EU regulations. Bradford has highlighted areas like electronic waste regulations in which state legislatures copy or borrow significant provisions from European Law.<sup>298</sup> In that sense, we see legislative importation of foreign regulation.

Setting these mechanisms aside, it appears that when litigation imports foreign regulations, it seems to expand the Brussels Effect. As discussed above, all three channels of litigation-foreign regulation interaction seem

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<sup>295</sup> Bradford, Brussels Effect Article, *supra* note 53, at 64.

<sup>296</sup> Comm’n Eur. Cmities., Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: A Single Market for Citizens 7 (Feb. 21, 2007).

<sup>297</sup> Bradford, Brussels Effect Book, *supra* note 40, at 131–32.

<sup>298</sup> Bradford, Brussels Effect Article, *supra* note 53, at 29–30.

to strengthen the hand of foreign agents: (1) sometimes documents produced to foreign regulators shape massive MDL cases, increasing the burden on regulated entities above FDA standards; (2) plaintiffs' attorneys often draw or piggyback on European decisions or investigative strategies and (3) the European Commission often submits letters and amicus briefs that freeze the production of documents in antitrust cases. Even the rising number of cases involving GDPR shows the powerful effect of European law. It seems, then, that the Brussels Effect is alive in domestic litigation: European regulators are exporting their agendas to U.S. litigation.

There may be reason to worry about this side of the Brussels Effect, especially if European regulators are not aware of their impact on U.S. cases. For starters, regulators may be over-detering conduct and miscalibrating their enforcement priorities. Each legal order has a carefully constructed system of deterrence that depends on some balance of substantive law, procedure, rules of evidence, and remedies. For instance, the EU's substantive antitrust standards are *de jure* stricter than in the U.S. in part because the EU does not have as robust remedies or private rights of action.<sup>299</sup> However, the deterrence effect of each system may be the same because the U.S. may achieve it through a combination of criminal sanctions, class actions, and treble damages. But if you start mixing the stringent substantive standards of the EU with U.S. private litigation and harsh remedies, you may over-deter. This can happen if EU deterrence calculations are based only on European conduct and not on U.S. liability. Suppose that the European Commission negotiates a settlement with tech companies, reaching the optimal amount that, in its calculation, will force the companies to stop violating European law. If those companies are then sued in the U.S. based on the settlement, the companies may be overly deterred from what might be beneficial behavior. Moreover, in such a scenario, European regulators would not internalize the full consequences of their regulation. Again, their cost-benefit analyses might be inadequate.

While powerful, these scenarios also show the ability of U.S. domestic actors—litigants and judges—to decide whether to incorporate foreign regulations. In all these cases, the interaction with foreign regulation begins because of American procedure: private rights of action, pleading standards, broad discovery, MDLs, and class actions. As discussed above, in all these steps the main gatekeeper is the U.S. federal judge. It is

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<sup>299</sup> I thank Anu Bradford for some of this language.

ultimately the judge that decides whether to admit foreign regulatory documents, or whether a claim that cites the GDPR meets the plausibility pleading standard. Even if the judge is focused on the individual case rather than optimal systemic deterrence, there is a U.S. government official deciding whether to import foreign regulations through complex litigation. This is quite different from the typical Brussels Effect where multinational companies decide unilaterally whether to comply with European standards worldwide.

Moreover, when litigation is the vehicle for importing European regulations, the Brussels Effect can only operate on a case-by-case basis. Some courts can use documents produced to European environmental agencies, while other courts may reject documents produced to European health ministries. Again, this is radically different from the regulatory Brussels Effect where industries can decide in a single moment whether to comply with GDPR wholesale and worldwide. The case-by-case approach gives U.S. courts space and power to incorporate foreign regulations at their pleasure.

The Brussels Effect on litigation seems weak relative to its influence on multinational markets. It does not present a situation of “[u]nilateral regulatory globalization,” where “a law of one jurisdiction migrates into another in the absence of the former actively imposing it or the latter willingly adopting it.”<sup>300</sup> Rather, litigation gives U.S. actors many tools to adopt or reject European regulation. Indeed, it also gives U.S. litigants and courts the ability to adopt such regulation in a piecemeal fashion. While the Brussels Effect supports broader European competitiveness goals, the extraterritorial use of European regulations in American litigation has the potential to weaken or distort European standards. As discussed above in the antitrust context, American discovery can weaken European antitrust leniency programs.<sup>301</sup> American judges thus have unilateral power to shape compliance with European standards.

The use of litigation to import foreign regulations also complements legislative borrowing of EU laws. As discussed above, when state legislatures draw on European law, they take advantage of existing expertise, experience, and application of law in comparable countries. Litigation completes this process by allowing the judiciary to mirror what legislatures are already doing. Indeed, these two types of regulatory

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<sup>300</sup> Bradford, Brussels Effect Article, *supra* note 53, at 4.

<sup>301</sup> 2 Max Huffman & Andre Fiebig, *Antitrust and American Business Abroad* § 15:24 (4th ed. 2020).

imports (legislative versus judicial) go hand-in-hand and increase the legitimacy of the entire process: if a legislature can draw on foreign law, litigants and courts should be able to do it as well.

All of this also raises a separate question: should foreign regulators care that American litigators are free riding on their work? On the one hand, European regulators may like the resulting effects of uniformity, harmonization, and predictability on American litigation. It allows their policies and work to have broader effects. On the other hand, as discussed above, piggyback cases may disrupt their antitrust leniency programs and deterrence calculations. From a more cosmopolitan angle, litigation free riding may seem improper. But it is unclear what other effects it may have on European calculations.

Taking all of this together, it seems like the litigation-foreign regulation interaction expands and alters the Brussels Effect and gives U.S. judges a powerful gatekeeper role.

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Bringing all these sections together, we can draw some preliminary normative conclusions. Table 2 below summarizes the potential positive and negative effects of the three channels:

**Table 2: The Channels' Effects**

Effect	Potential Benefits	Potential Costs
1. Domesticating Foreign Regulations	Audits the work of domestic agencies; operates as a failsafe to circumvent regulatory capture; increases expertise and information-gathering; and forces companies to standardize compliance across borders	Overlapping investigations have a bias toward false-positives (overdeterrence); administrative lassitude; strategic avoidance of certain jurisdictions
2. Harmonizing Regulation with Litigation	Regulatory convergence promotes consistency for regulated entities; transnational cross-pollination and coordination; reduces conflicts of laws; can be pro- or deregulatory	Litigation is ad hoc and lacks consistency; lacks foreign affairs legitimacy; may distort U.S. law

3. The Brussels Effect	Judges have gatekeeping power to selectively incorporate or reject foreign regulation; limits Brussels Effect to a case-by-case basis; complements legislative borrowing of EU laws	Empowers foreign regulators; overdeterrence due to overlapping liability; free riding can disrupt foreign leniency programs
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As this Section and table demonstrate, foreign regulations in American litigation shows a new way in which foreign law can influence the U.S. legal system, with a variety of consequences. This Part compared and contrasted litigation-with-foreign-regulations from the Brussels Effect, transnational regulatory networks, and simple citations to foreign decisions. This comparison allows us to begin a normative inquiry on whether foreign input is beneficial for the U.S. legal system. On the one hand, the sections above specify several theoretical benefits: a way to avoid agency capture, borrow foreign expertise, audit the work of American regulators, and increase the ease of cross-border commerce and harmonization. On the other hand, there may be potential drawbacks too, including over-deterrence, the misguided use of foreign standards, and the haphazard use of regulations in a case-by-case and unsystematic manner. Nonetheless, it may be particularly important to see the positive and balancing effect that comes from litigation-led importation *now* when (1) some evidence suggests that lobbying expenditures in the United States are relatively high<sup>302</sup> and (2) there appears to be a concerted attack on the administrative state.<sup>303</sup> If so, litigation may be providing a needed backstop to other problems. Insofar as this phenomenon is problematic, Part III proposes a way to calibrate foreign input.

### III. DOMESTIC AGENCY INFORMATION PROVIDERS

Thus far, the Article has explored the intersections between domestic litigation and foreign regulation and the many ways this interaction can affect domestic and foreign institutions, domestic law, and regulatory

<sup>302</sup> See Bradford, *Brussels Effect Book*, *supra* note 40, at 251.

<sup>303</sup> David L. Noll, *Administrative Sabotage*, 120 *Mich. L. Rev.* (forthcoming 2021) (manuscript at 4) (on file with author).

harmonization. This Part highlights existing doctrinal and practical problems in the intersections explored above and attempts to resolve them. I propose that federal courts invite domestic agencies to help courts determine the propriety of admitting foreign regulatory information.

*A. Existing Doctrinal and Institutional Questions*

As discussed above, the three channels of litigation-foreign regulation interaction have produced difficult doctrinal and practical questions that courts have not fully resolved. The three most important problems seem to be: (1) If foreign regulatory information is discoverable, should it be admissible in evidence? And, if admissible, for what purposes? (2) Should district courts consider an ongoing foreign investigation a “plus” factor in a plausibility analysis? How should district courts evaluate conflicting foreign regulations? (3) What level of deference is due when foreign regulators file letters requesting that information remain confidential and inadmissible? The current judicial approach to these questions reflects appropriate pragmatism. But these cases raise broader questions about courts’ expertise.

*1. The Discoverability and Admissibility Problem*

As discussed above, courts typically find that foreign regulatory records are discoverable. Even courts that have refused to order the production of foreign materials have justified their decisions on grounds unrelated to discoverability.<sup>304</sup> The run-of-the-mill discovery requests in MDL cases take place within a massive discovery process. Thus, plaintiffs must often specify a regulatory agency, making their request less burdensome and appropriate. Some plaintiff requests, however, can be much broader, prompting defendants to push back. Most courts sided with plaintiffs in these cases, rejecting the argument that the information was irrelevant or too burdensome to produce.<sup>305</sup> Corporate defendants sometimes also argue that disclosing foreign regulatory information would risk violating foreign statutes that render such information confidential. But almost across the board, courts either reject this defense

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<sup>304</sup> See Section I.A.

<sup>305</sup> See, e.g., *In re Incretin-Based Therapies Prods. Liab. Litig.*, 721 F. App’x 580, 583 (9th Cir. 2017).

or require defendants to raise it in the context of an actual threat of foreign sanctions.<sup>306</sup>

As a doctrinal matter, courts are mostly correct on the discovery question. In a typical case, information generated by foreign regulation should be discoverable.<sup>307</sup> Our broad discovery rules require only that the information be in the possession, custody, or control of the defendant.<sup>308</sup> While overly broad requests should always be slapped down as unduly burdensome, there is likely no such burden in these cases, because defendants have already assembled and produced the documents to foreign agencies.

Setting aside discoverability, courts divide over whether the resulting information is admissible in evidence and for what purpose it can be used. As an initial matter, courts often denied motions in limine to prevent the introduction of foreign regulatory evidence altogether.<sup>309</sup> Some courts have excluded foreign regulatory evidence on the basis of Rule 403 unfair prejudice.<sup>310</sup> Other courts have declared such information admissible for the purpose of showing defendant had knowledge and notice of side effects of a medication.<sup>311</sup> In these cases, courts have ruled that the documents can speak to defendants' motive, are relevant, are not hearsay, and jurors are unlikely to be confused.<sup>312</sup> But courts have also denied admissibility based on findings that European regulatory standards are too different from our own, or concerns "that the jury would be confused by references to foreign regulations and standards because the jury must decide the case based on standards in the United States."<sup>313</sup>

Disagreements among courts reflects judges' fears about the uses of foreign regulatory information, leading them to admit it for some

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<sup>306</sup> See Zambrano, *Comity*, supra note 63, at 206–07.

<sup>307</sup> Manual for Complex Litigation, Fourth § 11.494 (2004).

<sup>308</sup> Zambrano, *Comity*, supra note 63, at 164–67.

<sup>309</sup> See, e.g., *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 551–53 (S.D.N.Y. 2004).

<sup>310</sup> See, e.g., *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 965–66 (D. Minn. 2009). But see *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 553 (S.D.N.Y. 2004) ("The Court finds no legal basis upon which now to rule . . . that testimony regarding foreign regulatory actions is irrelevant as a matter of law in a United States products liability case governed by American law.")

<sup>311</sup> *Mahaney ex rel. Est. of Kyle v. Novartis Pharm.*, 835 F. Supp. 2d 299, 318 (W.D. Ky. 2011).

<sup>312</sup> *Schedin v. Ortho-McNeil-Janssen Pharms.*, 808 F. Supp. 2d 1125, 1138 (D. Minn. 2011).

<sup>313</sup> *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 2017 WL 4168410, at \*3 (E.D. La. 2017); see, e.g., *In re Seroquel Prods. Liab. Litig.*, 601 F. Supp. 2d 1313, 1318 (M.D. Fla. 2009); *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1336 (S.D. Fla. 2010).

purposes but not others. Courts' main fear, and perhaps source of confusion, is that they are trying to balance two opposing principles: (a) foreign regulatory information can often shed light on the knowledge and conduct of the defendant, (b) but courts do not want foreign law to set the standard for what counts as a violation under U.S. law and may not even trust the reliability of foreign findings of fact.<sup>314</sup> This core conflict presents a problem in these cases.

## *2. Foreign Enforcement Actions Should Influence Twombly's Plausibility Standard*

In a separate series of cases, U.S. litigants have introduced foreign regulatory studies and evidence to support their claims. One pressing question in this context is whether an ongoing foreign investigation should count as a "plus" factor in a motion to dismiss plausibility analysis. In other words, does the foreign investigation make a complaint more plausible, increasing the odds of survival under *Twombly* and *Iqbal*. Some courts have refused to take foreign investigations into account, reasoning that foreign law may impose completely different requirements not recognized by U.S. law.<sup>315</sup> Another complication is that not all foreign regulations may be created equally. Perhaps U.S. courts should be more open to regulations from comparable industrialized countries with a similar tradition. This would mean EU or U.K. regulations might be a plus factor but perhaps not similar behavior from other countries.

But a blanket rule that rejects all foreign regulatory investigations as irrelevant is highly questionable. For one, it may well be that specific foreign countries have statutes that closely mimic U.S. antitrust laws. Moreover, even if a foreign country's laws are mostly different, they may be similar in the most important ways.

Most importantly, however, a foreign investigation results in a cascade of documents that would make discovery cheaper in a U.S. case. *Twombly's* changes to the motion to dismiss standard—from notice to plausibility—were based almost entirely on the *problem of discovery costs*.<sup>316</sup> But a company on notice of a foreign investigation will have significantly reduced discovery costs. A foreign investigation mitigates

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<sup>314</sup> Cf. Maggie Gardner, *Parochial Procedure*, 69 *Stan. L. Rev.* 941, 958–67 (2017) (discussing how judges approach foreign cases).

<sup>315</sup> See, e.g., *Jones v. Micron Tech. Inc.*, 400 F. Supp. 3d 897, 921 (N.D. Cal. 2019).

<sup>316</sup> See *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557–58 (2007).

the costs of danger and *should* increase the plausibility of a complaint. When foreign regulators investigate a multinational, it puts them on notice of potential liability, triggers internal investigations, and forces companies to run audits and amass relevant documents. This chain of behavior would be highly relevant to a plausibility analysis.

These cases also raise the question of how U.S. courts should address concerns that it is inappropriate to incorporate foreign law. And whether it is efficient for courts to expend time and resources to decipher foreign law. In the latest wave of class action cases, plaintiffs use GDPR violations to allege securities fraud.<sup>317</sup> And in mass torts cases, plaintiffs have relied on the results of foreign medical studies.<sup>318</sup> In *Roundup*, both plaintiffs and defendants argued that foreign regulatory findings supported their position.<sup>319</sup> These cases also raise questions about foreign affairs and how to weigh foreign findings. One may even wonder whether U.S. law should allow such information only if there were procedural protections in the foreign country (akin to the collateral estoppel requirements of full and fair opportunity to litigate).

### 3. *What Deference Is Due to Foreign Regulators?*

The final problem presented by the interaction between domestic litigation and foreign regulation is the degree of deference due to letters from foreign regulators.<sup>320</sup> In addressing these letters, courts have sometimes applied a comity balancing test that considers several factors.<sup>321</sup> Although courts have developed a balancing test, the analysis is riddled with a set of open questions and problems. Under current law, courts have no good standard for which entities even deserve comity to begin with.<sup>322</sup> Even if foreign regulatory letters are entitled to comity-based deference, courts have not quite decided how to take regulatory interests into account. Courts have deferred to the wishes of the European

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<sup>317</sup> Alexis Kramer, Securities Fraud Claims Get Boost From EU Data Privacy Rules, *Bloomberg L.* (Feb. 1, 2019), [https://www.bloomberglaw.com/bloomberglawnews/tech-and-telecom-law/XFD6V9SC000000?bna\\_news\\_filter=tech-and-telecom-law#jcite](https://www.bloomberglaw.com/bloomberglawnews/tech-and-telecom-law/XFD6V9SC000000?bna_news_filter=tech-and-telecom-law#jcite) [<https://perma.cc/W5QW-Z36F>].

<sup>318</sup> See e.g., *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 368 F. Supp. 3d 94, 108 (D. Mass. 2019).

<sup>319</sup> See *In re Roundup Prods. Liab. Litig.*, 385 F. Supp. 3d 1042, 1047 (N.D. Cal. 2019).

<sup>320</sup> See *supra* Section I.C.

<sup>321</sup> See *In re Rubber Chems. Antitrust Litig.*, 486 F. Supp. 2d 1078, 1082 (N.D. Cal. 2007).

<sup>322</sup> See *Animal Sci. Prods., Inc. v. Hebei Welcome Pharm. Co. Ltd.*, 138 S. Ct. 1865, 1868 (2018).

Commission, while rejecting those of other regulators.<sup>323</sup> The Supreme Court has not addressed what district courts should do when the foreign regulatory letter is attempting to shape American litigation under domestic law.<sup>324</sup>

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The problems raised in this Section are clear:

1. In making both discovery and evidentiary decisions, courts need to better understand how to weigh foreign regulatory findings and how litigants can use those findings;
2. To understand the impact of foreign regulatory actions on domestic claims, courts need a better grasp of the interaction between U.S. regulatory regimes and foreign ones, the operation of foreign laws like GDPR, and the meaning of foreign regulatory studies from different countries; and
3. In their consideration of foreign regulatory letters, courts need to better understand how much deference to give specific foreign regulators and how to consider their impact on U.S. law and regulatory frameworks.

#### *B. Domestic Agency Input in the Transnational Context*

In this Section, I propose that the best way to address all the problems raised above is straightforward: courts should sometimes solicit the views of U.S. regulators. This argument draws from Catherine Sharkey's "agency reference model" which calls on courts to solicit input from agencies to determine procedural questions like preemption.<sup>325</sup> This form of agency input would allow U.S. courts to harness the expertise of our domestic regulators, better understand regulatory actions, promote harmonization and coordination, and retain a case-by-case pragmatic approach that does not set bright-line rules or imposes undue costs on

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<sup>323</sup> See, e.g., *In re Rubber Chemicals*, 486 F. Supp. 2d at 1081–84; European Commission Letter, *supra* note 169, at 8 (citing several district court decisions).

<sup>324</sup> *Animal Sci. Prods.*, 138 S. Ct. at 1875 (limiting the Court's holding to foreign letters that seek to aid in interpreting foreign law).

<sup>325</sup> Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 *Geo. Wash. L. Rev.* 449, 477 (2008) [hereinafter Sharkey, *Products Liability Preemption*]; Sharkey, *Opioid*, *supra* note 86, at 686. In the international context, the closest work comes from Jenny S. Martinez, *Towards an International Judicial System*, 56 *Stan. L. Rev.* 429, 434 (2003) (calling for more transnational communications among judiciaries).

litigants. Most importantly, it allows courts to leverage existing cross border regulatory networks.

### *1. What Domestic Agencies Can Contribute*

Domestic agencies have a set of characteristics that make them ideal to police the input of foreign regulators. In litigation involving foreign regulation, agencies can provide expertise, coordinate with domestic regulators, offer insights into both foreign and American regulatory regimes, and confer the legitimacy of the executive branch. Each of these benefits are developed further below.

First, as the literature and common wisdom recognize, domestic agencies are specialists in their fields, with unique insight into particular areas of law.<sup>326</sup> This expertise gives domestic agencies a deep understanding of their organic statutes, Congressional goals, and the aggregate costs and benefits of particular regulated conduct. Agencies can thus conduct cost-benefit analyses to understand if foreign regulatory input is appropriate, fair, or harmful to the market or regulated entities. As David Engstrom has argued, “[i]n performing this inquiry, an ideal agency will also consider whether a particular claim or set of claims advancing a novel statutory or regulatory interpretation strays beyond the core legislative design by, for instance, imposing liability for conduct that does not . . . fall within legislative purposes.”<sup>327</sup>

Second, domestic agencies are adept at managing relations with foreign regulators, and they can also harness the executive power’s constitutional authority.<sup>328</sup> Agencies across the spectrum have developed international networks to coordinate, share best practices, or at the very least understand foreign regulatory agendas. The FTC, for instance, is part of the International Competition Network.<sup>329</sup> The EPA has participated in international talks on a wide range of environmental topics.<sup>330</sup> These agencies and others have developed a rich understanding of foreign

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<sup>326</sup> Sharkey, *Products Liability Preemption*, supra note 325, at 485.

<sup>327</sup> See Engstrom, *Gatekeepers*, supra note 211, at 657.

<sup>328</sup> David Zaring, *Sovereignty Mismatch and the New Administrative Law*, 91 *Wash. U. L. Rev.* 59, 74–75 (2013).

<sup>329</sup> Stanley M. Gorinson & Robert Pambianco, *U.S. and European Merger Policies Move Towards Convergence*, Wash. Legal Found. (Aug. 9, 2002), <https://www.wlf.org/2002/08/09/publishing/u-s-and-european-merger-policies-move-towards-convergence/> [<https://perma.cc/MJ2C-J255>].

<sup>330</sup> See Robert V. Percival, *The EPA as a Catalyst for the Development of Global Environmental Law*, 70 *Case W. Res. L. Rsrv.* 1151, 1152–85 (2020).

regulatory trends, agendas, and operating frameworks. They are therefore well-positioned to evaluate the work of foreign agencies and to understand how it may interact with American regulatory regimes. In this sense, agencies have comparative institutional advantages over courts.

To be sure, agencies may be reluctant to weigh in on some of these matters, so there should be no obligation for them to do so.

Moreover, the combination of both executive power and delegated Congressional power gives domestic agencies a unique form of legitimacy when they deal with litigation that touches on foreign interests. In this sense, agencies can appropriately exercise the executive's constitutional foreign affairs powers, filling in for the perceived illegitimacy of the judiciary. Courts have long recognized that the President has a vast suite of foreign affairs powers.<sup>331</sup> But administrative law scholars—outside of the unitary-executive group—have also argued that “the President’s foreign affairs power [can] extend to other executive branch actors.”<sup>332</sup> Not only can agencies exercise foreign affairs power, some have also argued that agencies can also exercise delegated power from Congress in the context of foreign affairs.<sup>333</sup> As Galbraith and Zaring noted, “Quite often, Congress empowers executive branch actors to seek international cooperation or international agreements . . . in particular subject areas while providing little guidance on the content of these agreements.”<sup>334</sup> Agencies can use these powers to shape litigation involving foreign affairs.

Third, concerns about domestic regulatory capture are lessened when a foreign agency serves as a backstop. Administrative law scholars and economists have long worried about agencies' susceptibility to capture by regulated entities. The standard version of capture theory predicts that agencies will be overly influenced by the entities they regulate and will favor certain groups over others in the long run.<sup>335</sup> But all three channels of interaction between domestic litigation and foreign regulation present instances where a foreign regulator can serve as a backstop. On the one hand, this potential failsafe role means that agencies cannot easily disagree with foreign regulators and openly act on behalf of regulated

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<sup>331</sup> *Am. Ins. Ass'n v. Garamendi*, 539 U.S. 396, 414 (2003) (“[I]n foreign affairs the President has a degree of independent authority to act.”).

<sup>332</sup> Galbraith & Zaring, *Soft Law*, supra note 46, at 768.

<sup>333</sup> *Id.* at 770–73.

<sup>334</sup> *Id.* at 771.

<sup>335</sup> See Engstrom, *Gatekeepers*, supra note 211, at 674–80.

entities. This is especially true when a judge will ultimately review an agency's input. On the other hand, incorporating foreign regulation risks domesticating foreign regulatory capture. This may be especially risky in a *Roundup*-like case, where the defendant has argued that foreign regulatory evidence is exculpatory.<sup>336</sup>

Finally, domestic agencies already keep tabs on important cases and develop procedures to interact with courts. The gatekeeping literature has recently highlighted the rich variety of ways by which agencies already influence our private enforcement system. Agencies from the FTC to the EEOC intervene in ongoing cases, sometimes at the front end and at other times at the back end of private litigation.<sup>337</sup> The State Department also opines on the foreign affairs consequences of certain cases.<sup>338</sup> Take for instance the EEOC's power over Age Discrimination in Employment Act claims, which includes the ability to "formally terminate[]" plaintiffs' rights' to go forward with a case.<sup>339</sup> The EPA has the power to "oversee individual lawsuits brought under the various 'citizen suit' provisions in federal environmental statutes."<sup>340</sup> These processes are already in place and normalized, giving agencies the ability to respond quickly to ongoing litigation.

The potential benefits of agency input in this context are therefore clear: agencies can provide expertise, coordination with domestic regulators, an understanding of both foreign and American regulatory regimes, and the legitimacy that comes with the involvement of the executive branch. Scholars have recognized these benefits. That is why, for example, Catherine Sharkey has recently argued that the FDA should be nudged to intervene in the opioids litigation.<sup>341</sup>

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<sup>336</sup> Monsanto Company's Notice of Motion for Scheduling Order Regarding General Causation and Memorandum of Points and Authorities in Support at 6, *Hardeman v. Monsanto Co.*, (N.D. Cal. 2016) (No. 3:16-cv-00525); Transcript of Proceedings of the Official Electronic Sound Recording 2:14 PM–3:01 PM at 21–22, *Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037 (N.D. Cal. argued May 3, 2016) (No. 3:16-cv-00525).

<sup>337</sup> Sharkey, *Products Liability Preemption*, supra note 325, at 471–80 (highlighting many examples of agency amicus briefs).

<sup>338</sup> See Diego A. Zambrano, *Foreign Dictators in U.S. Court*, 89 *U. Chi. L. Rev.* (forthcoming) (manuscript at 31) (on file with author).

<sup>339</sup> Engstrom, *Agency Gatekeepers*, supra note 211, at 652.

<sup>340</sup> *Id.* at 648.

<sup>341</sup> Sharkey, *Opioid Litigation*, supra note 86, at 670–71.

## 2. *How Domestic Agencies Can Contribute*

Even if we accept that agency input is important in managing domestication of foreign regulation, we must then decide how to structure it. Here, I argue that when judges face cases involving foreign regulations and the difficulties discussed above, they should ask litigants to notify the relevant agencies. That would allow the agency to intervene in the case whenever they deem it appropriate. To be sure, judges should only do so in large MDLs or complex litigation, not in routine or small cases, lest they increase the costs of regular litigation.

David Engstrom has highlighted that agency gatekeeping can come in a variety of flavors that represent a “rich diversity of . . . designs,” giving agencies varying powers over litigation.<sup>342</sup> The most robust form of agency gatekeeping would involve giving regulators binding power to license or veto litigation and even eliminate private rights of action.<sup>343</sup> The weakest form would give regulators retail advisory power over individual cases, allowing them to make non-binding recommendations to courts on whether to allow a claim to proceed or not. One example of this weaker power comes from Title VII of the Civil Rights Act of 1964, which provides that a “claimant can mount a private enforcement effort in court only once she has obtained a ‘right to sue’ letter from the [EEOC].”<sup>344</sup> This gives the EEOC a powerful influence over specific cases.

Considering the range of potential gatekeeper options, one possibility would be to give U.S. agencies a direct licensing role. For example, prior to seeking evidence of foreign regulatory information, claimants would be obligated to request a “right to sue” letter from the relevant regulator. But this option runs into several potential problems. First, it may dramatically slow down litigation, giving domestic agencies agenda-setting power and depriving litigation of flexibility. Second, it forces agencies to opine on cases that have yet to begin, despite knowing little about the facts or how foreign regulators interacted with defendants. Third, it runs into domestic regulators’ status quo bias: the FDA and FAA may be wary of allowing private plaintiffs to showcase their failures by pointing to the comparatively better work of foreign regulators. This may be the ideal place for regulatory capture to set in. Indeed, a “right to sue”

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<sup>342</sup> Engstrom, *Gatekeepers*, *supra* note 211, at 644.

<sup>343</sup> *Id.* at 649–50.

<sup>344</sup> *Id.* at 649.

approach may effectively eliminate litigation's private check on regulatory capture.

A potential alternative is to give agencies notice of pending litigation, implicitly inviting them to submit letters to the court or amicus briefs. This could either be optional—giving judges the power to decide whether to request letters—or could be an official requirement imposed on litigants. So, for instance, plaintiffs in a mass torts case wishing to request the production of records to foreign regulators would simultaneously file a letter with the FDA, alerting the agency about the potential use of the foreign records. This approach has several potential benefits. First, as discussed above, agencies have already shown that they can keep track of ongoing cases in their areas and sometimes file letters in complex litigation cases. For instance, in the *In re Opioids* litigation, the Drug Enforcement Administration recently lodged an objection to ongoing discovery because it had the potential to disclose the details of an ongoing DEA investigation.<sup>345</sup> Two major benefits of this option are the potential for cross-pollination and regulatory convergence. If agencies are encouraged to track ongoing complex cases, they are more likely to learn from litigation and from foreign regulatory actions. As discussed above, this could potentially nudge regulators to internalize lessons from foreign regulation.

Second, there is already precedent for a complex litigation notice requirement in the Class Action Fairness Act.<sup>346</sup> CAFA specifically contains a provision that “mandates that notice of every class action settlement within CAFA’s purview must be provided to ‘appropriate’ federal and state officials.”<sup>347</sup> The legislative history of the statute justifies this provision as, among other things, giving officials the opportunity to “react if the settlement appears . . . inconsistent with applicable regulatory policies.”<sup>348</sup> All the evidence indicates that litigants and courts have honored the provision and regulators are content to have the notice and ability to intervene in these cases.

Finally, this option both empowers agencies to intervene when appropriate, but also allows litigants to proceed with their case without

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<sup>345</sup> *In re Nat’l Prescription Opiate Litig.*, No. 1:17-md-2804 (N.D. Ohio Apr. 11, 2018) (order granting discovery request).

<sup>346</sup> See Catherine M. Sharkey, *CAFA Settlement Notice Provision: Optimal Regulatory Policy?*, 156 U. Pa. L. Rev. 1971, 1972 (2008).

<sup>347</sup> *Id.*

<sup>348</sup> The Class Action Fairness Act of 2005, S. Rep. No. 109-14, at 32 (2005).

waiting for a “license” from regulators. Agencies could also provide sufficient information in letters or amicus briefs, especially if they are required to “provide a reasoned accounting of its retail-level decisions akin to what the APA requires in the formal adjudication context.”<sup>349</sup>

If this option seems optimal, judges could either *ad hoc* require litigants to give notice to agencies or could even require it under their local rules. Judges already have the power to solicit notice to relevant regulators and can do so whenever they request discovery or file cases that involve foreign regulation. And, whenever agencies do intervene, judges should engage in “hard look” review of the input.<sup>350</sup> As Engstrom mentioned, this form of gatekeeping would give regulators “retail advisory” power to make non-binding recommendations to courts on particular cases.<sup>351</sup>

### 3. *Four Scenarios of Agency Notice*

If the best solution here is to give agencies notice of pending cases that involve foreign regulatory information, how, exactly, would a court make use of the agency’s input? Again, Sharkey’s “agency reference model” is instructive here. Because of the danger of biased regulatory decisions, courts should not accord deference to agency input but should, instead, just refer to it. As Sharkey notes, “[a]pplying ‘hard look’ review, courts should scrutinize the basis for the agency’s determination to ensure that there is sound empirical basis for its underlying decisions.”<sup>352</sup> If there is such an empirical basis, courts can accept the agency’s input and rule accordingly. The benefits would materialize in at least the following four hypothetical scenarios:

1. *Instructing Courts on Foreign Law*: Plaintiffs piggyback on a foreign antitrust enforcement investigation in Mexico, filing claims in U.S. courts and arguing that the existence of a foreign investigation should count as a plus in a plausibility analysis. Plaintiffs give notice to the FTC about the ongoing claim. The FTC then writes a letter to the court, noting that Mexican antitrust law is similar to U.S. law. On this basis, the district court considers the foreign investigation as a plus factor.

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<sup>349</sup> Engstrom, *Gatekeepers*, supra note 211, at 687.

<sup>350</sup> Sharkey, *Opioid Litigation*, supra note 86, at 686.

<sup>351</sup> Engstrom, *Gatekeepers*, supra note 211, at 646.

<sup>352</sup> Sharkey, *Opioid Litigation*, supra note 86, at 686.

2. *Instructing Courts on U.S. Regulations*: In an ongoing torts case, plaintiffs request that defendants hand over all documents produced to French regulators regarding a drug label. Plaintiffs give notice to the FDA about the discovery request. The FDA then writes a letter to the court, noting that the FDA explicitly considered but rejected the French-informed labeling. The FDA argues the French information would disrupt its regulatory framework. Because of this letter, the district court denies a motion to compel the discovery request.
3. *Allowing Agencies to Learn About Foreign Cases*: Plaintiffs file a securities fraud claim against a large technology company, citing European regulations extensively. Plaintiffs give notice of the claim to the SEC. In response, the SEC begins a study on the European regulations and considers rule-making on the subject at issue in the litigation.
4. *Allowing Agencies to Learn About Gaps in Their Regulations*: In an ongoing torts case, plaintiffs request that defendants produce all documents produced to German regulators regarding a drug label. Plaintiffs give notice to the FDA about the discovery request but the FDA decides not to intervene. The court orders production and plaintiffs find that based on what defendants produced to German regulators, the defendants misled the FDA. In response, the FDA considers rule-making on the subject at issue.

The benefits described in these four scenarios are clear: agencies can gain knowledge about foreign regulations and their own domestic regulations and can inform courts in these cases.

#### CONCLUSION

This Article described a recent phenomenon: a vast array of complex litigation in the United States involves, at its core, foreign agencies and regulations. The intersections between American litigation and foreign regulation cover discovery of foreign regulatory records, class actions that piggy-back on foreign regulatory findings or enforcement, and even letters written by foreign regulators to U.S. courts. These cases raise a wide variety of questions about regulatory harmonization, the relationship between litigation and regulation, and the role of foreign law in U.S. court. The Article argued that we should appreciate the benefits of foreign

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regulations, but we also should channel and regulate it by giving courts sufficient agency input.

**Appendix I: Discovery Requests for Foreign Regulatory Documents<sup>353</sup>**

Citation	Case	Countries/Agencies Implicated	Discoverable?
317 F.R.D. 562	In re Bard IVC Filters Prods. Liab. Litig. (D. Ariz. 2016)	Examples include Canada; U.K.	No
1:15-md-02657-FDS (Order on Plaintiffs' Motion to Compel Production of Foreign Regulatory Files)	In re Zofran (Ondansetron) Prods. Liab. Litig. (D. Mass. Aug. 24, 2017).	Japan	Yes, partially
2019 WL 341909	In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig. (S.D. Ohio Jan. 28, 2019)	Examples include Canada; U.K.	Yes
2016 WL 1222229	Hodges v. Pfizer, Inc. (D. Minn. Mar. 28, 2016)	Examples include France; U.K.; the Netherlands	Yes
2011 WL 2118983	Hardy v. Pharmacia Corp. (M.D. Ga. May 27, 2011)	Not specified	Yes
307 F.R.D. 291	Kubicki ex. rel. Kubicki v. Medtronic (D.D.C. 2014)	Mexico; Canada	Yes, partially
2014 WL 1056526	St. Jude Med. S.C., Inc. v. Sorin CRM USA, Inc. (D. Colo. Mar. 9, 2014)	Not specified	Yes

<sup>353</sup> This is not necessarily a representative sample of MDL cases but just all the discovery or evidentiary decisions I could find on Bloomberg Law/Westlaw using search terms related to foreign regulatory evidence.

721 F. App'x 580	In re Incretin- Based Therapies Prods. Liab. Litig. (9th Cir. 2017)	Not specified	Yes
1999 WL 311697	SmithKline Beecham Corp. v. Apotex Corp. (N.D. Ill. May 13, 1999)	Not specified	No
2008 WL 508391	In re Seroquel Prods. Liab. Litig. (M.D. Fla. Feb. 21, 2008)	Examples include U.K.; Australia; Canada	Yes
1992 WL 186037	Com. Bank of Korea, Ltd. v. Charone, Inc. (N.D. Ill. July 29, 1992)	South Korea	No
463 F. Supp. 2d 310	Linde v. Arab Bank, PLC (E.D.N.Y. 2006)	Jordan; Lebanon; the Palestinian territories	Yes
2014 WL 5462496	In re Cathode Ray Tube (CRT) Antitrust Litig. (N.D. Cal. Oct. 23, 2014)	Various	Yes
2009 WL 10424741	In re Levaquin Prods. Liab. Litig. (D. Minn. Nov. 25, 2009)	Various	Yes
2011 WL 3759699	In re Yasmin & Yaz: (Drospirenone) Mktg., Sales Practices & Relevant Prods. Liab. Litig. (S.D. Ill. Aug. 18, 2011)	Netherlands; European Union	Yes, partially
2014 WL 12587032	Brunston v. Bayer Healthcare Pharm., Inc. (C.D. Cal. May 16, 2014)	European Union	Yes, partially

111 A.D.2d 68	Alba v. Ford Motor Co. (N.Y. 1985)	Examples include Norway; Denmark; New Zealand	No
486 F. Supp. 2d 1078	In re Rubber Chems. Antitrust Litig. (N.D. Cal. 2007)	European Commission (EC)	No
2010 WL 3420517	In re Payment Card Interchange Fee and Merchant Disc. Antitrust Litig. (E.D.N.Y. Aug. 27, 2010)	European Commission (EC)	No
2015 WL 4463809	Campbell v. Facebook Inc. (N.D. Cal. July 21, 2015)	Ireland	No
2018 WL 5919515	In re Interest Rate Swaps Antitrust Litig. (S.D.N.Y. Nov. 13, 2018)	European Commission (EC)	No
MDL No. 2327 (Pretrial order #68)	In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig. (S.D. W.Va. Sept. 18, 2014)	Various	Yes
2017 WL 4399198	In re Abilify (Aripiprazole) Prods. Liab. Litig. (N.D. Fla. Sept. 29, 2017)	Various	Yes
183 F. Supp. 3d 409	Laydon v. Mizuho Bank, Ltd., (S.D.N.Y. 2016)	U.K.	Yes

**Appendix II: Requests for the Admissibility in Evidence of Foreign  
Regulatory Materials<sup>354</sup>**

Citation	Case	Countries/Agencies Implicated	Admissible?
2012 WL 827245	Winter v. Novartis Pharm. Corp. (W.D. Mo. Mar. 8, 2012)	Not specified	No
835 F. Supp. 2d 299	Mahaney ex rel. Est. of Kyle v. Novartis Pharm. Corp. (W.D. Ky. 2011)	Not specified	Yes
2007 WL 1288354	In re Accutane Prods. Liab. (M.D. Fla. May 2, 2007)	Not specified	No
309 F. Supp. 2d 531	In re Rezulin Prods. Liab. Litig. (S.D.N.Y. 2004)	U.K.; Australia	Yes, partially
844 F.2d 769	Deviner v. Electrolux Motor, AB (11th Cir. 1988)	Sweden	No
2017 WL 4168410	In re Xarelto (Rivaroxaban) Prod. Liab. Litig. (E.D. La. Sept. 20, 2017)	Examples include Canada	No
808 F. Supp. 2d 1125	Schedin v. Ortho-McNeil-Janssen Pharm., Inc. (D. Minn. 2011)	Not specified	Yes
658 F. Supp. 2d 950	In re Viagra Prods. Liab. Litig. (D. Minn. 2009)	Various	No
709 F. Supp. 2d 1323	In re Trasylol Prods. Liab. Litig. (S.D. Fla. 2010)	Various	No
181 F. Supp. 3d 278	In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig. (E.D. Pa. 2016)	Examples include Canada	Yes
2001 WL 36102165	Tobin v. SmithKline Beecham Pharms. (D. Wyo. May 18, 2001)	Not specified	Yes
169 F. Supp. 3d 396	In re Mirena IUD Prods. Liab. Litig. (S.D.N.Y. 2016)	Federal Institute for Drugs and Medical Devices (BfArM) (Germany)	No
2014 WL 5465741	Eghnayem v. Bos. Sci. Corp. (S.D. W. Va. Oct. 28, 2014)	Not specified	Yes

<sup>354</sup> This is not necessarily a representative sample of MDL cases but just all the discovery or evidentiary decisions I could find on Bloomberg Law/Westlaw using search terms related to foreign regulatory evidence.

2017 WL 2780760	In re Xarelto (Rivaroxaban) Prods. Liab. Litig. (E.D. La. May 26, 2017)	Various	Yes, partially
532 F. Supp. 2d 1029	In re Baycol Prods. Litig. (D. Minn. 2007)	Various	No
601 F. Supp. 2d 1313	In re Seroquel Prods. Liab. Litig. (M.D. Fla. 2009)	Japan; France; Netherlands	No
2015 WL 7863032	In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig. (M.D. Ga. Dec. 3, 2015)	Not specified	Yes, partially

**Appendix III: GDPR Cases**

<b>Citation</b>	<b>Case</b>	<b>Nature of Suit</b>	<b>Defendant's HQ Country</b>	<b>Issue</b>	<b>Outcome</b>
2019 WL 618554	Finjan, Inc. v. Zscaler, Inc. (N.D. Cal. Feb. 14, 2019)	IP (Patent Infringement)	United States	Discovery (party claims production would violate GDPR)	D ordered to produce documents
405 F. Supp. 3d 809	In re Facebook, Inc. Sec. Litig. (N.D. Cal. 2019)	Securities Fraud	United States	Merits (materially false and misleading statements)	Case dismissed on 12(b)(6) without prejudice
2019 WL 5800270	In re Mercedes-Benz Emissions Litig. (D.N.J. Nov. 7, 2019)	Consumer Fraud	Germany	Discovery (Ds seek to stay a special master's order compelling discovery until its appeal is resolved)	Request for a stay denied
2020 WL 487288	In re Mercedes-Benz Emissions Litig. (D.N.J. Jan. 30, 2020)	Consumer Fraud	Germany	Discovery (party claims production would violate GDPR)	D ordered to produce documents
364 F. Supp. 3d 243	In re Hansainvest Hanseatische Inv.-GmbH (S.D.N.Y. 2018)	Foreign Lawsuit	Germany	Discovery (§1782 action for discovery in relation to a foreign lawsuit)	D ordered to produce documents

332 F.R.D. 117	Pearlstein v. BlackBerry Ltd. (S.D.N.Y. 2019)	Securities Fraud	U.K.	Discovery (party claims production would violate GDPR)	Motion to compel denied
2019 WL 6327580	Johnson v. Costco Wholesale Corp. (W.D. Wash. Nov. 26, 2019)	Securities Fraud	United States	Merits (materially false and misleading statements)	Case dismissed on 12(b)(6) without prejudice