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Keeping Imports Safe: A Proposal for Discriminatory Regulation of International Trade

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INTRODUCTION

In September 2007, Chicago area toy company RC2 Corporation announced a recall of Thomas the Tank Engine wooden railway toys manufactured in China. The recall, prompted by the presence of lead paint in the toys' finish, was the second by the company within a three-month period. In all, the company recalled 1.8 million units of the extremely popular toy.¹ These were not the only toys recalled. That year, almost forty million Chinese-made toys or other items used by children were recalled—about one for every household with children.²

This story of defective or dangerous imports does not end with toys.

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1. See Parija B. Kavilanz, *More Thomas & Friends Toys Recalled for Lead*, CNNMoney.com, Sept. 26, 2007, http://money.cnn.com/2007/09/26/news/companies/toy_recall/index.htm.

2. See U.S. CENSUS BUREAU, CURRENT POPULATION SURVEY, 2007 ANNUAL SOCIAL AND ECONOMIC SUPPLEMENT, *available at* http://pubdb3.census.gov/macro/032007/hhinc/new04_003.htm.

Contamination of a Chinese-produced ingredient used by an American pharmaceutical company in its blood-thinner has led to the death of nineteen patients and recalls in several countries.³ In April 2007, the Food and Drug Administration (FDA)—which inspects only 1% of food from foreign countries—rejected shipments of food from China because they contained contaminants such as salmonella, veterinary drugs, the carcinogen nitrofurantoin, banned antibiotics, and putrefying bacteria.⁴ In July 2007, ginger imported from China was found to contain a dangerous pesticide only after the product had been put on the shelf.⁵

In addition, personally-identifiable medical and financial information shared with foreign sub-contractors has been breached, raising deep concerns about threats to data privacy as U.S. companies increasingly outsource business process functions overseas.⁶

These incidents, along with many other similar ones, evidence a tension between American safety concerns and the realities of a global marketplace. Americans understandably want to enjoy the benefits of internationally sourced goods and services while simultaneously maintaining high levels of safety and security in those same products. As more foreign products find their way into the American marketplace, however, the mix of economic, legal, and societal forces that influence safety and reliability changes. American regulators are left with the task of ensuring appropriate levels of consumer protection without frustrating the economic gains from global trade.

This article offers a conceptual framework for understanding the governance challenge presented by increased international trade, and for

3. See Gardiner Harris & Walt Bogdanich, *Drug Tied to China Had Contaminant*, *F.D.A. Says*, N.Y. TIMES, Mar. 6, 2008.

4. See Diedra Henderson, *Chicken From China? Questionable Farming Practices Fuel Skepticism of US Plan to Import Poultry*, BOSTON GLOBE, May 9, 2007.

5. See Nicholas Zamiska & David Kesmodel, *Growing Concern: Tainted Ginger's Long Trip From China to U.S. Stores*, WALL ST. J., Nov. 19, 2007, at A1.

6. See FED. DEPOSIT INS. CORP., OFFSHORE OUTSOURCING OF DATA SERVICES BY INSURED INSTITUTIONS AND ASSOCIATED CONSUMER PRIVACY RISKS 2-3 (2004), available at http://www.fdic.gov/regulations/examinations/offshore/offshore_outsourcing_06-04-04.pdf (identifying increased forms of risk to consumer privacy); U.S. GOV'T ACCOUNTABILITY OFFICE, PRIVACY: DOMESTIC AND OFFSHORE OUTSOURCING OF PERSONAL INFORMATION IN MEDICARE, MEDICAID, AND TRICARE 18 (2006) [hereinafter *GAO Privacy Outsourcing Report*] (noting that a substantial number of federal contractors and state Medicaid agencies reported privacy breaches involving personal health information, while admitting that many remain unreported); David Lazarus, *Looking Offshore: Outsourced UCSF Notes Highlight Privacy Risk; How One Offshore Worker Sent Tremor Through Medical System*, S.F. CHRON., Mar. 28, 2004, at A1 (detailing risks after medical information breach by Pakistani business process outsourcer); Larry Ponemon, *SURVEY REPORT, Outsourcing: Privacy Data Protection and Security Considerations in Outsourcing Decisions*, 6 BNA PRIVACY & SECURITY LAW REPORT, no. 42 (Oct. 22, 2007) [hereinafter *Privacy Survey*] (reporting that 37% of respondents state that outsourcing partners have experienced data loss or theft as a result of negligence, IT glitches, or mistakes, and another 19% have outsourcing partners that experienced data loss as a result of malicious insider activities).

considering how best to ensure optimal consumer-protection levels for imported products and outsourced services. Part I explains that the provision of goods and services is subject to two regulatory processes or, as we call them, “levers.” We describe them as levers to emphasize that they represent possible approaches to the problem. The decision maker can pull one or both of these levers. As we describe below, when one lever becomes unavailable, policymakers must search for alternatives to achieve similar objectives.

The first lever looks to outcomes. It focuses on the final product or service rather than the process through which that good was produced. We refer to this approach as “outcome-based regulation” or the “outcome lever.” The second lever constrains firm behavior during the process of production, or through which a service is provided. We refer to this approach as “production-based regulation” or the “production lever.”

This typology is similar to the way in which trade scholars often distinguish between “process and production methods” (PPMs) and the product or service itself.⁷ It differs, however, from the usual ways that scholars of regulation categorize regulatory approaches. Rather than exploring the variety of regulatory instruments—tort liability, command and control approaches, direct oversight and monitoring, performance standards, negotiation and contract, market-based incentives, or information-forcing regimes, for example⁸—our typology focuses on the stage of the process at which particular examples of these instruments seek to alter incentives. This understanding of governance is critical to the evaluation of competing strategies for applying domestic safety and consumer protection norms to foreign goods or services that could potentially harm U.S. consumers.

The most pervasive form of legal regulation of domestic goods and services utilizes the outcome lever. Administrative regulation establishes rules governing outcomes and creates an apparatus for inspecting finished products, coordinating recalls, forcing disclosure to affected consumers, and imposing administrative penalties through enforcement actions. Tort law similarly

7. See Robert Howse & Donald Regan, *The Product/Process Distinction—An Illusory Basis for Disciplining 'Unilateralism' in Trade Policy*, 11 EUR. J. INT'L L. 249 (2000).

8. For discussion of the variety of regulatory instruments see Kenneth A. Bamberger, *Regulation as Delegation: Private Firms, Decisionmaking, and Accountability in the Administrative State*, 56 DUKE L.J. 377, 388-91 (2006) (discussing a variety of forms of regulation); Cary Coglianese & David Lazer, *Management-Based Regulation: Prescribing Private Management to Achieve Public Goals*, 37 LAW & SOC'Y REV. 691, 696-700 (2003) (describing the use of management-based regulation in the areas of food safety, industrial safety, and pollution prevention); Cary Coglianese et al., *Performance-Based Regulation: Prospects and Limitations in Health, Safety, and Environmental Protection*, 55 ADMIN. L. REV. 705 (2003) (summarizing a dialogue among regulators and researchers about performance-based regulation); Christine Parker, *Reinventing Regulation Within the Corporation: Compliance-Oriented Regulatory Innovation*, 32 ADMIN. & SOC'Y 529, 547 (2000) (discussing “outcome-based” regulation); and Stephen D. Sugarman & Nirit Sandman, *Fighting Childhood Obesity Through Performance-Based Regulation of the Food Industry*, 56 DUKE L.J. 1403, 1411-28 (2007) (setting forth a typology of regulatory instruments).

imposes liability for harms actually incurred.

The baseline assumption guiding domestic consumer-protection policy in many contexts is that these forms of government regulation, combined with non-legal social and market forces affecting firm behavior, will ensure sufficient levels of consumer protection. But noncompliance is difficult to detect through *ex post* inspection or before consumer harm has actually occurred; harm may become apparent only long after use of the product; and social and market compliance incentives are sometimes insufficient to generate optimal levels of safety. In these situations, regulators have employed the production lever as a means of reducing risks and preventing harms by mandating that private firms adopt internal procedures and assessments intended to prevent risks before they occur, or by overseeing production processes directly through inspection, monitoring, reporting and licensing, to ensure a high level of safety before goods ever leave the plant or reach the market.

The production lever, however, is largely disabled in the trade context, primarily because of the legal and practical limits on the extraterritorial reach of government power. Lacking regulatory authority in foreign states, or the resources to ensure comprehensive monitoring, reporting, or inspection of production processes, American regulators cannot hope to use production-based regulation against imports comparably to the way it is used against domestic production. Regulators cannot easily place themselves, in a figurative sense, in a foreign producer's delivery bay to keep an eye on the inputs being purchased, on the factory floor to monitor production, or in the information processing center to ensure that sensitive personal data is kept secure. Thus, in the very context that policymakers might ordinarily turn to production-based regulation, the production lever is largely unavailable.

A number of proposals before Congress attempt to address the problem by increasing the resources allocated for U.S. government inspections.⁹ Inspections would examine both products entering the United States and, where

9. A somewhat extreme solution that has been mentioned would put in place border measures to block or slow trade with countries like China, the source of many of the tainted products. This remedy is problematic from both practical and legal perspectives. Because it is not possible to identify *ex ante* which products will pose safety risks, any categorical restraint on trade with these countries will inevitably discourage the importation of safe and valuable imports as well. Virtually every category of imported product can be dangerous if improperly made, which means no practical way exists to target only dangerous imports. The most salient concerns to date, for example, have been in the areas of children's toys, pharmaceuticals, and food products. But in March 2008 it was discovered that imported electronic devices may come with harmful viruses already loaded. See Jordan Robertson, *Your Next Gadget May Come with a Pre-Installed Virus*, USA TODAY, Mar. 13, 2008, available at http://www.usatoday.com/tech/news/computersecurity/2008-03-13-factory-installed-virus_N.htm. As a legal matter, it would likely violate the rules of international trade to erect barriers to imported products from China (or elsewhere) without evidence that specific products or lines of products are harmful. The erection of trade barriers also has a political dimension. If calls for increased safety become a pretext for protectionism, the gains provided by robust international trade will be undermined.

possible, production processes abroad. Although these proposals might have a salutary effect on consumer safety, they are at most partial solutions. There is no practical way to inspect more than a tiny fraction of imports, and attempts to extend regulation of production to foreign facilities run into severe jurisdictional challenges. Furthermore, success would require the commitment of significant resources above and beyond that which the government spends on domestic regulation.¹⁰

The reality of international trade requires regulatory solutions that directly reflect the fact that the production lever is unavailable when governing extraterritorial activity. To ensure optimal safety levels for imported products, policymakers must seek substitutes for direct U.S. government regulation of production and process. Part II of this article identifies three such substitutes: (1) regulation by foreign governments; (2) governance of processes by private or industry third-parties; and (3) regulation by domestic partners of foreign producers.

The first two substitutes cannot offer a solution that is complete or timely. To be sure, both can play a role in preserving the benefits of international trade while ensuring appropriate levels of safety. These two substitutes, however, will take time to become effective in countries where they are not currently operating, and the United States can play at most a minor role in that process. For this reason, we focus primarily on the third substitute for the production lever: the use of American private parties to play the role of *de facto* regulator with respect to their foreign business partners.

We make the case in Part III that where U.S. regulators expect a threat to consumer protection from foreign goods and services, they should augment the legal penalties imposed against domestic partners in international trade. These firms within the reach of U.S. law should be accountable for violations against consumers. This enhanced threat of legal liability would serve to ensure that these parties act as *de facto* regulators of the foreign activity from which they benefit, even when those activities themselves are beyond the reach of American law. Importantly, those legal measures would take the form of heightened penalties *in addition to those imposed on violations of consumer protection norms by wholly domestic activity*.

If the incentives were so adjusted, the government could motivate American firms (or other firms within the reach of the American legal system) to make the choices that the political process engages in domestically:

10. There would also be political challenges to implementing such a program of inspections. American taxpayers would bear the cost of ensuring the safety of foreign activity, while individual firms would reap the benefits of foreign production. The costs of monitoring and inspection would not be taken into account by firms making decisions about where to produce or purchase their products, and would not find their way into the price of products sold in the United States. In effect, a form of subsidy would be provided for foreign production, encouraging firms to over-invest in foreign, as opposed to domestic, production.

assessing the effectiveness of the legal, social, and economic constraints on the behavior of foreign firms, and then supplementing those forces as a necessary condition to doing business. By internalizing the costs of exercising the production lever over foreign firms with which they contract (or foreign facilities they own), private regulators have an incentive to ensure that imported goods and services meet domestic consumer-protection norms.

In the case of toys, for example, if a company like Mattel, whose products have been the target of numerous safety recalls, faces appropriate penalties for safety problems, it will include that potential cost in its business decisions and behave accordingly. Put differently, Mattel will seek the most cost effective way to address the relevant safety risks. If liability levels are set correctly (i.e., to reflect the full social cost of unsafe products), Mattel will weigh the costs and benefits of increased safety in much the same way as regulators. This may lead Mattel to oversee foreign production more actively, change the identity of the parties with whom it contracts abroad, integrate vertically to control the production process more directly, support efforts to strengthen foreign regulatory systems, or perhaps even choose to avoid foreign production entirely.

Several conclusions emerge from our argument. First, regulators must look more carefully and creatively at imposing sanctions on importers to match what they currently achieve domestically with the production lever.¹¹ Second, American importers and sellers of foreign products must face a form of strict regulatory liability; they must be held legally accountable for violations of regulatory requirements regardless of the measures they take to protect consumers, and even if they do not know that a product is unsafe. Third, a system of penalties for violations of outcome-based regulation must discriminate between domestic and foreign production by imposing larger sanctions on imported products that fail to satisfy outcome-based regulatory requirements. Fourth, because the cost of increasing safety varies by country, the incidence of harmful products may vary somewhat from one country to another even when regulation is optimally formed. Finally, although the policy we propose raises some international trade issues, and although there has been no definitive ruling from the WTO on this form of discrimination, it is likely to be judged permissible under existing international trade laws.

I

FRAMING THE REGULATORY PROBLEM

The legal protection of consumer well-being in the United States rests on

11. We have framed the discussion in terms of what American authorities ought to do. In fact, there is nothing uniquely American about our discussion or proposal beyond some of the specific examples used and statements about current law. The lessons of the article apply with equal force to any country with a well-developed system of production-based regulation applied to domestic producers.

a patchwork of regulatory tools that vary by product and service. To reduce safety and security risks, regulators use a variety of instruments, including detailed “command-and-control” regulations, mandated performance outcomes, and process requirements. Compliance is pursued through a host of inspection and enforcement regimes at various points in the production process. Additionally, tort liability both sets forward-looking performance standards, and creates incentives to limit risky behavior.

To understand the divergence in regulatory capacity between foreign and domestic goods and services, a distinction must be made between types of regulation based on when during the production process they operate. This Part, therefore, differentiates two categories of governance mechanisms: (1) regulation, inspection, and enforcement targeted at *outcomes*—whether a finished good or input is safe or whether a completed service has violated a consumer-protective norm; and (2) measures that seek to regulate, identify, and ameliorate risk while a product is being *produced*, or *before* a service is completed.

This simple taxonomy provides a functional framework for considering the realm of consumer protection in a unified manner despite its fragmentation, and points to the critical difference between the regulation of domestic goods and foreign goods. Although regulators employ the production lever domestically to ameliorate shortcomings in their governance of outcomes, the production lever is often unavailable or impractical when those shortcomings arise in the context of foreign activity.

A. The Two Levers of Domestic Consumer-Safety Regulation

1. The Outcome Lever

The most pervasive form of government involvement in the regulation of domestic goods and services uses the outcome lever. This form of regulation includes a variety of instruments, including rules requiring or prohibiting particular outcomes, inspections of finished products, *ex post* agency enforcement actions, and the imposition of penalties. The Consumer Product Safety Commission (CPSC), for example, promulgates regulations governing outcomes—such as those limiting the use of lead paint and setting standards for toys intended for young children.¹² It possesses the authority to bring civil and criminal enforcement actions against those who violate specific legal mandates;¹³ and it can impose penalties of up to \$15 million on companies that

12. See, e.g., 16 C.F.R. pt. 1303 (1978) (1978 CPSC standard banning the sale of paint containing in excess of 0.06% lead intended for consumer use, and banning toys and other articles intended for use by children that use paint with a lead content in excess of 0.06%); Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, § 101, available at <http://www.cpsc.gov/cpsia.pdf> (setting new lower lead limits).

13. See *California Company To Pay \$200,000 Civil Penalty For Importing And Selling*

fail to inform the agency when they discover unsafe toys on the market.¹⁴

After the finding of a violation or increased risk of consumer harm, outcome regulation may also require ameliorative measures. For example, the CPSC has a program designed to encourage the reporting of unsafe goods and coordinate their recall. Alternatively (or perhaps in addition), responsible parties may be forced to publicize the risk they have created, as is the case in the thirty-eight states with laws requiring notification of data breaches to affected consumers.¹⁵ The outcome lever, moreover, operates at all levels of government; various forms of food safety testing, for example, are carried out by both federal and state officials.¹⁶ And the governance of outcomes extends beyond administrative regulation: tort law, too, may impose liability for physical harms actually caused by unsafe products or behavior.¹⁷

The success of these formal legal mandates frequently rests in part on the presence of a variety of social and economic factors promoting compliance. These include the normative commitments of firms,¹⁸ advocacy of consumer-protection groups, threat of more comprehensive government regulation, operation of standards bodies, and, perhaps most importantly, reputational constraints. These forces serve to encourage compliance by domestic manufacturers with both legal mandates and voluntary standards promulgated by groups such as the American National Standards Institute and the American Society for Testing and Materials.¹⁹

For a number of reasons, however, policymakers may conclude that in a given context the outcome lever is insufficient to achieve consumer-safety

Illegal Children's Toys, FDCH REGULATORY INTELLIGENCE DATABASE; Jan. 12, 2004, available at <http://search.ebscohost.com/login.aspx?direct=true&db=buh&AN=32W0651393109&site=ehost-live>; *California Man Charged In Illegal Toy Importation Case*, FDCH REGULATORY INTELLIGENCE DATABASE; May 17, 2001, available at <http://search.ebscohost.com/login.aspx?direct=true&db=buh&AN=00220019200003802&site=ehost-live>.

14. See Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, § 217(a)(1)(B) (raising civil penalty cap to \$15 million).

15. See Scott Berinato, *Data Breach Notification Laws, State By State*, CSO, Feb. 1, 2008, available at <http://www.csoonline.com/read/020108/ammmap/ammmap.html> (providing interactive map); see generally Paul M. Schwartz & Edward J. Janger, *Notification of Data Security Breaches*, 105 MICH. L. REV. 913 (2007) (discussing laws); CASS R. SUNSTEIN, RISK AND REASON ch. 8 (2002) (discussing disclosure of information as a means of regulation).

16. See, e.g., Ron Sparks, Ala. Dep't of Agric. & Indus., Food Safety Editorial (May 6, 2007), http://agi.alabama.gov/press_releases/2007may06?pn=2 ("At the Alabama Department of Agriculture & Industries we take samples of all food products sold in Alabama and test them in our Food and Drug Lab in Montgomery in an effort to help protect consumers.").

17. See generally W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS 677-724 (5th ed. 1984) (discussing the law of products liability).

18. See EUGENE BARDACH & ROBERT A. KAGAN, GOING BY THE BOOK: THE PROBLEM OF REGULATORY UNREASONABLENESS 64-66 (1982) (arguing that most regulated enterprises are "good apples," agents for whom conformity with the law derives from "bottom-up" commitments, which legal sociologists credit for much, if not most, legal compliance).

19. See, e.g., ASTM, Standard Consumer Safety Specification for Toy Safety, http://enterprise.astm.org/REDLINE_PAGES/F963.htm (last visited July 29, 2008).

objectives. Performance outcomes may be difficult to identify in advance or to assess contemporaneously.²⁰ This is the case, for example, if the harm from a defective product is observable only after a long period of time (as with certain health effects), or the harm is diffuse and difficult to associate with specific products (as with some environmental effects). Similarly, outcome-based measures may be difficult to implement if product failures are themselves hard to observe (as with information databases that are inadequately secured).

Non-legal incentives for compliance with consumer-protective outcomes, moreover, may vary by context. The same informational difficulties that undermine the outcome lever's direct efficacy can undermine social safety norms and reputational mechanisms. Furthermore, if it is difficult for consumers or consumer groups to assign blame for unsafe products—perhaps because it is difficult to observe each step in a long supply chain—the incentive effect of these informal mechanisms is weakened. If consumers have difficulty identifying the risks posed by products, and if organization of consumer groups is difficult (perhaps because a product is used in small amounts by a large number of geographically-diverse consumers), these problems will be exacerbated.²¹

2. The Production Lever

For any of these reasons, policymakers may decide that production-based approaches—alone or in concert with outcome-based approaches—should be employed to reduce the incidence of harmful or defective products,²² or achieve a given level of consumer protection more efficiently.²³

The cases of consumer data, food, and drugs provide illustrations. As to the first, regulators have sought to govern and monitor the process by which data is handled to ensure that consumers' private information is kept secure. For example, the Federal Trade Commission's 2003 implementation of the data-protection provision of the Gramm-Leach-Bliley Act²⁴ requires financial

20. See Bamberger, *supra* note 8, at 388-91 (describing such contexts, including data privacy protection).

21. See Neil Gunningham, Robert A. Kagan & Dorothy Thornton, *Social License and Environmental Protection: Why Businesses Go Beyond Compliance*, 29 LAW & SOC. INQUIRY 307 (2004) (identifying visibility of harm and natural communities of interest as key components in social license constraints).

22. It is possible to debate the desirability of using production-based regulation either in general or in specific cases. For the purposes of this article, however, we simply take the use and effectiveness of this form of regulation as given. We do so because reviewing the full debate about the merits of production-based regulation would serve only to distract from the focus of this Article.

23. See Cary Coglianese, Reducing Risk with Management-Based Regulation, Notes on the Columbia/Wharton-Penn Roundtable on Risk Management Strategies, at 2 (2002), http://www.ideo.columbia.edu/chr/documents/meetings/roundtable/pdf/notes/coglianese_cary_note.pdf (last visited Aug. 4, 2008).

24. Pub. L. No. 106-102, 113 Stat. 1338 (1999) (codified at 15 U.S.C. §§ 6801-6827 (2000)).

institutions to develop data-security systems “appropriate to [their] size and complexity, the nature and scope of [their] activities, and the sensitivity of any customer information at issue.”²⁵ This includes periodic risk assessments, and sanctions against employees that fail to comply.²⁶

In the context of food and drugs, regulators govern and monitor the process of product manufacture extensively. The United States Department of Agriculture (USDA) and the FDA’s Hazard Analysis and Critical Control Point (HACCP) programs governing food safety compel firms to assess food-safety hazards and to identify points in the production process at which they can be eliminated, minimized, or reduced to an acceptable level.²⁷ They also establish procedures to measure and address risks at those points through corrective action.²⁸ And those same agencies have developed programs for testing and inspecting during the production process in order to ensure safe outcomes, such as the USDA’s on-site inspections of meat processing facilities,²⁹ and the FDA’s quality-control inspections of drug manufacturing plants.³⁰

Indeed, as the Department of Health and Human Services’s 2004 Task Force on Drug Importation has described, “[a] fundamental principle of drug regulation is that quality cannot be tested into a product,” but must instead be “built into the product through the manufacturing process.”³¹ Chemical testing of finished products might “verify if the active ingredient is present;” yet it is inadequate to identify the product’s purity and potency, or whether it was manufactured pursuant to best industry practices, was stored under adverse or inappropriate conditions, has expired, or is counterfeit.³²

B. Regulatory Levers in the Context of Imports

1. The Weakened Outcome Lever

However policymakers choose to regulate production, particular challenges are present when goods and services come from abroad. Consider

25. 16 C.F.R. § 314.3 (2006).

26. Paul M. Schwartz & Edward J. Janger, *Notification of Data Security Breaches*, 105 MICH. L. REV. 913, 920 (2007) (summarizing Interagency Guidelines Establishing Information Security Standards, 69 Fed. Reg. 77,610 (Dec. 28, 2004)).

27. See Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems, 61 FED. REG. 38,806 (July 25, 1996); Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, FED. REG. 60: 65,096-202 (Dec. 18, 1995); Coglianese & Lazer, *supra* note 8, at 696-98 (discussing HACCP food safety programs).

28. See *id.*

29. See Federal Meat Inspection Act, 21 U.S.C. § 604 (2000); Poultry Products Inspection Act, 21 U.S.C. § 455 (2000).

30. See 21 C.F.R. § 210.1 (2008).

31. U.S. DEP’T OF HEALTH AND HUMAN SERVS., HHS TASK FORCE ON DRUG IMPORTATION, REPORT ON PRESCRIPTION DRUG IMPORTATION 21 (Dec. 2004), available at <http://www.hhs.gov/importtaskforce/Report1220.pdf> [hereinafter HHS DRUG IMPORT REPORT].

32. *Id.*

first how these problems affect the outcome lever. When producers are located abroad, enforcement mechanisms are hindered. Extraterritorial application of U.S. safety norms by means of administrative proceedings or tort liability, for example, is significantly constrained as against foreign defendants, and may run into jurisdiction or *forum non conveniens* problems. Even when a plaintiff can obtain an American court judgment, it may be difficult or impossible to enforce.³³

To be sure, federal and state entities test products entering the United States. Yet the volume of imports, and the challenges inherent in *ex post* inspection techniques render the impact of this approach, on its own, quite limited. Approximately 9.1 million imported food shipments enter the United States annually.³⁴ But in 2006, the FDA visually inspected only 115,000 shipments, and sent 20,000 samples for laboratory analysis.³⁵ Toys—87% of which are produced overseas³⁶—currently undergo no testing at all by regulators. The compromise of consumer data takes place entirely abroad. And no technology exists to test completed drugs effectively at the border, a reality underscored by the recent incident in which nineteen patients died from contamination of Heparin, a blood thinner produced by drug manufacturer Baxter International.³⁷ While routine testing indicated that the manufactured product contained a “Heparin-like” ingredient, it did not detect the counterfeit element, which proved fatal before its recall.³⁸ Indeed, even if the means existed, the task of testing pharmaceutical imports would be, in the words of U.S. Department of Health and Human Services, “logistically impossible” and “prohibitively expensive.”³⁹

Moreover, extra-legal incentives for compliance by foreign parties may not exist or may not operate in the same way. Local safety norms may be different in foreign states, and local consumer groups may not exist or may not be concerned with exports. The producing firm may also face slight or nonexistent reputational constraints because it is several links in the supply chain—and possibly thousands of miles—away from consumers. Certainly, a brand name product may suffer negative reputational consequences when a hazardous product finds its way to the market, and even a supplier that is

33. See Donald C. Clarke, *The Enforcement of United States Court Judgments in China: A Research Note*, (Geo. Wash. Legal Studies Research Paper No. 236, 2004), available at <http://ssrn.com/abstract=943922>.

34. See Marc Kaufman, *FDA Scrutiny Scant in India, China as Drugs Pour Into U.S.*, WASH. POST, June 17, 2007, at A1, available at <http://www.washingtonpost.com/wp-dyn/content/article/2007/06/16/AR2007061601295.html>.

35. See Alexei Barrionuevo, *Food Imports Often Escape Scrutiny*, N.Y. TIMES, May 1, 2007, <http://www.nytimes.com/2007/05/01/business/01food.html>.

36. PUBLIC CITIZEN, SANTA'S SWEATSHOP: “MADE IN D.C.” WITH BAD TRADE POLICY (2007), available at <http://www.citizen.org/documents/Santas%20Sweatshop.pdf>.

37. See Harris & Bogdanich, *supra* note 3.

38. See *id.*

39. HHS DRUG IMPORT REPORT, *supra* note 31, at 21.

invisible to consumers may suffer if intermediaries or sellers recognize that the supplier's products are unsafe. Yet when supply chains stretch across countries and continents, these reputational effects are muted at best. For example, a supplier's reputation may not spread from buyers in one country to another, and purchasers may not be able to observe whether a new supplier is the same or different from an existing supplier with a poor reputation.

For all of these reasons, outcome-based regulation as currently used faces significant challenges when addressing imported products.

2. *Problems Enforcing the Production Lever*

In the domestic context, when the outcome lever proves insufficient, regulators can elect to supplement it with the production lever. With respect to imported goods and services, however, the production lever will normally operate less effectively than it does in the domestic context, and will often be entirely unavailable. Simply stated, while U.S. regulation frequently purports to subject imported goods and services to the same set of legal regulations as those produced or performed entirely within the United States, significant functional barriers obstruct the exercise of the production lever against foreign production and service provision. As a practical matter these barriers often leave only the outcome lever as a relevant tool, reducing the effectiveness of the regulation of imports.

Imported drugs and food illustrate the way in which foreign production disables the production lever. In the drug context, manufacturers in India and China supply an ever-increasing share of the U.S. drug market, particularly generic and over-the-counter medications. India exported \$800 million worth of 350 varieties of antidepressants, heart medications, antibiotics, and other drugs to the United States in 2006. This was up from just eight generic drugs a decade ago. Chinese manufacturers, in turn, sold \$675 million in drug ingredients and products in 2006, a figure that more than doubled in five years.⁴⁰ Drug industry analysts trace 20% of finished generic and over-the-counter drugs to India and China, as well as more than 40% of the active ingredients in American-made medications.⁴¹

All drug-ingredient manufacturers, whether foreign or domestic, ostensibly face the same regulatory regime. They must register drug ingredients and other information with the FDA. The FDA both approves new drugs and regulates the manufacture and distribution of brand-name and generic medicines⁴² by providing minimum good manufacturing guidelines and conducting quality-control inspections.⁴³ However, because FDA regulators do

40. See Kaufman, *supra* note 34.

41. See *id.*

42. See 21 C.F.R. § 207.20 (2008); 21 C.F.R. § 207.37 (2008).

43. See 21 C.F.R. § 210.1 (2008).

not have the authority to enter foreign factories unannounced, as they do in the United States, they must schedule inspections in advance through an American-based agent of the foreign company.⁴⁴ And, due to resource constraints, foreign inspections are dramatically less frequent than those conducted in the United States. In 2006, for example, the agency performed thirty-two quality-assurance inspections in India, fifteen in China and 1,222 in the United States.⁴⁵ Moreover, some of the inspections conducted abroad were related to the initial drug approval, rather than to manufacturing procedures, and others involved inexpensive HIV/AIDS drugs that would not be sold in the United States.⁴⁶

Similar practical constraints limit the exercise of the production lever to ensure the use of safety-enhancing processes in the foreign production of food. For example, foreign processors that ship fish or fishery products to the United States are formally required to operate in conformance with the FDA's seafood HACCP Regulations.⁴⁷ But FDA inspection trips to foreign countries simply cannot ensure worldwide compliance. The chance of any one processor being subject to administrative inspection is extremely low, and regulators change targets, and even countries, year by year. Accordingly, should an inspection take place it is virtually certain that it will be a long time before any further inspections occur.⁴⁸ With regard to manufactured goods, the CPSC lacks broad jurisdiction to test a product's safety before it reaches the market.⁴⁹

Several recent policy proposals have suggested enhancing both outcome-based inspections and the production-based component in U.S. regulation of foreign activity.⁵⁰ As to the first, increased post-production inspections could yield benefits in some important contexts, but provides at most an incomplete response. Approximately \$2 trillion of products were imported into the United States in 2006, from more than 150 countries.⁵¹ More than 825,000 importers brought shipments into the United States through more than 300 ports, border

44. See 21 C.F.R. § 207.40 (2008).

45. See Kaufman, *supra* note 34.

46. See *id.*

47. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65,096, 65,111 (Dec. 18, 1995) ("FDA must be able to verify the existence of the evidence of compliance by the foreign processor.").

48. See FDA, CFSAN/Office of Seafood, FDA's Evaluation of the Seafood HACCP Program for Fiscal Years 2002/2003 (May 13, 2005), <http://www.cfsan.fda.gov/~comm/seaeval3.html>.

49. U.S. Consumer Prod. Safety Comm'n, Frequently Asked Questions, <http://www.cpsc.gov/about/faq.html> (last visited July 30, 2008) (explaining that "CPSC doesn't have the legal authority" to "test or certify products for safety before they can be sold to consumers").

50. See Agence France-Presse, *U.S. Senator Calls for Inspection of All Imported Chinese Toys*, *INDUSTRY WEEK*, Aug. 15, 2007, <http://www.industryweek.com/ReadArticle.aspx?ArticleID=14805>; text and citations at nn. 53-57.

51. Foreign Trade Statistics, U.S. Census Bureau, available at <http://www.census.gov/foreign-trade/balance/c0015.html#2008>.

crossings, and postal facilities.⁵² Furthermore, the value of imports is increasing over time.⁵³ A system of inspections could never achieve the scale and scope necessary for the comprehensive regulation of such an enormous volume of imports.

As to the second, production-based proposals have arisen from a variety of sources. FDA Commissioner Andrew C. von Eschenbach has proposed an initiative called "FDA Without Borders," through which FDA inspectors and technical advisers would be based in China, India, the Middle East, and three other regions.⁵⁴ He also requested that the State Department approve a permanent FDA presence at the U.S. Embassy in Beijing and two American consulates in China.⁵⁵ More generally, the FDA has explored requiring inspections of foreign plants before foreign-manufactured active drug ingredients are allowed in FDA-approved prescription medication.⁵⁶ And the Interagency Working Group on Import Safety convened by President George W. Bush⁵⁷ has similarly called for an increased presence overseas in order to inspect goods before they enter the United States, and to integrate inspections of processes into the regulatory framework.⁵⁸

52. Andrew Martin, *Cabinet Study Says Safety Must Precede U.S. Border*, NEW YORK TIMES, Sept. 11, 2007, available at <http://www.nytimes.com/2007/09/11/business/11foods.html?scp=2&sq=andrew+martin+cabinet+study+&st=nyt>.

53. See *id.*

54. See *More Inspectors a Top Priority for FDA*, MQN WKLY. BULL., Mar. 14, 2008, available at <http://www.fdanews.com/newsletter/article?issueId=11400&articleId=104906>.

55. See Marc Kaufman, *FDA Says It Approved The Wrong Drug Plant*, WASH. POST, February 19, 2008, at A1.

56. *Science And Mission At Risk: FDA's Self Assessment: Hearing Of The Oversight And Investigations Subcommittee Of The House Committee On Energy And Commerce*, 110th Cong. (2008), available at http://energycommerce.house.gov/cmte_mtg/110-oi-hrg.012908.FDASelfAssessment.shtml (including statements of Catherine Woteki, former Under Secretary for Food Safety, U.S. Department of Agriculture, and Peter Barton Hutt, former Chief Counsel for the Food and Drug Administration).

57. See Import Safety, <http://www.importsafety.gov> (last visited July 30, 2008). The Working Group included the Secretaries of the Department of Health and Human Services, the Department of State, the Department of the Treasury, the Attorney General, the Secretaries of the Department of Agriculture, the Department of Commerce, the Department of Transportation, the Department of Homeland Security, the Director of the Office of Management and Budget, the United States Trade Representative, the Administrator of the Environmental Protection Agency, and the Chairman of the Consumer Product Safety Commission. The Food and Drug Administration, Customs and Border Protection, and the Food Safety and Inspection Service were active participants in the Working Group as well.

58. See INTERAGENCY WORKING GROUP ON IMPORT SAFETY, ACTION PLAN FOR IMPORT SAFETY: A ROADMAP FOR CONTINUAL IMPROVEMENT 49-57 (2007), available at <http://www.importsafety.gov/report/actionplan.pdf> [hereinafter ACTION PLAN]; INTERAGENCY WORKING GROUP ON IMPORT SAFETY, PROTECTING AMERICAN CONSUMERS EVERY STEP OF THE WAY: A STRATEGIC FRAMEWORK FOR CONTINUAL IMPROVEMENT IN IMPORT SAFETY: A REPORT TO THE PRESIDENT (2007), available at <http://www.importsafety.gov/report/report.pdf>; see also Michael O. Leavitt, Sec'y, Dep't of Health & Human Servs., Developing a Comprehensive Response to Food Safety, Testimony Before the Committee on Health, Education, Labor and Pensions, U.S. Senate (Dec. 4, 2007), available at http://help.senate.gov/Hearings/2007_12_04/Leavitt.pdf.

One problem with such proposals is the sheer size that a program of extraterritorial inspections and regulations would have to achieve to be effective. The resources required to achieve an important presence in all the places from which the United States imports products and services are simply not available.⁵⁹ Even if the United States were to focus only on China, an effective regulatory team in that country would need a much larger staff than would be required for similar tasks here in the United States. This is so both because China is much larger than the United States, and because its political, social, and economic context is different. There is, moreover, reason to believe that American inspectors and officials operating in China would be less effective than those operating domestically simply because they would lack the language and cultural skills to navigate Chinese society and to understand local business practices.⁶⁰ This phenomenon is evidenced in the case of the 2008 deaths arising from Heparin blood thinner, in which FDA inspectors thought they had inspected the Chinese plant that manufactured the fatal contaminant, but later learned that they had been taken to a different pharmaceutical plant with a similar name.⁶¹

The high cost of this regulatory approach would be borne by American taxpayers, and would not be reflected in product prices. When decisions are made about where to produce or source goods and services, this cost will be ignored, creating a distortion in such decisions. That distortion would be economically inefficient and costly to the United States.

A related problem with this form of direct extraterritorial regulation is that American authorities operating overseas must generally do so without any formal legal authority granted by the local jurisdiction. Thus, they are unable to demand anything from the firms they are inspecting, including, for example, access, information, and responses to questions. It is true that the United States could attempt to condition access to U.S. markets on cooperation with inspectors, but doing so would require detailed knowledge of supply chains. Without this knowledge, the government cannot ensure that the output from

59. See, e.g., Susan Heavey, *U.S. Mulls Private Drug Checks Despite Device Lessons*, REUTERS (June 12, 2008), available at <http://www.signonsandiego.com/news/business/20080612-0943-fda-inspections.html> (quoting Janet Woodcock, head of the FDA's Center for Drug Evaluation and Research: "It's very difficult to see how we could actually cover the entire globe.").

60. See, e.g., Janet Woodcock, Deputy Comm'r for Scientific and Med. Programs, Chief Med. Officer and Acting Director of FDA's Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Statement Before the House Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Subcommittee (Feb. 27, 2008), http://www.fda.gov/ola/2008/drugsafety_budget022708.html (describing the "fundamental challenges of many different languages and protocols" arising from "the globalization of the supply chain [to include] an ever-growing number of brokers, traders, distributors, repackagers, and other players involved in the import of pharmaceuticals").

61. Kaufman, *supra* note 55 ("The Chinese facility that supplies the active ingredient of the widely used blood thinner heparin was never inspected . . . because the [FDA] confused its name with another just like it, agency officials said yesterday.").

production facilities refusing to cooperate is not presented as the output of an approved facility.

Furthermore, even if American authorities were to discover a violation of a production standard abroad, they often would have difficulty enforcing any relevant sanction. To begin with, if a would-be violation concerns products that have not yet entered the United States, there may not have been any violation of American legal requirements, even if as a practical matter the products were destined for the United States. Because these are American authorities investigating the issue, there need not have been any violation of local law, and if a violation exists, local authorities may not wish to pursue the matter.⁶²

All of these problems with the enforcement of the production lever reduce the incentive that firms have to comply with U.S. standards. The lower the expected sanction for conduct inconsistent with American requirements, the less reason they have to adjust their behavior.

II

HOW TO REGULATE THE SAFETY OF IMPORTS: THREE SUBSTITUTES FOR THE PRODUCTION LEVER

The discussion in the prior section demonstrates that the regulation of domestic safety presents a challenge. While the outcome lever remains an important part of the regulatory system, it is insufficient to achieve American safety objectives and, in any event, is weaker in the context of imports than in the context of domestic production. The production lever, used domestically to address the shortcomings of the outcome lever in the domestic context, is severely disabled when it comes to foreign production. How, then, should the United States go about providing for consumer safety in the context of imports? The answer to this question is developed in this section. After a brief discussion of some assumptions, we consider three regulatory substitutes for the production lever. These substitutes are provided by three different groups of actors and we examine each in turn. The first, and most obvious, are foreign governments. The second are third-parties, including self-regulatory institutions, able to credibly certify goods and services. The final substitute, and the one that is developed in this Article, can be provided by the American participants in cross-border transactions.

Before proceeding, however, it is helpful to be explicit about an important (if inconvenient) feature of the regulation of safety. Though one would always prefer more rather than less safety, regulators do not have the luxury of demanding a perfect record of product safety from any producer. Unsafe

62. Of course, foreign producers sometimes have sufficient presence in the United States to satisfy relevant subject matter and personal jurisdictional requirements. Where that is the case, some use of the production lever may still be possible. However, the other challenges with regulating foreign production remain.

products are an inevitable part of production. More precisely, the marginal cost of increasing the safety of products will normally increase with the level of safety. At some point it ceases to be efficient to devote additional resources, whether private or public, to further increases in safety. For example, any system of food production, from time to time, will generate impure and unhealthy food. Regulators can improve the safety of food in many ways, and no matter how much effort goes into safety, still further effort is likely to produce safer food. But at a certain point the improvements are small and expensive, and a judgment must be made about whether to expend scarce resources in this way. To isolate the ways in which the existing regulation of imports deviates from the optimal tradeoff, it is assumed in this Article that existing regulation is, indeed, optimal for domestic production. This is a simplifying assumption that is not necessary for our results, but that clarifies the presentation.⁶³

Assuming, then, that regulation is chosen because it suits the needs of domestic regulation, it follows that imports are under-regulated and should exhibit a higher incidence of unsafe products.

This reduction in safety can be avoided if there exists an appropriate substitute for the disabled production lever. We consider three possible substitutes: (1) product-based regulation by foreign governments; (2) third-party regulation by relevant industry groups or certifying organizations; and (3) regulation by domestic private actors engaged in outsourcing, motivated by outcome-based regulation. The first two approaches are familiar and will be described briefly. The third approach offers a strategy for dealing with the more difficult cases of regulating foreign production such as health concerns with respect to production. We examine this approach in depth, considering both its promise and challenges, in Part III.

A. Regulation by Foreign Governments

1. The Potential of Relying on Foreign Governments

As applied by American regulators, the production lever often fails to reach imports because production takes place abroad. This suggests that the most obvious substitute for that lever is regulation of production by the relevant

63. We do not make this assumption because we believe it to be true. Each of us has views on how existing regulatory approaches could be improved. See Bamberger, *supra* note 8; Andrew T. Guzman, *Is International Antitrust Possible?*, 73 N.Y.U. L. REV. 1501 (1998); see also Kenneth A. Bamberger, *Global Terror, Private Infrastructure, and Domestic Governance*, in 2 THE IMPACT OF GLOBALIZATION ON THE UNITED STATES: LAW AND GOVERNANCE (Beverly Crawford, et al., eds.), (forthcoming 2008); Stephen Choi & Andrew T. Guzman, *Portable Reciprocity: Rethinking the International Reach of Securities Regulation*, 71 S. CAL. L. REV. 903 (1998). Rather, we make this assumption because it allows us to emphasize the ways in which imports differ from domestic production.

foreign government. As long as the regulatory objectives in the United States and the foreign state in question are compatible, and as long as the regulation in the foreign state is effective in a way that is comparable to that of the United States, the foreign government's efforts might stand in for American regulation without difficulty.

U.S. regulators expressly use this approach in the context of food imports. Imported meat, poultry, and egg products, for example, may originate only in countries that the U.S. Department of Agriculture deems eligible, and only from establishments certified by the foreign government.⁶⁴

Congress has authorized this regulatory method in the pharmaceutical context, although it has not been adopted administratively. Specifically, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.⁶⁵ The Act creates a prescription drug benefit for seniors and people with disabilities. It authorizes the Secretary of Health and Human Services (HHS) to promulgate regulations allowing importation of prescription drugs from Canada, so long as the Secretary certifies to Congress that implementation will "pose no additional risk to the public's health and safety; and result in significant reduction in the cost of covered products to the American consumer."⁶⁶ Such authority creates an exception from the mandates of the "closed" system established by the Federal Food, Drug, and Cosmetic Act, which provides that the FDA must regulate the manufacture, marketing, and labeling of all drugs sold in the United States. While comments received by the HHS Task Force suggested that the importation of drugs be permitted from countries that "have a regulatory system equivalent to the U.S.,"⁶⁷ that group ultimately concluded that "[f]oreign governments have little incentive and limited resources to ensure the safety of drugs exported from their countries, particularly when those drugs are transshipped or are not intended for import."⁶⁸ It further noted that "[n]o country expressed any interest or willingness to ensure the safety and effectiveness of drugs exported from their country in any expansion of legal U.S. importation."⁶⁹ The Secretary has accordingly not acted on this authorization, instead taking action to stop the importation of drugs whose manufacture it does not regulate directly.⁷⁰

64. Once eligibility is established, however, the Animal and Plant Health Inspection Service's restrictions determine the specific types of products that can be imported from the country. *See generally* USDA Food Safety and Inspection Service, Foreign Countries and Plants Certified to Export Meat and Poultry to the United States, http://www.fsis.usda.gov/Regulations_&Policies/Eligible_Foreign_Establishments/index.asp (last visited Aug. 4, 2008).

65. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 177 Stat. 2066.

66. *Id.* at § 1121(l)(1)(A), (B), 177 Stat. at 2468.

67. HHS DRUG IMPORT REPORT, *supra* note 31, at 10.

68. *Id.* at XI.

69. *Id.*

70. *See, e.g.,* United States v. Rx Depot, Inc., 290 F. Supp. 2d 1238 (N.D. Okla. 2003) (supporting FDA finding that storefront pharmacy was illegally importing drugs from Canada);

Finally, the European Union has adopted a strategy of relying on regulation by foreign governments for the protection of consumer privacy. Specifically, subject to certain exceptions, its Privacy Directive⁷¹ permits the transfer of personal data to parties in non-European Union nations only if those countries' privacy-protection regimes are considered "adequate."⁷²

U.S. regulators have also pursued preliminary measures along these lines. In 2007, senior HHS officials met with senior Chinese officials and developed two agreements, one on food and feed,⁷³ and the other on drugs and medical devices.⁷⁴ Both agreements focused on registration, certification, and verified compliance. Through the food-and-feed agreement, China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) agreed to provide the FDA access to records from inspections conducted by Chinese regulators and give it a list of manufacturers who do not meet Chinese standards.⁷⁵ In addition, the AQSIQ agreed to notify the FDA within twenty-four hours whenever it determines that a product exported to the United States could cause serious adverse health consequences.⁷⁶ Through the drugs-and-medical-devices agreement, the two countries agreed on a framework for information sharing and regulatory cooperation.⁷⁷ CPSC officials also negotiated a Memorandum of Understanding (MOU) with the Chinese government, covering certain targeted products including children's toys, clothing, fireworks, and cigarette lighters.⁷⁸

Vermont v. Leavitt, 405 F. Supp. 2d 466 (D. Vt. 2005) (prohibiting state from importing drugs from Canada).

71. Parliament Directive 95/26, On The Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 I.J. (281) 31 (EC), available at http://ec.europa.eu/justice_home/fsj/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf.

72. See *id.* at art. 254.

73. Agreement Between the Department of Health and Human Services of the United States of America and the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China on the Safety of Food and Feed [hereinafter Agreement on Food and Feed], available at <http://www.globalhealth.gov/news/agreements/ia121107a.html>.

74. Agreement Between the Department of Health and Human Services of the United States of America and the State Food and Drug Administration of the People's Republic of China on the Safety of Drugs and Medical Devices [hereinafter Agreement on Drugs and Medical Devices], available at <http://www.globalhealth.gov/news/agreements/ia121107a.html> (last visited Aug. 5, 2008).

75. Agreement on Food and Feed, *supra* note 74, at Annex § II.B.4-5; see also *U.S. Gains Access to Chinese SFDA Inspection Information*, INTERNATIONAL PHARMACEUTICAL REGULATORY MONITOR, Jan. 15, 2008.

76. Agreement on Food and Feed, *supra* note 74, at Art. IV.3.

77. Agreement on Drugs and Medical Devices, *supra* note 74.

78. Memorandum of Understanding between the U.S. Consumer Prod. Safety Comm'n and the General Admin. of Quality Supervision, Inspection and Quarantine of the People's Republic of China, available at <http://www.cpsc.gov/CPSCPUB/PREREL/prhtml04/04124mou.html>. Paradoxically, some have noted that the certification regime detailed in the MOU may actually lead to a reduction in border inspections of Chinese products, a measure that the United States has declined to implement with regard to imports from Canada and Mexico. While the proposed

2. *The Limits of Relying on Foreign Governments*

While the enlistment of foreign government substitutes for domestic consumer protection offers promise in particular areas and with regard to specific jurisdictions, there are obvious limits to this approach.

As an initial matter, differing domestic political contexts suggest that there will often be at least some differences between the regulatory priorities and goals of different states. Even close allies of the United States with broadly similar concerns and objectives will adopt regulatory standards different from ours, or will enforce them differently. For example, the HHS Task Force Report on drug imports, in rejecting the import of drugs whose manufacture the FDA did not oversee, expressed concerns that Japanese law would permit the import of expired medical products, re-packaging them as “new,” and exporting them to other countries—activities that would be illegal under U.S. law.⁷⁹

More troubling is that, as a practical matter, many foreign states will employ regulatory standards that are significantly less stringent than those of the United States, or have systems that are inept, corrupt, or even non-existent, and therefore cannot operate as adequate regulatory substitutes. To date, this is largely the regulatory situation with respect to production in China, the world’s largest exporter of manufactured goods.⁸⁰ As foreign regulatory regimes deviate from the American system, the resulting tradeoff between cost and safety moves away from that which is preferred by the U.S. political system, a particular problem where differences are difficult for consumers to observe.

While some long-term strategies of negotiation and harmonization might serve to reduce the differences among jurisdictions, the existence of foreign states with regimes that diverge radically from U.S. norms will remain a practical reality for many years to come. Even under a hopelessly optimistic view, and even assuming a major effort by the United States, Europe, and others with the complete cooperation and support of the Chinese government, it would still be decades before China can engage in systematic regulatory oversight that approaches the standards to which Western states are accustomed. Until such a system is in place, some other substitute for the production regulation used in the United States is necessary. Moreover, while China is the focus of these concerns at the moment, it is not the only country with a weak regulatory system that is exporting to the United States. Many

certification program is limited to certain enumerated product categories, and neither party would be obligated to make decisions on imports based on certifications, the MOU leaves open the possibility that U.S. inspectors could waive inspections on the basis of certifications. *See U.S.-China Food Safety Deal Could Give China Preferential Treatment*, INSIDE US-CHINA TRADE, Dec. 19, 2007.

79. HHS DRUG IMPORT REPORT, *supra* note 31, at 21.

80. *See* Richard McCormack, *China Replaces U.S. As World’s Largest Exporter: Trade Imbalances Could Cause Financial Upheaval; MAPI Analyst Implores U.S., IMF To Act Now On China’s Yuan*, MANUFACTURING & TECH. NEWS, Sept. 5, 2006, available at <http://www.manufacturingnews.com/news/06/0905/art1.html>.

other countries, including many developing countries, are similarly unlikely to provide domestic regulatory oversight sufficient to substitute for the American system.

Moreover, there is reason to believe that regulatory divergence will continue into the long term. Indeed, competition among jurisdictions for business makes it extremely unlikely that regulation by foreign governments will ever become more than a context-specific substitute for domestic government regulation. To illustrate the competitive effect of foreign regulatory substitutes, consider the following example: both India and the United States represent potential locations for provision of business process services. Although there are other factors that affect a firm's decision where to locate production, one factor may be the regulatory environment. It follows that states will be tempted to reduce the regulatory burden on firms in an effort to attract them to the local jurisdiction, which may explain why India has resisted enacting meaningful legal protections for the privacy of personal information, despite the fact that its business process market controls 44% of global outsourcing and back-office services.⁸¹ Whether one views this competition positively depends in part on one's assumptions about the political economy of regulation. Some think that competition is good because it causes regulators to fully account for the burden of regulation on firms. Others view this competition as harmful and threatening to quality and safety.

Whatever one's view, the combination of trade and competition can be hazardous. To see this most clearly, imagine an extreme example in which activity takes place in India, but all of its effects are felt by U.S. consumers. Because India bears none of the costs of lax regulations, but gains from the presence of producers, it has an incentive to weaken its regulations. When a product or service is "consumed" outside of a jurisdiction, that jurisdiction has different objectives with respect to its quality or safety.⁸²

Regulation by a foreign jurisdiction, then, can be expected to develop into a good regulatory substitute for domestic regulation under certain circumstances: when either (1) only a small share of production is exported and the rest is consumed internally, or (2) regulatory standards are sustained by trade reciprocity in which each jurisdiction realizes that if it fails to adequately regulate local production of goods and services intended for export, other jurisdictions will do the same. Reciprocity alters the choice set of each state by making each state choose between mutual cooperation (full regulation) and

81. See *India Controls 44 Percent of Outsourcing*, FORBES.COM, June 12, 2005, <http://www.politico.com/politics/indiacontrols44ofoutsourcing.pdf> (reporting that the main infotech trade body said that revenues for Indian companies reached \$17.2 billion in U.S. currency in the year that ended in March 2005).

82. For a similar argument in the context of antitrust and the regulation of competition policy, see Guzman, *supra* note 63.

mutual non-cooperation (reduced regulation for exported products).⁸³ Where neither of these situations exists, however, overcoming the distortions caused by trade flows will often require sustained effort—perhaps in the form of a formal agreement—to address the strategic interests of the states.⁸⁴

B. Third-Party and Self-Regulation

1. The Potential of Third-Party and Self-Regulation

A second possible substitute for production regulation relies on private parties to regulate and certify the safety and reliability of products and services. This alternative is widely used and takes a variety of forms. More than 2,700 municipal, city, and state governments within the United States mandate private safety certifications for certain types of products sold or installed within their jurisdictions.⁸⁵ The bulk of such certifications is provided by Underwriters Laboratories, a private firm founded over a century ago, that through its sixty-two laboratory, testing, and certification facilities serving customers in ninety-nine countries, places over twenty-one billion certification “marks” on 72,000 manufacturers’ products each year.⁸⁶

In other contexts, regulators rely on self- or industry-group certifications. While the United States itself fails to meet the adequacy standard required by the European Privacy Directive for extraterritorial transfer of European consumer data discussed above, for example, the European Union and the United States have negotiated a Safe Harbor agreement, administered by the U.S. Department of Commerce, by which particular companies can self-certify annually that they meet the adequacy standard individually.⁸⁷

Consistent with this notion of third-party oversight as a substitute for

83. See ANDREW T. GUZMAN, *HOW INTERNATIONAL LAW WORKS: A RATIONAL CHOICE THEORY* 42-45 (2008) (discussing and analyzing reciprocity in international law).

84. The process of determining which foreign regulatory systems should be accepted as substitutes raises a host of further issues, many of which are outside the scope of this Article. Inevitably this decision will be influenced by political concerns as well as the nature of the foreign system. Even where the system is not politically driven, one would want to consider who makes the decision, what sort of review is available to a producing state that feels its regulatory system should be considered adequate, whether there should simply be a binary determination (under which a foreign system is either adequate or inadequate), or a system with several categories (where systems are graded to reflect their adequacy as a substitute and the result affects how the United States treats imported products), and so on. For present purposes it is enough to point out that identifying jurisdictions whose regulatory system is accepted as a substitute has high stakes for American producers, foreign producers, importers, and foreign states. The same is true for the establishment of a metric with which to evaluate foreign regulatory practices. These facts make the process of approving a foreign regulatory system complicated and difficult.

85. See Harold Furchtgott-Roth et al., *The Law and Economics of Regulating Ratings Firms*, 3 J. COMPETITION L. & ECON. 49, 88 (2006).

86. See Underwriters Laboratories, <http://www.ul.com/about/> (last visited July 30, 2008).

87. See Export.gov, *Welcome to the Safe Harbor*, <http://www.export.gov/safeharbor/> (last visited July 30, 2008).

government production regulation, industry and standards-setting groups have begun to organize in an attempt to promote robust consumer protection when goods or services are imported.⁸⁸ Some U.S. retailers rely on GlobalGap, a private standards-setting organization organized by European food retailers, which certifies compliance of over 81,000 farms and plants in seventy-six countries with food industry safety guidelines.⁸⁹ U.S. drug importers have contracted with the nonprofit drug-quality standards-setting group U.S. Pharmacopoeia, whose offices in Hyderabad, India and Shanghai, China offer services that monitor products and processes in those two countries.⁹⁰ In 2007, the National Association of Software and Services Companies (NASSCOM), the non-profit group established by the Indian software and business process outsourcing industry,⁹¹ established the Data Security Council of India (DSCI) after unsuccessful attempts at lobbying the Indian legislature to enact formal data protection legislation.⁹² The DSCI is a self-regulatory initiative to develop standards and certification processes, enforced by disaccreditation and penalties, that ensure compliance with U.S. and European data privacy and security practices.⁹³

Several current consumer protection proposals also recognize the promise of private third-party regulation. The Interagency Working Group on Import Safety's September 2007 *Action Plan for Import Safety* included in its proposals the verification of compliance by foreign producers with U.S. safety standards through voluntary and mandatory certification requirements, the development of "good importer practices" through public-private partnerships, and the accreditation by third-party inspectors of products outside the United States for compliance with FDA standards.⁹⁴ These measures would be

88. See generally Margaret M. Blair et al., *The New Role for Assurance Services in Global Commerce*, 33 J. CORP. L. 325 (2008) (discussing the emergence of a private-sector compliance and enforcement infrastructure in global commerce).

89. See GLOBALG.A.P., <http://www.globalgap.org>; see also John W. Miller, *Private Food Standards Gain Favor: Wal-Mart, McDonald's Adopt European Safety Guidelines*, WALL ST. J., Mar. 11, 2008, at B1 (last visited Oct. 13, 2008).

90. See News Release, U.S. Pharmacopoeia-India Site Inaugurated at ICICI Knowledge Park, Hyderabad (Feb. 8, 2006), available at <http://www.usp.org/aboutUSP/media> (follow "News releases" hyperlink; search "Site Inaugurated" in "Headline"); News Release, U.S. Pharmacopoeia Inaugurates New Facility in Shanghai (Sept. 6, 2007), available at www.usp.org/aboutUSP/media (follow "News releases" hyperlink; search "Inaugurates New Facility in Shanghai" in "Headline").

91. See NASSCOM, About NASSCOM, <http://www.nasscom.in/Nasscom/templates/NormalPage.aspx?id=5365> (last visited July 30, 2008) (discussing trade organization).

92. See NASSCOM, Data Security Council of India (DSCI): A Self Regulatory Initiative in Data Security and Privacy Protection, <http://www.nasscom.in/Nasscom/templates/NormalPage.aspx?id=51973> (last visited July 30, 2008).

93. See *id.*; Moumita Bakshi Chatterjee, *Nasscom Working on Data Security Council*, BUSINESS LINE, June 11, 2007, available at <http://www.thehindubusinessline.com/2007/06/11/stories/2007061101150200.htm> (discussing standards, auditing, and certification proposal).

94. See ACTION PLAN, *supra* note 58, at 15-26.

promoted, in part, by access to expedited import privileges for those who meet the certification requirements. The Consumer Product Safety Improvement Act of 2008, signed into law on August 14, 2008, requires safety certification of children's products by accredited third-party assessment organizations.⁹⁵

2. *The Limits of Third-Party and Self-Regulation*

Like foreign law, third-party oversight offers promise as an effective substitute for domestic regulation. Like foreign law, too, however, its role is often circumscribed. Self-regulatory systems do not normally arise on their own and overnight. The rapid emergence of China as a major exporter of goods and services, for example, has not generated a simultaneous emergence of comprehensive self-regulatory mechanisms to govern production processes.

Indeed, many sector- or country-based private standards movements are in the early stages of development, and their compliance mechanisms have neither been fully tested nor developed. The reputation and credibility that self-regulatory systems require to function are difficult to generate from scratch. Moreover, such "self-regulatory" apparatuses have historically proven most successful when there is a credible threat of government regulation to provide industry groups with an incentive to act.⁹⁶ This government pressure is missing in many of the very contexts involving extraterritorial activity with U.S. consumer protection implications. Each of these factors limits their promise as a comprehensive solution, especially in the short-term.

C. Regulation by U.S. Participants in Globalized Trade

While both regulation by a foreign government and self-regulation can sometimes provide satisfactory substitutes for the regulatory tools that fail to adequately reach foreign production, those substitutes will often prove inadequate. There remain, therefore, important categories of imports for which American authorities must find some additional way to respond. In Part III, we propose that for this specific set of imports (where neither regulation by foreign governments nor self-regulation are sufficient) domestic regulatory authorities engage a third substitute. More precisely, we suggest that they establish a set of obligations that turns private parties within the reach of the American legal system into better *de facto* regulators of the foreign activities from which they benefit.

U.S. regulators have already sought, in a small number of instances, to rely on parties with a presence in the United States to ensure that foreign

95. Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, § 102, available at <http://www.cpsc.gov/cpsia.pdf>.

96. See generally Guy Halfteck, *Legislative Threats*, 61 STAN. L. REV. (forthcoming 2008), available at <http://ssrn.com/abstract=1113173> (discussing the phenomenon of "non-use of legislative power" in return for firms' commitment to change their conduct).

partners comply with safety norms required under relevant production-based regulations. For example, the FDA relies on American drug makers to test ingredients they purchase abroad.⁹⁷ Importers of foreign fish and fishery products are obligated to take “affirmative steps” to determine whether their foreign suppliers are complying with U.S. HACCP requirements.⁹⁸ And the Guidance implementing Gramm-Leach-Bliley’s data protection provisions requires that U.S. financial institutions exercise “appropriate due diligence in the selection of service providers,” including a review of the measures taken by a service provider to protect customer information, a contract with each of its service providers that requires each provider to implement appropriate measures designed to meet data privacy objectives, and to exercise “an appropriate level of oversight over each of its service providers to confirm that the service provider is implementing the provider’s security measures.”⁹⁹

These attempts have proven incomplete because of more general barriers—discussed earlier—related to the monitoring and enforcement of foreign compliance with American production regulation. U.S. partners have, in general, performed poorly as “regulators” of foreign activities. They have failed, among other things, to expend the resources necessary to properly monitor foreign supply chains.¹⁰⁰ For example, in the face of competitive pressures, the older practice of batch-testing products at foreign suppliers’ factories is giving way to the practice of “outsourc[ing] periodic product tests to the suppliers themselves, thereby opening the door to poorer quality controls.”¹⁰¹

U.S. food and drug companies sometimes do not know the identity of some of their suppliers, let alone participate in comprehensive monitoring and oversight.¹⁰² This was the case in the recent recall of fresh ginger packaged and distributed under the name of a large California firm. It turned out that the ginger, tainted with the banned pesticide aldicarb sulfoxide, was of unknown origin.¹⁰³ Similarly, American pharmaceutical company Baxter was ignorant of the source of the fatal Chinese-produced ingredient it incorporated in its blood-

97. See *Kaufman*, *supra* note 34 (“FDA officials say that they are not aware of any health problems caused by drugs imported from India or China and that the American companies that import them usually do their own quality and safety testing.”).

98. 21 C.F.R. 123.12(a)(2)(ii) (2008).

99. *Interagency Guidelines Establishing Standards for Safeguarding Customer Information*, 66 Fed. Reg. 8616, 8624 (Feb. 1, 2001) (to be codified at 12 C.F.R. pt. 30).

100. DELOITTE CONSULTING, *SUPPLY CHAIN’S LAST STRAW: A VICIOUS CYCLE OF RISK 3* (2007), available at http://www.deloitte.com/dtt/cda/doc/content/us_consulting_suppchain_wp_090107.pdf.

101. Parija B. Kavilanz, *Blame U.S. Companies for Bad Chinese Goods*, CNNMONEY.COM, Aug. 14, 2007; see also Zamiska & Kesmodel, *supra* note 5 (documenting California firm’s failure to identify, let alone monitor, the supply chain that produced Chinese tainted ginger).

102. See U.S. DEP’T OF AGRIC., OFFICE OF FOOD SAFETY & TECHNICAL SERV., *FOOD AND AGRICULTURAL IMPORT REGULATIONS AND STANDARDS REPORT (FAIRS)* (1999) available at <http://www.fas.usda.gov/itp/ofsts/us.html>.

103. See Zamiska & Kesmodel, *supra* note 5.

thinning Heparin drug.¹⁰⁴ In the data protection context, firms' implementation of affirmative steps to oversee foreign partners has proven similarly spotty. Recent surveys indicate that, although a substantial number of firms handling medical or financial data have suffered a breach at the hands of a business process vendor, fewer than half assess privacy practices when selecting a vendor, or monitor vendor performance on privacy practices.¹⁰⁵

In sum, existing means have failed to take advantage of the potential that private parties with a U.S. presence offer as regulatory substitutes to discourage products or practices that threaten consumer safety. As we argue below, however, given the constraints on the ability of U.S. policymakers to enlist quickly and effectively the capacity of other substitute regulators—such as foreign governments and third-parties—this substitute should be explored more vigorously.

III

THE REGULATORY PROPOSAL: U.S. IMPORTERS AS *DE FACTO* REGULATORS

The remainder of our analysis explains how it is possible to establish more appropriate incentives for private parties within the reach of the American regulatory system. When imports escape regulatory obligations that domestic production must satisfy, or avoid extra-legal pressures to increase safety, foreign producers will produce less safe products, all else equal. In other words, they will be able to compete on the level of consumer protection accorded by their behavior, rather than on its cost. We argue, therefore, that where existing regulatory structures fail to ensure satisfactory consumer-protection levels for imported goods and outsourced data, U.S. partners in international trade should be subject to *additional* outcome-based regulatory penalties for safety and other consumer protection violations beyond those imposed on those who engage in purely domestic activity.¹⁰⁶

Such a system of discriminatory penalties should be structured to ensure that U.S. partners in international trade to internalize the full cost of harmful products. This, in turn, will motivate them to monitor the production process and outputs of their trading partners to ensure that those partners pay proper attention to safety issues. These private parties become *de facto* regulators, pursuing the same objectives as domestic regulators would, while influencing foreign activities in ways that domestic regulators cannot.

104. See Harris & Bogdanich, *supra* note 3.

105. See GAO *Privacy Outsourcing Report*, *supra* note 6, at 18; Ponemon, *Privacy Survey*, *supra* note 6 (While 56% of respondents experienced data loss or theft, only 55% of respondents say they evaluate the outsourcer's data protection practices before engaging them or transferring information).

106. Importantly, we do not here advocate changes to substantive safety requirements. Our focus instead is on the penalties assessed when stated requirements are not met.

*A. The Case for Discriminatory Penalties**1. Why Discriminate?**a. The Residual Power of U.S. Regulation*

As described previously, regulators seeking to protect U.S. consumers from harms associated with foreign goods and services face significant obstacles. They frequently have little power over extraterritorial actors; they possess little capacity to regulate, monitor, or even gain information regarding production or process; substitutes for improving processes involved in providing goods and services are often weak; and changing the level of consumer protection laws would skew substantive choices governing domestic activity.

Domestic regulators, however, do retain important regulatory tools. First, even when regulators cannot exercise power over foreign parties, the activity of concern almost always involves some entity in the role of importer, outsourcer, distributor, or seller within the reach of American legal authorities. These parties may not be those most culpable for consumer harm, and may not be optimally situated to promote safety. Yet they are the ones on whom the American system can credibly impose regulatory obligations and penalties, and are involved in the stream of commerce at some point prior to the final purchase by the consumer.

Second, regulators possess the capacity to observe, regulate, and punish outcomes in the form of services or finished products that threaten or cause harm in the United States.

Third, they retain control over rules governing liability for violations of outcome restrictions, and—perhaps most importantly—over associated penalties.

b. Our Proposal

Our proposal operates within these confines. Unlike the regulation of domestic processes, regulation of partially-foreign activity often limits the regulatory options to the use of the outcome lever against domestic market players. Accordingly, regulators should seek to equalize regulatory outcomes subject to this constraint. In other words, they should use liability standards and penalties directed against American parties (or at least parties within reach of the U.S. legal system) to achieve appropriate levels of safety.

Specifically, in certain circumstances the United States should impose strict regulatory obligations on importers and sellers without regard to what they know, should have known, or even could have known about the process of production and service provision. Moreover, ensuring that U.S. consumer protection standards are achieved will at times require higher penalties for

harmful products or services made or provided abroad than for those arising from wholly domestic activity.

To see why this is so, recall that a key goal of regulation is to establish sufficient incentives at each stage of the chain of production to realize optimal levels of consumer safety. The optimal level of safety is the level of safety that would be chosen by a producer or consumer who internalizes the full costs and benefits of a product. When imports escape (or are less fully subject to) regulatory obligations that domestic producers must satisfy, or when they avoid extra-legal pressures to increase safety, foreign producers do not internalize the cost of harmful products as fully as their American counterparts. Foreign producers, then, have weaker incentives to produce safe products.

At root, our proposal is a fairly straightforward result of the existing literature on tort law, combined with the recognition that imported products often must be regulated entirely through the outcome lever. In the tort context, for example, the imposition of strict liability forces actors to internalize the full cost of defective or harmful products. Penalties, moreover, should be set at the level necessary to ensure that the costs of harmful behavior are internalized by relevant actors. Those actors then have an incentive to take action to reduce this risk up to the point where the cost of further reductions exceeds the benefit of reduced liability.

The same strategy of strict liability is proposed here, although in the context of outcome-based sanctions. Those participants in the stream of commerce that are within the reach of American authorities and that bring imported products to market should be subject to penalties for regulatory noncompliance regardless of the level of care they take, or their actual knowledge about product safety.¹⁰⁷ The associated penalties, moreover, should be set at levels that force actors within the reach of domestic authorities to internalize the full social costs of increased risks to consumer welfare. Specifically, penalties should make up for the discount provided by engaging in more harmful behavior while escaping the domestic costs of safety they would otherwise face under domestic regulation.

Accordingly, any distinction between domestic and imported products is more "corrective" than "discriminatory." In current practice, production-based regulation already affects domestic production more than foreign production. Our emphasis on outcome-based regulation for imports is intended to offset discrimination already in place under the domestic production-based regulation model.¹⁰⁸

107. More precisely, only those participants within the reach of American authority and operating in a context where other substitutes for the production lever are insufficient should be subject to such liability.

108. One could also eliminate production-based liability for domestic producers, but because we assume that this liability is efficient in achieving governmental objectives, eliminating it would also present significant costs.

c. The Proposal's Goals

In this way, the system would encourage importers and sellers to become *de facto* regulators. The potential of liability for products that fail to meet outcome requirements represents a cost. Importers and sellers may not have direct control over this cost, and, indeed, they may not even have knowledge of the relevant risks or production methods. The threat of liability, however, will provide these parties with the incentive to achieve some level of control over the quality of the product, or to find a way to shift liability to parties that do have such control. Thus, even if importers and sellers themselves do not know the quality of individual imported products, the liability scheme will encourage them to take action to ensure that the quality is of a sufficiently high level to protect them from undue costs.

For importers or sellers to manage their exposure to liability, they must therefore estimate the risk of liability with respect to a particular product and adjust their behavior to reflect that potential cost. This can be achieved in any number of ways. A firm could, for example, acquire the producer, allowing it to manage quality issues directly. Or it could enter into a joint venture with the producer, ensuring that it could manage and monitor quality. Other options include inspecting imports before they reach the American market, seeking producers from jurisdictions that ensure high quality products through regulation of their own, or even contractual specifications to increase the quality and safety of the product. It could also take actions that resemble production-based regulation as practiced by governments; it might require on-site inspections, specify the inputs to be used and where they are to come from, demand that the producer adopt better internal practices and procedures to reduce the risk of a hazardous product being produced, and so on. The importer or seller could demand that such contractual obligations be enforceable, either through local courts in the country of the producer—if those are thought to be reliable and unbiased—or through arbitration.

One way or another importers and sellers can generate enforcement through contractual mechanisms (including the choice of whom they contract with) that may be impossible for domestic regulatory authorities to achieve directly. The threat of legal sanctions, in turn, may lead to the creation of an industry of intermediaries able to certify the quality of products or suppliers, or an insurance industry willing to offer coverage against this form of legal obligation. The intermediary or insurance company would then take action to reduce the risk of unsafe products reaching the market.

Focusing on firms within the reach of American authorities also addresses the problem of fly-by-night foreign enterprises, which engage in production until a problem arises and then simply close up shop only to appear later under a different name. Domestically-based parties are much better situated than regulators to identify and avoid such operators.

If, after considering whichever of the above strategies (or others) provides

the best way to manage the risk of liability, it remains impossible to get the expected cost of liability to a point at which the importer or seller can expect to earn a profit, the importer or seller will simply decline to participate in the process of bringing the product to market. The importer or seller will instead seek other producers of the product, perhaps from the United States or perhaps from countries where the liability issues can be managed more effectively. This private decision to exclude the product represents a regulatory success (assuming the level of liability is set correctly). Because the importer or seller has internalized the expected cost of harm from the product, its decision not to participate reflects the fact that the potential safety issues are large enough that importing the product represents a net harm to the United States.

Appropriate administrative penalties, then, both align the interests of regulators and domestic partners in global trade, and enlist the party with superior oversight and decision-making capacity. This strategy satisfies the need to ensure safe products while allowing foreign producers to supply the American market with affordable goods and services. The regulator is concerned about damage caused by harmful products. The importer or seller comes to have this same concern if its expected penalty is equal to the cost of the relevant harm. And while domestic regulators are constrained in their ability to assess accurately which foreign actors should be allowed to engage in trade that affects domestic consumer well-being, importers and sellers have a different set of tools that accord a much greater ability to influence quality, identify sellers with appropriate safeguards in place, or avoid certain transactions altogether.

In sum, by enlisting American private parties to fill the role of *de facto* regulators of their foreign business partners, this strategy seeks to permit domestic firms to compete on the cost of consumer protection, rather than on the level of safety.

2. When Should Discriminatory Regulation Be Used?

Throughout this Article we have assumed that domestic regulatory approaches are optimal for the regulation of domestic production.¹⁰⁹ It is only when those approaches are unavailable that we believe a different policy response is needed. We do not advocate a general shift away from the status quo toward a system that relies exclusively on the outcome lever.

This limitation begs the question of when we believe our proposed outcome-based regulatory strategy should be utilized. The first, and simplest point is that if it were possible to reproduce the domestic regulatory system by making importers and sellers responsible for compliance with regulatory requirements, the problem of quality and safety in imports would be straightforward. Domestic authorities could use precisely the same regulatory

109. See Part II.

mix of production and outcome regulation for imports as they do for domestic production, which might achieve a similar level of safety.¹¹⁰ The only necessary adjustment would be to identify the actors who are to be held responsible for compliance with regulatory requirements.

In at least two contexts, however, the domestic strategy is inapplicable to the foreign context. The first situation occurs when a determination has already been made in the domestic context that outcome-based regulation is insufficient, and the production lever has been employed to improve safety outcomes. Put another way, this is the category—which includes drugs, food, and data—in which the production lever determines the level of safety of domestic products.

Here, the use of the production lever greatly reduces the products' risk of danger, so the threat of outcome-based liability is unlikely to have a significant effect in compelling producers to make additional investments in safety. Thus, it is the production lever that determines the safety of the final product. Since the production lever operates less effectively against foreign activity, for regulators to replicate the cost and safety balance in this context, they will have to compensate for the lost production regulation by relying on outcome-based liability.

The second context in which discriminatory regulation is needed is when goods and services are regulated only by means of the outcome lever, but the outcome requirements are motivated not only through threat of legal action, but also by other non-legal incentives in place. These non-legal incentives are the economic or social factors that influence safety decisions, and include, for example, reputational issues, ethical commitments, and industry group pressures. Sometimes these extra-legal incentives are lacking or work differently once activity is moved outside U.S. borders. In these cases, ensuring the requisite level of consumer safety may require that regulators increase the penalties associated with failures to satisfy outcome-based regulation.

3. Impact on Safety and the Incidence of Harm

Just as the cost of production is higher in some countries and lower in others, the cost of safety varies from country to country. Precisely how this variation plays out is difficult to predict.

From one viewpoint, low production costs may signal more expensive implementation of safety regulation. For example, imagine that in one country a producer cannot easily ensure that the paint it purchases for use in production is lead-free, whereas in another country this issue is easy to control. In the former situation the foreign producer will have difficulty ensuring safe inputs

110. To be precise, the resulting level of safety would not necessarily be identical to that in the United States because the costs of compliance with both production and outcome-based regulation will differ from place to place.

for the same reason that the U.S. importer has difficulty ensuring that the final product is safe—because it is difficult to verify the origin and content provided by suppliers. This greater difficulty may lead to greater costs. This outcome—one in which safety improvements are expensive—is more likely to come about if the regulatory and business environments in a country function poorly. Such poorly functioning regulatory environments, are of course, more likely to exist in countries with low per capita incomes and low production costs. This reasoning leads one to expect increases in safety to be more expensive in countries with low costs of production such as China or India.

On the other hand, it is possible that increases in safety may be less expensive in low-cost countries for the same reasons that other costs of production are low. If increases in safety require more labor-intensive inspections and oversight, for example, this may be inexpensive in countries with low wage costs. If increasing safety requires a change in the inputs used, this change may itself be less expensive in countries with low production costs. This reasoning leads one to expect increases in safety to be relatively inexpensive in countries with low costs of production and more expensive in high cost countries.

In other words, it is not possible (without more information) to predict the relative costs of increased safety in different countries. This is not surprising if the cost of increased safety is viewed as simply another cost associated with the production and sale of the product. In this vein, some of the relevant costs will be lower for imported products (e.g., labor costs, regulatory burdens) while others will be lower for domestic products (e.g., transportation).

While it may be difficult to estimate the cost of implementing increased safety procedures in foreign countries, it is possible to predict the impact of increased safety on the incidence of harmful products reaching the American market. In an effort to maximize profits, producers invest in safety up to the point where the marginal cost of additional safety is equal to the marginal benefit to the firm. If improving safety is more expensive in one country than another, the profit maximizing level of safety will be lower in the first (where the marginal cost is higher) than in the second (where it is lower). This is consistent with the intuition that safety levels will be lower in countries where it is more expensive to establish safety. One implication of this fact, however, may be contrary to some readers' intuition. When safety costs vary from country to country and when legal penalties for non-compliance cause producers to fully internalize the social costs of increased consumer risks, the incidence of unsafe products will differ based on the country of production. Stated more directly, it is to be expected that producers in different countries will provide different levels of safety. For any given level of regulation, the country with a higher cost of safety improvements will, in equilibrium, have a lower level of safety. Under our proposal—or any other regime that designs penalties to ensure internalization of harm—jurisdictions compete on the costs

of safety, not on the level of safety.

The practical impact of differing costs of safety is that safety levels may vary based on the country in which a product is produced. Though one might initially think that the product with the lower level of safety is always less desirable, that is not necessarily the case. The assumption underlying the above analysis is that the outcome-based penalties imposed when imports fail to meet American safety standards represents the full cost of the resulting harm. In that sense, the United States is indifferent between compliance and a violation that is accompanied by payment of penalties. If it is possible to have a lower cost for a product even after producers factor these penalties into their costs, then the United States is better off with that outcome.

This issue of the level of safety is simply a variation on the familiar observation that any production, whether in the United States or abroad, comes with the risk of defective or harmful products. Reducing that risk to zero often costs more than we are prepared to pay, so we accept that there will occasionally be defects in our products. When the cost of production and safety differs between two countries, there is no reason to think that the tradeoff between costs and safety should be made in the same way. There is no reason to demand that both systems produce the same levels of safety.

Of course, if the social cost of harm is high enough, and if it is reflected appropriately in sanctions, risks can be reduced to very low—perhaps vanishingly low—levels and, more importantly, can make the importation of dangerous products prohibitively costly. If, for example, the social cost of a tainted drug is deemed to be extremely high—in the tens of millions of dollars per dose, for example—and the penalties are set at that level,¹¹¹ then importers and sellers will take that into account in their actions. If a more expensive domestic drug is less likely to be dangerous it may be the case that the expected penalties are large enough to cause importers and sellers to avoid the foreign product and work instead only with domestic producers. In this instance the safer product will be the only thing on the shelves.

The key point here is that regulation should aim to have importers and sellers internalize the cost of harm rather than achieve a specified level of safety. If that is done, either foreign or domestic producers may produce safer products. As long as consumers can distinguish among the alternatives they purchase, these products should be allowed to compete in the market to determine which satisfies the needs of consumers better.¹¹²

Imagine, for example, that two companies offer a medication to treat heart disease. The drugs are equally effective. One company produces the drug in

111. Or perhaps penalties can be set even higher to account for the tainted products that may never be identified or penalized.

112. If one believes that consumers must be protected against their own judgment and decisions—say because they are myopic, for example—then some additional constraints on the choices consumers face might be justified.

China, and the other company produces its drug in the United States. For both companies, there is a small risk that problems in the production of the drug will cause it to be tainted and harmful to consumers. In such cases the users of the drug suffer from dizziness, nausea, and blackouts. Production in China is less expensive than in the United States, but increases the risk of tainted products. The risk that the Chinese-made product is harmful is one in three million. For the American-made product it is one in five million. The cost of the product if made in China is one-half the cost of the American-made product.

If one wanted to determine whether both of these products should be allowed into the market, much more information would be needed. For example, how expensive are the drugs in absolute terms? Will excluding the Chinese drugs cause people to go without the medication altogether because the American drug is too expensive? How serious are the side effects?

If one sought instead to establish penalties that reflect the cost of harm from a tainted version of the drug, the regulator's job is limited to estimating that cost. Doing so is not an easy task and involves a host of political and moral judgments.¹¹³ But those same judgments must be made for any regulatory strategy. Once penalties are set to reflect those costs, the market can be left to determine which of the products better suits the needs of consumers.¹¹⁴

It may turn out that individuals with greater means will opt for the more expensive product while those with tighter budget constraints will opt for the less expensive one. Decisions of this sort—between cost and safety—are made everyday by consumers in virtually every part of their lives, including the car they drive, the neighborhood they live in, whether they filter their drinking water, whether they take vitamins, and, indeed, what medications they use.¹¹⁵

It may turn out that only one of the products survives. The social costs of harm may be large enough that the foreign-produced product is no longer economically viable and only the domestic product remains. Or, the social costs may be small enough that the foreign product retains a large cost advantage and consumers are unwilling to pay the cost of the domestic product.

One final possibility exists. If the cost of safety is lower in China than in the United States, then by setting penalties appropriately regulators will cause Chinese producers to dramatically increase the safety of their product. Imported

113. Some disagreements about safety and imports relate to different views of social costs. We take no position on how such costs should be calculated.

114. Again, this requires clear labeling of other efforts to inform consumers about the relative dangers of the two drugs.

115. Tort law, for example, recognizes this trade-off explicitly. The "primary" test for design defect in tort asks "whether a reasonable alternative design would, at reasonable cost, have reduced the foreseeable risks of harm posed by the product and, if so, whether the omission of the alternative design by the seller or a predecessor in the distributive chain rendered the product not reasonably safe." RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2, cmt. d (1998); *see, e.g.,* *Ford Motor Co. v. Miles*, 967 S.W.2d 377, 386 (Tex. 1998) ("[A] manufacturer is not required to design the safest possible product . . .").

products may come to be both safer and less expensive than domestic products.

B. Objections and Concerns

1. Reconciling Discriminatory Regulation and International Trade Rules

Importers and sellers facing higher expected costs from our proposed system of discriminatory regulation will try to reduce costs by improving safety, but they may also pass these costs along to consumers by raising prices.¹¹⁶ Raising the domestic price of imports obviously serves to make domestic production more competitive relative to imports. This discrimination between domestic and foreign producers raises the question of whether our proposed system would be permitted under existing international trade treaties and, in particular, the rules of the World Trade Organization (WTO).

We begin with an analysis of Article III of the General Agreement on Tariffs and Trade (GATT). This rule, known as the national treatment obligation, prohibits states from imposing regulations on imports that are “less favourable than that accorded to like products of national origin.”¹¹⁷ If a measure fails to meet this requirement, it is nevertheless permitted if it satisfies any one of several available exceptions. The exception of interest in the case of our discriminatory regulation proposal can be found in Article XX(d) of GATT, which provides an exception for measures “necessary to secure compliance with laws or regulations which are not inconsistent with the provisions” of the GATT.¹¹⁸

The discriminatory liability regime we propose distinguishes products based on whether they are produced domestically or abroad, which immediately makes them suspect under Article III. Mere differences in treatment, however, are not enough to conclude that a measure is inconsistent with Article III.¹¹⁹ Imports and domestic products may be treated differently as

116. The increase in prices need not correspond exactly to the increase in costs felt by the importer or seller. Depending on the market structure, the importer or seller may simply absorb some of the increased cost in the form of lower profits. It may also be able to force producers to accept lower profits themselves. At least some of the increase in costs, however, will be passed along to consumers.

117. General Agreement on Tariffs and Trade (GATT), art. III.4.

118. *Id.* at art. XX(d). One could also advance arguments about exceptions provided by Article XX(b) and the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), both of which address health and safety concerns. We omit these because the exception in GATT XX(d) is more appropriate for this situation and, in any event, to the extent the other exceptions might apply the reasoning would be quite similar to the discussion of GATT XX(d).

119. See, e.g., Appellate Body Report, *European Communities—Measuring Affecting Asbestos and Asbestos-Containing Products*, ¶ 100, WT/DS135/AB/R, (Mar. 12, 2001) [hereinafter Appellate Body Report, *EC—Asbestos*], available at [http://www.worldtradelaw.net/reports/wtoab/ec-asbestos\(ab\).pdf](http://www.worldtradelaw.net/reports/wtoab/ec-asbestos(ab).pdf); Appellate Body Report, *Korea—Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, ¶¶ 135-36, WT/DS161/AB/R, WT/DS169/AB/R, (Dec. 11, 2000) [hereinafter Appellate Body Report, *Korea—Various Measures on Beef*], available at [http://www.worldtradelaw.net/reports/wtoab/korea-beef\(ab\).pdf](http://www.worldtradelaw.net/reports/wtoab/korea-beef(ab).pdf).

long as the outcome-liability scheme we propose does not cause imports to receive "less favourable" treatment than that applied to domestic products.

It is clear that if one looks at the outcome-based liability component of the regulatory system in isolation, ignoring the production-based obligations faced by domestic producers, then imposing higher penalties on foreign producers would be a violation of Article III.4. And while it makes more sense to examine the production and outcome-based liability schemes together, even if one does so, it is likely our proposal is inconsistent with the requirements of Article III.4.

The problem is that our proposed outcome-based liability scheme imposes larger penalties on imports even if safety levels are the same as for domestic products. Suppose, for example, that domestically produced products achieve a given level of safety primarily because they are subject to rigorous quality control and inspection protocols mandated by government regulation. Though some outcome-based obligations exist, including penalties, assume that it is the production lever that determines the ultimate level of safety. This is exactly the sort of situation in which we propose discriminatory regulation in the form of higher outcome-based penalties on imports than on domestic products.

Imagine that a foreign producer chooses to mimic the quality control and inspection system required of American producers. Suppose that this foreign producer puts these systems into place and achieves the same level of safety (at the same cost) as do American producers. Now imagine that an unsafe product makes it to the market despite these safety efforts. If the product is from the American producer the penalty will be smaller than if it is from the foreign producer. The foreign producer, then, even if it behaves in exactly the same way as the American producer, faces a higher cost from unsafe products. This amounts to discrimination in contravention of Article III.4.

Our proposed discriminatory regulation is saved, however, by the already mentioned Article XX(d). Our proposal is intended to secure compliance with laws or regulations governing safety and quality, and the latter are quite clearly consistent with the provisions of the GATT. The question is whether such measures are "necessary."

The question of whether the discriminatory penalties are "necessary" to secure compliance invokes a well-developed GATT jurisprudence. In general, the relevant WTO cases have concluded that the necessity of a measure under GATT XX(d) must be judged based on a balancing of relevant factors, including (1) the relative importance of the interest the regulation seeks to protect; (2) the extent to which the measure contributes to compliance with the regulation; and (3) the impact on international trade.¹²⁰

The central thrust of this article has been that regulators have almost no

120. Appellate Body Report, *Korea-Various Measures on Beef*, *supra* note 119, at ¶¶ 162-63.

choice in the tools they use to address the safety of imports.¹²¹ Furthermore, we advocate discriminatory regulation only when other, less trade distorting alternatives are unavailable or ineffective, including regulation by a foreign government and self-regulation. We also propose the use of discriminatory regulation only where existing regulatory structures aimed at domestic producers are unable to provide appropriate incentives to foreign producers. A system of discriminatory regulation, then, should be used only when it is the only practical response available. Needless to say, if no other option exists, discriminatory regulation is also the least trade restrictive approach.

The protection of safety is acknowledged by the WTO as being of paramount importance, placing considerable weight on the scale in favor of the legality of our proposal.¹²² Moreover, we have shown both that discriminatory regulation serves the goal of promoting compliance with relevant safety requirements, and that it is the only way to ensure that foreign producers internalize the full cost of harm from dangerous products. In this sense, the measure contributes directly to compliance with relevant safety regulations.

The three-factor balancing test mentioned above, then, is satisfied by our proposed system of discriminatory regulation: the measure at issue addresses an interest of vital importance, contributes directly to compliance with relevant safety regulations, and is the least trade restrictive alternative available to decision makers.

The exception provided by Article XX(d) requires, in addition to the above, that the relevant measure not be a means of “arbitrary or unjustified discrimination between countries where the same conditions prevail” or be a “disguised restriction on international trade.”¹²³ Suffice it to say that the use of discriminatory regulation as we have described it does not constitute an abuse of the GATT Article XX(d) exception of a sort likely to cause difficulty under the “chapeau” of Article XX, as these provisions are called. The regulation is neither arbitrary nor unjustified; as discussed prior, it is only utilized when no other alternatives are available.¹²⁴

Finally, to meet the requirements of the WTO, the outcome-based

121. Indeed, one of the reasons that the production lever works poorly for imports is that the trading rules generally do not allow importing states to demand specific production methods.

122. Appellate Body Report, *EC-Asbestos*, *supra* note 120, ¶ 172 (2001) (“In this case, the objective pursued by the measure is the preservation of human life and health The value pursued is both vital and important in the highest degree.”).

123. GATT, *supra* note 118, at art. XX.

124. Importantly, to be compliant with the trading rules, the use of discriminatory regulation must be used only when other alternatives are not available. Thus, for example if reliance on foreign regulatory systems will achieve a state’s safety objectives, discriminatory regulation may well be forbidden by WTO rules. Similarly, if the safety of domestic production is determined by outcome-based regulation, and if that outcome-based regulation can be applied to foreign production, there is no justification for discriminatory regulation under either our proposal or the rules of international trade. Using the language of the WTO, discrimination in penalties would not be “necessary” in that context.

penalties imposed on foreign products must be calibrated to reflect the social harm from dangerous products. This is precisely what we have proposed. Larger penalties would trigger concerns that the measure is a “disguised restriction on international trade” or is not “necessary” under the Article XX(d) exception.¹²⁵

2. Practicalities

Finally, it is worthwhile to touch upon a few practical questions that may arise from the establishment of different outcome-based liability regimes for domestic products and imported products. First, it may be that not only producers in the United States should face the lower level of liability, but also producers in jurisdictions that themselves have acceptable production-based liability schemes. These producers, after all, face regulatory burdens that are equivalent to those placed upon American producers and so there is no reason to subject them to additional outcome-based regulations beyond those faced by American producers. But how will American authorities judge whether a country qualifies for the lower-liability category? A country-by-country approach is problematic as different industries require different standards. An industry-by-industry approach may do better, but would be expensive and cumbersome to implement as every industry-country combination would have to be evaluated. Some of the cost could perhaps be placed on the producer of the imported product, but this raises anew concerns about trade protectionism.

Second, there are further difficulties in identifying the producing country when production occurs in a variety of foreign countries. This is a familiar problem in international trade and could presumably be addressed in the same way—through rules-of-origin. These rules vary from country to country and context to context, but normally a product is considered to emanate from a particular country if a large enough share of the product’s value-added can be attributed to that country. Thus, for example, a product whose value-added from Brazil is greater than some threshold level—say 35%—is considered to be a Brazilian product.

Finally, and perhaps most seriously, imposing liability on importers or

125. Readers with some familiarity with the WTO system might wonder why the Agreement on the Application of Sanitary and Phytosanitary Measures (known as the “SPS Agreement”) is not discussed. The SPS Agreement deals with measures put in place to protect against risks arising, *inter alia*, from “additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs,” and “disease carried by animals, plants or products thereof, or from the entry establishment or spread of pests.” SPS Agreement, Annex A.1.b-c. Though some of the safety concerns that are relevant to our discussion might fit within these definitions, we are interested in a much broader array of potential safety concerns. To the extent that a measure does meet the definition of an SPS measure it would have to be consistent with the SPS agreement. The requirements therein, however, are similar to those present in GATT XX(d), and would be satisfied for essentially the same reasons as are discussed in the context of that exception.

sellers may fail to generate appropriate incentives if those parties are damage-proof or nearly so. The problem is more acute when one realizes that importers and sellers could organize themselves in such a way as to shield assets from potential liability. Rather than operating as a single large importer, for example, a firm could establish a large number of relatively small corporations, each of which imports a single specific product or a small group of products. These corporations would hold minimal assets and so their exposure to liability would be quite limited. But this same problem exists for any regulation that relies on sanctions or penalties, including regulation of domestic production. It is perhaps somewhat more acute in the context of imports because production may require a certain scale and sufficient assets to reduce the risk that a firm is damage-proof but an importer has no such needs. On the other hand, the distribution of products within the United States often requires a large entity, as does the sale of products under familiar brand names.

These concerns are legitimate ones, but they are problems that come up in this or other regulatory contexts under existing rules. Where they have come up, they have not proved fatal to the enactment and effective use of regulation. Notice, furthermore, that whatever challenges these concerns pose, and even if they prevent the application of a perfect regulatory regime, they do not change the fact that a system of discriminatory liability provides better incentives for foreign producers than is the case under the status quo.

CONCLUSION

The globalization of commercial activity is a reality that is here to stay and that provides far more benefits than costs. That said, responsible domestic governments should be in the business of reducing unnecessary social costs wherever they occur, and those associated with this phenomenon are no exception.

This Article has explained why conventional regulatory strategies are insufficient to address the challenges of importing products from foreign jurisdictions, especially when neither foreign regulatory structures nor self-regulation represent viable options to ensure safety. When goods and services are provided abroad, producers and suppliers can evade American regulatory obligations and extra-legal pressures to increase consumer safety. In particular, they can avoid measures that protect consumers by preventing unsafe products before production is completed. Accordingly, foreign producers will not internalize the cost of harmful products as fully as their American counterparts, and will, therefore, invest less in ensuring the safety of their products.

Moves to remedy this imbalance through increased oversight, inspection, and enforcement by domestic regulators can improve consumer protection, but will provide only a partial solution in the face of imports on a massive scale. Moreover, the increased cost of safety in foreign activity would be borne by the U.S. taxpayer, while individual firms would continue to reap the benefits of

offshore outsourcing.

We have shown that a liability scheme aimed at parties within the reach of American authorities can address this problem. Where alternate mechanisms are unavailable for preventing the production of unsafe goods, then, the domestic firms that benefit from foreign activity should be forced to internalize the domestic costs of their activity through increased penalties for the violation of consumer protection norms. In this manner, these domestic firms' superior capacity for oversight, monitoring, risk shifting, and decision making about location, organizational form, and activity-level can be brought to bear in the very context in which domestic regulators are impeded by lack of information, resources, and jurisdiction.

To be sure, implementation of our proposal would require some delicate judgments about which products from which countries should be subject to the higher liability scheme. There may be agreement that Chinese products should be subject to this heightened scheme, but what about Brazilian ones? Or South African ones? And given that even jurisdictions with comprehensive and well-functioning regulatory systems on par with those of the United States will often have different priorities, how much difference should be accepted before the heightened regulatory scheme is applied? Similarly, which self-regulatory structures should be deemed sufficient to allow producers to avoid the higher damages system?

These are real and important questions, of course, and we cannot hope to answer them here. In practice they require careful and sober judgments about individual regulatory structures. There is, without a doubt, a risk of political meddling, though that risk exists in virtually every form of lawmaking that impacts foreign states and their interests. One modest way to begin would be with a presumption that states and their producers and suppliers are excluded from the strict liability, high-damages regime unless they are specifically included. Most countries would then retain the status quo regulatory system. Individual states, however, could be added to the new system of heightened liability and damages. This would put on notice not only these states, but also those doing business with them. Thus, for example, Mattel and other toy sellers would be on notice that they need to either live with the heightened risk of liability or find alternative suppliers.

Adding a country to the high liability and high damages list might be politically sensitive, but that would be true of any regime that successfully addressed concerns about the safety of imports. Furthermore, this sort of system is surely better for exporting countries than one that bans their products from the American market altogether.

The underlying spirit of our proposal is enthusiastic about cross-border trade in goods and services. As with any business activity, it is appropriate for governments to establish regulations that encourage the internalization of externalities. In the context of safety, that means that domestic and foreign

producers will at times be subject to different regulatory systems. As we propose, as long as the legal system forces foreign producers to internalize costs in a way comparable to the way in which domestic producers do, the resulting rules cannot be described as unfair to foreign producers.

From the perspective of American consumers, our proposal has the great advantage of ensuring appropriate levels of safety while at the same time encouraging healthy competition among domestic and foreign producers and suppliers. In fact, by encouraging the internalization of costs, our proposal permits firms to compete on the cost of safety—thereby rewarding those that produce safety at the lowest cost—without allowing them to compete on the level of safety.

