THE VALUES-BASED TRADE AGENDA

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With the increasing trade tensions between the United States and China, pressures created by Brexit, and the COVID-19 pandemic, most trade scholars have focused on rising protectionism exhibited through defensive strategies such as tariffs and export controls. However, this focus ignores the fundamental shift in international trade goals of the United States and the European Union towards a values-based trade agenda.

Instead of merely focusing on free trade based on efficiency and market access, trade regulators on both sides of the Atlantic have independently pursued measures designed to address environmental sustainability and social equity. These policies resonate with their domestic constituencies and allows them to promote their values along global supply chains. These values-based agendas, however, are likely to create new trade conflicts rather than partnerships. This is due in part to the fact that the transatlantic trade relationship remains embedded in international regulatory frameworks predominantly focused on efficiency gains and cutting red tape to ease the flow of products and services.

Through two comparative case studies on cosmetics and medical devices, we highlight how the promotion of competitive liberalization in transatlantic trade has not generated the promised harmonization result. Instead, it has created social and environmental inequities. The case studies point out that to incorporate social and environmental equity adjustments for vulnerable and marginalized communities, trade regulators, negotiators, and lawyers alike ought to assess the ex-ante distributive effects in regulatory cooperation and the ex-post enforcement tools of regulation of their values-based trade agenda.

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INTRODUCTION

When COVID-19 exploded into a global pandemic in 2020, companies such as Dyson, Coca-Cola, Givenchy, Tesla, and Tito's Vodka—along with smaller distilleries and manufacturing companies

Psychopomp and Burton Snowboards—shifted their production model to making ventilators, alcohol-based hand sanitizers, and personal protective equipment in response to public health shortages.[1] With supply chains disrupted by the pandemic, companies responded with both voluntary and government-supported efforts to produce these products as regulatory standards were relaxed in the European Union and the United States.[2] While such waivers were common in the early stages of the pandemic, regulatory agencies have now halted emergency use authorizations. Instead, those unauthorized manufacturers must seek product approval or cease making these products.[3] Despite the temporary relief from strict regulated standards that eased the flow of needed products, strategic trade interests have meant that there remain unresolved issues in relation to regulatory barriers based on divergent standards and processes between the United States and the European Union.[4] Both governments recognize that the pandemic disrupted efforts to liberalize trade policies and created a disproportionate effect on vulnerable groups.[5] Despite the discourse on strengthening social

1. *See* Francisco Betti & Thierry Heinzmann, *From Perfume to Hand Sanitiser, TVs to Face Masks: How Companies are Changing Track to Fight COVID-19*, World Econ. F. (Mar. 24, 2020), https://www.weforum.org/agenda/2020/03/from-perfume-to-hand-sanitiser-tvs-to-face-masks-how-companies-are-changing-track-to-fight-covid-19/ [https://perma.cc/49JJ-S4EM]; Rob Davies, *From Vacuum Cleaners to Ventilators: Can Dyson Make the Leap?*, Guardian (Mar. 26, 2020), https://www.theguardian.com/technology/2020/mar/26/from-vacuum-cleaners-to-ventilators-can-dyson-make-the-leap [https://perma.cc/P3YV-N3JF]; Kellen Browning, *Distilleries Raced to Make Hand Sanitizer for the Pandemic. No Longer*, N.Y. Times (Aug. 4, 2020), https://www.nytimes.com/2020/08/04/business/distilleries-hand-sanitizer-pandemic.html [https://perma.cc/CB4M-DNZU].

2. *See* Press Release, U.S. Food & Drug Admin., FDA in Brief: FDA Withdrawing Temporary Guidances for Alcohol-Based Hand Sanitizers, (Oct. 12, 2021), https://www.fda.gov/news-events/press-announcements/fda-brief-fda-withdrawing-temporary-guidances-alcohol-based-hand-sanitizers [https://perma.cc/3HUH-VKKM].

3. *See Hand Sanitizers; COVID-19*, U.S. Food & Drug Admin. (Oct. 10, 2022), https://www.fda.gov/drugs/coronavirus-covid-19-drugs/hand-sanitizers-covid-19.

4. Simon Evenett & Richard Baldwin, *Introduction and Recommendations for the G20*, *in* The Collapse of Global Trade, Murky Protectionism, and the Crisis: Recommendations for the G20 1, 4–5.

5. A new report by the ITC on Distributional Effects of Trade and Trade Policy on U.S. Workers highlighted the uneven employment and wage effects of trade for minority racial groups and women in the workforce. U.S. Int'l Trade Comm'n, Distributional Effects of Trade and Trade Policy on U.S. Workers 17–19 (Oct. 2022), https://www.usitc.gov/publications/332/pub5374.pdf. This was prompted by Ambassador Katherine Tai's request that "[i]n order to formulate and implement trade policies that will be effective in providing benefits to our economy, workers, and communities, particularly those who have been historically underserved, we must be able to assess the impact of our existing trade policies on those communities and workers." *See* Press Release, U.S. Trade Representative, Statement from Ambassador Katherine Tai Following the Release of the USITC Report on the Distributional Effects of Trade and

values and inclusion in their respective domestic contexts, it has not led to greater cooperative efforts to promote specific equity or environmental concerns. This article shows how international regulatory cooperation between Europeans and Americans should not exclusively focus on competition and efficiency, but rather ought to incorporate the new values-based trade agenda.

Previous efforts to promote transatlantic regulatory cooperation focused on attributing the absence of necessary convergence to a host of resilient institutional differences rather than on their distributive impact.[6] The purpose of international regulatory cooperation is not simply to create regulatory convergence, but should also structure patterns of behavior to create a sustainable balance between efficiency and fairness in which there is the necessary enforcement to avoid negative distributional effects among workers and consumers.[7] While in the past these efforts have been hampered by divergent policy values and different governance structures across the Atlantic, the United States and Europe increasingly recognize that more integrated systems are needed for rule-making and implementation. Moreover, these systems should be subject to the constraints of democratic values like accountability, transparency, and social equity.[8] As a result, transatlantic partners who had already promoted international regulatory cooperation as part of their administrative processes[9] contend that new strategic approaches towards values-based trade are warranted with like-minded

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Trade Policy (Nov. 15, 2022), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2022/november/statement-ambassador-katherine-tai-following-release-usitc-report-distributional-effects-trade-and [https://perma.cc/X8MC-75R9]. The ITC report has already created turmoil in mainstream trade circle because the word "protectionism" was not mentioned once in the report. *See* Simon Lester, *The ITC Report on Distributional Effects of US Trade and Trade Policy: What About Protectionism?*, INT'L ECON. L & POL'Y BLOG (Nov. 20, 2022) https://ielp.worldtradelaw.net/2022/11/the-itc-report-on-distributional-effects-of-us-trade-and-trade-policy-what-about-protectionism.html [https://perma.cc/857D-UNTK].

6. Reeve T. Bull et al., *New Approaches to International Regulatory Cooperation: The Challenge of TTIP, TPP, and Mega-Regional Trade Agreements*, 78 L. & CONTEMP. PROBS. 1, 5-6 (2015).

7. *See* Fernanda G. Nicola*, Genealogies of Cost Benefit Analysis in Transatlantic Regulatory Cooperation,* in *Genealogies of European Governance*, 15 COMPAR. EUR. POL. 729 (2016); Tamara Perisin & Sam Koplewicz, *Blame It on Brussels: EU Law and the Distributive Effects of Globalisation*, 14 CROAT. Y.B. EUR. L. & POL'Y 7 (2018).

8. *See* K. SABEEL RAHMAN, DEMOCRACY AGAINST DOMINATION (2016); ORG. FOR ECON. COOP. & DEV., OECD BEST PRACTICE PRINCIPLES ON INTERNATIONAL REGULATORY CO-OPERATION 15 (Sept. 15, 1994).

9. *See* Exec. Order No. 13609, 3 C.F.R. (2013); *Better Regulation: Why and How*, EUR. COMM'N, https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation_en (last visited Jan. 28, 2022).

countries to maintain effective global trade rules while departing from neoliberalism under the new Cornwall Consensus.[10]

The pandemic's public health challenges highlighted the need for closer cooperation as the scope of inspections, approvals, testing, and impact assessments has become global. Yet attention has focused on the governance and resilience of supply chains. Coupled with the effects of export restrictions in the initial stages of the pandemic, these effects underscore the trade effects—rather than the role of regulatory cooperation—on the continued safety, quality, and efficacy of medical products and equipment in a global economy.[11] While this emergency regime allowed accelerated and innovative regulatory pathways to facilitate the availability of crucial medical devices, it also provided important lessons and opportunities about the value of increased regulatory cooperation among nations.[12] As the urgency to expedite regulatory processes becomes clear, regulators need to consider the distributive implications of the product approval and authorization process on the disadvantaged communities most affected by the pandemic.[13] The selection of our case studies is based on two sectors that remain central to transatlantic trade, but yet are filled with regulatory obstacles for different reasons. On the one hand, medical devices re-

10. *See The Cornwall Consensus*, G7 (2021), https://www.g7uk.org/wp-content/uploads/2021/06/G7-Economic-Resilience-Panel-The-Cornwall-Consensus.pdf; Mu Lu, *Cornwall Consensus a Sign that Neoliberalism is at Crossroads*, GLOB. TIMES (June 17, 2021), https://www.globaltimes.cn/page/202106/1226461.shtml#:~:text=According%20to%20Li%2C%20the%20Cornwall%20Consensus%20demonstrates%20that,problems%20and%20to%20take%20measures%20to%20fix%20them [https://perma.cc/2AME-UJKZ]. In the aftermath of the COVID-19 pandemic, G7 leaders set out a new and ambitious agenda to move towards "greater equity and solidarity in global health responses" in addition to more specific calls to action. This includes a Data Technology and a Financial Stability Board to spur greater Western collaboration along similar values.

11. Elizabeth Golberg, *Regulatory Cooperation to Combat Public Health Crises*, REGUL. REV. (Apr. 27, 2020), https://www.theregreview.org/2020/04/27/golberg-regulatory-cooperation-combat-public-health-crises/ [https://perma.cc/GKL7-4AX9].

12. *See generally* ORG. FOR ECON. COOP. & DEV., NO POLICY MAKER IS AN ISLAND: THE INTERNATIONAL REGULATORY CO-OPERATION RESPONSE TO THE COVID-19 CRISIS (June 8, 2020), https://www.oecd.org/coronavirus/policy-responses/no-policy-maker-is-an-island-the-international-regulatory-co-operation-response-to-the-covid-19-crisis-3011ccd0/; ORG. FOR ECON. COOP. & DEV., OECD REGULATORY POLICY OUTLOOK 2021 107 (2021), https://read.oecd-ilibrary.org/governance/oecd-regulatory-policy-outlook-2021_38b0fdb1-en#page2.

13. *See* Ruqaiijah Yearby & Seema Mohapatra, *Law, Structural Racism, and the COVID-19 Pandemic*, 7 J. L. & BIOSCIENCES 1 (2020); Abigail E. Lowe, Kelly K. Dineen & Seema Mohapatra, *Structural Discrimination in Pandemic Policy: Essential Protections for Essential Workers,* 50 J. L., MED. & ETHICS 67 (2021); Ruqaiijah Yearby & Seema Mohapatra, *Systemic Racism, the Government's Pandemic Response, and Racial Inequities in COVID-19*, 70 EMORY L. J. 1419 (2021).

main a sector highly impacted by the COVID-19 pandemic, which has led to greater administrative flexibility due to public health concerns and social inequities. On the other hand, the cosmetics sector is filled with environmental challenges and social inequities reflected by the divide between workers in the Global South and firms and consumers in the Global North.

In needing to address the global pandemic, a major economic downturn, systemic racial inequality, and climate change, President Biden's administration has begun to modernize its regulatory review by explicitly asking agencies to consider distributive implications of regulation to ensure that regulatory initiatives do not burden "disadvantaged, vulnerable or marginalized communities."[14] In contrast, the European Union has, under European Commission President Ursula Von der Leyen, renewed its commitment to its better regulation mandate solely promoting efficiency and transparency rather than including social equity and sustainability.[15] However, in the aftermath of the disruption of global supply chains, the Commission undertook major initiatives to enforce European standards and values including sustainability and fair labor standards along the supply chains.[16]

Today, the United States and the European Union are considering similar normative conceptions of distributive justice in trade policy[17] but with different operational tools.[18] They hope that their efforts at regulatory cooperation will not promote trade alignments.[19] While the

14. *See Modernizing Regulatory Review*, WHITE HOUSE (Jan. 20, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/modernizing-regulatory-review; Susan Dudley, *Distributional Effects in Regulatory Impact Analysis,* GEO. WASH. REGUL. STUD. CTR. (May 12, 2021).

15. *See* Susan E. Dudley, *The U.S. And Europe Are Embarking on Dramatically Different Paths to Better Regulation*, FORBES (June 21, 2021), https://www.forbes.com/sites/susandudley/2021/06/21/the-us-and-europe-are-embarking-on-dramatically-different-paths-to-better-regulation/ [https://perma.cc/9YSD-85TT].

16. *Communication from the Commission on Updating the 2020 New Industrial Strategy*, COM (2021) 350 final (May 5, 2021); Resolution on Corporate Due Diligence and Corporate Accountability, EUR. PARL. DOC. (P9 73) 2021, https://www.europarl.europa.eu/doceo/document/TA-9-2021-0073_EN.html.

17. DANI RODRICK, STRAIGHT TALK ON TRADE: IDEAS FOR A SANE WORLD ECONOMY 4 (2016); Paul Krugman, *Globalization: What Did We Miss?*, *in* MEETING GLOBALIZATION'S CHALLENGES 113–120 (Luís A. V. Catão & Maurice Obstfeld ed., 2019).

18. *See* Paulo Barrozo, *Critical Legal Thought: The Case for a Jurisprudence of Distribution*, 92 UNIV. COLO. L. REV., 1043, 1054-6 (2021) (offering a variety of elements that are necessary to create a practical agenda for a normative jurisprudence of distribution).

19. *Periodic Retrospective Review*, ADMIN. CONF. U.S. (June 17, 2021), https://www.acus.gov/sites/default/files/documents/Redline%20-%20Periodic%20Retrospective%20Review%20-%20Final.pdf; Susan Dudley, *Regulatory Re-*

United States' administration has repurposed its administrative branch to take into account the distributional effects of domestic regulations on disadvantaged communities, social equity is also considered a core element of U.S. trade and investment policy. The Biden Administration's worker-centric trade policy is meant to raise standards domestically, but also focuses on high-standard commitments from partners to raise labor standards through eliminating exploitation overseas.[20] Similarly, the European Union has focused its trade effect on global value chains in enforcing labor and human rights protections with its trading partners. Though both promote values-based trade, the United States has been focusing on the distributional effects of its trade policies on workers and underserved communities,[21] while the European Union has been more explicit in pushing a green and digital transformation by prioritizing sustainable value chains and addressing the digital divide.[22]

The stalled transatlantic trade agenda thus calls for a new regulatory approach that can operationalize its new declaratory goals based on broad values, including both sustainability and social equity. In Part I, we analyze the history of international regulatory cooperation (IRC) in transatlantic trade to show that despite initial political optimism during the Obama administration, there were numerous roadblocks and regulatory obstacles that led to the halting of the comprehensive Transatlantic Trade and Investment Partnership agreement (TTIP) between the European Union and the United States. Dur-

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set, REGUL. REV. (Feb. 19, 2021); Claudio Radaelli, *Will the EU Make its Better Regulation Strategy Truly Better?,* REGUL. REV. (June 1, 2020); Claudio Radaelli, *The State of Play With the Better Regulation Strategy of the European Commission*, (S.T.G. Policy Papers, European Univ. Inst., June 2021) https://cadmus.eui.eu/handle/1814/70901.

20. *See* Sally Katzen, A Project Worth Watching at OIRA, GEO. WASH. REGUL. STUD. CTR. (Mar. 29, 2021), https://regulatorystudies.columbian.gwu.edu/project-worth-watching-oira.

21. *See* Press Release, Off. U.S. Trade Representative, Fact Sheet: One Year In, Ambassador Katherine Tai is Advancing President Biden's Trade Agenda and Getting Results for American Workers (March 2022), https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2022/march/fact-sheet-one-year-ambassador-katherine-tai-advancing-president-bidens-trade-agenda-and-getting.

22. Marco Bronckers & Giovanni Gruni, *Taking the Enforcement of Labour Standards in the EU's Free Trade Agreements Seriously*, 56 Common Mkt. L. Rev. 1591, 1595 (2019); *Promoting Decent Work For All: The EU Contribution to the Implementation of the Decent Work Agenda in the World*, at 4, COM (2006) 249 final (May 24, 2006); *Council Conclusions on Human Rights and Decent Work in Global Supply Chains* 2–4, SOC 772 (2022) (Dec. 1, 2020); ADRIAN SMITH ET AL., FREE TRADE AGREEMENTS AND GLOBAL LABOUR GOVERNANCE: THE EUROPEAN UNION'S TRADE-LABOUR LINKAGE IN A VALUE CHAIN WORLD (Routledge 2021) (criticizing E.U. trade-labor linkage in global vachains).

ing the TTIP negotiations international regulatory cooperation (IRC) was implemented by lawyers and regulators through what appeared as neutral and trade-enhancing paradigms based on efficiency and transparency.[23] In Part II, we show how the efficiency paradigm in IRC prioritized the competitive cutting of bureaucratic red tape, the reduction of regulatory interference, and the use of market strength to incentivize others to adopt or reciprocate these regulations. Later, the transparency paradigm in IRC refocused trade lawyers and negotiators on opening processes to business and civil society alike that streamlined regulations and removed unnecessary bilateral regulatory differences. Regulators were encouraged by trade lawyers to promote environmental, safety, and health goals, but with the objective of developing efficient and transparent standards that would ultimately lower the regulatory burden on the implementing states. As the enduring failure of TTIP shows, international regulatory cooperation was, and still is, ill-equipped to address the new post-pandemic values-based agenda. Only by pursuing international regulatory cooperation in relation to the distributive effects of trade can politically cohesive agreements be forged, and only by focusing on a convergence in regulatory enforcement backed by institutional processes will both sides of the transatlantic relationship be able to achieve a newly cohesive, sustainable, and equitable trade paradigm.

In Part III, we delve into a comparative sectoral analysis through two case studies on cosmetics and medical devices showing how the international regulatory cooperation paradigms of efficiency and transparency were ill-equipped to overcome institutional, regulatory, and values-based differences that arose in both sectors. We show how, without anticipating the distributive consequences of transatlantic trade, new challenges arose to enforcing standards and regulations in both sectors. In our conclusion we highlight that in pursuing a value-based agenda, trade lawyers, regulators, and negotiators alike will have to openly acknowledge ex ante the distributive effects of trade adjustments and ex-post engage with enforcement mechanisms to en-

23. International Regulatory Cooperation is a set of interpretive tools for governments, promoted by bilateral or multilateral trade agreements such as TTIP or TPP through regulatory alignments. *See* REEVE BULL, IMPROVING INTERNATIONAL REGULATORY COOPERATION IN AN AGE OF TRADE SKEPTICISM (July 14, 2022), https://www.brookings.edu/research/improving-international-regulatory-cooperation-in-an-age-of-trade-skepticism/. International Organizations such as the OECD's Regulatory policy aim to create more harmonization among domestic regulatory regimes while at the same time promoting a high quality rulemaking. *See, e.g.*, Org. for Econ. Coop. & Dev., *International Regulatory Co-operation: The Role of International Organizations in Fostering Better Rules of Globalisation* (2016), https://www.oecd.org/gov/regulatory-policy/international-regulatory-co-operation-9789264244047-en.htm.

sure that politically cohesive, equitable, and sustainable trade agreements can be forged.

I.
THE RELEVANCE OF INTERNATIONAL REGULATORY COOPERATION

Rather than focus on trade negotiations themselves, which have received significant scholarly attention over the past two decades, this Article posits that there needs to be a rethinking of the paradigm that underpins the goals of trade liberalization through IRC. Trade policy needs to navigate a regulatory agenda where there are profound changes in international production and trade flows in global supply chains, the rise of a systemic rival that does not fully commit to the rules of the multilateral trade regime, and the increasing concerns about the distributional consequences of globalization. This creates pressure for a different mode of regulatory governance where the United States and the European Union seek to balance broad social, economic, and environmental objectives that can fit a more inclusive agenda.[24] While domestic politics have forced governments to confront broad concerns ranging from labor rights and environmental sustainability to national security, there are fears that the current pressure for better enforcement of trade rules could result in more insular and protectionist trade policies.[25] At a time when the United States is focusing on a rising China and its critical role in key technologies and supply chains, coordination with Europe on shaping global rules, norms, and practices has become increasingly salient.

While the United States and the European Union are navigating this rapidly shifting landscape exacerbated by the COVID-19 pandemic, the normative goal for both is ensuring that the weaponization of trade through protectionist and defensive trade practices[26] does not disrupt the values-based trade agenda.[27] This trend is evident in the respective new trade policy strategies of the United States and the Eu-

24. *See* Richard Parker, *Four Challenges for TTIP Regulatory Cooperation*, 22 COLUM. J. EUR. L. 1, 5 (2015); Fernanda G. Nicola, *The Politicization of Legal Expertise in the TTIP Negotiation*, 78 L. & CONTEMP. PROBS. 175, 176 (2015).

25. Céline Carrère et al., *Labor Clauses in Trade Agreements: Hidden Protectionism?*, 17 REV INT'L ORG. 453, 463 (2021).

26. *See* DANIEL DREZNER ET AL., THE USES AND ABUSES OF WEAPONIZED INTERDEPENDENCE (2021).

27. *Trade Policy Review - An Open, Sustainable and Assertive Trade Policy*, at 1, COM (2021) 66 final (Feb. 18, 2021); *see also* European Commission Press Release 2011/833/EU, Trade for All: European Commission Presents New Trade and Investment Strategy (Oct. 14, 2015), https://ec.europa.eu/commission/presscorner/detail/en/IP_15_5806.

ropean Union. The European Union's 2021 Communication "An Open, Sustainable, and Assertive Trade Policy" emphasizes the need for "open strategic autonomy" to ensure the "EU's ability to make its own choices . . . reflecting its strategic interests and values," and to strengthen its market resilience and competitiveness, sustainability and fairness, and assertiveness and rule-based cooperation.[28] The European Union plans to use its single-market strength to protect labor standards, gender equality, and combat climate change and biodiversity loss.[29] The policy also supports the strengthening of supply chain resilience, the development of "stable, predictable and transparent trading rules," and analyzing strategic dependencies and new opportunities to diversify sources of supply through greater coherence between its internal and external policies.[30]

Similarly, in the new Biden Administration's "Build Back Better Agenda," the United States seeks to stabilize and strengthen domestic production by placing American workers at the forefront.[31] Biden has made clear that new trade agreements will not be negotiated until the administration has focused on the American workforce and infrastructure, including resilient supply chains. The United States trade agenda's primary goal is "building a stronger industrial and innovation base so the future is made in America."[32] The Biden Administration is also working to restore the US's role as a global standard-setter in labor rights and protections, gender equality, sustainable energy, climate change, and renewable-energy supply chains. Investment in domestic medical equipment production, rather than relying on imported supplies, tops the agenda's policies in fighting the COVID-19 pandemic.[33] The agenda prioritizes a worker-centered trade policy as central to United States free trade agreements. Other issues mentioned in the agenda include promoting sustainable trade and development, advancing racial equity, countering China's unfair trade practices, restor-

28. *Trade Policy Review*, *supra* note 28, at 4.

29. *Id.* at 6-14.

30. *Id.* at 7.

31. *See $1B Build Back Better Regional Challenge*, U.S. ECON. DEV. ADMIN, https://www.eda.gov/funding/programs/american-rescue-plan/build-back-better [https://perma.cc/7MSG-P857].

32. Press Release, Off. U.S. Trade Representative, Biden Administration Releases 2021 President's Trade Agenda and 2020 Annual Report (Mar. 1, 2021), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/march/biden-administration-releases-2021-presidents-trade-agenda-and-2020-annual-report.

33. Exec. Order No. 14001, 86 Fed. Reg. 7,219 (Jan. 21, 2021).

ing American partnerships and alliances, and enforcing trade commitments.[34]

A. Background to International Regulatory Cooperation

In recent decades, the European Union and the United States have developed various institutional innovations in attempts to overcome numerous roadblocks in their regulatory differences to enhance transatlantic trade.[35] The expansion and integration of the European states into a single market pressured the United States to maintain market access or else forever be locked out of "Fortress Europe,"[36] shielded by the *Cassis de Dijon* standard.[37] According to Peter Chase and Jacques Pelkmans, the European Union and United States' inward-looking regulatory approaches of the past have eroded the benefits of the growing interconnectedness of both economies, while also raising costs on producers.[38] Slow progress at the World Trade Organization (WTO) meant that the European Union and the United States needed to hash out their regulatory differences bilaterally rather than wait on a comprehensive multilateral agreement.[39]

Transnational lawyers, particularly administrative and trade lawyers, paid special attention to EU-US transatlantic regulatory develop-

34. U.S. TRADE REPRESENTATIVE, 2021 TRADE POLICY AGENDA AND 2020 ANNUAL REPORT (2021), https://ustr.gov/sites/default/files/files/reports/2021/2021%20Trade%20Agenda/Online%20PDF%202021%20Trade%20Policy%20Agenda%20and%202020%20Annual%20Report.pdf.

35. In 2011, seventeen percent of EU exports were destined for the American market, while eleven percent of EU imports came from the US. In 2019, EU and American goods and services trade totaled roughly $1.1 trillion, with exports at $468 billion and imports at $598 billion. US FDI into the EU is $2.4 trillion and EU FDI into the US is $2 trillion, nearly a three percent increase in both from the previous year. *See European Union*, OFF. U.S. TRADE REP., https://ustr.gov/countries-regions/europe-middle-east/europe/european-union (last visited Jan. 25, 2023).

36. "Fortress Europe" refers to U.S. trade analysts' fears of the European Union reducing internal barriers for trade while raising regulatory standards on goods arriving from outside. *See* Brian T. Hanson, *What Happened to Fortress Europe?: External Trade Policy Liberalization in the European Union*, 52 INT'L ORG. 55, 57 (1998).

37. The *Cassis de Dijon* standard refers to the European Court of Justice's finding that internal barriers inhibiting the free movement of goods between the Member States violate Article 36 of the TFEU. *See* Case 120/78, Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein, 1979 E.C.R. 649 (outlining measures heaving an effect equivalent to quantitative restrictions).

38. Peter Chase & Jacques Pelkmans, *This Time it's Different: Turbo-Charging Regulatory Cooperation in TTIP*, CTR. EUR POL. STUD. 10 (2015) (arguing that the European Union and the United States in their TTIP negotiations should frame regulatory coherence and cooperation in terms of regulatory autonomy that is enshrined with good regulatory principles, practices, and tools to tighten the transatlantic relationship of regulators rather than merely seeking to remove non-tariff barriers).

39. *Id.*

ments, as issues of domestic regulation became increasingly international in nature.[40] Innovations in transatlantic regulatory cooperation were meant to prioritize equivalence and acceptance by targeting unnecessary and costly trade barriers that raise producer and consumer costs.[41] In developing these institutions, transatlantic negotiators sought results in three ways: 1) regulatory efficiency by creating regulations with common assessments and goals, 2) regulatory compliance, and 3) enforcement through centralized and decentralized means, and increased cooperation through dedicated national administrative agencies. In the following section, some of the core transatlantic innovations are listed to shed light on how the European Union and the United States have tried to bridge the gaps in their regulations.

B. History of Transatlantic Trade

For the European Union and the United States, the primary transatlantic regulatory cooperation goals were to eliminate unnecessary and costly trade barriers and remove widespread and entrenched inconsistencies.[42] Prior to the Transatlantic Trade and Investment Partnership (TTIP) negotiations, many EU and American regulatory institutional innovations exemplified the drive to close the regulatory gaps across the Atlantic. The Transatlantic Business Dialogue (TABD), established in the early 1990s, focused on the differences in EU-US policy, regulatory, and procedural roadblocks while encouraging stakeholder advice and participation in international regulatory cooperation.[43] The TABD established the Transatlantic Advisory Committee on Standards, Certification, and Regulatory Policy, a part of the U.S. Department of Commerce aided by the EU Commission, at the 1995 Seville Conference.[44] Around the same time, the Clinton Administration developed another bilateral regulatory initiative, the New Transatlantic Agenda, the results of which are mixed and ultimately failed to overcome the more concerning roadblocks of transatlantic

40. *See* Bull, *supra* note 23; David Henig, *EU and US Regulatory Coherence in TTIP—Similarities and Differences*, *in* FRAMING CONVERGENCE WITH THE GLOBAL LEGAL ORDER, 129–42 (2020).

41. Bernard Hoekman, *Fostering Transatlantic Regulatory Cooperation and Gradual Multilateralization*, 18 J. INT'L ECON. L. 609, 614 (2015).

42. Richard Parker, *Four Challenges for TTIP Regulatory Cooperation*, 22 COLUM. J. EUR. L. 1, 3 (2015).

43. Nicola, *supra* note 24, at 180–81; Chase & Pelkmans, *supra* note 38, at 7.

44. *See* Paula Stern, New Paradigm for Trade Expansion and Regulatory Harmonization: The Transatlantic Business Dialogue, EUR. BUS. J., Autumn 1997, 36; Gregory Shaffer, *Reconciling Trade and Regulatory Goals: The Prospects and Limits of New Approaches to Transatlantic Governance through Mutual Recognition and Safe Harbor Agreements*, 9 COLUM. J. EUR. L. 29–77.

trade.[45] In 1997, the TABD released a mutual recognition agreement that permitted products approved in either the European Union or the United States may also be sold in the other's market.[46] In 1998, the European Union and the United States launched the Transatlantic Economic Partnership (TEP). The TEP's purpose was to increase E.U. and U.S. regulatory dialogue, promote agency-to-agency cooperation, and achieve convergence in technical rules. In 2005, the High-Level Regulatory Cooperation Forum (HLRCF) was created as a way to further increase E.U.-U.S. exchanges in best regulatory practices.[47] The HLRCF engages with both E.U. and U.S. officials and stakeholders on issues in horizontal cooperation and holds annual meetings to hold bilateral activities on regulatory approaches, analysis, and reforms.[48] Further U.S. efforts also include the Transatlantic Economic Council (TEC), a development led by then-Chancellor Angela Merkel during the German European Council Presidency,[49] and supported by the Bush Administration through its parallel Framework for Advancing Transatlantic Economic Integration.[50] At roughly the same time, the European Union launched its Better Regulation agenda, a manifestation of the European Union's rejuvenated interest in overseas regulatory cooperation.[51] The European Union and the United States signed a 2009 agreement on commercial aircraft airworthiness certifications and a 2012 agreement on mutual recognition of E.U. and U.S. ap-

45. *See* Mark Pollack & Gregory Schaffer, *Introduction, in* TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY (Rowman & Littlefield 2001); *see also* Anthony Gardner, *Long-term Significance of New Transatlantic Agenda*, POLITICO (Nov. 13, 1996), https://www.politico.eu/article/long-term-significance-of-new-transatlantic-agenda/ [https://perma.cc/3MP6-429X].

46. *See* Ellen L. Frost, *The Transatlantic Economic Partnership*, PETERSON INST. INT'L ECON. (1998), https://www.piie.com/publications/policy-briefs/transatlantic-economic-partnership.

47. Nicola, *supra* note 24, at 183–84.

48. Jonathan B. Weiner & Alberto Alemanno, *The Future of International Regulatory Cooperation*, 78 L. & CONTEMP. PROBS. 103, 114 (2015).

49. *Id.* at 115.

50. *See* Stormy-Annika Mildner & Oliver Ziegler, *A Long and Thorny Road. Regulatory Cooperation under the Framework for Advancing Transatlantic Economic Integration*, 44 INTERECONOMICS January/February 49 (2009) (focusing on regulatory cooperation that created the Transatlantic Economic Council under the Framework for Advancing Transatlantic Economic Integration agreed at the EU-US Summit on 30 April 2007).

51. In 2003, the European Parliament, the Council of the European Union and the European Commission signed an inter-institutional agreement on better-law-making where the three institutions made commitments to undertake impact assessments to support legislative proposals and substantive amendments. This agreement was replaced in April 2016 by a new agreement. 2016 O.J. (L 123) 1, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2016:123:TOC.

proaches to "organic" labeling.[52] Additional sectors of bilateral regulatory collaboration and mutual recognition include products in pharmaceuticals, marine equipment, and transportation security.[53]

While IRC dialogues between the United States and European Union have been ongoing for over twenty years, this has not been easy as Europe and the United States often have differences in their risk preferences or regulatory management policies. Experience has shown that despite a more institutionalized dialogue on good regulatory practices between the European Commission and the U.S. Office of Information and Regulatory Affairs (part of the Office of Management and Budget (OIRA/OMB)) the emphasis has been on transnational dialogues rather than the actual practice of regulatory cooperation. Despite impressive estimates of the perceived benefits, both the United States and European Union have set low levels of ambition for regulatory cooperation in their respective trade agreements. [54]

It is against this backdrop that the TTIP negotiations began in 2013.[55] The E.U. Commission's goals for regulatory cooperation in TTIP were increased exchanges in information, promotion of transparent regulatory practices, and the development of a long-term institutional framework. At the same time, TTIP commitments would establish a regulatory cooperation body to identify additional opportunities for cooperation in the future. While negotiating the TTIP, European Union and United States negotiators generally had three distinct modes of regulatory cooperation.[56] The first mode was the harmonization of new regulations to develop a single standard; the second was increased degrees of mutual recognition; and third was the elimination of duplicate testing, inspection, and conformity assessment proce-

52. Council Decision (EC) No. 719/2011 of 7 March 2011, 2011 O.J. (L 291) (establishing an agreement on cooperation in the regulation of civil aviation safety); Press Release, Kathleen Merrigan, U.S. Dep't Agric., Organics Take a Major Step Forward with U.S.-EU Partnership (Feb. 21, 2017), https://www.usda.gov/media/blog/2012/02/22/organics-take-major-step-forward-us-eu-partnership [https://perma.cc/XR6Z-2CWV].

53. Chase & Pelkmans, *supra* note 38, annex 1.

54. *See Evaluation of the Implementation of the Free Trade Agreement between the EU and its Member States and the Republic of Korea*, EUROPEAN COMM'N (2018), http://trade.ec.europa.eu/doclib/docs/2019/march/tradoc_157716.pdf (focusing on the regulatory changes enacted for compliance, including by surveying civil servants regarding the extent to which regulatory changes had been enacted in response to the Agreement.).

55. Michelle Egan, *Is TTIP Really that Different?*, *in* THE TTIP: THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP BETWEEN THE EUROPEAN UNION AND THE UNITED STATES 19 (Joaquín Roy & Roberto Domínguez eds., 2014), https://eucenter.as.miami.edu/_assets/pdf/ttip.pdf.

56. Mildner & Ziegler, *supra* note 50.

dures.[57] Both the European Union and the United States remained committed to high levels of protection of health, safety, the environment, and economic security.[58] However, low levels of transparency on both the E.U. and especially the U.S. side has led to two consequences: the first being an insufficient flow of advice and expertise on complex technical issues, and the second being increased contestation and mobilization by civil society and consumer and environmental interest groups towards specific elements of the E.U. and U.S. negotiations.[59]

Under discussion for three years, negotiations on TTIP ground to a halt in 2017 driven by a change in the negotiating conditions. A surge of anti-TTIP sentiment across Europe made the agreement increasingly contentious.[60] The talks had lost momentum before Donald Trump's election, with increased concern and wariness about the United States as a partner under the new administration, given the economic nationalism and skepticism towards free trade espoused by Trump during the election campaign. While some European national governments generated significant mistrust by failing to promote the benefits of trade liberalization to a domestic audience, the British referendum to leave the European Union also meant that a key supporter of moving the transatlantic trade deal forward was no longer part of the bloc.[61] The demise of regulatory cooperation efforts meant that there was limited institutional coordination between the United States and European Union on international trade issues.

Instead, the European Union sought a broad collation to support liberal rules-based trade through negotiating free trade agreements with like-minded partners such as Canada, Japan, and Korea to foster good regulatory practice.[62] The Canadian-EU Trade Agreement (CETA) has both sectoral and horizontal regulatory cooperation provisions, a Regulatory Cooperation Forum, and a work plan that includes animal welfare, 'cosmetic like' drug products, and pharmaceutical inspections. CETA also includes a protocol on conformity assessment

57. *Id*.

58. Eugenia C. Heldt, *Contested EU Trade Governance: Transparency Conundrums in TTIP Negotiations*, 18 COMP. EUR. POL. 215 (2020).

59. *Id.*; Ferdi De Ville & Gabriel Siles-Brügge, *Why TTIP is a Game-Changer and Its Critics Have a Point*, 24 J. EUR. PUB. POL'Y 1491 (highlighting how civil society organizations have become more active for social and environmental values in TTIP).

60. ALASDAIR YOUNG, THE NEW POLITICS OF TRADE: LESSONS FROM TTIP 111 (2017).

61. *Id*.

62. Chris Kimura & Fernanda G. Nicola, *EU-Asian Free Trade Agreements: The Negotiating Capital of Trade Experts*, *in* LAW, LEGAL EXPERTISE, AND EU POLICY-MAKING (2022).

which is the first in any European free trade agreement (FTA). The EU-Japan FTA also has provisions on regulatory cooperation. Like CETA, "the Agreement includes the establishment of a Regulatory Cooperation Committee to exchange good practice, promote areas for bilateral regulatory cooperation, and enhance cooperation in international standards setting organizations."[63]

However, with a new U.S. Administration, the United States and European Union have once again refocused their attention on regulatory cooperation with the formation of a Trade and Technology Council (TTC) in 2021.[64] This new strategic forum is focused on promoting regulatory cooperation in areas of technology, global supply chains, and investment screening based on shared principles of democratic values.[65] Emphasizing areas of regulatory commonalities in trade and technology rather than market access, it moves beyond earlier efforts at transatlantic cooperation by excluding what were often controversial issues that stymied agreement in recognition of previously limited tangible outcomes as detailed below.[66] TTC is reflective of newer challenges and as such is less about a neoliberal approach to maximize economic efficiency and growth in the transatlantic relationship, but rather takes a more geopolitical approach to trade through concepts like 'resilience', 'reshoring', and 'strategic autonomy.'[67] Given acute challenges posed by Russia, as well as the surge of Chinese access to advanced technologies, and supply chain issues, TTC is an effort at strategic interdependence that is meant to strengthen the broader transatlantic technology relationship. In response to the rise of China, both the United States and the European Union have begun to emphasize their common values rather than their regulatory differences.[68] For instance, greater attention in TTC is given to specific values-based trade policies—notably the eradication of forced labor—promoting broader

63. *See* Elizabeth Golberg, *Regulatory Cooperation—A Reality Check*, HARV. KENNEDY SCH., 17 (Apr. 2019), https://www.hks.harvard.edu/sites/default/files/centers/mrcbg/img/115_final.pdf.

64. Press Release, White House, U.S.-EU Trade and Technology Council Inaugural Joint Statement, (Sept. 29, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/29/u-s-eu-trade-and-technology-council-inaugural-joint-statement/.

65. *See* Alasdair R. Young, *The Transatlantic Regulatory Relationship: Limited Conflict, Less Competition and New Approach to Cooperation*, *in* THE ROUTLEDGE HANDBOOK OF TRANSATLANTIC RELATIONS (Elaine Fahey ed., 2023).

66. *Id.*

67. *Id.*

68. *Id.*

social justice values.[69] TTC is not framed in terms of workers' rights, human rights, public health, or environmental sustainability, but rather a forum for coordinating a more geostrategic trade alliance. It could be a key mechanism for transatlantic cooperation on values if the United States and the European Union can promote the kind of democratic, human rights-based tech governance that alleviates the regulatory disconnect that, as detailed below, has often been impeded by distinctive legislative and regulatory systems.

C. Roadblocks to Revamping Transatlantic Regulatory Cooperation

The roadblocks and issues inhibiting transatlantic and international regulatory cooperation have mostly remained consistent. Though the United States and the European Union share many similar approaches to regulation, including impacts assessments and a participatory model for notice and comments to rulemaking, scholars have consistently focused on transatlantic roadblocks like the domestic institutional differences between the European Union's multilevel model and the United States' fragmented federalism which are inherent in the different constitutional foundations of the United States and the European Union.[70] The United States has long championed notice and comment rulemaking to enhance transparency in its agreements as an effective method of early notice to facilitate stakeholder participation during notice-and-comment, a process crucial to IRC.[71] In spite of President Obama's 2012 Executive Order (13609), aimed at strengthening exports and growth by eliminating unnecessary regulatory differences between the United States and other countries, agen-

69. Jan Orbie, "EU Trade Policy Meets Geopolitics: What about Trade Justice?" 26 Eur. Foreign Aff. Rev. 2, 197–202 (2021). *See also U.S.-EU Joint Statement of the Trade and Technology Council*, WHITE HOUSE (May 16, 2022), https://www.whitehouse.gov/wp-content/uploads/2022/05/TTC-US-text-Final-May-14.pdf.

70. *See* Jean-Louis Dewost, *Globalization and the Rule of Law*, *in* TRANSATLANTIC REGULATORY COOPERATION: LEGAL PROBLEMS AND POLITICAL PROSPECTS (Bermann et al. eds., 2000); David Andrews, *Listening in on the US-EU Legal Dialogue*, *in* TRANSATLANTIC REGULATORY COOPERATION: LEGAL PROBLEMS AND POLITICAL PROSPECTS (Bermann et al. eds., 2000); Jonathan R. Macey, *US and EU Structures of Governance as Barriers to Transatlantic Regulatory Cooperation*, *in* TRANSATLANTIC REGULATORY COOPERATION: LEGAL PROBLEMS AND POLITICAL PROSPECTS (Bermann et al. eds., 2000).

71. *See* Stijn Smismans, *Regulatory Procedure and Participation in the European Union, in* COMPARATIVE LAW AND REGULATION: UNDERSTANDING THE GLOBAL REGULATORY PROCESS (David Zaring & Francesca Bignami eds., 2018).

cies continually fail to flag rules with an international impact.[72] As a result, the opportunity for public comment is reduced even though it could have generated substantial interest in rules with significant outcome on international trade partners.[73] Additionally the most important U.S. agency in charge of negotiating trade agreements, the Office of the U.S. Trade Representative (USTR), is often a *primus inter pares*, sharing some of its responsibilities with the Commerce Department and other agencies, yet only voluntarily subjects its rules to notice and comments under the Administrative Procedure Act.[74] This discretion for the USTR to follow or depart from the APA notice and comments requirements, depending on the executive preferences, has created large transparency concerns among NGOs and academics alike about the USTR's practices, despite its new efforts like the transparency principles.[75]

The European Parliament has advocated for a similar administrative procedures law,[76] though the European Commission has remained unconvinced about the benefits of codifying administrative law given that the European Union has a model of administrative pluralism. Changes stemming from the Lisbon Treaty create an ability to legislate over the administrative activity of the member states, which are now defined as a "matter of common interest" (art. 197 TFEU) and constitute a "duty to regulate administrative procedure" (art. 298 TFEU). A group of scholars has prepared model rules on E.U. Administrative Procedures as a sort of European restatement for administrative law.[77]

At the transatlantic level, although scholars have functionally compared similarities and differences of E.U. and U.S. regulatory re-

72. For data, *see* Daniel Pérez, *Identifying Regulations Affecting International Trade and Investment: Better Classification Could Improve Regulatory Cooperation* 13–14 (Geo. Wash. Univ. Regul. Stud. Ctr. Working Paper, 2015).

73. *Id.*

74. *See* Kathleen Claussen, *Trade Administration*, 107 VA. L. REV. 845 (2018) (explaining the executive power of the USTR and how trade served as an administrative constraint).

75. *See* Off. U.S. Trade Representative, United States Trade Representative Transparency Principles, https://ustr.gov//sites/default/files/files/about/USTRTransparencyPrinciples.pdf.

76. *See* EU Rules on Aministrative Procedure—State of Play, EUR. PARL., (April 2020), https://www.europarl.europa.eu/RegData/etudes/ATAG/2020/642833/EPRS_ATA(2020)642833_EN.pdf.

77. *See ReNEUAL Model Rules 2014*, RSCH. NETWORK ON EU ADMINISTRATIVE LAW (2014), http://www.reneual.eu/images/Home/ReNEUAL-Model_Rules-Compilation_BooksI_VI_2014-09-03.pdf. These serve as a proposal for binding legislation and they are based on comparative research to find best practices in different specific regulatory areas of E.U. policy.

gimes,[78] the structural differences between the United States and European Union member states' administrative law systems remain because each regulatory practice is embedded in the political economy of the administrative state through compromises between regulators and special interests, where regulation is a central site for mobilization and contestation in democratic policies.[79]

However, structural regulatory differences can create roadblocks that have remained present in the post-TTIP debate, where its failure revealed a deeper public skepticism and desire for greater regulatory transparency, especially when driven by trade agreements, than many scholars had previously indicated.[80] This is not to say pre-TTIP scholars underestimated the importance of transparency and regulatory autonomy as part of a legitimate, democratic regulatory process, but in getting TTIP to a "yes," the existing solutions may not have been enough to boost public confidence in the negotiations.[81] Robert Howse pointed to problems deriving from the European Union and the United States' lack of a shared "common vocabulary," which will in turn force the parties to rely on "intermediate experts with attendant agency cost problems."[82] Sol Picciotto recommended EU-U.S. transatlantic transparency be bolstered through the development of an information media that provides a space for public participation and deliberation.[83] Picciotto brought to the fore public concerns over the closed nature of transatlantic decision-making and emphasized the need for increased external critical input into the deliberative process.[84]

78. *See* Richard W. Parker & Alberto Alemanno, *A Comparative Overview of EU and US Legislative and Regulatory Systems: Implications for Domestic Governance & the Transatlantic Trade and Investment Partnership*, 22 COLUM. J. EUR. L. 61 (2015).

79. *See* Rahman, *supra* note 8 at 139–65 (showing how even in the regulatory process democratic action and participation can serve as antidote to economic domination).

80. *See Growing Skepticism: TTIP Under Pressure in Germany and the USA*, BERTELSMANN STIFTUNG (April 21, 2016), https://www.bertelsmann-stiftung.de/en/topics/latest-news/2016/april/growing-skepticism-ttip-under-pressure-in-germany-and-the-usa.

81. *See* Thomas J. Bollyky & Anu Bradford, *Getting to Yes on Transatlantic Trade*, FOREIGN AFFAIRS (July 10, 2013), https://www.foreignaffairs.com/articles/united-states/2013-07-10/getting-yes-transatlantic-trade (focusing on efficiency gains and the need to eliminate duplicative policies).

82. Robert Howse, *Transatlantic Regulatory Cooperation and the Problem of Democracy*, *in* TRANSATLANTIC REGULATORY COOPERATION: LEGAL PROBLEMS AND POLITICAL PROSPECTS (Bermann et al. eds., 2001).

83. Sol Picciotto, *North Atlantic Cooperation and Democratizing Globalism*, *in* TRANSATLANTIC REGULATORY COOPERATION: LEGAL PROBLEMS AND POLITICAL PROSPECTS (Bermann et al. eds., 2000).

84. *Id.*

Other criticisms have been levied at the rising role of private sector standards bodies setting out regulatory guidelines, independent of public sector guidance and oversight.[85] The result is that specific global industries enjoy disproportionate benefits from international cooperation, as their private standards can become de facto mandatory through incorporation into public legislation or market dominance, especially if they are used in local production or in segments of global value chains.

While democratic and transparency concerns have not changed much since TTIP's demise, it is unclear whether such frameworks went far enough to raise confidence in transatlantic trade.[86]

Today scholarly solutions are replete with civil society concerns regarding institutional transparency and democratic deficiencies in the negotiations, as well as heightened fear that business interests will dominate any bilateral agreement provisions and start a race-to-the-bottom in areas of public health and sustainability.[87] While American and European business interests across different sectors adopted common positions on specific aspects of an agreement, opposition came more directly from less traditional trade actors like consumer and environmental groups in Europe that were concerned about the erosion of valued regulations.[88] It is amid this debate among trade lawyers and negotiators who are rethinking tools and processes for the new values-based trade agenda announced by the European Union and the United States that we think it is vital to put forward a new analysis for international regulatory cooperation. This new analysis should help to avoid regulatory disconnects like the ones we describe in detail on our two case-studies on medical devices and cosmetics.

85. Richard B. Stewart, *Remedying Disregard in Global Regulatory Governance: Accountability, Participation, and Responsiveness*, 108 AM. J. INT'L L. 211, 214 (2014).

86. *See generally* Leif Johan Eliasson & Patricia Garcia-Duran Huet, *TTIP Negotiations: Interest Groups, Anti-TTIP Civil Society Campaigns and Public Opinion*, 16 J. TRANSATLANTIC STUD. 101 (2018) (showing the increasing contestation about the content of the agenda and the potential effects of regulatory outcomes generated significant protests and criticism that derailed the TTIP negotiations).

87. Parker & Alemanno, *supra* note 78.

88. Alasdair R. Young, *Not Your Parents' Trade Politics: the Transatlantic Trade and Investment Partnership Negotiations*, 23 REV. INT'L POL. ECON. 345, 378 (Mar. 23, 2016).

II.
Models and Failures in IRC

A. Three Models of International Regulatory Cooperation

As sustained crises have led to challenges to the rule-based international order, regulatory cooperation in the transatlantic relationship has evolved. Amplified by the trade policies of the previous U.S. administration, the non-market behavior of China, the gridlock within the WTO disrupted by the United States,[89] and the stresses from the global pandemic, the transatlantic relationship is premised on the needs of international competitiveness in an era of rapidly globalizing markets.[90] For some, neoliberal logic pushed the goal of prioritizing efficiency that would maximize economic welfare. Efficiency was achieved through the liberalization of markets abroad and encouraging inflows of trade and investment domestically. This push for efficiency often led to contestation by civil society groups, notably progressive groups, trade unions, and the broader public have sought increased transparency.[91] These groups exert intense pressure on policymakers to ensure that domestic regulatory objectives are not undermined even as trade liberalization drives heightened domestic interest in ensuring inclusiveness and democratic accountability.[92] The growing experience of regulators means that due to the changing trade agenda, the maximization of economic welfare in trade negotiations has increased the salience of trade values such as environmental, public health, and social equity concerns to ensure that the objectives of protective social regulations are not diminished.

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89. *See* Gregory Shaffer, Emerging Powers and the World Trading System: The Past and Future of International Economic Law 9, 271 (2020) (showing how the US disenchantment in the WTO that led to the undermining of the Appellate Body jurisprudence also affected internally the transnational legal order for trade).

90. Contestation and Polarization in Global Governance: European Responses (Michelle Egan, et.al., eds.,) (2023) (focusing on the limits of the rule-based international order in which transatlantic efforts have been undermined by rising power politics and the tensions with China over market practices).

91. *See generally* Tamara Kay & R.L. Evans, Trade Battles: Activism and the Politicization of International Trade Policy (2018); Ho-Fung Hung, *Reviewed Work: Trade Battles: Activism and the Politicization of International Trade Policy by Tamara Kay, R. L. Evans*, 49 Contemp. Socio. 59,59–61 (2020); L. Johan Eliasson & Patricia Garcia-Duran, *The Saga Continues: Contestation of EU Trade Policy, Global Affairs*, 6 Glob. Aff., 433, 433–45 (2020); Stuart Trew *CETA Negotiations: Civil Society Engagement in the Provinces, Municipalities, and Europe,* Int'l J., Dec. 2013, 568–74.

92. *See* Gregory Shaffer, *How Do We Get Along? International Economic Law and the Nation-State*, 117 Mich. L. Rev. 1229, 1244 (2019) (addressing the discontent on trade policy by domestic actors asking for more "policy space").

Yet just as the European Union and the United States emphasize the need for a more democratic, equitable, and sustainable trade system, their values-based paradigm faces geoeconomic competition from China.[93] Even then, the premise is often that failure to solve differences between the two trade partners—the European Union and the United States—increases costs while also impacting inward investment, slowing productivity growth, and disrupting supply chains.

While the logics of trade policy remain competitive and focus on market access according to the free market ideology, there has been a shift in trade discourse and ideas with new value-based trade paradigms. The U.S. and E.U. regulatory policies have migrated from their original neoliberal aims—cutting through bureaucratic red tape, implementing cost-benefit analysis and impact assessments, and eliminating non-tariff measures—towards one of reasserting regulatory authority and autonomy in domestic and international frameworks. This reassertion has had notable implications for sustainability, public health, and social equity, particularly in standard setting[94] and in assessing the distributive impact on vulnerable communities.[95] Yet despite European and American efforts to promote E.U. and U.S. trade values down the supply chain—and link their efforts to trade justice goals—their methods of achieving sustainability and other social equity goals in the domestic administrative sphere differ. This leads to a regulatory disconnect when they try to foster regulatory cooperation, as illustrated in the two case studies below. This will have further significance for the transatlantic relationship as they move into regulating new technology and export sectors as part of the TTC, if they do not align their regulatory goals and outcomes with a common set of trade values.

1. Efficiency in Regulatory Cooperation

> "Over decades, differences in our regulatory and standards approaches have created unnecessary barriers, raising costs, deterring

93. JOHAN ADRIAENSEN & EVGENY POSTNIKOV, A GEO-ECONOMIC TURN IN TRADE POLICY: EU TRADE AGREEMENTS IN THE ASIA-PACIFIC, 4-6 (Palgrave 2022).

94. *See generally Sustainable Development Goals*, EUROPEAN COMMISSION, https://ec.europa.eu/international-partnerships/sustainable-development-goals_en (last visited Apr. 30, 2021) [https://perma.cc/RQ6E-9UEH]; Xavier Seuba, *Trade, Public Health, and the 2030 Agenda for Sustainable Development*, INT'L CTR. FOR TRADE AND SUSTAINABLE DEV. (2017).

95. *See* ITC Investigation of Trade Distribution Effects on Workers and Underserved Communities, *supra* note 5.

> trade and investment, and negatively impacting our competitiveness and our consumers."[96]

IRC in pursuit of efficiency stems from a commitment to neoliberal economic principles. Classic neoliberalism, as expressed through privatization, deregulation, and the pursuit of free markets, does not stand independent from the sociopolitical and legal context in which markets express themselves.[97] As opposed to a purely liberalized, Hayekian system,[98] neoliberalism engages with these societal contexts in its pursuit of more efficient markets and deregulation of capital.[99] Neoliberalism therefore contends with questions of who is subject to market discipline, who is exempt, and, crucially, on what rationale such decisions are made.[100]

The neoliberal system was most clearly embodied in the Washington Consensus of the 1980s, 90s, and early 2000s.[101] Unfortunately, many states in the global trading system found that the costs entailed by the commitments to liberalization outweighed the benefits.[102] Successive shocks to the system, such as the 2008 financial crisis, failure of the Doha round at the WTO, and collapse of TTIP reflected an erosion of transatlantic support for the Washington Consensus that had already taken in root in much of the developing world.[103] The distributive consequences of the efficiency system have only become more apparent, both between states and within them, as the decline of organized labor, widening inequality, and divergent ca-

96. Michael Froman, U.S. Trade Rep., Exec Office of the President, Remarks on the United States, the European Union, and the Transatlantic Trade Partnership (Sept. 30, 2013), https://ustr.gov/about-us/policy-offices/press-office/speeches/transcripts/2013/september/froman-us-eu-ttip.

97. David Grewal & Jedidiah Purdy, *Law and Neoliberalism*, 77 L. & CONTEMP. PROBS. 1, 8 (2015).

98. *See* FRIEDRICH HAYEK, THE ROAD TO SERFDOM, (Routledge 1949). Hayek was a leading thinker against market planned economies and promoter of economic neoliberalism advocating for privatization and minimal role for the state involvement in market economies.

99. *Id.* at 13–14.

100. *Id.* at 18.

101. Sally Anne Weller & Phillip M. O'Neill, *An Argument with Neoliberalism, Australia's Place in a Global Imaginary*, 4 DIALOGUES HUM. GEOGRAPHY 105, 111, 150 (2014).

102. Michael J. Trebilcock & Thomas M. Boddez, *The Case for Liberalizing North American Trade Remedy Laws*, 4 MINN. J. GLOB. TRADE 1, 10 (1995); GREGORY SHAFFER, EMERGING POWERS AND THE WORLD TRADING SYSTEM: THE PAST AND FUTURE OF INTERNATIONAL ECONOMIC LAW 15 (2021).

103. Weller & O'Neill, *supra* note 101, at 152; David Singh Grewal, *Three Theses on the Current Crisis of International Liberalism*, 25 IND. J. GLOB. L. STUD. 595, 612–13 (2018).

pacities to address global challenges like climate change have only intensified.[104]

Concerning the transatlantic relationship, the United States and European Union constructed a regulatory cooperation regime with neoliberal objectives in mind since the 1980s. Initially, through efforts like the Trans-Atlantic Business Dialogue, U.S.-E.U. High-Level Regulatory Cooperation Forum, and numerous working groups, reports, and guidelines, lawyers were laying the foundations to better integrate transatlantic markets.[105]

Former World Bank President Robert Zoellick's position aligns closely with the neoliberal camp but with geopolitical implications. He emphasizes that the United States must lead the world in the new global order. His vision promotes a universal liberalization through the adoption of competitive market access and efficient regulatory standards for other countries to reciprocate a "race to the top" phenomenon.[106] Professor Anu Bradford's notion of the "Brussels Effect" takes a similar stance to Zoellick, although in her view it is the EU's regulatory regime, through competitive efficiency, that will incentivize other nations to adopt EU-mirroring regulations to maintain market access.[107] Much research and scholarly work have been published on the transnational push and pull effects of states that possess regulatory competitive advantages.

Promoting a similar neoliberal perspective but in a cooperative framework, Dan Hamilton and Jacques Pelkmans favored a competitive regulatory model within the TTIP framework in *Rule-Makers or Rule-Takers?*, arguing that a TTIP-style agreement "can quickly become a benchmark for global models."[108] In light of the United States' and European Union's economic strength, their regulatory benchmarks will prevent other states from imposing stringent, protectionist requirements or lower standards resulting in a race to the bottom.[109] Further, Hamilton and Pelkmans argued that TTIP would act as a "living agreement", with the potential to eliminate regulatory re-

104. Grewal & Purdy, *supra* note 97 at 614; Weller & O'Neill, *supra* note 103, at 152-54.

105. Chase & Pelkmans, *supra* note 38, at 7.

106. Robert Zoellick, *A New US International Economic Strategy*, WALL ST. J. (Feb. 5, 2013), https://www.wsj.com/articles/SB10001424127887324039504578261812638282242 [https://perma.cc/N722-M6VV].

107. *See* ANU BRADFORD, THE BRUSSELS EFFECT: HOW THE EUROPEAN UNION RULES THE WORLD (Oxford Univ. Press 2020).

108. *See* Dan Hamilton & Jacques Pelkmans, *Rule-Makers or Rule-Takers? An Introduction to TTIP*, *in* RULE-MAKERS OR RULE-TAKERS?: EXPLORING THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP 3 (eds. Hamilton & Pelkmans, 2015).

109. *Id.* at 3.

dundancies and promote efficiency and good practices.[110] Hamilton and Pelkmans emphasized the strategic importance of the U.S.-E.U. transatlantic regulatory relationship and the need for both powers to remain "rule-makers" in light of their waning international authority.[111] A successful TTIP would have also represented a "symbolic and practical assertion of Western renewal, vigor, and commitment."[112] Hints of Zoellick's view can be seen, albeit prioritizing a bilateral U.S.-E.U. relationship rather than a unilateral U.S. one.

2. *Transparency in Regulatory Cooperation*

> "We now have an unprecedented initiative on transparency. Basically, all the documents related to TTIP from the European side are online, legal-type proposals, background papers, position papers, explanatory papers and as we develop common positions as negotiations go on we will put them online as well."[113]

As the neoliberal system continued pursuing efficient trading relationships through the early 2000s, a growing recognition of the need for transparency in regulatory cooperation began to emerge. Scholars have noted how deepening transatlantic regulatory cooperation through the late 1990s and early 2000s led to increasingly technical, and thus publicly inaccessible, regulatory action.[114] This growing opacity in the transatlantic regulatory relationship led to skepticism, and at times hostility, to further cooperation, thus prompting a reevaluation of the need for transparency in transatlantic trade relations.[115] The shift was perhaps best expressed in European Ombudsman Emily O'Reilly's 2015 report on increasing transparency in the Union's trilogue process,[116] noting that such transparency was vital not only to

110. *Id.* at 11.
111. *Id.* at 12.
112. *Id.* at 9.
113. Suzanne Lynch, *Staying Positive in the Maelstrom of EU-US Trade Negotiations*, IRISH TIMES (Mar. 27, 2015), https://www.irishtimes.com/business/economy/staying-positive-in-the-maelstrom-of-eu-us-trade-negotiations-1.2154415 [https://perma.cc/9SZ6-P8XZ] (quoting Cecilia Malmström, E.U. Trade Commissioner 2014–19).
114. Chase & Pelkmans, *supra* note 38, at 8.
115. *Id.*
116. European Ombudsman Press Release No. 9/2015, Ombudsman Opens Investigation to Promote Transparency of "Trilogues" (May 27, 2015), https://www.ombudsman.europa.eu/en/press-release/en/59975; *see* Emilio De Capitani, *Progress and Failure in the Area of Freedom, Security, and Justice, in* EU LAW IN POPULIST TIMES 375–76 (Francesca Bignami ed., 2020)(showing that because the Member States continue to control the AFSJ Area of Freedom Security and Justice, very little effective policy has been developed at the European Union level so that Member States are preserving pre-Lisbon non-transparent structures).

trade negotiations but to Union political stability as a whole,[117] a notion reflected in then-European Commissioner for Trade Cecilia Malmström's comments above.

Several scholars reflect this shift from the purely neoliberal paradigm to a more nuanced approach to efficiency that expresses greater concern with transparency and accountability.[118] Simon Lester and Inu Barbee found that the potential gains from regulatory cooperation were smaller than some might hope, and instead recommended that states must "focus on aligning regulations that are arbitrarily different rather than changing the substantive nature of the regulation."[119] The focus here is not on regulatory outcomes, but the differences within the regulatory process.[120] Lester and Barbee use the example of the U.S.-Canada Regulatory Cooperation Council as a useful standard for the U.S.-E.U. relationship, especially the Cooperation Council's "broad engagement from both the public and private sector", the "key reason for its success."[121] The authors warn regulators to avoid the "bureaucratic trap" and suggest implementing measures to address bureaucratic red-tape and remove incompatible rules and regulations, while also substantively increasing private input: "A transparent, inclusive, and open process that involves all stakeholders . . . is a good model for achieving regulatory cooperation going forward."[122]

Peter Chase's and Jacques Pelkmans' article *This Time It's Different* represents a shift away from the neoliberal and competitive framework for regulatory cooperation.[123] They prioritize the building of social bridges and creating social objectives while also letting states maintain a strong sense of regulatory autonomy, and enhancing regulators' abilities to protect their citizens.[124] Chase and Pelkmans focus less on the removal of unnecessary differences in regulation that lack any "corresponding regulatory or social benefit."[125] They recommend that regulators be concerned about regulatory transparency and coherence. Regulatory coherence, in their view, should build trust and con-

117. Martin Banks, *Emily O'Reilly: Lack of Transparency Damaging EU*, PARLIAMENT MAGAZINE (June 23, 2017), https://www.theparliamentmagazine.eu/news/article/emily-oreilly-lack-of-transparency-damaging-eu [https://perma.cc/GJT8-VSW3].
118. *See* Weiner & Alemanno, *supra* note 48, at 127.
119. Simon Lester & Inu Barbee, *The Challenge of Cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership*, 16 J. INT'L ECON. L. 847, 849 (2013).
120. *Id.* at 863.
121. *Id.* at 862.
122. *Id.*
123. Chase & Pelkmans, *supra* note 38.
124. *Id.*
125. *Id.* at 25–26.

fidence in the other side's domestic rulemaking procedures through the implementation of obligations. These obligations will ensure that regulators' decisions are informed by an assessment of the proposal's potential impacts on the other side, generating a transatlantic impact analysis.[126]

Policymakers also sought to reduce the influence of public regulators in favor of increased participation from the private sector, particularly through a better or more "transparent" access to regulatory processes including impact assessments and cost-benefit analyses.[127] For instance, Richard W. Parker and Alberto Alemanno identified greater procedural transparency between the United States and the European Union as critical to achieving progress in the then-nascent TTIP negotiations.[128] Jonathan B. Weiner and Alemanno likewise identified TTIP as a possible stepping stone to a "global regulatory laboratory", whereby intergovernmental transparency would be a critical factor in advancing regulatory coordination globally.[129]

Although TTIP ultimately failed, it entrenched in IRC principles of regulatory transparency, public participation, accountability, and evidence-based regulation[130] while also politicizing the broad notion of transparency.[131] As a result, these ideas surrounding the centrality of openness and accountability for both regulators and businesses in trade negotiations and regulations present a revision of the neoliberal foundation of the efficiency paradigm in international regulatory cooperation.[132] Even if the instruments to promote values became more substantial, the political conditions to achieve such regulatory cooperation require a bold departure from neoliberalism, as the United States and the European Union have raised expectations over the past three decades about addressing the myriad of trade barriers between their respective economies. Much of this discourse by transatlantic trade lawyers has been wedded to the economic logic to reduce transaction costs and facilitate commercial transactions from a neoliberal standpoint. This view has been supplemented by a more sociological en-

126. *Id.* at 16–17.

127. Lester & Barbee, *supra* note 119, at 863; *see also* Howard Beales et al., Government Regulation: The Good, The Bad, & The Ugly, THE REGULATORY TRANSPARENCY PROJECT OF THE FEDERALIST SOCIETY (June 12, 2017); Parker & Alemanno, *supra* note 79.

128. Parker & Alemanno, *supra* note 78, at 66.

129. Weiner & Alemanno, *supra* note 49, at 132–35.

130. *See* Better Regulation, Taking Stock and Sustaining Our Commitment, COM (2019), 156 final (Apr. 15, 2019), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52019DC0178&from=EN.

131. *See* Nicola, *supra* note 24, at 175.

132. *See* Heldt, *supra* note 58.

gagement that legal networks with authoritative and policy-relevant expertise can collaborate and shape common legal principles through benchmarking, best practices, impact assessments, and policy learning. Gregory Shaffer has recommended that both the United States and European Union focus on "creating processes . . . to identify risks. . .so that systems and processes . . . can 'co-evolve' by learning from each other's experiences."[133] Rather than prioritize the cutting of bureaucratic red tape, Shaffer recommends the importance of allowing regulators to create new regulatory processes for the sake of learning and developing good regulatory practice.

3. Values-based Regulatory Cooperation—The Future?

> "According to the standard view, trade policy was all about boosting economic growth and creating jobs, by lifting trade barriers and opening markets . . . However trade is seen as a tool to attain broader objectives more than ever . . . Trade, now in the spotlight, has the chance to be an accelerator for positive change.[134]

Today, due the rising wealth inequalities in the aftermath of financial crises and the COVID-19 pandemic, the distributional consequences of market opening are more salient for the transatlantic relationship. For critics of trade agreements, the United States and European Union need to make growth compatible with social and environmental protection as nontrade goals have become more prominent.[135] This means that regulatory cooperation is not just about the adoption of certain practices that aim to create frameworks that are mutually equivalent, but about the need for values-based regulatory cooperation seeking to achieve greater sustainability and social equity. Although regulatory cooperation does not constitute a new trend in trade politics, the transatlantic relationship is now embedded in global value chains that require the United States and the European Union to focus on the implications of the global nature of production on their own values and standards.[136]

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133. *See* Gregory Shaffer, *Alternatives for Regulatory Governance under TTIP: Building from the Past,* 22 COLUM J. EUR. L. 403, 418 (2016).

134. Sabine Weyand, *Sabine Weyand on Role of Trade Policy in Fighting Climate Change*, ECONOMIST (Oct. 16, 2021), https://www.economist.com/by-invitation/2021/10/16/sabine-weyand-on-role-of-trade-policy-in-fighting-climate-change [https://perma.cc/HK6M-CU4F].

135. *See e.g*., Young, *supra* note 88, at 351 (discussing the importance of social and environmental groups in the United States and the European Union disapproving of TTIP for fear of lower environmental standards, thus requiring more cooperation between the bodies in order to discuss these non-trade interests).

136. Gary G. Hamilton & Gary Gereffi, *Global Commodity Chains, Market Makers, and the Rise of Demand-Responsive Economies*, *in* FRONTIERS OF COMMODITY CHAIN

Rather than debate the relative merits of their own regulatory standards relative to each other, which has hindered cooperation in the past, they must face the associated risks that products not only cross borders to be assembled in the final production but may also have different process or production methods. As Bernard Hoeckman notes, "such differences are also a matter of concern to consumers, who worry about the health consequences and safety of products produced as part of global supply chains."[137] As a result, the United States and the European Union have shifted their narrative to focus more on the values-based priorities that are needed to underpin international regulatory cooperation.[138] Trade negotiators are more sensitive to the values and concerns of civil society and public opinion, and so trade agreements increasingly include environmental, health, safety, and labor concerns. But for the United States and the European Union the values-based agenda must be codified through regulatory cooperation given that the prospects of a trade agreement have diminished. Given the surge of economic nationalism and protectionism, coupled with concern about a rising China and its nonmarket practices, regulatory cooperation is a strategy to draft a new generation of rules on trade and investment that are anchored in a shared vision of governance.[139]

For transatlantic regulatory cooperation, this means that the United States and European Union need to balance a rights-based agenda, associated with the promotion of values through legal and policy norms, and a market rationality where more decentralized privatized governance sets out standards for market access. While most explanations are based on the premise that the European Union and the United States want to export rules to each other, which is difficult to do in terms of the transatlantic space given the relative size of their economies, Alasdair Young argues that the European Union often recognizes that specific demands may jeopardize the entire agreement resulting in more pragmatic regulatory cooperation efforts.[140] He

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RESEARCH 136, 138–41 (Jennifer Bair ed., 2008); *see generally* FRONTIERS OF COMMODITY CHAIN RESEARCH (Jennifer Bair ed., 2008).

137. Bernard Hoeckman, *International Regulation Cooperation and Trade Agreements*, *in* THE OXFORD HANDBOOK OF INSTITUTIONS OF INTERNATIONAL ECONOMIC GOVERNANCE AND MARKET REGULATION (Eric Brousseau et al. eds., 2019).

138. *The New Order of Trade*, ECONOMIST (Oct. 6, 2021), https://www.economist.com/special-report/2021/10/06/the-new-order-of-trade [https://perma.cc/4SLE-2BW6].

139. *See* Andrew Small et al., *US-European Cooperation on China and the Indo-Pacific*, GERMAN MARSHALL FUND (Feb. 2, 2022).

140. *See* Alasdair R. Young, *Liberalizing Trade, Not Exporting Rules: The Limits to Regulatory Co-ordination in the EU's 'New Generation' Preferential Trade Agreements*, 22 J. EUR. PUB. POL'Y 1253, 1254 (2015) (discussing how the European Union

notes that such regulatory pragmatism means that a balanced and progressive trade strategy has to anticipate that its partners would be less willing to make commitments.[141]

For the European Union, a "balanced and progressive" trade strategy is designed to use trade agreements to raise other countries' standards with respect to "human rights, working conditions, food safety, public health, environmental protection and animal welfare."[142] The European Union enshrines these principles in an "essential elements" clause included in trade agreements, providing a legal mechanism enabling the unilateral suspension of trade commitments when such human rights or rule of law values are breached.[143] While the European Union includes provisions on labor rights in its trade and sustainable development chapters (TSD), it has higher obligations than those commonly provided in labor and environmental provisions of U.S. FTAs. The European Union's recent successful challenge in the E.U.-Korea labor dispute mechanism,[144] as well as the E.U.-Ukraine environmental dispute mechanism, demonstrates the importance of values-based trade agreements, in seeking to raise and enforce labor and environmental standards beyond their borders.[145]

By contrast, Lotte Dreighe and Diana Potjomkina argue that "provisions on market access are binding, concrete and detailed, while those with values are often vague, not binding or are, in practice, al-

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tempers its regulatory approach in PTAs due to concerns that regulatory changes, the so called Brussels effect, would hinder an agreement with negotiating partners).

141. *Id.*; Lachlan McKenzie & Katharina L. Meissner, *Human Rights Conditionality in European Union Trade Negotiations: The Case of the EU-Singapore FTA*, 55 J. COMMON MKT. STUD. 832, 834, 840–41 (2016) (contending that E.U. commercial interests opposed including strong human rights provisions in the European Union's FTA with Singapore because it would prompt Singapore to reject the agreement).

142. *Reflection Paper on Harnessing Globalisation*, at 14, COM (2017) 240 (May 10, 2017); *see also Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A Balanced and Progressive Trade Policy to Harness Globalisation*, at 3, COM (2017) 492 final (Sept. 13, 2017); *Shared Vision, Common Action: A Stronger Europe*, at 8 (June 2016) https://op.europa.eu/en/publication-detail/-/publication/3eaae2cf-9ac5-11e6-868c-01aa75ed71a1.

143. Ionel Zamfir, European Parliamentary Research Service, *Human Rights in EU Trade Agreements* (July 2019), https://www.europarl.europa.eu/RegData/etudes/BRIE/2019/637975/EPRS_BRI(2019)637975_EN.pdf.

144. Jill Murray et al., *Panel of Experts Proceeding Constituted Under Article 13.15 of the EU-Korea Free Trade Agreement: Report of the Panel of Experts*, at 78–79 (Jan. 20, 2021) (on file with author).

145. *See Environment*, Mission of Ukr. to the Eur. Union (Apr. 15, 2021), https://ukraine-eu.mfa.gov.ua/en/2633-relations/galuzeve-spivrobitnictvo/ohorona-dovkillya.

most never enforced."[146] Regulatory cooperation reflects a more modest endeavor in trade relations, suggesting that the European Union is less an exporter of rules than a promotor of regulatory alignment across specific issue areas.[147] However, there are also indications that the European Union's increased attention to enforcement efforts illustrates the importance of instrumentalized international trade agreements, to help raise and more securely enforce labor and environmental standards around the world.[148] The European Union has institutionalized changes with the centralization of trade enforcement within the European Commission allowing for complaints involving both market access as well as social issues.[149] The United States also provides for enforceable remedies with regards to breaches of labor standards.[150] The new United States-Mexico-Canada Agreement (USMCA) negotiated by the Trump Administration has added provisions on labor protection under Article 23 which are not unlike the provisions in recent E.U.-Mexico and E.U.-Canada agreements with the possibilities of challenging labor violations via a formal dispute settlement system.[151]

Efforts to promote trade values have both an economic and political rationale and also encompass what are perceived as unfair trading practices from nonmarket economies that are not playing by the rules of the multilateral trading system.[152] This stance—notably more strident in the United States than in Europe—has also pushed regulatory

146. Lotte Drieghe & Diana Potjomkina, *EU's Value-based Approach in Trade Policy: (Free) Trade for All?*, 5 GLOB. AFFS. 63, 68 (2019).

147. *Cf*. Bradford, *supra* note 107. For a critical engagement with Bradford's theory, *see* Peter Lindseth, *Book Review: Anu Bradford, The Brussels Effect: How the European Union Rules the World,* AM. J. COMPAR. L. (forthcoming Apr. 2021).

148. *See, e.g*., *Chief Trade Enforcement Officer*, Eur. Comm'n, https://ec.europa.eu/trade/trade-policy-and-you/contacts/chief-trade-enforcement-officer/ (last visited Jan. 27, 2023); European Commission Press Release IP/21/6642, The Commission, E.U. Strengthens Protection Against Economic Coercion (Dec. 8, 2021).

149. European Commission Press Release IP/20/2134, Commission Launches New Complaints System to Fight Trade Barriers and Violations of Sustainable Trade Commitments (Nov. 16, 2020), https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2134 [https://perma.cc/9RGB-KF2B].

150. *Chapter 31 Annex A; Facility-Specific Rapid-Response Labor Mechanism*, OFF. U.S. TRADE REPRESENTATIVE, https://ustr.gov/issue-areas/enforcement/dispute-settlement-proceedings/fta-dispute-settlement/usmca/chapter-31-annex-facility-specific-rapid-response-labor-mechanism.

151. The USMCA utilizes the Rapid Response Mechanism for labor enforcement. We are grateful to Desirée LeClerq about her clarification about the Mechanism and its future implications influencing future Canadian and E.U. trade policies.

152. *See generally* Richard Lockridge, *Doubling Down in Non-Market Economies: The Inequitable Application of Trade Remedies Against China and the Case for a New WTO Constitution*, 24 S. CAL. INTERDISC. L. J. 249 (2014).

cooperation to expand into critical and emerging technologies, including artificial intelligence and communication technologies.[153] Yet this should also be linked to value-based regulatory enforcement as the goal is to set global standards to ensure digital connectivity and privacy, while also protecting human rights, securing infrastructure, and facilitating information flows free from undue interference and control.

While the new Transatlantic Trade and Cooperation Council (TTCC) reflects a shift in discourse towards the promotion of shared economic growth that also reinforces democratic values while ensuring that regulatory cooperation is built on addressing social goals of climate and sustainability, workers' rights, forced labor, and sustainable and resilient supply chains, it does not—as yet—provide specific mechanisms for regulatory cooperation.[154] As such, transatlantic regulatory cooperation in whatever institutionalized forum that emerges needs to be consistent with promoting fundamental values and rights.

Yet the stakes are higher with a more contested and expansive regulatory agenda, as the multilateral system is unable to close the governance gap due to gridlock.[155] At this juncture, trade rules not only do not match the reality of trade patterns and production in the world, but they are struggling to devise a proactive trade strategy that fosters a values-based trade agenda. Domestic political hurdles will remain for the United States and the European Union to cooperate on many regulatory issues, but they also face a trading system where the multilateral accomplishments have been marginal.[156] Overall, studies apply a normative value framework to the analysis of trade policy across specific sectors, notably, health, environment, and labor rights. Yet empirical analysis of regulatory cooperation is predominantly framed as one of competition.[157] Trade policy is after all, an attempt at

153. *See, e.g.*, CAMERON F. KERRY ET AL., BROOKINGS INST. STRENGTHENING INTERNATIONAL COOPERATION ON AI, (Oct. 25, 2021), https://www.brookings.edu/research/strengthening-international-cooperation-on-ai/.

154. European Commission Press Release IP/21/2990, The Commission, EU-US Launch Trade and Technology Council to Lead Values-Based Global Digital Transformation (June 15, 2021).

155. SAMUEL WOOLLEY & DOMINIKA HADJU, BROOKINGS INST., AN AGENDA FOR US-EU COOPERATION ON BIG TECH REGULATION (Aug. 9, 2021), https://www.brookings.edu/techstream/an-agenda-for-us-eu-cooperation-on-big-tech-regulation/ (noting the gridlock that has previously stalled both sides of the Atlantic in regulatory cooperation).

156. *See id*.

157. *See generally* CARY COGLIANESE, ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT [OECD], MEASURING REGULATORY PERFORMANCE (Aug. 2012), https://www.oecd.org/gov/regulatory-policy/1_coglianese%20web.pdf.

international cooperation and the question that has evolved in how the United States and the European Union can design inclusive agreements.[158] Coupled with an increased focus on trade defense instruments and enforcement, the transatlantic relationship needs to bring together civil society, workers, and consumers to further strengthen values through trade. This democratic and participatory approach could achieve more if their view of trade policy as regulatory competition between big powers aiming to set global standards, shifted towards one in which they conceptually investigate how trade agreements *can be designed* to meet values-based cooperation.

B. Failures in Transatlantic Regulatory Cooperation

The shift of paradigms in international regulatory cooperation has been marked by a practical failure to achieve transatlantic trade cooperation due to political economy, institutional, and values divergences between the two main trading partners. This section addresses some of the practical failures of the efficiency and transparency paradigm in negotiating transatlantic regulatory cooperation, while it anticipates possible failures of the new values-based trade paradigm. Each paradigm shift is addressed in terms of goals and strategies in the table below.

TABLE 1 : PARADIGM SHIFTS IN INTERNATIONAL REGULATORY COOPERATION

	Efficiency	**Transparency**	**Values**
GOALS	Cost-benefit Analysis	Participation & Information	Social Equity & Sustainability
STRATEGIES	Mutual Recognition & Conformity	Notice and Comment & Impact Assessments	Redistributive Impact on Disadvantaged Communities

1. Failures In Implementing An Efficient System

In the previous few decades, the perception of regulatory cooperation was one primarily thought of in terms of neoliberal underpinnings, namely privatization and deregulation as means to favor free

158. Charles Sabel & Bernard Hoekman, *Open Plurilateral Agreements, International Regulatory Cooperation and the WTO*, 10 GLOB. POL'Y 297, 308–9 (2019).

markets and efficiency.[159] The solution to regulatory differences was primarily couched in strategies of harmonization and mutual recognition as means to the removal of nonessential regulatory measures. The main goal was the creation of a competitive global model not only for goods and services but also for regulation.[160] Such goals, if achieved through regulatory cooperation, would reduce the costs of selling goods and services across borders, increase stakeholder inputs, and create a universally applicable set of regulatory rules.

Conformity assessments recognizing the equivalence of testing and certification procedures to avoid duplicative and costly additional evaluations are one principal method through which the transatlantic relationship has pursued efficiency in trade.[161] The European Union and the United States, in the past, varied in terms of the structure of their conformity assessment practices.[162] In the United States, there are several bodies that perform accreditation that are in competition with each other.[163] In the European Union, conformity assessment relies on Notified Bodies, with each state providing one recognized government body.[164]

In the United States, conformity assessment bodies can be conducted through first party, second party, or third parties. To conduct these assessments, bodies must meet the requirements specified by in-

159. For an analysis of neoliberalism's evolution, *see* Grewal & Purdy, *supra* note 97. For an analysis of neoliberalism in a labor law context, *see* Brishen Rogers, *Three Concepts of Workplace Freedom of Association*, 37 BERKELEY J. EMPL. & LAB. L. 177 (2015).

160. David Henig, *EU and US Regulatory Coherence in TTIP–Similarities and Differences*, *in* FRAMING CONVERGENCE WITH THE GLOBAL LEGAL ORDER: THE EU AND THE WORLD 142 (Elaine Fahey ed., 2020); *see also* Weiner & Alemanno, *supra* note 48; Robert Zoellick, *A New US International Economic Strategy*, WALL ST. J. (Feb. 5, 2013); Lester & Barbee, *supra* note 119.

161. Conformity assessment is the set of procedures by which products and processes and evaluated by a designated conformity assessment body or notified bodies that are third parties. Conformity assessments help ensure products conform to particular standards or regulations set by administrative agencies. *See* Michelle Egan, *Market Management: Assessing and Evaluating the Standards Process, in* CONSTRUCTING A EUROPEAN MARKET: STANDARDS, REGULATION, AND GOVERNANCE 210, 229–30 (2001).

162. *See generally Commission Publishes Proposal for Agreement on Conformity Assessment with United States*, BILATERALS.ORG (Nov. 22, 2019), https://www.bilaterals.org/?commission-publishes-proposal-for [https://perma.cc/N45R-UTDK].

163. *See U.S. Conformity Assessment System: Key Organizations*, AM. NAT'L STANDARDS INST., https://www.standardsportal.org/usa_en/conformity_assessment/key_organizations.aspx (last visited Jan. 30, 2022).

164. *Notified Bodies*, EUROPEAN COMM'N, https://ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies_en [https://perma.cc/AB8B-SKUA].

dividual agencies.[165] First party assessment is conducted by the manufacturer at the end of the production cycle and includes test, inspection, and supplier's declaration of conformity.[166] In second party conformity assessments, a person or organization with a user interest in the object determines compliance.[167] This process includes testing and inspection. Third party conformity assessments create a public-private partnership with the government in conducting third-party assessments of standards compliance.[168] Third party conformity assessment activities include testing, inspection, certification, registration, and accreditation.[169]

A criticism of these programs is that first, second, and third-party assessments may not have a third party observing and monitoring the quality of their work.[170] Also, given resource constraints, the United States relies on third party verification developed as private standards to now review public regulations in a host of areas from imported food to telecommunications equipment and medical devices.[171] Concerns about the quality of auditing has generated greater focus on use of third parties in the United States to verify compliance with federal standards. These third-party certification bodies in the U.S. trade relationship have been raised by European trade associations as creating barriers to data acceptance and raising the costs of compliance.[172]

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165. *See generally* U.S. CONSUMER PROD. SAFETY COMM., REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES CONFORMITY ASSESSMENT BODIES (2013), http://www.cpsc.gov/en/Regulations-Laws——Standards/Federal-Register-Notices/2013/Requirements-Pertaining-to-Third-Party-Conformity-Assessment-Bodies [https://perma.cc/J7LK-V5XJ].

166. *U.S. Conformity Assessment: 1st Party Conformity Assessment*, AM. NAT'L STANDARDS INST., http://www.standardsportal.org/usa_en/conformity_assessment/suppliers_declaration.aspx [https://perma.cc/RQ5T-EQW5].

167. *U.S. Conformity Assessment: 2nd Party Conformity Assessment*, AM. NAT'L STANDARDS INST., http://www.standardsportal.org/usa_en/conformity_assessment/2party_conformity_assessment.aspx [https://perma.cc/2YDK-N94L].

168. *U.S. Conformity Assessment: 3rd party Conformity Assessment*, AM. NAT'L STANDARDS INST., http://www.standardsportal.org/usa_en/conformity_assessment/3party_conformity_assessment.aspx [https://perma.cc/C6L6-33DU].

169. For details on standards, certification and conformity assessment processes, *see* Egan, *supra* note 161.

170. LISA J. CARNAHAN & AMY L. PHELPS, NAT'L INST. STANDARDS AND TECH, ABC'S OF CONFORMITY ASSESSMENT 10–13 (2018).

171. Egan, *supra* note 161.

172. *See*, *e.g.*, International Trade Centre, *Navigating Non-Tariff Measures: Insights From A Business Survey in the European Union*, at 8–9, https://trade.ec.europa.eu/doclib/docs/2016/Europer/tradoc_155181.pdf (noting how an Italian exporter requires conformity certification from a third party before delivering goods to the US, delaying shipment by up to fourteen days).

On the other hand, E.U. legislation gives manufacturers some choice regarding conformity assessment, depending on the level of risk involved in the use of the product.[173] These range from manufacturer self-certification to a full quality assurance system type of examination where a designated and independent notified body verifies the safety and performance requirements.[174] In Europe, independent certification bodies, known as notified bodies, have been officially accredited by competent member state authorities to test and certify to E.U. requirements.[175]

In the TTIP negotiation, a recurrent critique put forward by the U.S. administration is that, while the European Standard bodies are centralized, the procedural requirements concerning certification are highly decentralized.[176] The problem is that member states often do not trust each other's implementation of a European standard even though the proof of compliance comes from a notified body.[177] This suspicion has been fueled by famous scandals like the case of the French breast implants that created an enormous recall due the leaking of silicon prosthesis in over four hundred thousand women.[178] The German certification company TÜV Rheinland, a market leader in product certification, has now been sued to compensate Poly Implant Prothèse (PIP) victims Germany, France, and elsewhere for the damages created by the defective product.[179] At the core of the litigation was the lack of a adequate national system to register the use of breast implants, which led to the production of breast implants containing industrial silicone gel.[180]

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173. *See* BILATERALS.ORG, *supra* note 162.

174. *Id.*

175. *Id.*

176. *See* Parker, *supra* note 42, at 3; *see also* Parker & Alemanno, supra note 78, at 66.

177. *See* Giandomenico Majone, *Mutual Trust, Credible Commitments and Evolution of the Rules of the Single Market* (Eur. Univ. Inst. Working Papers 95/1, 1995).

178. Paul Verbruggen & Barend Van Leeuwen, *The Liability of Notified Bodies under the EU's New Approach: The Implications of the PIP Breast Implants Case*, 3 EUR. L. REV. 394, 402–03 (2018).

179. *See id*. ("[m]ore than 20,000 women around the world have opted to join the latest French collective action."); *see also* Bundesgerichtshof [BGH] [Federal Court of Justice], Apr. 9, 2015, Schmitt v TÜV Rheinland LGA Products GmbH (C-219/15).

180. *See* Verbruggen & Van Leeuwen, *supra* note 178, at 394, 397 (explaining that many women received breast implants without knowing whether PIP produced the product due to the absence of adequate national systems to register the use of breast implants). *See also* John Lichfield, *Breast Implants Ruling in PIP Scandal Could Lead to Compensation for 400,000 Women*, INDEPENDENT (Nov. 14, 2013), http://www.independent.co.uk/news/world/europe/court-finds-german-firm-liable-over-pip-implants-8940208.html# [https://perma.cc/ZT8K-PA3V].

2. Failures in implementing a transparent system

Transatlantic scholars have highlighted the common transatlantic commitment to transparency in trade.[181] One such way transparency is achieved in the transatlantic trading system is through the standards-setting process.[182] While scholars emphasize the need to promote transparency in creating regulatory standards, they often overlook their different notions of regulatory standards themselves. The United States and the European Union fundamentally disagree over what constitutes an international standard. Americans view any professional or trade associations as able to provide international standards, not just nationally recognized standards bodies, since the mark of an international standard is its use by other countries.[183] Europeans maintain that an international standard is the product of an international collaboration in which international standards organization offer equal representation of all countries with consensus procedures that legitimate international standards.[184] Since international standardization is organized principally along national lines open to the most broadly representative member of standardization in each country, the relative combined weight of the European standards bodies is much greater than that of the singular U.S. representation. Both negotiating parties must keep this institutional difference in mind when making commitments as the politicization of standardization and the increasing importance of standards in supporting international trade should not detract from their historically divergent institutional approaches.[185]

In the European Union, European standards are central to the functioning of the single market. The European Union relies heavily on private standards bodies to adopt European standards, which are not compulsory, but confer considerable legal and business advantages

181. *See, e.g.*, Michelle Egan & Jacques Pelkmans, *TTIP's Hard Core: Technical Barriers to Trade and Standards*, CTR. FOR EUROPEAN POL'Y STUD. 12–17 (2015) (noting how E.U. and U.S. government communiqués repeatedly mention transparency as a goal in trade negotiations).

182. *See* Tim Büthe and Jan Martin Witte, *Product Standards in Transatlantic Trade and Investment: Domestic and International Practices and Institutions*, AM. INST. CONTEMP. GER. STUD. 8 (2004).

183. *See* SAMUEL KRISLOV, HOW NATIONS CHOOSE PRODUCT STANDARDS AND STANDARDS CHANGE NATIONS, 105-106 (1997).

184. *See id.* at 38; Egan & Pelkmans, *supra* note 181.

185. HARM SCHEPEL, THE CONSTITUTION OF PRIVATE GOVERNANCE: PRODUCT STANDARDS IN THE REGULATION OF INTEGRATING MARKETS (Hart Pub., 2005) (Schepel highlights the different institutional structure and operating norms of U.S. and E.U. standards).

to firms that use them in trading in goods and services in Europe.[186] Under the New Approach, the European Union adopts the broad framework laws known as 'essential requirements' through which products must comply in order to benefit from the free movement provisions in the single market.[187] The European Union determined that private bodies at the regional level are the best agents to achieve those public policy objectives. Thus, the European Standards Bodies (ESO's)—including the European Committee for Standardization (CEN), European Committee for Electrotechnical Communication (CENELEC), and the European Telecommunications Standards Institute (ETSI)—are mandated to provide specific standards to meet the legal requirements of European directives.[188] Although these standards are not mandatory, they do have the presumption of conformity as they are published in the Official Journal of the European Union.[189] These European standards are then transposed into national standards without amendments as there is a presumption that they become national standards.[190] However, it is important to recognize that the European Standards Organizations do not restrict their activity only to standard-setting under the New Approach.[191] While the practice of incorporation by reference of European standards into E.U. legislation provides the easiest way for manufacturers to meet their regulatory obligations in the aforementioned European directives, European standards bodies are also free to develop their own work programs as pri-

186. *See generally id.*; *see also* HERWIG C.H. HOFMANN, GERARD C. ROWE & ALEXANDER H. TÜRK, ADMINISTRATIVE LAW AND POLICY OF THE EUROPEAN UNION 589 (Oxford Univ. Press, 2012).

187. See Council Resolution of 7 May 1985 on a New Approach to Technical Harmonization and Standards, 1985 O.J. (C136/1) 1, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEX:31985Y0604(01).

188. *See* Egan, *supra* note 161; *see also* Schepel, *supra* note 185, at 101.

189. Egan & Pelkmans, *supra* note 181; Hofmann, Rowe, & Türk, *supra* note 186, at 589.

190. More than 3,600 harmonized standards allowing companies to demonstrate compliance with E.U. law have been developed and transposed into national standards. These European standards are transposed into national law. *See* CEN/CENELEC Guide 5, article 5, https://www.cencenelec.eu/media/Guides/CEN-CLC/cenclcguide1.pdf. A more recent publication provides more details. Eur. Comm. for Standardization, Implementation of European Standards—ENs Not Corresponding to National Standards on a One-to-One Basis, https://boss.cen.eu/reference-material/guidancedoc/pages/impl/.

191. Büthe & Witte, *supra* note 182; Schepel, *supra* note 186. *See also*, Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardization.

vate bodies.[192] Consequently, the bulk of their standards work comes from requests from national bodies, as well as European trade, professional, technical or scientific organizations.[193]

In contrast, the U.S. system is considered more decentralized than the E.U., even though it is constrained by a regulatory framework. The private U.S. standards organizations can often compete among each other, and the system is demand-driven.[194] Unless Congress has regulated a particular standard through statutes, there is no centralized or harmonized standardization process. The United States seeks to use standards as a means of gaining competitive advantages in the marketplace through establishment of a preferred technical solution as an industry standard.[195] In the United States, private-sector standards developers produce competing standards for many different products. Standardization is very fragmented, and there is a tendency toward market solutions based on private sector organizational solutions rather than government mandates.[196] Consequently, competing standards exist for many products based on the premise of market openness and technological innovation.[197] In the United States, regulatory agencies select among published standards—those that will best suit their needs.[198] In fact, federal agencies must justify the adoption of unique government standards so that federal agencies have increasingly incorporated privately drafted standards into thousands of fed-

192. Regulators often lack technical expertise, so they rely on private standards developed by private standards organizations or industry consortia adopting them into law through a practice known as incorporation by reference.

193. *CEN and CENELEC Work Programme*, EUROPEAN COMM'N FOR STANDARDIZATION & EUROPEAN COMM'N FOR ELECTROTECHNICAL STANDARDIZATION 1 (2014).

194. U.S. DEP'T JUST., COMMENTS ON THE U.S. STANDARDS STRATEGY (Sept. 8, 2020).

195. *Id.*

196. *See, e.g.*, KATHLEEN L. CASEY, COMMISSIONER, U.S. SEC. & EXCH. COMM'N, THE ROLE OF INTERNATIONAL REGULATORY COOPERATION AND COORDINATION IN PROMOTING EFFICIENT CAPITAL MARKETS (Jun. 12, 2010) (showing the ongoing debate about how regulatory cooperation can be involved as a support for capital markets and not the common fear of the two in conflict).

197. *Setting the Standards: Strengthening U.S. Leadership in Technical Standards: Hearing Before the Subcomm. on Rschr. & Tech. of the H. Science, Space, & Tech. Comm.*, 117th Cong. 5–6 (2022) (statement of Alissa Cooper, Vice Pres. & Chief Tech. Off. for Tech. Pol'y and a Fellow, Cisco Sys.), https://www.congress.gov/117/meeting/house/114508/witnesses/HHRG-117-SY15-Wstate-CooperA-20220317.pdf.

198. Nina Mendelson, *Private Control Over Access to the Law: The Perplexing Federal Regulatory Use of Private Standards* 737, 742 (Univ. of Mich. L. Sch. Working Paper No. 358, 2013).

eral rules.[199] Private standards define the content of federal rules in areas ranging from toy safety to nuclear power plants.[200]

The clash of values between the United States and European Union has translated into their different approaches used towards standard-setting. Although there have been calls for greater dialogue and exchange of information between European and American standards bodies since the 1980s, these differences have been a significant hurdle in addressing duplicative models of testing and conformity.[201] The United States has often criticized European standard-setting for its lack of transparency.[202] This is echoed in recent comments in the Annual Trade Barrier Report which noted:

> U.S. persons are not able to participate directly and effectively in the development of regulations, standards and conformity assessment procedures in the EU. Some institutional arrangements in the EU appear to either accord exclusive rights to, or effectively favor, EU entities in the development and implementation of such measures. Further, there appears to be no effective mechanisms to ensure accountability to non-EU interests in the adoption and implementation of such measures."[203]

Such concerns were also directed at the level of centralization of European standard-setting in contrast to the market driven approach in the United States. For many years, the United States complained that this provides an unfair advantage in international negotiations as the European states form a collective bloc of twenty-eight members of the international standards bodies in contrast to the single American vote, making it more difficult for American standards to prevail as the dominant choice.[204] However, studies of voting patterns indicate that

199. *Id.* at 740.

200. *Id*.

201. For a recent timeline of U.S.-E.U. trade relations, see Eric Davies, *Information Guide EU-US Relations*, Cardiff University European Documentation Centre (2014), http://aei.pitt.edu/75414/2/EU-US-Relations.pdf. For differences in standards, see Michelle Egan, Private Rule-Making in TTIP: The Role of Standards, CATO ONLINE FORUM (Oct. 14, 2015), https://www.cato.org/cato-online-forum/private-rule-making-ttip-role-standard-setting [https://perma.cc/8328-6DQB]; Emily Bremer, *American and European Perspectives on Private Standards in Public Law*, 91 TUL. L. REV. 325 (2016).

202. *See* Egan & Pelkmans, *supra* note 181.

203. U.S. TRADE REPRESENTATIVE, 2014 REPORT ON TECHNICAL BARRIERS TO TRADE 48 (2014).

204. *See Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee*, at 18, COM (2012) 673 final (Jan. 6, 2011) ("standardization bodies based in the European Union should therefore continue to put forward proposals for international standards in those areas where Europe is a global leader to maximize European competitive advantage").

Europeans do not always vote as a bloc in international standard setting due to differences in infrastructure as well as economic preferences.[205] European standards bodies have come under criticism as U.S. officials argued that the European Union promotes its standards as part of trade agreements, aggressively pushing its 'market power,' so that its standards are frequently adopted in other markets. Thus, divergences between the United States and the European Union do not just hinder U.S. exports to the European Union, but to other countries as well.[206]

E.U. trade negotiators found that the fragmentation among standards bodies in the United States made it difficult to promote regulatory equivalence in terms of conformity assessment, testing, and standards recognition. There is concern that the market-led approach to standardization undercuts efforts to coordinate, as the diversity of stakeholders in this decentralized system can make collective agreement around a singular standard difficult.[207] For some, this proliferation of standards committees ironically undermined the purpose of promoting greater cooperation and coordination.[208] The United States does require standards referenced in regulations to be accredited by the American National Standardization Institute (ANSI) under the U.S. National Technology Transfer and Advancement Act of 1995 (NTTAA).

This institutionally fragmented system has not been without its critics. There are concerns that delegating to private bodies increases risk behavior, especially in relation to accounting and financial standards, where private standard setting failed to serve public policy objectives which were exacerbated during the economic crisis.[209] There is also scope for misapplication of legal standards. In the United

205. *See, e.g.*, *US-Europe Myths and Perceptions*, AM. NAT'L STANDARDS INST., https://share.ansi.org/Shared%20Documents/Standards%20Activities/Background%20Papers/Supporting%20Documents/US-Europe%20Myths%20Document.pdf.

206. *See* MARK SCHAPIRO, EXPOSED: THE TOXIC CHEMISTRY OF EVERYDAY PRODUCTS AND WHAT'S AT STAKE FOR AMERICAN POWER (Chelsea Green Pub. 19, 2007).

207. *See, e.g.*, DIETER ERNST, AMERICA'S VOLUNTARY STANDARDS SYSTEM: A 'BEST PRACTICE' MODEL FOR ASIAN INNOVATION POLICIES? 1, 22–4 (East-West Center, 2013).

208. *See, e.g.*, Andrew L. Russell, "Industrial Legislatures": Consensus Standardization in the Second and Third Industrial Revolutions 69 (2007) (Ph.D. dissertation, Johns Hopkins University) (on file with Johns Hopkins University Library system).

209. *See, e.g.*, *Testimony Concerning Transparent Financial Reporting for Structured Finance Transactions Before the Senate Permanent Subcommittee on Investigations, Committee on Governmental Affairs*, 107th Cong. (2002) (statement of Annette L. Nazareth, Director, Division of Market Regulation, U.S. Securities & Exchange Commission).

States, antitrust agencies act as enforcement bodies in ways like other business review bodies, but they do not adjudicate the legality of standards development activity. American courts, consequently, have not developed a consistent or unified way of treating private standards. The U.S. International Trade Administration defended this system as providing "technological innovation"[210] with proponents arguing that it is "open and accessible."[211]

While standardization processes differ across industrial sectors in the United States, reflecting differences in market structure, technology, and organizational approaches, industry has been resistant to government intervention in the process.[212] This heterogeneity of standard-setting has also led to concerns which stalled the transatlantic trade negotiations that specific industries or corporations may dominate the process, which may not lead to the most optimal or efficient standard adopted.[213]

3. Potential failures in values-based trade

The convergence of transatlantic trade agendas with respect to human rights, labor, gender, sustainable development, and public health goals as an integral part of the Trade Plus agenda—not only between the United States and E.U. governments but also in the WTO and United Nations Conference on Trade and Development[214]—has signaled a renewed shift in trade law and policy offering a second chance to the debacle of the Doha Round negotiations.[215] The challenges presented by the COVID-19 pandemic and effects of climate

210. Ernst, *supra* note 207.

211. AM. NAT'L STANDARDS INST., UNITED STATES STANDARDS STRATEGY 23 (2020), https://share.ansi.org/Shared%20Documents/Standards%20Activities/NSSC/USSS-2020/USSS-2020-Edition.pdf.

212. *See* Tim Büthe & Walter Mattli, *Setting International Standards: Technological Rationality or Primacy of Power?* 56 WORLD POL. 1 (2003).

213. *See* U.S. CONG. OFF. TECH. ASSESSMENT, TCT-512, GLOBAL STANDARDS: BUILDING BLOCKS FOR FUTURE (1992). In the US, this led to observations about "internecine warfare in the standards community" as the diffusion of standards development created institutionally entrenched interests that generated roadblocks to cooperation.

214. *See* UNCTAD U.N. Conference on Trade and Development, *Better Trade for Sustainable Development: The Role of Voluntary Sustainability Standards* (2021) https://unctad.org/system/files/official-document/ditctab2021d2_en.pdf.

215. *See* Rafiqul Islam, *Globalisation of Trade Liberalisation under the WTO: Its Effects on Human Rights and Social Justice*, 1 INDIAN J. INT'L ECON. 1 (2008) (examining the distributive effects of human rights and socio-economic justice under the WTO and neoliberal trading system and finds them relegated to a secondary role); *see also* Peter M. Gerhart, *Slow Transformations: The WTO as a Distributive Organization*, 17 AM. U. INT'L REV. 1045 (2002) (portraying the Doha round as having the potential to reformulate the WTO system from one focused on principles of neoliberal

change have undoubtedly accelerated such values-based convergence among Western liberal democracies. From a geopolitical perspective, this renewed alliance in transatlantic trade also entails a stronger push back against non-democratic and human rights violations of trade standards by the Chinese government, who is now the main target for both trade and investment scrutiny by E.U. and U.S. legislatures.

We nevertheless show that this new values-based approach only succeeds when translated into a regulatory cooperation framework that openly addresses the distributive effects of regulation through notice-and-comment procedures that identify how regulations will impact racial minorities, women, and other vulnerable populations. This is not a new perspective as economists like Paul Krugman have long acknowledged how economists, lawyers, and government officials largely missed the redistributive harm that unconstrained, neoliberal globalization would bring to large sectors of Western societies, referencing now-common ideas such as the "China shock" and the ills of hyper globalization.[216] Lawyers have begun focusing on the distributive effects of international trade to show the inequalities born out of law and globalization within the European Union and the inadequate responses offered to each member state.[217] With respect to climate policies, authors have focused on climate change's distributional effects. For instance, George Zachmann has explored different potential manifestations of the differential effects due to climate policy—such as carbon tariffs and regressive standards—which admit the difficulties in drawing overall conclusions about the distributive effect of climate policy in these areas.[218]

The USTR approach to "good regulatory practices" includes the assurance of transparency and accountability in the creation and implementation of regulation through public comments and impact assessments to "avoid unnecessary redundancies" while ensuring "internal coordination" and creating space for "expert regulatory" advice.[219] In a similar way, the E.U. approach in its Better Regulation agenda also addressed the notion of greater stakeholder participation

efficiency to one that takes into account the results and distributional effects of its policies).

216. *See* KRUGMAN, *supra* note 17.

217. Perišin & Koplewicz, *supra* note 7.

218. Georg Zachmann et al., *The Distributional Effects of Climate Policies*, 28 BRUEGEL BLUEPRINT SERIES 6, 44 (2018).

219. See OFF. OF THE U.S. TRADE REPRESENTATIVE, UNITED STATES-EUROPEAN UNION NEGOTIATIONS: SUMMARY OF SPECIFIC NEGOTIATING OBJECTIVES (2019), https://ustr.gov/sites/default/files/01.11.2019_Summary_of_U.S.-EU_Negotiating_Objectives.pdf.

and evidence-based regulation rather than a "hidden deregulatory agenda" as a way to address "economic, social and environmental impacts together."[220] While praised by the Organisation for Economic Co-operation and Development (OECD) for its reforms, the Commission's new 2015 framework allows for stakeholder engagement with public consultation, similar to the U.S. system of notice and comment to lawmaking.[221] However, the Commission has expressed concerns that the new consultation process is not well known, and the way the Commission used the outcomes of its public consultation are not sufficiently transparent.[222]

Beyond transparency, the systematization of impact assessments, evaluations, and independent quality expertise have served to translate into evidence and quantify the costs and benefits of regulatory cooperation. The E.U. Better Regulation Toolbox also encourages the use of data from national agencies or international organizations using statistics and indicators.[223] However the Commission has recognized the difficulty of in-depth impact assessments, arguing that its stakeholders would like impact assessments to be more "user friendly" while also presenting a "deeper analysis of a varying set of impacts".[224]

Take for example the OECD's summary of the costs and benefit of IRC to either economic gains through the reduction of transition costs or more transparency in regulatory practices or the cost associated to duplication cost of regulation, the lack of effective enforce-

220. *Better Regulation: Taking Stock and Sustaining out Commitment*, at 1, COM (2019) 178 final (May 15, 2019).

221. See Emily Bremer, *On the Cost of Private Standards in Public Law*, 63 KAN. L. REV. 279, 279–80 (2015) (explaining the problem of incorporating private standards into regulations); Emily Bremer, *Incorporation by Reference in an Open-Government Age*, 36 HARV. J. L. & PUB. POL'Y 131 (2012) and Emily Bremer, *The Undemocratic Roots of Agency Rulemaking*, CORNELL L. REV. (2022).

222. Bremer, *The Undemocratic Roots of Agency Rulemaking*, *supra* note 221, at 6 (explaining the different challenges to create a truly open and inclusive process that is not simply limited to those repeated players already involved in the regulatory process but rather ensures an adequate representation of all affected interests); *see also* Wendy Wagner, *Regulatory Procedure and Participation in the European Union*, *in* COMPARATIVE LAW AND REGULATION: UNDERSTANDING THE GLOBAL REGULATORY PROCESS, 109, 124 (2018) (expressing her skepticism toward the truly open and inclusive procedure of the notice and comment to rulemaking).

223. *See* Org. for Econ. Corp. Dev. [OECD], *Rethinking Rulemaking Through International Regulatory Co-operation*, *in* OECD REGULATORY POLICY OUTLOOK 2021, (2021); *see also* DEP'T FOR BUS., ENERGY & INDUS. STRATEGY, INTERNATIONAL REGULATORY COOPERATION TOOLKIT (2022).

224. *Better Regulation: Taking Stock and Sustaining our Commitment*, at 7, COM (2019) 178 final (Apr. 15, 2019), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52019DC0178&from=EN.

ment, and the difficulty of reaching compromises.[225] Both the OECD and the European Union—through a recent report of the European Court of Auditors—have praised the relevance of ex-post evaluations as an avenue of cooperation through information exchanges and better monitoring of regulatory implementation.[226] Some bilateral trade agreements such as E.U.-Japan, CETA, and USMCA include ex-post evaluations on the sharing of information and post-implementation reviews tackling the cost and benefits of regulatory divergences to different constituencies impacted by environmental and public health measures.[227]

Such approaches to IRC are clearly at odds with the new values-based trade agenda because they do not engage openly with the distributive consequences of the losers of trade agreements, especially minority and vulnerable populations who have been more heavily impacted by climate change and the COVID-19 pandemic.[228] While trade lawyers are lagging behind, Diana Mutz's book shows that the American public's view on trade issues is much more simplistic than the economic reality and is largely reflective of overall expressive or symbolic reasons based on in-group/out-group dynamics. Her findings highlight that despite opposite economic outcomes, U.S. support is higher for trade with countries that are identified as economically and culturally similar to the United States. Another finding is that United States racial and ethnic minorities' attitudes differ from white Ameri-

225. ORG. FOR ECON. CORP. DEV. [OECD], INTERNATIONAL REGULATORY CO-OPERATION: ADDRESSING GLOBAL CHALLENGES (2013), https://www.oecd-ilibrary.org/governance/international-regulatory-co-operation_9789264200463-en; *see generally* KAUFFMANN, CELINE & NIKOLAI MALYSHEV, INTERNATIONAL REGULATORY CO-OPERATION: THE MENU OF APPROACHES (ICTSD & World Economic Forum, 2015), https://e15initiative.org/wp-content/uploads/2015/09/E15-Regulatory-Coherence-Kauffmann-and-Malyshev-Final.pdf.

226. Eur. Ct. Auditors, *Ex-Post Review of EU Legislation: A Well-Established System, But Incomplete* ¶¶ 52–56, 85–87 (2018).

227. *See, e.g.*, *Trade Sustainability Impact Assessment of the Free Trade Agreement Between the European Union and Japan* (2016), https://trade.ec.europa.eu/doclib/docs/2016/may/tradoc_154522.pdf; *Final Environmental Assessment of the Canada-European Union Comprehensive Economic and Trade Agreement* (2017), https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/ea-ee.aspx?lang=Eng.

228. *See* U.N. Working Group of Experts on People of African Descent, Statement on COVID 19: Racial Equity and Racial Equality Must Guide State Action (Apr. 3, 2020), https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=25768&LangID=E#_ftn1sheilagoo; Sheila Foster, *Vulnerability, Equality and Environmental Justice: The Potential and Limits of Law*, in ROUTLEDGE HANDBOOK OF ENVIRONMENTAL JUSTICE (Jayajit Chakraborty & Gordon Walker eds., 2017); Zachmann et al., *supra* note 218, at 44 (analyzing the effects of a green discount on various income rates in Denmark.).

cans in their views of trade, despite most Americans not focusing on trade's actual impact.[229] Not only is there a lack of information of the real costs and benefits of trade agreements on vulnerable populations, but there are also wide misconceptions of how different groups should become more vocal about the enforcement of trade-based rules. It is precisely this lack of ex ante impact assessments and ex post enforcement tools in IRC geared towards addressing the environmental, social, and racial inequities of international trade agreements that is likely to undermine the new transatlantic cooperation driven by a broad values-based agenda.

III.
CASE STUDIES IN TRANSATLANTIC TRADE

A. Case Study: Cosmetics

Cosmetics range from everyday hygiene products like certain shampoos, deodorants, and toothpastes to luxury beauty items like perfumes and makeup.[230] The cosmetics industry is a multibillion-dollar industry composed of a significant number of large manufacturers and smaller specialized firms.[231] In 2018, the European cosmetics market was valued at $95 billion, making Europe the largest market for cosmetic products globally. The U.S. market ranked second at $81 billion.[232] Within the European Union, Germany ($17 billion), France

229. *See generally* DIANA MUTZ, WINNERS AND LOSERS: THE PSYCHOLOGY OF FOREIGN TRADE (2021) (offering a comprehensive look at how U.S. public opinion interacts with international trade issues, done largely through opinion polls and direct surveys of American voters divides along political, class, gender and racial line and showing how US public opinion on trade largely divorced from the actual economic impact trade has on the US economy or on individual American lives).

230. *See* U.S. Food & Drug Admin., *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, (Feb 25, 2022), https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap [https://perma.cc/5PWF-WM84]. Some shampoos, deodorants, and toothpastes are considered a cosmetic drug. For instance deodorant with antiperspirant or toothpaste with fluoride is a cosmetic drug. AN OVERVIEW OF FDA REGULATED PRODUCTS: FROM DRUGS AND COSMETICS TO FOOD AND TOBACCO 217 (Eunjoo Pacifici & Susan Bain eds., 2018).

231. Exports totaled $69.8 billion in 2021, up by 40.7% over a five-year period starting in 2017. Sales for these specialized personal care exports increased 12.3% from 2020 to 2021. *See* Daniel Workman, *Beauty Cosmetics and Skincare Exports by Country*, WORLD'S TOP EXPORTS, http://www.worldstopexports.com/beauty-cosmetics-and-skincare-exports-by-country/ [https://perma.cc/5XQD-39AR].

232. *See* COSMETICS EUROPE, SOCIO-ECONOMIC CONTRIBUTION OF THE EUROPEAN COSMETICS INDUSTRY, 5 (2019), https://www.cosmeticseurope.eu/files/4715/6023/8405/Socio-Economic_Contribution_of_the_European_Cosmetics_Industry_Report_2019.pdf. The data for the European and U.S. statistics are in euros and converted the overall value into dollars.

($14 billion), and Italy ($12 billion) have domestic cosmetic markets that would each rank within the ten biggest globally.[233]

The cosmetics market has steadily grown over the past decade, garnering $380.2 billion in 2019. The market is projected to reach $463.5 billion by 2027.[234] Regulators across the globe will have to deal with several challenges connected with the increasing risk of liability, globalizing markets, and regulatory changes. The cosmetics sector has considerable sensitivities in the trade negotiations as the United States and the European Union have rules on what qualifies as "cosmetics" and different approval, testing, and certification practices for evaluating different products.[235] There are also vast differences in the process and production methods and regulatory requirements for cosmetic products produced in different markets. These differences are due to differing standards over nanotechnology, animal testing, and ecolabels in these jurisdictions. All of these standards can have significant public health and environmental effects.[236]

1. U.S. Regulatory Framework

The U.S. regulatory system for cosmetics was established in 1938 through the Food, Drug, and Cosmetics Act (FDCA). The system was then supplemented with the Fair Packaging and Labeling Act (FPLA) enacted in 1967, which gave broad authority to the Food and Drug Administration (FDA) to ensure that cosmetics are safe and accurately labeled.[237] The statute prohibits using any poisonous or deleterious

233. *Id.* at 15.

234. The COVID-19 pandemic impacted the sales of cosmetics in 2020, but sales have rebounded. Sales among Black Americans reached $6.6 billion in 2021. David Baboolall et al., *Black Beauty Consumers and Brands Face Deep Challenges When It Comes to Equity. Removing Those Barriers Can Lead to Greater Opportunity for Everyone in the Industry*, McKinsey, https://www.mckinsey.com/industries/consumer-packaged-goods/our-insights/black-representation-in-the-beauty-industry [https://perma.cc/DK3P-F8X8]; *see also Allied Market Research, Global Cosmetics Market to Reach $463.5 Billion by 2027: Allied Market Research*, Glob. Newswire (Feb. 4, 2021), https://www.globenewswire.com/news-release/2021/02/04/2170144/0/en/Global-Cosmetics-Market-to-Reach-463-5-Billion-by-2027-Allied-Market-Research.html#:~:text=04%2C%202021%20(GLOBE%20NEWSWIRE),5.3%25%20from%202021%20to%202027 [https://perma.cc/EA4Y-NDW9].

235. 21 U.S.C. 9 § 321. The Federal Food Drug and Cosmetic Act (FFDCA) defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering the appearance."

236. Elizabeth Foley, *The Cosmetic Industry: Comparing the Industry Oversight in the European Union and the United State*s, 11 Creighton Int'l & Comp. L. J. 4-2 (2019).

237. *See* An Overview of FDA Regulated Products: From Drugs and Cosmetics to Food and Tobacco 217 (Eunjoo Pacifici & Susan Bain eds., 2018).

substances as well as false or misleading labeling that results in an adulterated or misbranded product.[238] The FDA is the main regulatory body that governs the cosmetics industry in the United States. The FDA verifies that cosmetic products meet the appropriate requirements, including those of the FDCA, CFR Title 21 & 16, FPLA, and the Safe Cosmetics Act 201. These requirements cover restricted substances, allowable colorants, and labeling.[239] Cosmetics packaging needs to meet the Toxics in Packaging Clearing House (TPCH) requirements.[240]

The FDA also requires ingredient declarations in cosmetics labeling, relying on its authority under the Fair Packaging and Labeling Act.[241] Based on the International Cosmetic Ingredient Dictionary (ICID), these ingredients provide the nomenclature for cosmetic ingredients that were established by industry and incorporated by reference into U.S. law and adopted in the European Union and other jurisdictions around the world.[242]

Although cosmetics do not require pre-approval in terms of specific tests to demonstrate the safety of individual products or ingredients, the Voluntary Cosmetic Registration Program (VCRP) assists the FDA in regulating cosmetics.[243] Cosmetic establishments, where cosmetics are manufactured and packaged, may register with this program, and file a cosmetic product ingredient statement (CPIS) for each product.[244] The FDA uses the information to evaluate cosmetics on

238. Food, Drugs, and Cosmetics Act of 1938 § 601, 21 U.S.C. § 361.

239. Cosmetic Products Warning Statements/Package Labels, 40 Fed. Reg. 8763, 8916 (Mar. 3, 1975). The FDA has stated that "the safety of a product can be adequately substantiated through (a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to the particular cosmetic, and (b) performance of any additional toxicological and other tests that are appropriate in light of such existing data and information."

240. *Comparative Analysis*, TOXICS IN PACKAGING CLEARINGHOUSE, https://toxicsinpackaging.org/state-laws/comparative-analysis/ (last visited Jan. 21, 2022).

241. Fair Packaging and Labeling Act: Regulations Under Section 4 of the Fair Packaging and Labeling Act, 16 C.F.R. § 500, (1994) https://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/fair-packaging-labeling-act.

242. CFTA: Cosmetic Ingredient Dictionary, 21 C.F.R. § 701.3 (1974); Opinion of The Scientific Committee on Cosmetic Products and Non-Food Products Intended For Consumers on the 1st Update of the Inventory of Ingredients Employed in Cosmetic Production, SCCNFP/0299/00 final (June 28, 2000), http://ec.europa.eu/health/archive/ph_risk/committees/sccp/documents/out123_en.pdf.

243. *Voluntary Cosmetic Registration Program*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program (last visited Apr. 30, 2021).

244. *Id.*

the market.[245] This information also goes to the Cosmetic Ingredient Review (CIR), an independent, industry-funded panel of scientific experts that assists the panel in assessing ingredient safety and determining priorities for ingredient safety review.[246] The FDA requests firms file an ingredient statement with each of their products to carry this out.[247] However, the FDA is not required to act on the CIR's findings, and only eleven percent of ingredients found in cosmetics have been assessed for safety by the panel.[248]

The United States classifies some cosmetics as over-the-counter drugs (OTC) and uses different safety assessments and authorizations based on FDA inspections. Cosmetic products used for the prevention or treatment of disease or affecting the structure or function of the body are regulated as both drugs and cosmetics—some example substances being sunscreens, toothpaste, and lip balms.[249] For example, sunscreens are categorized as a drug in the United States because they prevent sunburn, protect the skin against harm from the sun, and prevent skin damage through overexposure to the sun.[250]

In terms of enforcement, the FDA is the primary authority overseeing the production and sale of cosmetics in the U.S. At the same time, it coordinates regulatory and enforcement activities with the Federal Trade Commission (FTC), Customs and Border Protection (CBP), and the Department of Agriculture (USDA). The FTC has the authority to investigate and punish business practices that harm consumers; such power crosses into the cosmetics industry when producers, for example, are deceptive about their product's health benefits.[251] Likewise, when imported cosmetics appear to be adulterated or mis-

245. *Id.* Because filings are not mandatory, voluntary submissions provide FDA with the best information available about cosmetic products and ingredients, their frequency of use, and businesses engaged in their manufacture and distribution.

246. *Id.* (referencing 73 Fed. Reg. 76360 (2008)). This private expertise from outside the government does play a role in standard-setting. The Cosmetic Ingredient Review (CIR), established by the Personal Care Products Council, the leading cosmetics trade association, provides private support to the FDA to review the safety of cosmetics, hence allowing private experts to shape market practices like that of European standards bodies.

247. *Id.*

248. JAN VERNON & TOBE A. NWAOGU, RISK & POL'Y ANALYSIS LTD, Comparative Study on Cosmetics Legislation in the EU and Other Principal Markets with Special Attention to so-called Borderline Products 3, 25–26 (2004).

249. *See* AN OVERVIEW OF FDA REGULATED PRODUCTS, *supra* note 237, at 218.

250. *See Sunscreen: How to Help Protect Your Skin from the Sun*, U.S. FOOD & DRUG ADMIN. (Aug. 29, 2019), https://www.fda.gov/drugs/understanding-over-counter-medicines/sunscreen-how-help-protect-your-skin-sun#:~:text=Any%20sunscreen%20sold%20in%20the,aging%20caused%20by%20the%20sun.

251. *See, e.g.*, Press Release, U.S. Fed. Trade Comm'n, L'Oréal Settles FTC Charges Alleging Deceptive Advertising for Anti-Aging Cosmetics (June 30, 2014),

branded, CBP may examine and ultimately destroy or refuse the product's importation.[252] As for the labeling of cosmetics ingredients, the USDA oversees the National Organic Program (NOP), certifying organic labeling on agricultural ingredients. Thus, if a producer wishes to label a product organic, the producer must abide by the USDA definition and the FDA labeling and safety requirements.[253]

Past efforts by the FDA to increase its oversight over cosmetics regulation—including legislative proposals to strengthen product recall, promote review of specific ingredients used in cosmetics, and encourage alternatives to animal testing—have largely failed.[254] However, the 116th Congress introduced some notable amendments to the Federal Food, Drug, and Cosmetic Act. Part of this came in the wake of the U.S. Food and Drug Administration (FDA) independent testing of certain teen brands, namely Claire's and Justice, that found asbestos in specific cosmetics, promoting pressure for voluntary recall highlighting the lack of regulatory oversight FDA has over the cosmetics industry.[255]

In response, the Safe Cosmetics and Personal Care Products Act of 2019 seeks to strengthen regulations around the production and sales of cosmetics.[256] The Act includes heightened requirements for ingredients labels, with a requirement for the online publication of each ingredient in descending order of predominance and each ingredient's function.[257] Similarly, the Natural Cosmetics Act tightens regulations on using the term "natural" to describe cosmetics unless those cosmetics meet specific standards.[258] Lastly, the Cosmetic Safety Enhancement Act of 2019 strengthens the safety standard of cosmetics

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https://www.ftc.gov/news-events/press-releases/2014/06/loreal-settles-ftc-charges-alleging-deceptive-advertising-anti.

252. *Cosmetics Importers*, U.S. Food & Drug Admin. (Aug. 24, 2020), https://www.fda.gov/cosmetics/cosmetics-international-activities/cosmetics-importers.

253. "*Organic" Cosmetics*, U.S. Food & Drug Admin. (Aug. 24, 2020), https://www.fda.gov/cosmetics/cosmetics-labeling-claims/organic-cosmetics.

254. The Personal Care Products Safety Act, S. 1014, 114th Cong. § 608, § 618 (2015).

255. Sokolove Law Team, *Claire's and Justice Products Test Positive for Asbestos Says FDA*, Sokolove L Blog (Mar. 11, 2019), https://www.sokolovelaw.com/blog/claires-justice-products-asbestos/ [https://perma.cc/9VXK-F7MR].

256. The Safe Cosmetics and Personal Care Products Act of 2019, H.R. 4296, 116th Cong. § 615(a)-(b) (2019). The new regulation would require cosmetic brand owners, excluding microbusinesses, to annually register with the Secretary their cosmetic-related activities and a list of all cosmetic products brought to the market.

257. *Id.* at § 613(e). The bill also includes provisions on adulterated or misbranded cosmetics, including voluntary and mandatory recalls, as well as orders to cease distribution, notifications to the consumers and health officials, and a ban on the use of animal testing to develop a cosmetic.

258. The Natural Cosmetics Act, H.R. 5017, 116th Cong. § 2(g) (2019).

by requiring cosmetic companies to register facilities and ingredients, ensuring the finished product's safety in a written determination, and granting the FDA the authority to conduct ingredient safety reviews.[259] These amendments represent efforts at the federal level to revitalize an outdated law while also extending government oversight in the cosmetics market. Similar efforts have been undertaken by local governments,[260] especially in the realm of sunscreen regulation[261] that is creating much frustration among U.S. consumers who are increasingly shopping online from third party sellers to bypass FDA notice.[262]

2. *European Regulatory Framework*

The original Cosmetics Directive (Directive 76/768/EEC) in 1976 established a single market for cosmetics products in Europe. Though it has been the cornerstone of cosmetics regulation for more than thirty years, the directive has been adjusted in light of scientific developments, resulting in a patchwork of amendments viewed as ripe for regulatory simplification.[263] The original regulatory framework had modest provisions for labeling without declarations of ingredients, a general product safety requirement, and lists of permitted, banned, and restricted substances.[264] A cosmetics regulation was adopted in

259. The Cosmetic Safety Enhancement Act of 2019, H.R. 5279, 116th Cong., (2019).

260. Aris Folley, *Hawaii Lawmakers Approve Ban on Sunscreens with Chemicals Harmful to Coral Reefs*, HILL (May 2, 2018), https://thehill.com/business-a-lobbying/385823-hawaii-lawmakers-pass-bill-banning-sunscreens-with-chemicals-harmful-to [https://perma.cc/49KB-Y4AD]. In Hawaii, state legislation restricts the use of personal care products containing oxybenzone and octinoxate due to the chemicals harmful effect on coral reefs. Similarly, there is a new legislation in California that is broader than Hawaii's sunscreen ban. The California bill focuses on banning several chemicals in cosmetics.

261. Lindsey Bever, *Key West Bans Popular Sunscreens to Help Keep Coral Alive*, WASH. POST (Feb. 6, 2019), https://www.washingtonpost.com/climate-environment/2019/02/06/we-have-one-reef-key-west-bans-popular-sunscreens-help-keep-coral-alive/ [https://perma.cc/5RLQ-JQT5]. In 2019, the Key West City Commission in Florida passed a law banning the sale of certain sunscreens within the city limits of these Florida beaches.

262. Amanda Mull, *You're Not Allowed to Have the Best Sunscreen in the World,* ATLANTIC (July 1, 2022), https://www.theatlantic.com/technology/archive/2022/07/us-sunscreen-ingredients-outdated-technology-better-eu-asia/661433/ [https://perma.cc/S5DH-9D42].

263. *Cosmetics Liability and Safety Regulation: Retrospective and Prospective Perspectives*, HOGAN LOVELLS (Mar. 17, 2011), https://www.hoganlovells.com/-/media/hogan-lovells/pdf/publication/eu-cosmetic-regulation-retrospective-and-prospective-study_pdf.

264. *Id.*

2009 and entered into force in 2013, replacing the 1976 directive.[265] The European Union has adopted binding rules for the cosmetic sector, strictly regulating acceptable agreements through a positive and negative list system.[266]

Although consumer safety was of course one of the objectives of Directive 76/768/EEC, the newer 2009 regulation, applicable across all member states, requires responsible persons to produce a safety report before placing a cosmetics product on the market, by specifying the composition of the cosmetic product, its toxicological profile, and a safety assessment.[267] Although carcinogenic substances are separated into three categories under the old cosmetics legislation, with two out of three expressly prohibited, the new regulation allows for acceptable use in cosmetic products under specified circumstances designed to harmonize and ensure that food cosmetics were not subject to contradictory requirements.[268] It determines that the person responsible for placing the cosmetic product on the market must have "evidence of the effect claimed for the cosmetic product, where justified by the nature or its effect" readily accessible to the competent authority concerned.[269] Another notable focus of the 2009 legislation is compliance with good manufacturing practice (GMP). These obligations extend from cosmetics manufacturers down to the retailer's store if the retailer prepares the cosmetics using either a device or employee preparation, requiring the device or employee training to be maintained to satisfy the legislation's standards.[270]

While consumer safety, product traceability, and the transparency of their composition become the primary objectives of this new regu-

265. *Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products*, 2009 O.J. (L 342/59), https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/cosmetic_1223_2009_regulation_en.pdf.

266. David Bach and Abraham L. Newman, *Governing Lipitor and Lipstick: Capacity, Sequencing, and Power in International Pharmaceutical and Cosmetics Regulation*, 17 REV. INT'L POL. ECON. 665, 686, 688 (2010).

267. Regulation (EC) 1223/2009, *supra* note 265, at Art. 3. According to Article 3, "a cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use." This requires a Cosmetic Safety Product report as noted in Cosmetic Product Safety Report (CPSR).

268. Regulation (EC) 1223/2009, *supra* note 265, at 79–80 (assessing the safety risks of finished product "cosmetic product safety information").

269. Regulation (EC) 1223/2009, *supra* note 265 at Art. 11 (2)(d). The product information file must contain evidence of the effect claimed for the cosmetic product if this is justified by the nature of the cosmetic product or its effect.

270. Helena Eixarch et al., *The Regulation of Personalized Cosmetics in the EU*, 6 COSMETICS 29 (2019), https://www.mdpi.com/2079-9284/6/2/29 (detailing on the requirements of the Cosmetics Regulation 1223/2009).

lation, the European Commission has extended oversight over cosmetics through a reporting system starting from where the product was manufactured or imported from, although it is not a pre-approval system. In 2014 the European Court of Justice ruled that E.U. law makes no distinction on where the animal testing was carried out,[271] and access to the E.U. market is conditional upon compliance with the prohibition of animal testing.[272] Indeed, this system allows for greater surveillance and product recall.[273] The regulation oversees what ingredients are permitted using positive lists designating acceptable colorants, preservatives, and ultra-violet filers. The negative list pertains to banned substances. So far, the European Union has prohibited 1,328 ingredients, where only eleven substances are banned in the United States.[274]

3. Regulatory Disconnect in Testing, Certification and Labeling

While the United States and European Union do not require premarket approval, both strengthened the initial reporting requirements for cosmetics, even if they still differ in their testing, certification, and labeling practices. In contrast to "organic" labeling standards in the United States, European Union requirements for using the term "organic" on cosmetics vary across twenty-seven member states of the Union, because different organizations across Europe have developed their own standards and certification systems.[275] Numerous international and national standards and certifying bodies were established, creating a plethora of different private standards[276] and causing the

271. *See* Case C-592/14, Euro. Fed'n for Cosm. Ingredients v. Sec'y of State for Bus., Innovation and Skills, ECLI:EU:C:2016:703 (Sept. 21, 2016). The ECJ held that companies cannot circumvent European bans on cosmetic products containing ingredients that have been tested on animals. This contrasted with the European Federation for Cosmetic Ingredients' view that companies could conduct animal testing outside the European Union so that the cosmetic products containing certain ingredients could be sold outside the European Union to Japan and China.

272. Court of Justice of the European Union Press Release No. 105/16, E.U. law protects the E.U. market from cosmetic products containing ingredients which have been tested on animals (Sept. 21, 2016), https://curia.europa.eu/jcms/upload/docs/application/pdf/2016-09/cp160105en.pdf.

273. *Id.*

274. *See* Regulation (EC) 1223/2009, *supra* note 265, at 59, 83-127.

275. *See What Requirements Must Natural Ingredients for Cosmetics Comply with to be Allowed on the European Market?* NETHERLANDS MINISTRY OF FOREIGN AFF. CTR. FOR THE PROMOTION OF IMP. FROM DEVELOPING COUNTRIES (last updated Jan. 25, 2022), https://www.cbi.eu/market-information/natural-ingredients-cosmetics/buyer-requirements.

276. *The Organic Logo*, EUR. COMM'N, https://ec.europa.eu/info/food-farming-fisheries/farming/organic-farming/organic-logo_en (last visited Jan. 30, 2022) (noting that

fragmentation of labeling schemes and standards in the United States and the European Union.[277] At the heart of the European Union's approach are a set of laws known as REACH (Registration, Evaluation, Authorization and Restriction of Chemicals), which require manufacturers to prove to regulators that a product is safe before consumer use.[278] The United States has similar rules for new chemicals entering the market but no precautionary principles for the thousands of potential toxins already in use.[279] Although both systems require prior review and approval of a limited number of specific types of cosmetic ingredients, they predominantly rely on manufacturers to substantiate the safety of their products according to principles established by the respective domestic regulations.

The iconic example of a cosmetics product where the United States and the European Union have diverging regulations is sunscreen.[280] Generally, the European Union's regulation of sunscreen is considered much stricter than the United States'.[281] In the European Union, testing methods for sunscreens are subject to standardization by the European Committee for Standardization (CEN). The European Union is perceived as having stricter labeling standards than the United States, in that European sunscreens must protect not only against UVB rays by using the SPF factor, but also against UVA rays.[282] Also, whereas the European Union recently introduced a la-

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the organic logo is not used on cosmetic products to denote European Union certified organic products).

277. *See generally* MICHELLE EGAN, CONSTRUCTING A EUROPEAN MARKET: STANDARDS, REGULATION, AND GOVERNANCE (2001).

278. *Understanding REACH*, EUR. CHEM. AGENCY, https://echa.europa.eu/regulations/reach/understanding-reach.

279. *Id.*; *see* Joanne Scott, *From Brussels with Love: The Transatlantic Travels of European Law and the Chemistry of Regulatory Attraction*, 57 AM. J. COMPAR. L. 897 (2009) (outlining the influence of REACH on the U.S. legislation).

280. *Federal Food, Drug, and Cosmetic Act*, FOOD & DRUG ADMIN., https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act (last visited Feb. 10, 2022); *see* Tim Bella & Janne Wandell, *Johnson & Johnson Recalls Five Neutrogena, Aveeno Sunscreen Products Containing Traces of Benzene*, WASH. POST (July 16, 2021), https://www.washingtonpost.com/health/2021/07/15/johnson-johnson-sunscreen-recall-benzene/ [https://perma.cc/F59K-3NFD].

281. *See* TOXIC CHEMICALS IN AMERICA: CONTROVERSIES IN HUMAN AND ENVIRONMENTAL HEALTH 74 (Kelly A. Tzoumis ed., 2020) (noting that "[t]he European Union has more stringent and protective laws for cosmetics than the United States").

282. Roni Caryn Rabin, *The New Rules for Sunscreen*, N.Y. TIMES (May 27, 2013), https://well.blogs.nytimes.com/2013/05/27/the-new-rules-for-sunscreen/ [https://perma.cc/R4R8-N2QJ]. Since 2012 the FDA began labeling but not regulating UVA protection with the "broad spectrum" label without mandatory protection. *See* Nathaniel Lee & Jessica Orwig, *American Sunscreens May Not Be As Effective As European Sunscreens. Here's Why*., INSIDER (May 29, 2021), https://www.businessinsider.com/

beling requirement for nanoparticle ingredients, the United States has no such requirement.[283]

However, ironically, the European Union labels sunscreen as a "cosmetic," while the United States labels it as a "drug." This regulatory disconnect has practical implications on transatlantic trade. For example, between 2003 and 2010, European sunscreen producers applied for FDA permission to use several broad-spectrum chemical filters but were met with untimely responses by the FDA.[284] As a result, the United States banned European sunscreens.[285] The failure of the FDA to respond to these applications prompted Congress to pass the Sunscreen Innovation Act of 2014 (SIA), which aimed to encourage the evaluation of sunscreen filter applications. However, despite the SIA's passing, some of the compounds used in the European Union have been awaiting approval since 2002.[286] Even with the passage of SIA, differing standards and values that sunscreens present have impeded transatlantic trade of such products.

Although SIA speeds up the timeline of sunscreen review, it does not address the United States' reluctance to approve new ingredients and adapt to new scientific evidence. For instance, the FDA often asks cosmetics producers for more studies to rule out the dangers of chronic exposure, especially for pregnant women and children. The FDA has continued to insist the companies provide it with data to show the products are both safe and effective before approving under the Time and Extent Application (TEA) process.[287] However, the

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sunscreen-us-uva-rays-skin-cancer-health-2018-10?utm_source=Copy-link&utm_medium=Referral&utm_content=Topbar [https://perma.cc/YV3L-4F97].

283. Jody McCutcheon, *Is Sunscreen Safe? Eluxe Investigates*, ELUXE MAGAZINE (June 8, 2014), https://web.archive.org/web/20150404221348/http://eluxemagazine.com/magazine/is-sunscreen-safe/.

284. Sophia Akhiyat & B. Olasz Harken eds., *Update on Human Safety and the Environmental Impact of Physical and Chemical Sunscreen Filters,* PRAC. DERMATOLOGY (Feb. 2019), https://practicaldermatology.com/articles/2019-feb/update-on-human-safety-and-the-environmental-impact-of-physical-and-chemical-sunscreen-filters [https://perma.cc/X2M5-NKS6].

285. *See* Marc S. Reisch, *After More Than a Decade, FDA Still Won't Allow New Sunscreens*, C&EN (May 18, 2015), http://cen.acs.org/articles/93/i20/Decade-FDA-Still-Wont-Allow.html.

286. *Id.*; *see also* Marc S. Reisch, *After More Than A Decade, FDA Still Won't Allow New Sunscreens*, C&EN (May 18, 2015), http://cen.acs.org/articles/93/i20/Decade-FDA-Still-Wont-Allow.html [https://perma.cc/YQR2-NU7V].

287. *See* Alexander Gaffney, *Under Pressure from Congress, FDA Holds Firm on Rejection of New Sunscreen Ingredients*, REGUL. FOCUS (Feb. 24, 2015), http://www.raps.org/Regulatory-Focus/News/2015/02/24/21467/Under-Pressure-from-Congress-FDA-Holds-Firm-on-Rejection-of-new-Sunscreen-Ingredients/#sthash.PVlI8uO2.dpuf [https://perma.cc/2MWC-2STC]. The Time and Extent Application was established in 2002 to facilitate the approval of new sunscreens. Ingredi-

FDA's current list contains seventeen approved sunscreen filters, of which only eight are commonly used for UVB, and only two offer good UVA protection, which is not mandatory.[288] In contrast, the European Union maintains a list of twenty-seven approved sunscreen molecules that cover both UVB and UVA filters thus requiring higher quality and cost for European sunscreen.[289] In addition, the European Union has created a central reporting system for cosmetic products before that product enters the market. This reporting system allows the European Union to quickly remove specific products and ingredients from the market, like amino benzoic acid, which causes allergic reactions in sunscreens and is still permitted in the US.

Regulatory disconnects are also evident in emerging technologies like nanomaterials given the risk factors involving consumer safety and health risks in cosmetics.[290] In the European Union, companies that wish to include nanomaterials in their cosmetic products must notify the European Commission six months before placing it on the market under the new cosmetics regulation. This requirement has led the European Union to emphasize transparency on the producer's use of nanomaterials. The European Union has defined specific nanomaterials that, if used, must be clearly labeled as such.[291] In the United States, the FDA has provided guidance to firms but places the onus on the manufacturer to ensure nanomaterials are safe and labeled and do not require premarket approval.[292] Instead, European manufacturers support international efforts in ISO, OECD, and the Scientific Committee on Emerging and Newly Identified Health Risks[293] to provide common definitions, standards, and norms for nanotechnologies,

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ents with a five-year history of extensive and safe OTC use in another country would be eligible for a fast-track application process. The FDA promised a response in 180 days.

288. *See* Mull, *supra,* note 262.

289. *Id.*

290. *See* Georgios Fytianos et al., *Nanomaterials in Cosmetics: Recent Updates*, 10 NANOMATERIALS 979 (2020).

291. Patrick Coppens and Francesco Planchenstainer, *The Labelling of Nanomaterials under EU Law, with a Particular Focus on France*, EUR. FOOD & FEED L. REV., no. 2, 2019, at 152–59.

292. U.S. FOOD & DRUG ADMIN., CONSIDERING WHETHER AN FDA-REGULATED PRODUCT INVOLVES THE APPLICATION OF NANOTECHNOLOGY: GUIDANCE FOR INDUSTRY (June 2014), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considering-whether-fda-regulated-product-involves-application-nanotechnology.

293. *See generally* Martin Miernicki et al., *Legal and Practical Challenges in Classifying Nanomaterials According to Regulatory Definitions*, 14 NATURE NANOTECHNOLOGY 208 (2019) (explaining the legal variation across food, cosmetics and other products and the importance of addressing legal uncertainty through a coherent regulatory approach).

given the health and environmental risk factors involved. Considering new E.U. cosmetic regulations and mandatory labelling, European firms are pushing to ensure that they do not lose their competitive advantage in nanomaterial standard-setting as the U.S. government has begun providing recommendations for evaluation and risk nanotech administration of nanomaterials.[294]

4. Distributional Effects in Transatlantic Trade

Both the United States and the European Union have defined and implemented market rules on cosmetics leading to changes and adjustments in their respective approaches to rulemaking. While industry prefers greater international regulatory cooperation to reduce transaction costs, national approval processes' resilience can segment markets and result in incompatible rules and procedures. However, the International Cooperation on Cosmetics Regulation (ICCR) was established in 2007 to promote international regulatory cooperation to address obstacles to trade and bring together regulatory authorities working on cosmetics from the United States, the European Union, Japan, Brazil, Canada, and interested stakeholders, including consumer and trade associations.[295] Industry and regulatory authorities work together to make recommendations in allergens, nanotechnologies, and safety assessments. ICCR receives substantial participation and technical support from the cosmetics industry association in each of the participating jurisdictions.[296]

The European Union has played a leading role in aligning European standards with international norms, expanding its regulatory influence in the cosmetics field.[297] This trend is also noticeable in ASEAN's adoption of European cosmetic regulations that list banned and accepted ingredients.[298] China has also banned those substances on the EU's negative list in their production of cosmetics and has also joined international cosmetics forums like the ICCR as an observer

294. Adriana Melo et al., *The Role of Nanomaterials in Cosmetics: National and International Legislative Aspects*, 38 SciELO (May 2015).

295. Industry participation through umbrella trade associations comes from different regions including Personal care in the United States; Cosmetics Europe; European Federation of Cosmetics Associations; Japan Cosmetics Industry; and China Association of Fragrance, Flavor and Cosmetic Industries.

296. Risk & Pol'y Analysis Ltd. Comparative Study on Cosmetics Legislation in the EU and Other Principal Markets with Special Attention to so-called Borderline Products 3, 10 (2004).

297. *See* Bach & Newman, *supra* note 266. As Bach and Newman note, many South American countries adopted legislation using the European cosmetic definitions and opted for positive and negative list approaches.

298. *Id.*

state.[299] These trends highlight the global influence of European norms and the intersection between public and private governance at the international level.[300]

Yet in their effort to regulate cosmetics to enhance regulatory cooperation in transatlantic trade, the United States and the European Union have generated significant distributive effects on workers and marginalized communities. In the European Union, the cosmetics regulation does not cover the risk arising from workers exposed to chemical involved in cosmetics production focusing only on safety of consumers.[301] However, the requirements of the REACH Regulation necessitate testing to ensure occupational safety for workers in chemical manufacturing plants and may in fact include animal testing for data to assess chemical risks to workers from chemicals used in sunscreen manufacturing.[302] This led German manufacturer Symrise to seek an annulment as they had been asked to provide animal data on cosmetic ingredients by the European Chemicals Agency (ECHA) to ensure worker safety leading to a conflict due to the request for animal testing requirements under the new E.U. chemicals strategy for sustainability.[303] The issue squarely puts labor protection against animal rights, highlighting the consequences of enforcement of value-based trade.

The United States has also faced pressure to address the distributive consequences of cosmetic safety due to the prevalence of specific toxic chemicals in products used by women of color like skin lighteners, hair relaxers, blowout treatments, and acrylic nails.[304] The Safer Beauty Package Bill that has been introduced into Congress reflects the shift towards a value-based trade agenda. One bill bans certain chemicals in cosmetics and requires more ingredient transparency in

299. *Id.*

300. *See generally*, Bradford, *supra* note 107.

301. *See* Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, 2006 O.J. (L 396). For the relationship between the cosmetics and REACH regulations, *see* Eur. Chem. Agency, Factsheet: Interface Between REACH and Cosmetics Regulations, (October 2014), https://echa.europa.eu/documents/10162/17221/reach_cosmetics_factsheet_en.pdf.

302. *See* European Commission Press Release, Answer Given by Mr. Breton on Behalf of the European Commission (Mar. 11, 2021), https://www.europarl.europa.eu/doceo/document/E-9-2021-000087-ASW_EN.pdf.

303. Case C-282/21, Symrise AG v. European Chemicals Agency (July 16, 2021), https://curia.europa.eu/juris/document/document.jsf?text=&docid=244530&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=10037 (dismissing Symrise appeal with costs).

304. Lily Yang, *How the Beauty Industry is Hurting Women of Color*, DAILY CALIFORNIAN (Mar. 5, 2021), https://www.dailycal.org/2021/03/05/how-the-beauty-industry-is-hurting-women-of-color/ [https://perma.cc/KCQ3-Q525].

the supply chain.[305] Another bill, the Cosmetic Safety for Communities of Color and Professional Salon Workers Act focuses on the distributive implications of specific cosmetics while also strengthening enforcement measures to mitigate against risk.[306] Finally, with the enactment by Congress of the Modernization of Cosmetics Regulation Act (MRCA) this increases FDA rulemaking and enforcement authority more consistent with international standards.[307] In this respect, the future of a transatlantic trade in cosmetics committed to greater sustainability and social equity needs to incorporate the new focus on distributional effects of regulation, primarily impacts on the safety of workers and marginalized communities who face greater public health risks.

B. Case Study: Medical Devices

Medical devices production is highly concentrated in the U.S. and E.U. markets. They account for approximately seventy-four percent of the global medical device market, placing the United States and European Union as leaders in innovative health care product development.[308] There are over eight-thousand different types of medical devices available on the global market.[309] Both the United States and the European Union are seeking to foster increased coordination with each other in the medical devices market as China's medical device sales are expected by 2030 to represent over twenty-five percent

305. Alexandra B. Cunningham & Elizabeth Reese,*"Safer Beauty" Bill Package Targets PFAS, Phthalates, Formaldehyde, and Other Common Chemicals in Cosmetics*, NAT'L L. REV. (Oct. 26, 2021), https://www.natlawreview.com/article/safer-beauty-bill-package-targets-pfas-phthalates-formaldehyde-and-other-common [https://perma.cc/Z9ZF-EQA8].

306. Cosmetic Safety for Communities of Color and Professional Salon Workers Act of 2021, H.R. 5540, 117th Cong. (2021).

307. *See* Bergeson & Campbell, P.C., *Congress Enacts Modernization of Cosmetics Regulation Act of 2022, Significantly Strengthening Regulation of Cosmetics*, NAT'L L. REV. (Jan. 18, 2023), https://www.natlawreview.com/article/congress-enacts-modernization-cosmetics-regulation-act-2022-significantly [https://perma.cc/D6CK-8LFB]; COVINGTON & BURLING LLP, YEARS IN THE MAKING—CONGRESS MODERNIZES FDA'S COSMETICS AUTHORITIES (2022), https://www.cov.com/-/media/files/corporate/publications/2023/years-in-the-makingcongress-modernizes-fdas-cosmetics-authorities.pdf.

308. BECKY HORTON, AMERICAN ACTION FORUM, MEDICAL DEVICE REGULATION: UNITED STATES V. EUROPEAN UNION (2012), http://americanactionforum.org/sites/default/files/BeckyHortonPaper.pdf.

309. Christa Altenstetter, *Medical Device Regulation and Nanotechnologies: Determining the Role of Patient Safety Concerns in Policymaking*, 33 U. DENVER L. & POL'Y 227, 228 (Mar. 8, 2011).

of the global market.[310] Many domestic and international consensus standards address aspects of the safety and effectiveness of medical devices. However, E.U. and U.S. firms have indicated that they wish to reduce costs in clinical trials and inspections.

1. U.S. Regulatory Framework, Pre-Market Approval and Testing

Medical devices are regulated in the United States by a continuously changing framework based on the Medical Device Amendments of 1976 that gave the FDA primary authority to regulate medical devices and required the FDA to obtain "reasonable assurance of the safety and effectiveness" before marketing any new devices.[311] The FDA established three classes of medical devices based on the degree of control necessary to assure that the various types of devices are safe and effective. Class I is the least regulated[312] while Class II requires special controls,[313] and Class III requires pre-market approval.[314]

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310. *China's Medical Devices Industry: Key Market Entry Considerations*, CHINA BRIEFING, https://www.china-briefing.com/news/chinas-medical-devices-industry-key-market-entry-considerations/ [https://perma.cc/HU8N-Q8Z9].

311. US Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 9 § 321 http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/fdcactchaptervdrugsanddevices/default.htm#Part_A.

312. *Device Classification Panels*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels (last visited Jan. 23, 2022). A device is in Class I if (i) general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (ii) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but the device is not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness of injury.

313. *See id.* Class II means that the class of devices is or eventually will be subject to special controls. A device is in Class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish special controls, including the promulgation of performance standards, post-market surveillance, patient registries, development and dissemination of guidance documents (including guidance on the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the act), recommendations, and other appropriate actions as the Commissioner deems necessary to provide such assurance. For a device that is purported or represented to be for use in supporting or sustaining human life, the Commissioner shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

314. Class III is the most regulated class. It is the class of devices for which premarket approval is or will be required. A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls described in paragraph (c)(2) of this section would provide such assurance and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of sub-

Companies who wish to market a device not subject to PMA must submit a 510(k) to the FDA to demonstrate that the device is substantially equivalent to an already marketed device not subject to PMA.[315] The device may enter the market if it is substantially equal to a pre-existing device. In contrast to the 1,200 hours necessary to complete a PMA review, the 510(k) review takes an average of only 20 hours.[316] Ultimately, this process expedites devices and ensures improvements to existing devices quickly enter the market.[317] For purposes of pre-market approval,[318] the 1976 amendment divided Class III devices into three separate categories: pre-amendment devices,[319] post-amend-

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stantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury. Class III devices are subject to a rigorous premarket approval process (PMA). The FDA grants premarket approval to Class III devices only after determining that there is reasonable assurance of their safety and effectiveness. *See* 21 U.S.C. § 360c(a)(1)(C)(ii) (2022).

315. Establishment Registration and Device Listing for Manufactures and Initial Importers of Devices, 21 C.F.R. § 807 (2022), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFR-Search.cfm?CFRPart=807&showFR=1&subpartNode=21:8.0.1.1.5.5. Subpart E describes the requirements for a 510(k) submission. Before marketing a device, each submitter must receive an order, in the form of a letter, from the FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the US. This order "clears" the device for commercial distribution. Submitters must compare their device to one or more similar legally marketed devices and support their substantial equivalency claims. A legally marketed device, as described in 21 CFR 807.92(a)(3), is a device that was legally marketed prior to May 28, 1976 (pre-amendments device), for which a PMA is not required, or a device which has been reclassified from Class III to Class II or I, or a device which has been found SE through the 510(k) process. The legally marketed device(s) to which equivalence is drawn is commonly known as the "predicate." Although devices recently cleared under 510(k) are often selected as the predicate to which equivalence is claimed, any legally marketed device may be used as a predicate. Legally marketed also means that the predicate cannot be one that is in violation of the Act. *See* Premarket Notification 510(k), U.S. FDA (current as of Mar. 13, 2020), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/.

316. Medtronic Inc. v. Riegel, 552 U.S. 312, 318 (2008).

317. Medtronic Inc. v. Lohr, 518 U.S. 470, 478 (1996).

318. *PMA Approvals*, U.S. Food & Drug Admin. (current as of Dec. 16, 2021), http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm.

319. A pre-amendments device is one that was in commercial distribution before May 28, 1976, the enactment date of the Medical Device Amendments. Manufacturers of Class III pre-amendments devices are not required to submit a PMA until 30 months after the promulgation of a final classification regulation or until 90 days after the publication of a final regulation requiring the submission of a PMA, whichever period is later. FDA may allow more than 90 days after promulgation of a final rule for submission of a PMA. *See id.*

ment devices,[320] and transitional Class III devices.[321] This class structure applies different standards to devices already on the market. The process streamlines approval for devices marketed before 1976 while maintaining standards for newly created devices.[322]

If a device's safety and effectiveness are changed, the FDA Modernization Act of 1997 requires that marketers submit a PMA supplement.[323] Changes involving modifications to manufacturing procedures or methods of manufacture require companies to submit additional information.[324]

A Third-Party Review Program exists for some devices subject to 510(k) review. Through the FDA Modernization Act of 1997 (FDAMA), the FDA developed the Accredited Persons Program "to improve the efficiency and timeliness of the 510(k) process."[325] Businesses may submit a 510(k) review to an Accredited Persons Program member who forwards its review and recommendation to the FDA. The FDA will make a final determination within 30 days.[326] This pro-

320. *See id.* A post-amendments device is one that was first distributed commercially on or after May 28, 1976. Post-amendments devices that FDA determines are substantially equivalent to pre-amendments Class III devices are subject to the same requirements as the pre-amendment devices. FDA determines substantial equivalence after reviewing an applicant's premarket notification submitted in accordance with Section 510(k) of the act. Post-amendments devices determined by FDA to be not substantially equivalent to either pre-amendments devices or post-amendments devices classified into Class I or II are "new" devices and fall automatically into Class III. Before such devices can be marketed, they must have an approved premarket approval application or be reclassified into Class I (general controls) or Class II (standards).

321. Class III transitional devices and "new" devices (described in the paragraph above) are automatically classified into Class III by statute and require premarket approval by FDA before they may be commercially distributed. Applicants may either submit a PMA or Product Development Protocol (PDP), or they may petition FDA to reclassify the devices into Class I or Class II. Clinical studies in support of a PMA, PDP, or a reclassification petition are subject to the investigational device exemption (IDE) regulations. *See PMA Approvals*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm. (For further details on these regulations, refer to 21 CFR 812 for general devices or 21 CFR 813 for intraocular lenses.)

322. *Regulation of Medical Devices by the Food and Drug Administration in* OFF. TECH. ASSESSMENT, FEDERAL POLICIES AND THE MEDICAL DEVICES INDUSTRY 99 (Nov. 1984).

323. FDA Modernization Act of 1997, § 515(d)(6).

324. These types of manufacturing changes require a 30-day Notice or, where FDA finds such notice inadequate, a 135-day PMA supplement.

325. U.S. FOOD & DRUG ADMIN, 510(K) THIRD PARTY PERFORMANCE METRICS AND ACCREDITATION STATUS, https://www.fda.gov/about-fda/cdrh-transparency/510k-third-party-performance-metrics-and-accreditation-status [https://perma.cc/8KKE-ARWT].

326. U.S. FOOD & DRUG ADMIN., 510(K) THIRD PARTY REVIEW PROGRAM (current as of Aug. 18, 2020), https://www.fda.gov/medical-devices/premarket-submissions/510k-third-party-review-program.

gram also expanded to permit third parties to review many Class II devices for which there were no specific guidance documents.[327]

Medical device companies remain concerned that the FDA review process is almost twice as long as its European Union counterpart, the European Medicines Agency.[328] Critics are worried that medical innovation in the United States will decline if the current regulatory framework is not improved. This may result in patients migrating to seek medical intervention abroad.[329] Part of the problem is that the large clinical trials required by the FDA can be highly time-consuming and difficult to assemble. Broadening the scope of medical devices that are eligible for market entry under the 510(k) notification process could significantly decrease the amount of time new consumers have to wait for new medical devices.[330] Although compliance is costly, an enforcement regime that relies on private liability through limited state tort litigation against FDA approved products can outweigh such costs.[331] However, manufacturers of FDA-regulated products have enjoyed nearly a decade of favorable rulings based on federal preemption and deference to the FDA.[332] Since the 1980s, there has been ample mass tort litigation on malfunctioning FDA approved products, but "the defensive doctrine of federal preemption [. . .] has gradually swung the pendulum toward dismissal of claims."[333]

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327. *Id.*

328. U.S. FOOD & DRUG ADMIN., COMPARE PMA APPROVALS (2021), and EUR. MED. AGENCY, MEDICAL DEVICES, https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices (last visited Feb. 4, 2022).

329. Stephen Barlas, *Critics Assail FDA Medical Device Approval Process*, 36 PHARMACY & THERAPEUTICS, 395 (July 2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3171816/.

330. Paul Citron, *Medical Devices: Lost in Regulation*, 27 ISSUES SCI. & TECH. no. 3, (Spring 2011) at 23, 26, http://issues.org/27-3/p_citron/ [https://perma.cc/5LSB-FYAQ].

331. See Beth S. Rose, *Medical Devices: Parallel Claims against Device Manufacturers Post-Riegel?* NAT'L L. REV. (Aug. 8, 2014), http://www.natlawreview.com/article/medical-devices-parallel-claims-against-device-manufacturers-post-riegel#sthash.aGDURwEW.dpuf [https://perma.cc/C4Y8-G3Y2].

332. Michael A. Walsh, *Preemption Pendulum: Medical Products and Parallel Claims*, LAW360 (June 27, 2014), http://www.law360.com/articles/552243/preemption-pendulum-medical-products-and-parallel-claims [https://perma.cc/QJ8D-QK9S].

333. *Id.*

2. The European Regulatory Framework

Until the 1990s, each European Union member state had an individual approach to medical device evaluation.[334] Under the European Union's "New Approach," medical device standardization activities operate under a new harmonized framework.[335] These directives also generally aim to ensure a high level of protection for the Single Market's human health and safety. They are partially a response to the French PIP breast implant scandal as well as general technological advances.[336]

The current three medical device directives contain what are called harmonized standards. A harmonized standard "is regionally recognized, requiring all national standards bodies to implement or transpose this standard in identical fashion at the national level . . . [and withdraw] any conflicting national standard."[337] Manufacturers are not obligated to use the European harmonized standards. If medical device manufacturers comply with the relevant harmonized standards, their product will benefit from a presumption of conformity with the essential requirements and receive a Conformité Européenne (CE) marking.[338] Keeping this in mind, the directives do recognize the different levels of risk associated with various products.[339]

Collectively known as the European Economic Area (EEA), each European Union member state—along with Iceland, Lichtenstein, and Norway—have a competent national authority that conducts Medical Device Directive (MDD) and Active Implantable Medical Device Directive (AIMDD) conformity assessments for low-risk devices.[340] However, conformity assessments of more complex devices are handled by an authorized third party called Notified Bodies. If the medi-

334. Christa Altensetter & Govin Permanand, *EU Regulation of Medical Devices and Pharmaceuticals in Comparative Perspective*, 24 REV. POL'Y RSCH. 385, 389 (2007).

335. Council Directive 93/42, OJ L 169, 1993 (EEC) at 2–3 and Council Directive 98/79, OJ L 169, 1993 (EEC).

336. European Commission Memo, The Commission, Questions and Answers: Commission Tables Proposals for a New E.U. Regulatory Framework for Medical Devices and In Vitro Diagnostic Medical Devices (Sept. 26, 2012) at 2.

337. Egan, *supra* note 277.

338. CARLO BOCCATO, JOERG VIENKEN, & SERGIO CERUTTI, MEDICAL DEVICES: IMPROVING HEALTH CARE THROUGH A MULTIDISCIPLINARY APPROACH 36 (2022).

339. The MDD and AIMDD Directives outline four different classifications of risks divided into Class I, IIa, IIb, and III medical devices. See European Commission, DG Health and Consumer, *Medical Devices: Guidance Document*, MEDDEV 2 4/1 Rev. 9 (June 2010), at 4–5, https://ec.europa.eu/docsroom/documents/10337/attachments/1/translations/en/renditions/pdf.

340. Daniel B. Kramer, Shuai Xu, & Aaron S. Kesselheim, *Regulation of Medical Devices*, NEW ENGLAND J. MED., 366(9), 849 (Mar. 2012).

cal device meets all requirements, the Notified Body completes a Declaration of Conformity (DoC) permitting the manufacturer to affix the CE marking to their product. The MDD and AIMDD[341] require manufacturers to affix the CE marking before they can market and sell their product in the EEA.[342]

The two latest pieces of E.U. legislation on medical devices are the "Medical Device Regulation" (MDR) and the "*In-Vitro* Diagnostics Regulation" (IVDR), both proposed on 26 September 2012 and approved in 2017.[343] These two regulations adopted before COVID-19 acted as an overhaul of the European Union's previous medical device directives by addressing previous flaws while increasing device safety, effectiveness, and consumer transparency. In particular, in the aftermath of the Poly Implant Prothèse (PIP) scandal that left many women unable to recover for the damaged breast implants,[344] this created further suspicion towards decentralized certification coming from a company that transmitted that information to the centralized Notified Bodies.[345]

In this respect, the MDR changed the classifications of some devices, broadened the responsibilities of economic operators, expanded the role of evaluations and investigations, required a summary of safety and clinical performance, and requires further action from Noti-

341. Council Directive 2007/47, OJ L 2007 (EC) at 2, 3, 29, 30.

342. *Conformity Assessments and Notified Bodies*, EUR. COMM'N ENTERPRISE & INDUSTRY, https://ec.europa.eu/growth/single-market/goods/building-blocks/conformity-assessment_en. A DoC "should contain all relevant information to identify the legislation according to which it is issued, as well as the manufacturer, the authorized representative, the notified body if applicable, the product, and where appropriate a reference to harmonized standards or other normative documents."

343. DELOITTE, PREPARING FOR THE FUTURE: THE NEW EUROPEAN UNION MEDICAL DEVICES REGULATION 3–4 (2016), https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-eu-med-device-regulation.pdf.

344. *See* ECJ Judgment in Case C-581/18, RB v. TÜV Rheinland LGA Products GmbH and Allianz IARD SA (limiting the geographical coverage of the insurance of the defective medical device to French consumers only and excluding a German citizen from such coverage).

345. *See* Barend Van Leeuwen, *The Scope of Application of the Free Movement Provisions and the Role of Article 18 TFEU:* Allianz, 58 COMMON MKT. L. R. 1249, 1270 ("Overall, the victims of the PIP breast implants scandal could not be blamed for arguing that free movement of goods in the European Union is not really about the free movement of *safe* goods. The extent to which the European Union is taking responsibility for protecting victims of defective products remains limited. The Product Liability Directive is not of much use if the manufacturer has gone bankrupt. The regulatory framework for medical devices was improved with the adoption of the Medical Devices Regulation in 2017. However, the changes made by this Regulation were not very extensive. Most importantly, the new Regulation does not provide an obligation on the manufacturer to take out liability insurance. This remains an issue that is regulated by national law.").

fied Bodies to reapply for designation, and cooperated with the Commission.[346] However, due to the complications of managing the COVID-19 outbreak, the Parliament and Council issued Regulation 2020/561 postponing the MDR and IVDR's original application date from May 2020 until May 2022 to prevent critical medical device shortages or delays.[347]

3. Comparing Regulatory Responses to COVID-19: The Case of Ventilators

In response to the COVID-19 pandemic, the European Union has put its expansive domestic and overseas supply chains to the test, with guidelines from Brussels emphasizing increasing supply flexibility and increasing available supplies, equipment, and easing the strain on suppliers and regulatory assessments. Due to the complications of managing the COVID-19 outbreak, the European Parliament and Council issued Regulation 2020/561 considering medical sector protests of pandemic unpreparedness and to prevent shortages in pandemic medical device supplies.[348]

To combat COVID-19, the European Commission issued Recommendation 2020/403 in March on conformity assessment and market

346. Commission Regulation 2017/745, 2017 OJ L (117) 1 https://eur-lex.europa.eu/eli/reg/2017/745/2017-05-05; Marcelo Trevino, *8 Key Changes to Understand in the New European MDR and IVDR*, MED. DEVICE ONLINE (Sept. 16 2018), https://www.meddeviceonline.com/doc/key-changes-to-understand-in-the-new-european-mdr-and-ivdr-0001 [https://perma.cc/8TEQ-WJCE].

347. Commission Regulation 2020/561, 2020 O.J. (L 130) 18, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=Uriserv:OJ.L_.2020.130.01.0018.01.ENG&toc=OJ:L:2020:130:TOC; *see also* European Commission Press Release, Parliament Decides to Postpone New Requirements for Medical Devices (Apr. 17, 2020), https://www.europarl.europa.eu/news/en/press-room/20200415IPR77113/parliament-decides-to-postpone-new-requirements-for-medical-devices [https://perma.cc/KY4P-5T6X]. To further combat COVID-19, the European Commission issued in March Recommendation 2020/403 "on conformity assessment and market surveillance procedures within the context of the COVID-19 threat." *See* Commission Regulation 2020/561, 2020 O.J. (L130), 18 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=Uriserv:OJ.L_.2020.130.01.0018.01.ENG&toc=OJ:L:2020:130:TOC.

348. Regulation (EU) 2020/561 amending Regulation (EU) 2017/745 On Medical Devices, as Regards the Dates of Application of Certain of its Provisions, Regulation (EU) 2020/561, 2020 O.J. (L 130) 18, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=Uriserv:OJ.L_.2020.130.01.0018.01.ENG&toc=OJ:L:2020:130:TOC; Nicholas Wallace, *MDR-IVDR Bottleneck Persists as EU Launches 1st Eudamed Module*, MEDTECHDIVE (Dec. 4, 2020); *also see* European Parliament Press Release, Parliament Decides to Postpone New Requirements for Medical Devices (April 17, 2020), https://www.europarl.europa.eu/news/en/press-room/20200415IPR77113/parliament-decides-to-postpone-new-requirements-for-medical-devices [https://perma.cc/8E7S-JHM7].

surveillance procedures within the context of the COVID-19 threat.[349] The recommendation recognizes that global supply chains producing medical equipment, particularly face masks, are under severe strain and affirms the need for economic operators to redesign and diversify their pre-existing supply chains.[350] The Commission's recommendation suggests that the member states consider permitting derogations from conformity assessment procedures concerning medical devices and approve sales of adequately safe medical devices that have yet to finalize their conformity assessment procedures affixing CE labels.[351] The Commission limits its CE labeling exception by recommending the member states only keep these devices on the market for the duration of the current health crisis and that these devices should not enter regular distribution channels.[352]

With respect to enforcement and market surveillance, the Commission suggests the member state authorities refocus investigations to focus only on noncompliant equipment and devices that raise serious health risks instead of equipment and devices that have yet to finalize their assessment procedures.[353] Lastly, the Commission asks that the member states only permit these exception-based devices into the Single Market for the duration of the current health crisis.[354]

The European Commission also has relaxed requirements for the Notified Bodies. The recommendation suggests that Europe's Notified Bodies prioritize conformity assessment activities on necessary pandemic-related personal protective equipment to maintain steady supply stockpiles.[355] Additionally, the Commission has relaxed the Notified Bodies' on-site audit requirements.[356] The purpose of a Notified Bodies' on-site audit is to assess a medical device producer's quality management system, a prerequisite for a medical device's entry into the European market.[357] According to current regulations, a Notified Body shall audit the manufacturer's and supplier's premises to verify

349. Commission Recommendation (EU) 2020/403 on Conformity Assessment and Market Surveillance Procedures Within the Context of the COVID-19 Threat, 2020 O.J. (LI 79) 1, https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1584637182280&uri=CELEX:32020H0403.

350. *Id.*

351. *Id.*

352. *Id.*

353. *Id.*

354. *Id.*

355. *Id.*

356. *Commission Notice on Regulation (EU) 2017/745 and Regulation 2017/746 about Notified Bodies' audits performed in the context of quality management system assessment (EU) 2017/745,* 2021 O.J. (C 8) 1.

357. *Id.*

manufacturing and other processes, followed by a similar but annual on-site surveillance assessment.[358] However, quarantine restrictions across the European Union severely impeded the Notified Bodies' ability to conduct on-site audits. The medical device sector has also raised concerns over the incoming on-site audit conformity assessment deadlines for the now-delayed MDR and IVDR.[359] In response, on January 2021, the Commission issued a notice clarifying on-site audit requirements stating that the Notified Bodies' use of "extraordinary measures, including remote audits. . .appears to demonstrate an adequate level of safety and not to compromise the overall reliability of such assessments."[360] However, the use of remote audits should be limited and followed by an on-site audit as soon as possible and should only permit remote audits in light of "concrete obstacles" created by COVID-19 circumstances.[361] Despite this win for the medical device sector, national authorities and notified bodies have yet to determine a unified approach to remote audits.[362]

4. The U.S. Approach as National Security

Like that of the European Union, the United States' primary regulatory concern has been ensuring supplies of medical devices and equipment did not run out midst-pandemic. Despite similar goals, the United States has utilized its legal authorities to re-shore domestic production rather than strengthen foreign supply chains. Both President Donald Trump and President Joe Biden have invoked the Defense Production Act (DPA) to ramp up domestic procurement and production within the United States. In early 2020, President Trump was hesitant to use the DPA but later invoked the act to compel 3M, General Electric, and Medtronic to increase production of PPE.[363] The Department of Health and Human Services' first ventilator production contract with General Motors was priced at $489.4 million for 30,000 ventilators.[364] At roughly the same time, the FDA issued an enforce-

358. *Id.*
359. MEDTECHEUROPE, THE NEED FOR 'VIRTUAL AUDITS' UNDER THE MEDICAL DEVICE AND IN VITRO DIAGNOSTIC REGULATIONS IN THE CONTEXT OF A PANDEMIC, SUCH AS COVID-19 (June 2020).
360. 2021 O.J. (C 8) 1, ¶ 3.
361. *Id*.
362. Nick Paul Taylor, *EU Remote Audits Under MDR in Doubt as Divergent National Positions Persist*, MEDTECHDIVE (Mar. 10, 2021).
363. Gavin Bade, *Trump Expands DPA, Amid Mounting Pressure*, POLITICO (Apr. 2, 2020), https://www.politico.com/news/2020/04/02/trump-expands-dpa-order-162128 [https://perma.cc/4M6T-QLY7].
364. Delano Massey & Devan Cole, *HHS To Work With GM Under Defense Production Act to Produce 30,000 Ventilators for National Stockpile*, CNN (Apr. 8, 2020),

ment policy and an umbrella Emergency Use Authorization (EUA) to permit the modification of already approved medical devices into ventilators without additional FTA approval for safety, performance, and labeling.[365] The FDA has also issued EUAs for personal protective equipment and other relevant medical devices.[366]

Concerning supply chains, President Biden, shortly after entering office, issued Executive Order 14001 under the DPA. The order, titled "A Sustainable Public Health Supply Chain," requires an immediate review of available critical materials, treatments, and supplies, followed by a revision of operations and plans and the use of appropriate legal authorities, such as the DPA, to fill supply shortfalls.[367] The order requires that government authorities provide the President a strategy to sustain a long-term capability in the United States to manufacture supplies for future pandemics.[368] The plan also includes an analysis of foreign supply chains as part of the United States' pandemic supply chain, mechanisms to address "points of failure" in supply chains, and an approach to developing an implementation plan for domestic production of pandemic supplies.[369] The long-term effects of the pandemic have shifted underlying trade priorities in the European Union and the United States, with both parties now focusing on sustainability, public health and social equity not only domestically but also along the global supply chain.

C. Implications of the Case Studies for Transatlantic Trade

Both case studies highlight the shift from the competitive and efficiency dynamics underlying government regulation, to the importance of generating standards that have distributive effects that are in line with the values-based agenda in transatlantic trade. In cosmetics, the European Union has shaped the regulatory regime from the outset, whereas in medical devices, the United States set the initial standards for product market approval. In the case of cosmetics, there are clear disconnects about regulatory capacity in the United States, with the

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https://www.cnn.com/2020/04/08/politics/general-motors-ventilators-defense-production-act-coronavirus/index.html [https://perma.cc/7MA4-WZJ2].

365. *Ventilators and Ventilator Accessories EUAs*, U.S. Food & Drug Admin. https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas (last updated Apr. 21, 2020).

366. Ginny Hu, *Regulatory Considerations for EUA During COVID-19 Public Health Emergency for Medical Device Manufacturers*, Regul. Focus (June 22, 2020).

367. Executive Order 14001, 86 Fed. Reg. 7219, Jan. 21, 2021.

368. *Id.*

369. *Id.*

European Union using its legislation to project regulatory authority beyond its borders, working with international standards bodies to set market rules and good manufacturing practices. There are also regulatory disconnects in medical devices about independent national or regional approval reflected by different rules and incompatible procedures that can hinder transatlantic trade and investment.

While medical devices and cosmetics reflect two key sectors that were important during past iterations of trade negotiations between the United States and the European Union,[370] they are indicative of a broader regulatory disconnect. This is grounded in a regulatory cooperation paradigm that relies either on mutual adjustment of domestic procedures in light of efficiency or where more experimentalist approaches involve public and private stakeholders to increase transparency through joint efforts to bridge regulatory differences.

The case studies demonstrate how for at least two decades, the United States and the European Union have engaged in a framework that promotes international regulatory cooperation based on a premise that their own domestic model needs to be replicated to ensure equivalence and market access. This has produced limited results and greater regulatory disconnect as they start from two fundamentally different institutional approaches. The resulting divergent and unfair outcomes primarily harm marginalized communities and low-income workers.

Yet the starting premise of international regulatory cooperation requires a rethinking of the regulatory space towards reflecting their values as well as the economic strengths of their respective economies. This has prompted scholarship to suggest that a fundamental regulatory shift away from neoliberalism towards one that emphasizes environmental and social equity. International regulatory cooperation is not simply a zero-sum game in which both the United States and the European Union seek a regulation-imposed competitive advantage. Instead, politicians and lawyers need to build a transatlantic regulatory model around distributional consequences addressing consumer and workers' welfare where they suggest regulatory mitigation and identify the costs of regulations spurred by transatlantic trade.

Finally, the case studies show that distributive conflicts can make agreement difficult, especially if there are different regulatory philosophies or objectives across jurisdictions. This has not been easy because the structure of their respective standards and conformity

370. *See* Elisabet Ruiz Cairo, *Better Safe Than Sorry? The Impact of the EU-US Negotiations under TTIP on the Regulation of Cosmetic Products*, 11 CROAT. Y.B. EUR. L. & POL'Y (2015) https://www.cyelp.com/index.php/cyelp/article/view/218.

assessment regimes makes coordination difficult, as the social-institutional legacy, historical context, political choices, and global influence has evolved differently across the Atlantic. Even though both governments incorporate private rulemaking into public law, the impact of different national requirements from conformity assessment measures like standards, technical regulations, and certification requirements can increase the cost of manufacturing and reduce the access to foreign markets, especially if there is limited reciprocity or mutual equivalence of specific standards. This is made even more difficult where the cost of compliance with diverse regulatory systems and prescriptions derives from precautionary private standards rather than public ones.[371] Coupled with congressional limitations on the possibility of antitrust enforcement against standards development organizations in the United States, and similar legal reasoning in the European Union, public concerns over how such rules are administered brings to the fore the difficulties of reciprocity in relation to risk and conformity assessment as it involves mutual trust. Though private regimes may produce specific regulatory principles, the ordering of public rules, their scope and function, and their degree of legitimation through accreditation, certification and testing bodies can generate regulatory conflict. Even then, the challenges of accountability of diffuse representation do not mean that it is more effective in the sense that private rulemaking can reduce trade barriers in previously protected markets.

Europe and the United States have long been viewed through a competitive lens as rule-makers, setting down their modalities and frameworks despite their deep differences on regulatory standards and values.[372] The United States and the European Union should rethink how to ensure mutual trust and equivalence built on a basis of product quality in which equivalent norms of standards, testing, and certification provide goals beyond efficiency and market access to include goals of sustainability, consumer safety, and social equity for workers that have become increasingly salient given the global pandemic and its stress on global value chains. The COVID-19 pandemic has highlighted the importance of critical flows of supplies in integrated global value chains and raised the issues of efficacy in product quality in production to meet specific environmental and health goals. While medical devices and cosmetics have strict regulatory standards, as shown by traditional approval and certification procedures, this was

371. *See* Pascal Lamy, The New World of Trade: The Third Jan Tumlir Lecture at the European Center for International Political Economy (Mar. 9, 2015), https://www.econstor.eu/bitstream/10419/174861/1/ecipe-jtpe-2015-01.pdf.

372. Schepel, *supra* note 186; Egan, *supra* note 277.

short-circuited in the pandemic as several manufacturers stepped into the breach to bid on public contracts for various products ranging from ventilators to hand sanitizers. As a result, the United States and the European Union need to shift their regulatory paradigm based on efficiency and transparency to keep pace with new public policy objectives that stresses sustainability, public health, and social equity for marginalized communities.

CONCLUSION

The new value-based agenda outlined by the United States and the European Union provides an opportunity to reimagine the transatlantic trade relationship. The agenda will usher in trade-changing behavior in firms in global supply chains production and spur in governments in terms of negotiating objectives promoting social inequalities and climate change.[373] What emerged from the case studies is that the narrative and purpose of international regulatory cooperation efforts have shifted in response to changes in the trade environment during a global pandemic. The agenda's goals are to ensure that existing technology and product standards follow transatlantic rules and values that are often depicted in antithesis to Chinese ones. In this new light, international regulatory cooperation brings to the fore a value judgment on the equivalence of normative standards including public health, sustainability, and social justice. These goals drive the regulatory process beyond the efficiency or transparency paradigm by showing the distributional effects on the groups that will bear the benefits and the costs of the new values-based trade agenda.

This commitment to values-based trade, however, requires reorienting international regulatory cooperation away from efficient and cost-related market considerations by framing a values-based agenda as a means of shaping global market practices.[374] For both parties to come to terms with the pressures stemming from China's rise that has

373. *See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and Committee of the Regions, Trade Policy Review – An Open, Sustainable and Assertive Trade Policy*, COM (2021) 66 final (Feb. 18, 2021); OFF. OF THE U.S. TRADE REPRESENTATIVE, 2021 TRADE POLICY AGENDA AND 2020 ANNUAL REPORT OF THE PRESIDENT OF THE UNITED STATES ON THE TRADE AGREEMENTS PROGRAM (2021).

374. *See* Grewal & Purdy, *supra* note 98; Jedediah Britton-Purdy, David Singh Grewal, Amy Kapczynski & K. Sabeel Rahman, *Building a Law-and-Political-Economy Framework: Beyond the Twentieth-Century Synthesis*, 129 YALE L.J. 1784 (2020) (discussing in the abstract how private and public law regimes have encased neoliberal paradigm by shielding claims of justice and analyses of power); Angela Harris & James L. Varellas, *Law and Political Economy in a Time of Accelerating Crises*, 1 J.L. & POL. ECON. 1 (2020).

strained the global trading system and raised the prospect of alternative models of regulatory governance, the United States and the European Union need to focus on addressing how to frame their regulatory values in a common way. Rather than focus on competitive liberalization, a values-based trade approach could achieve a degree of regulatory cooperation. The agenda could foster greater government alignment in terms of distributive consequences of trade agreements, push firms to change their behavior in global supply chains, and encourage lawyers to achieve common standards in fostering compliance in trade practices.

To achieve socially and environmentally responsible international trade, both the United States and the European Union will need to openly grapple with the distributive consequences of their regulatory regime. They must consider the inevitable trade-offs for their workers, consumers, and businesses together with their ability to publicly enforce their values-based trade agenda. While much of the rationale for transatlantic trade was framed to promote regulatory cooperation based on a neoliberal paradigm promoting efficiency and transparency, there has been a corresponding realization that competitive liberalization has not generated the expected mutual gains from past transatlantic efforts. Instead it generated great inequities, especially among disadvantaged, vulnerable, and marginalized communities. Today, the United States and the European Union have committed to a value-based agenda determined to shape global rules by respecting environmental and public health standards with a focus on social equity for consumers and workers. However, without regulatory cooperation, the transatlantic relationship faces the prospect that domestic administrative standards and rule-making processes may not shape the landscape for future regulation that define how technologies work and offer a benchmark for environmental and social equity goals.[375]

International regulatory cooperation encompasses various mechanisms through which U.S. and E.U. regulators debate their divergences to align their regulatory requirements as far as feasible and desirable. They need to recognize that the outcomes of those standardization efforts have different distributive impacts on workers, consumers, and marginalized communities throughout their global supply chains. As a result, addressing differences in rule-making processes and impact assessments based on common values like sustainability

375. *See An EU Strategy on Standardizations: Setting Global Standards in Support of Resilient, Green and Digital EU Single Market*, at 5, COM (2022) 31 final, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=LEX:52022DC0031.

and social equity, transatlantic regulatory cooperation will necessarily re-define the substantive values and regulatory requirements for goods like cosmetics and medical devices in each jurisdiction.