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

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# KEEPING IMPORTS SAFE: A PROPOSAL FOR DISCRIMINATORY REGULATION OF INTERNATIONAL TRADE

Kenneth A. Bamberger & Andrew T. Guzman\*

*The benefits of overseas outsourcing have come at a cost. Americans enjoy unprecedented levels of safety and security in the domestically-produced goods they use, food and drugs they ingest, and services they employ. Yet as U.S. firms increase the efficiency of their production, become more competitive globally, and offer better price-quality combinations to their customers by contracting with foreign companies for the production of goods and the provision of services, the mix of economic, legal, and societal forces that serve to protect consumers changes. Widespread revelations of Chinese-manufactured toxic toys and toothpaste, tainted food and drugs from abroad, and the failure of foreign call centers to protect the privacy of U.S. consumer data all illustrate the challenge for domestic governance. Though international trade in goods and services provides clear economic benefits, it can also frustrate consumer protection efforts.*

*This paper provides a conceptual framework for understanding the mix of regulatory elements that govern domestic production of goods and services, and for understanding the ways in which international trade changes that mix. Specifically, it distinguishes between two types of domestic regulation—the first targeting the process by which goods are produced and services provided, and the second mandating particular outcomes. Foreign production disables the first type of regulation and weakens the second. Protecting domestic consumers in a globalized market, then, will frequently require the development of “substitutes” – including regulation by foreign governments and private regulators—for domestic forms of governance that are ineffective abroad.*

*We propose a novel and necessary solution for addressing the threat posed by the foreign production of goods and provision of services to consumer welfare. Specifically, we make the case that the best “substitute” for domestic regulation will often be oversight of safety issues by U.S. partners in global trade. To provide incentives to domestic firms U.S. regulators should make those firms legally accountable for harmful products that make it to the United States. Furthermore, they regulations should discriminate between domestic and foreign activity in regulation requiring safe outcomes, imposing higher penalties for violations of safety norms when production has taken place abroad.*

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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, 1.8 million units of the extremely popular toy were recalled.<sup>1</sup> And as parents across the country know, it was not only toy trains that were affected. That year almost 40 million Chinese-made toys or other items used by children were recalled—about one for every household with children.<sup>2</sup>

This story of defective or dangerous imports does not end with toys. Contamination of a Chinese-produced ingredient used by U.S. pharmaceutical company Baxter International in its blood-thinner Heparin has led to the death of 19 patients and recalls in several countries<sup>3</sup>. In April 2007 alone, the FDA—which inspects only 1% of food from foreign countries—rejected 51 shipments of catfish, eel, shrimp, and tilapia imported from China because of such contaminants as salmonella, veterinary drugs, and nitrofurans, a cancer-causing chemical; stopped frozen catfish laced with banned antibiotics; and barred scallops and sardines coated with putrefying bacteria.<sup>4</sup> In July 2007, ginger imported from China was found to contain a dangerous pesticide only after the product had been put on the shelf.<sup>5</sup> And security breaches involving personally-identifiable medical and financial data by foreign subcontractors have raised deep concerns about identity theft and other threats to consumer privacy, as U.S. consumer information is increasingly outsourced to overseas call centers and other “back-office” business process firms in South Asia and elsewhere.<sup>6</sup>

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<sup>1</sup> Paris B. Kavalanz, More Thomas & Friends toys recalled for lead, CNNMoney.com, September 26, 2007, available at [http://money.cnn.com/2007/09/26/news/companies/toy\\_recall/index.htm](http://money.cnn.com/2007/09/26/news/companies/toy_recall/index.htm).

<sup>2</sup> 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](http://pubdb3.census.gov/macro/032007/hhinc/new04_003.htm)

<sup>3</sup> See Gardiner Harris and Walt Bogdanich, *Drug Tied to China Had Contaminant*, F.D.A. Says, N.Y. TIMES (Mar. 6, 2008).

<sup>4</sup> See Diedra Henderson, *Chicken From China? Questionable Farming Practices Fuel Skepticism of US Plan To Import Poultry*, BOS. GLOBE (May 9, 2007).

<sup>5</sup> See Nicholas Zamiska & David Kesmodel, *Tainted Ginger's Long Trip From China to U.S. Stores*, WALL ST. JOURNAL at A1 (Nov. 19, 2007).

<sup>6</sup> See U.S. Government Accountability Office, *PRIVACY: Domestic and Offshore Outsourcing of Personal Information in Medicare, Medicaid, and TRICARE*, GAO-06-676, at 18

Americans enjoy high levels of safety and security in the domestically produced goods they use, food and drugs they ingest, and services they employ. Yet, as U.S. consumers gain from more efficient production abroad – whether done by American companies outsourcing production and service provision, or foreign firms competing in the American market – the mix of economic, legal, and societal forces that influence safety and reliability changes. Global trade increases competitiveness by providing access to cheaper labor, raw materials, and other imports, but it also presents a challenge to regulators charged with ensuring appropriate levels of consumer protection.

This Article offers a conceptual framework for understanding the governance challenge presented by increased international trade, and for considering how best to ensure optimal consumer protection levels for imported products and outsourced services. Specifically, in Part I, it explains that the provision of goods and services is subject to two regulatory processes or, as we call them, “levers.”<sup>7</sup> The first lever constrains firm behavior during the production process.<sup>8</sup> We refer to this approach as “production-based regulation” or the production lever. The second lever relies on outcomes. It focuses on the final product or service rather than the process through which that good was produced. We refer to this as the “outcome-based regulation” or the outcome lever.

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(Sept. 2006) (“*GAO Privacy Outsourcing Report*”) (reporting survey results showing that a substantial number of federal contractors and state Medicaid agencies reported privacy breaches involving personal health information, but many remain unreported); 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) (“*Privacy Survey*”) (industry 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). Federal Deposit Insurance Corporation, *Offshore Outsourcing of Data Services by Insured Institutions and Associated Consumer Privacy Risks* 2-3 (June 2004), available at [http://www.fdic.gov/regulations/examinations/offshore/offshore\\_outsourcing\\_06-04-04.pdf](http://www.fdic.gov/regulations/examinations/offshore/offshore_outsourcing_06-04-04.pdf) (identifying increased forms of risk to consumer privacy); David Lazarus, *SPECIAL REPORT: Looking Offshore: Outsourced UCSF notes highlight privacy risk; How one offshore worker sent tremor through medical system*, S.F. CHRON. (Mar. 28, 2004) (detailing risks after medical information breach by Pakistani business process outsourcer).

<sup>7</sup> We describe these 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 becomes unavailable policy makers must search for alternative levers to achieve similar objectives.

<sup>8</sup> In the case of services provided overseas, the production lever includes the process through which that service is provided.

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.<sup>9</sup> It differs, however, from the usual ways that scholars of regulation have categorized regulatory approaches. Rather than explore 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 example<sup>10</sup>—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 protection norms to goods that are manufactured, or services that are performed, abroad, and that risk harm to 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, imposes liability for harms actually incurred.

The baseline assumption guiding domestic consumer protection policy in many contexts—including toys and many other manufactured goods—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. In some areas, however, policymakers believe such forces will not achieve protective goals. This may be so for any of number of

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<sup>9</sup> See, e.g., Robert Howse and Regan, *The Product/Process Distinction--An Illusory Basis for Disciplining 'Unilateralism' in Trade Policy*, 11 EUROPEAN J. INT'L L. (2000).

<sup>10</sup> For discussion of the variety of regulatory instruments generally see Stephen D. Sugarman and Nirit Sandman, *Fighting Childhood Obesity Through Performance-Based Regulation of the Food Industry* 56 DUKE L. J. 1411-1428 (2007) (setting forth a typology of regulatory instruments); 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 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); 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).

reasons, including that noncompliance is difficult to detect through *ex post* inspection before consumer harm has actually occurred, that harm may only become apparent long after use of the product, or that social and market compliance incentives are weak. In these situations regulators have employed the production lever as a means of reducing risks and preventing harms. In the areas of data protection and seafood safety, for example, regulatory statutes mandate that private firms adopt internal procedures and assessments intended to prevent risks before they occur. In regulating the domestic production of meat and drugs, moreover, administrative agencies take an even more active role in oversight throughout the process, employing inspection, monitoring, reporting and licensing to ensure a high level of safety before goods ever leave the plant, or reach the market. This is the production lever in action.

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 in anything like 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 to remedy the shortcomings of outcomes requirements in protecting U.S. consumers from imported goods and outsourced services, the production lever is largely unavailable.

One solution would be to enact border measures that block or slow trade with countries like China, the source of many of the tainted products. This remedy, however, is problematic from both legal and practical perspectives. Because it is not possible to identify *ex ante* which products will pose safety risks, any categorical restraint on trade with China 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.<sup>11</sup> As a legal matter, it would likely violate the rules for international trade to erect barriers to imported products from China (or elsewhere) without evidence that specific products or lines of products are harmful. The drawbacks of a system of trade barriers are made all the more significant because there are political reasons why erecting barriers to trade may be tempting.<sup>12</sup> If calls for increased safety become a pretext for protectionism, the gains provided by robust international trade will be undermined.

A second approach—the principal focus of a number of proposals before Congress and elsewhere—would be to significantly increase the government resources allocated for U.S. government inspections, either of production processes abroad where possible, or of products ready to enter the U.S. market. While these proposals might have a salutary effect on consumer safety, their successes will, because of the challenges posed by regulating extraterritorial activity, be partial at best. There is no practical way to inspect more than a tiny fraction of imports, and attempts to extend regulation of production to foreign facilities runs into severe jurisdictional challenges. Furthermore, for these strategies to have any success at all would require the commitment of significant government resources above and beyond what is spent on domestic regulation. The increased cost of safety in foreign activity would therefore be borne by the U.S. taxpayer, while individual firms would still reap the benefits of offshore outsourcing. These high regulatory costs will not be taken into account by firms making decisions about where to produce or purchase their products, nor will they find their way into the price of products sold in the United States. This could inefficiently skew locational decisions towards offshore, rather than domestic, production.

The reality of international trade, then, requires regulatory solutions that directly reflect the fact that the production lever is unavailable when governing extraterritorial activity. More

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<sup>11</sup> Jordan Robertson, *Your Next Gadget May Come with a Pre-installed Virus*, USA TODAY, March 13, 2008, available at [http://www.usatoday.com/tech/news/computersecurity/2008-03-13-factory-installed-virus\\_N.htm](http://www.usatoday.com/tech/news/computersecurity/2008-03-13-factory-installed-virus_N.htm).

<sup>12</sup> There are some subtle legal questions about exactly what the United States could do to protect itself from unsafe products from China. If, however, one assumes (realistically) that the American government has no reliable way to predict which imports will pose hazards in the future, then any trade measure could equally well target any or all Chinese imports. It is hard to imagine that an across-the-board trade barrier against Chinese imports could be considered legal under WTO law.



specifically, to ensure optimal safety levels for imported products, policymakers must also seek substitutes for the direct U.S. government regulation of process that is achieved for domestic production through the use of that lever. 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, although the subject of several proposals before Congress, cannot offer a solution that is either complete or timely. To be sure, both can play a role in preserving the benefits of international trade while ensuring appropriate levels of safety. There is little doubt that the United States would benefit from the strengthening of foreign consumer protection regimes and the development of third-party oversight mechanisms, such as industry groups and independent certification bodies, in countries with weak regulatory structures. 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.

Specifically, we make the case in Part III that where U.S. regulators expect existing domestic regulation to fail in protecting consumers from hazards arising from foreign production or service provision, they should consider augmenting the one form of outcomes regulation most readily available to them: the legal penalties imposed against domestic partners in international trade. These firms within the reach of U.S. law that manufacture abroad, import foreign goods, or outsource services extraterritorially should be accountable for the violation of outcomes mandates that protect 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, American firms (or other firms within the reach of the American legal system) could be motivated to make the choices that the political process engages in domestically: assessing the effectiveness of the legal, social, and

economic constraints on the behavior of foreign firms, and then supplementing those forces as necessary as a condition of 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 the much same way regulators do. This may cause 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 at all.

Several conclusions emerge from our argument. First, regulators must look more carefully and creatively at imposing sanctions on importers as a way to achieve what they currently achieve with the production lever.<sup>13</sup> 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 – imposing larger sanctions on imported products that fail to satisfy outcome-based regulatory requirements. Fourth, because the cost of increasing safety varies from country to country, even when regulation is optimally formed the incidence of harmful products may vary somewhat from one country to another. Finally, although the policy we propose raises some international trade issues, and although there has been no definitive ruling from the WTO on

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<sup>13</sup> 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 paper apply equally well to any country with a well-developed system of production-based regulation applied to domestic producers.

this form of discrimination, it is permissible under existing international trade laws.

## I. FRAMING THE REGULATORY PROBLEM

The legal protection of consumer well-being in the United States rests on a patchwork of diverse regulatory tools that vary by product and service. Regulators use a variety of instruments, including detailed “command-and-control” regulations, mandated performance outcomes, and process requirements to reduce safety and security risks. Compliance is pursued through a host of inspection and enforcement regimes at various points in the production process. And tort liability both sets forward-looking performance standards, and creates incentives to limit risky behavior.

To understand the divergence in regulatory capacity over foreign, as opposed to domestic, goods and services, however, an important yet simple distinction must be made. This distinction is between types of regulation based on when in the production process they operate. This Part, therefore, develops a distinction between two categories of governance mechanisms. The first category includes regulation, inspection and enforcement targeted at outcomes—whether a good or input, in its final form, is safe; or whether a service, when completed, has violated a consumer-protective norm like information breach prevention. We call these regulatory mechanisms the “outcome lever.” The second category consists of production-based regulation, and seeks to regulate, identify and ameliorate risk while a product is being produced or before a service is completed. We refer to this as the “production lever.”

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. For while regulators employ the production lever domestically to ameliorate shortcomings in their governance of outcomes, when those shortcomings arise in the context of foreign activity the production lever is often unavailable or impractical.

### 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 regulations limiting the use of lead paint and setting standards for the size of parts in toys intended for young children—and conducts a limited program of inspections of finished products. The CPSC also possesses the authority to bring civil and criminal enforcement actions against those who violate specific legal mandates,<sup>14</sup> and to impose penalties of up to \$1.8 million dollars on companies who fail to inform the agency when they discover unsafe conditions in toys on the market.<sup>15</sup> Tort law, moreover, may impose additional liability for physical harms actually incurred.

Outcome regulation may also involve, after the finding of a violation or an increased risk of consumer harm, a requirement of ameliorative measures. For example, the CPSC has a program designed to encourage the reporting of unsafe goods and the coordination of 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 38 states with laws requiring notification of data breaches to affected consumers.<sup>16</sup> The outcomes lever, moreover, operates at all levels of government. Various forms of

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<sup>14</sup> See, e.g., “California Man Charged In Illegal Toy Importation Case,” FDCH Regulatory Intelligence Database; 05/17/2001, at <http://search.ebscohost.com/login.aspx?direct=true&db=buh&AN=00220019200003802&site=ehost-live>; “California Company To Pay \$200,000 Civil Penalty For Importing And Selling Illegal Children’s Toys”, FDCH Regulatory Intelligence Database; 01/12/2004, at <http://search.ebscohost.com/login.aspx?direct=true&db=buh&AN=32W0651393109&site=ehost-live>

<sup>15</sup> See The Consumer Product Safety Commission Reform Act of 2008, Senate Bill 2663 (2008) (proposing raising civil penalty cap).

<sup>16</sup> 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 SUNSTEIN, *RISK AND REASON*, ch. 8 (2002) (discussing disclosure of information as a means of regulation).

food safety testing, for example, are carried out by both federal and state officials.

The success of these formal legal mandates frequently rests in part on the presence of a variety of non-legal social and economic factors promoting compliance, such as the normative commitments of firms,<sup>17</sup> the advocacy of consumer protection groups, the threat of more comprehensive government regulation, the 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 standard-setting groups such as the American National Standards Institute and the American Society for Testing and Materials<sup>18</sup>— as well as a variety of societal expectations regarding safety, whether or not those expectations are embodied in law.

## 2. *The Production Lever*

Policymakers may conclude, for any number of reasons, that in a given context the outcome lever is insufficient to achieve consumer safety objectives. For example, performance outcomes may be difficult to identify in advance or to assess contemporaneously.<sup>19</sup> This is the case, for example, if the harm from a defective product is only observable after a long period of time (as might be the case for certain health effects), or the harm is very diffuse and difficult to associate with specific products, as might be the case for some environmental effects. Similarly, outcome-based measures may be difficult to implement if product failures are themselves hard to observe, as might be the case with information databases that are inadequately secured. In each of these instances, outcome-based regulation may fail to identify harmful or defective products. Production-based approaches are intended to intervene

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<sup>17</sup> 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).

<sup>18</sup> See, e.g., ASTM F963-08, Standard Consumer Safety Specification for Toy Safety, available at [http://enterprise.astm.org/REDLINE\\_PAGES/F963.htm](http://enterprise.astm.org/REDLINE_PAGES/F963.htm).

<sup>19</sup> See Kenneth A. Bamberger, *Regulation as Delegation: Private Firms, Decisionmaking, and Accountability in the Administrative State*, 56 DUKE L. J. 377, 388–91 (2006) (describing such contexts, including data privacy protection).

during the production process and reduce the incidence of such harmful products.<sup>20</sup>

Non-legal incentives for compliance with consumer-protective outcomes may vary by context. The same informational difficulties that undermine the outcome lever can undermine social norms and reputational mechanisms. Furthermore, if it is difficult for consumers of 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.<sup>21</sup>

For each of these reasons, then, policymakers may decide that the outcome lever, by itself, does not provide sufficient protection against unsafe products or, more accurately, that using the production lever in addition to the outcome lever allows the achievement of a given level of safety more efficiently.<sup>22</sup>

The case of consumer data and prescription drugs provide illustrations. As to the first, regulators have sought to govern and monitor the *process* by which data is handled, to ensure that mechanisms are in place to ensure that consumers' private information is kept secure. The Federal Trade Commission's 2003 standard implementing the data protection provision of the Gramm-

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<sup>20</sup> It is possible to debate the desirability of using production based regulation either in general or in specific cases. For the purposes of this paper, 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 only serve to distract from the focus on this paper, which is the question of how to respond to concerns about the safety of imports in light of existing regulatory structures. The basic objection to production-based regulation is that it limits the range of potential strategies that a firm can adopt in order to meet a given outcome-based objective. Rather than leaving the firm free to identify the most efficient way to, for example, improve safety, production-based regulation demand that specific actions be taken. Because firms are in a better position than government officials to determine how to manage their business and how to produce their product, this approach is unlikely, the argument goes, to be the lowest cost way to improve safety.

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

<sup>22</sup> Cary Coglianese, Reducing Risk with Management-Based Regulation, Notes on the Columbia/Wharton-Penn Roundtable on Risk Management Strategies 2 (2002), [http://www.ldeo.columbia.edu/chrr/documents/meetings/roundtable/pdf/notes/cogliane\\_se\\_cary\\_note.pdf](http://www.ldeo.columbia.edu/chrr/documents/meetings/roundtable/pdf/notes/cogliane_se_cary_note.pdf) (last visited Oct. 25, 2006).

Leach-Bliley Act,<sup>23</sup> for example, requires financial 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,”<sup>24</sup> including “periodic risk assessments,” and “sanctions against employees that fail to comply.”<sup>25</sup>

In the case of pharmaceuticals, 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.”<sup>26</sup> 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.<sup>27</sup> The recent incident in which nineteen patients died from contamination in the blood thinner Heparin produced by drug manufacturer Baxter International underscores this phenomenon.<sup>28</sup> While routine testing indicated that the manufactured product contained a “Heparin-like” ingredient, they did not detect the counterfeit element, which proved fatal before its recall.<sup>29</sup>

In the context of food and drugs, then, regulators govern and monitor the process of product manufacture. The USDA and FDA’s Hazard Analysis and Critical Control Point (“HACCP”) programs governing food safety compel firms to assess food safety hazards, identify points in the production process at which they can be eliminated, minimized, or reduced to an acceptable level, establish procedures to measure and address risk at those points, and take corrective action. And those same agencies have developed programs for testing and inspection during the production process

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

24. 16 C.F.R. § 314.3 (2006).

25. Interagency Guidelines Establishing Information Security Standards, 69 Fed. Reg. 77,620 (Dec. 28, 2004).

26. U.S. Department of Health and Human Services, HHS Task Force on Drug Importation, *Report on Prescription Drug Importation* viii (Dec. 2004), available at <http://www.hhs.gov/importtaskforce/> (“HHS Drug Import Report”).

27. *Id.*

28. Gardiner Harris & Walt Bogdanich, *Drug Tied to China Had Contaminant*, *F.D.A. Says*, N.Y. TIMES A1 (MAR. 6, 2008).

29. *Id.*

intended to ensure safe outcomes, such as the USDA's continuous, on-site inspections of meat processing facilities,<sup>30</sup> and the FDA's quality-control inspections of drug manufacturing plants.<sup>31</sup>

### B. Regulatory Levers and Imports

#### 1. The Weakened Outcome Lever

However policymakers choose to regulate production, particular challenges are present when goods and services come from abroad. Consider 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 an American court judgment can be obtained, it may be difficult or even impossible to enforce.<sup>32</sup>

Furthermore, extra-legal external constraints may not exist or may not exist in the same way. Local safety norms may be different in foreign states, local consumer groups may not exist or may not be concerned with exported products, and the producing firm may face slight or nonexistent reputational constraints because it is several links in the supply chain—and possibly thousands of miles—away from consumers.<sup>33</sup>

To be sure, federal and state entities, such as the FDA and the California Department of Pesticide Regulation, test products entering the United States. The sheer volume of goods produced abroad and entering the United States, however, renders the impact of this approach, on its own, quite limited. Approximately 9.1

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<sup>30</sup> See Federal Meat Inspection Act, 21 U.S.C. § 604; Poultry Products Inspection Act, 21 U.S.C. § 455.

<sup>31</sup> See 21 C.F.R. § 210.1 (2008).

<sup>32</sup> See Donald C. Clarke, *The Enforcement of United States Court Judgments in China: A Research Note*, (May 27, 2004). GWU Legal Studies Research Paper No. 236 Available at SSRN: <http://ssrn.com/abstract=943922>

<sup>33</sup> A brand name product may suffer negative reputational consequences when a hazardous products finds its way to the market, and even a supplier that is invisible to consumers may suffer if intermediaries or sellers recognize that the suppliers products are unsafe. When supply chains stretch across countries and continents these reputational effects can be muted. A supplier's reputation may not spread from buyers in one country to another, for example, or a purchasers may not be able to observe whether a new supplier is the same or different from an existing supplier with a poor reputation.



million imported food shipments enter the U.S. annually<sup>34</sup> but in 2006 the FDA visually inspected only 115,000, sending 20,000 samples for laboratory analysis.<sup>35</sup> No technology exists to test drugs comprehensively at the border, and even if it did, such a task would, in the words of U.S. Department of Health and Human Services, simply be “logistically impossible” and “prohibitively expensive.”<sup>36</sup> Toys—87% of which are produced overseas<sup>37</sup>—currently undergo no testing at all by regulators, and the compromise of consumer data takes place entirely abroad. For all of these reasons, outcome-based regulation as currently used faces significant challenges when addressing imported products.

## 2. *The Missing 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, as a formal matter, 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 process 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.

The way in which foreign production disables the production lever is illustrated by imported drugs and food. 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 U.S. in 2006, up from just eight generic drugs a decade ago; Chinese manufacturers, in turn, sold \$675 million in drug ingredients and

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

<sup>35</sup> Alexei Barrionuevo, *Food Imports Often Escape Scrutiny*, N.Y. Times, May 1, 2007, at <http://www.nytimes.com/2007/05/01/business/01food.html> (last visited Jan. 22, 2008).

<sup>36</sup> HHS Drug Import Report, *supra* note \_\_.

<sup>37</sup> Public Citizen, *Report: Santa's Sweatshop: Made in D.C. with Bad Trade Policy* (Dec. 19, 2007), available at <http://www.citizen.org/documents/Santas%20Sweatshop.pdf>.

products in 2006, a figure that more than doubled in five years.<sup>38</sup> Drug industry analysts trace 20 percent of finished generic and over-the-counter drugs to India and China, as well as more than 40 percent of the active ingredients in U.S.-made medications.<sup>39</sup>

All drug-ingredient manufacturers, whether foreign or domestic, ostensibly face the same regulatory regime. They must register drug ingredient and other information with the FDA, which both approves new drugs and regulates the manufacture and distribution of brand-name and generic medicines<sup>40</sup> by providing minimum good manufacturing guidelines and conducting quality-control inspections.<sup>41</sup> However, because FDA regulators do not have the authority to enter foreign factories unannounced, as they do in the U.S., they must schedule inspections in advance, through an U.S.-based agent of the foreign company.<sup>42</sup> 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 32 quality-assurance inspections in India, 15 in China and 1,222 in the U.S.<sup>43</sup> 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 U.S.<sup>44</sup>

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, although foreign processors that ship fish or fishery products to the U.S. are formally required to operate in conformance with the FDA's seafood HACCP Regulations, 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 the fact that regulators change targets, and even countries, year by year, means that should an inspection take place it is virtually certain that it will be a long time before any further inspections take place.<sup>45</sup> With

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<sup>38</sup> See Kaufman, *supra*, note \_\_\_\_.

<sup>39</sup> See *id.*

<sup>40</sup> See 21 C.F.R. § 207.20 (2008); 21 C.F.R. §207.37 (2008).

<sup>41</sup> See 21 C.F.R. § 210.1 (2008).

<sup>42</sup> See 21 C.F.R. §207.40 (2008).

<sup>43</sup> See Kaufman, *supra*, note \_\_\_\_.

<sup>44</sup> See *id.*

<sup>45</sup> FDA, CFSAN/Office of Seafood, FDA's Evaluation of the Seafood HACCP Program for Fiscal Years 2002/2003 (May 13, 2005).

regards to manufactured goods, moreover, the CPSC lacks jurisdiction to test a product's safety before it reaches the market.

Several recent policy proposals have suggested enhancing both outcome-based inspections and the production-based component in U.S. regulation of foreign activity. As to the first, increased post-production inspections certainly could yield benefits in some important contexts, but provides at most an incomplete response. More than \$2 trillion of products were imported into the United States in 2006, from more than 150 countries. More than 825,000 importers brought shipments into the United States, through more than 300 ports, border crossings, and postal facilities.<sup>46</sup> Furthermore, the value of imports is increasing rather than decreasing over time. 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.<sup>47</sup> 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.<sup>48</sup> More generally, the FDA has explored requiring inspections of foreign plants before foreign-manufactured active drug ingredients are allowed in FDA-approved prescription medication.<sup>49</sup> And the Interagency Working Group on Import Safety convened by President Bush<sup>50</sup> has similarly called for an increased presence

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<sup>46</sup> Andrew Martin, *Cabinet Study Says Safety Must Precede U.S. Border*, NEW YORK TIMES, Sept. 11, 2007, New York Times, available at <http://www.nytimes.com/2007/09/11/business/11foods.html?scp=2&sq=andrew+martin+cabinet+study+&st=nyt>.

<sup>47</sup> More Inspectors a Top Priority for FDA, THE MQN WEEKLY BULLETIN (FDA), Vol. 2 No. 11, March 14, 2008, available at <http://www.fdanews.com/newsletter/article?issueId=11400&articleId=104906>.

<sup>48</sup> Marc Kaufman, FDA Says It Approved The Wrong Drug Plant, WASH. POST, February 19, 2008, at A-1.

<sup>49</sup> *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) (statement of Catherine Woteki, former Under Secretary for Food Safety, U.S. Department of Agriculture, and statement of Peter Barton Hutt, former Chief Counsel for the Food and Drug Administration).

<sup>50</sup> See Import Safety, <http://www.importsafety.gov>. 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 and the

overseas in order to inspect goods before they enter the U.S., and to integrate inspections of processes into the regulatory framework.<sup>51</sup>

One obvious problem with such proposals is the sheer size that a program of extraterritorial inspections and regulations would have to achieve in order to be effective. The world is a big place, and the resources required to achieve an important presence in all the places from which the United States imports are simply not available. 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. American inspectors and officials operating in China would be less effective simply because they lack the language and cultural skills to easily navigate Chinese society and to understand local business practices.

The high cost of this regulatory approach would have to 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, then, this cost will be ignored, creating a distortion in such decisions. That distortion is 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 do so without any formal legal authority granted by the local jurisdiction. They are unable, without assistance from local authorities, to demand anything from the firms they are inspecting, including access, information, responses to questions, and so on. 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

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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 on the Working Group as well.

<sup>51</sup> See 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*, November 2007, available at <http://www.importsafety.gov/report/report.pdf>; Interagency Working Group on Import Safety *Action Plan for Import Safety: A roadmap for continual improvement*, 49-57 (Nov. 2007), available at <http://www.importsafety.gov/report/actionplan.pdf> (“*Action Plan for Import Safety?*”); see also *Developing a Comprehensive Response to Food Safety: Hearing Before the S. Comm. on Health, Educ., Labor and Pensions* (statement of Michael Leavitt, Secretary of Health and Human Services), available at [http://help.senate.gov/Hearings/2007\\_12\\_04/Leavitt.pdf](http://help.senate.gov/Hearings/2007_12_04/Leavitt.pdf);

knowledge of supply chains in order to ensure that the output from production facilities that have refused to cooperate is not presented as being 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 U.S. Because these are American authorities investigating the issue, there need not have been any violation of local law, and if there has been local authorities may not wish to pursue the matter.<sup>52</sup>

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

## II. EXPLORING SOLUTIONS

### *A. Assumptions*

Two assumptions are worth stating explicitly before solutions are explored. The first involves nature of safety as a regulatory goal, while the second involves the baseline against which we consider the efficacy of consumer protection regulation of foreign activity.

#### *1. How Safe Should Imports Be?*

Nobody likes or wants dangerous products, but regulators do not have the luxury of demanding a perfect record of product safety from any producer. Unsafe 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 worthwhile to devote additional resources (whether private or public) to further increases in safety. For example, any system of food production will, from time to time, generate impure and unhealthy food. Regulators can improve the

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<sup>52</sup> 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. Even in this case, however, the other challenges with regulating foreign production remain.

safety of food in any number of 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 it makes sense to expend scarce resources in this way.

For any product, then, regulators must determine how best to balance the costs of increased consumer protection with the costs that unsafe products impose on public welfare. Increased safety should be demanded only up to the point where the marginal cost of greater safety exceeds its marginal benefit. There is certainly plenty of political judgment with respect to these costs and benefits, but that does not change the fact that optimal levels of safety must take into account the cost of making products safer.

This point is true for imported products just as it is for domestic products. The appropriate level of safety for imports, then, depends in part on the cost of increased safety.<sup>53</sup> To illustrate, imagine a product that under status quo regulation will be dangerous in 1 out of 1000 cases. Now suppose that an alternative regulatory regime is proposed under which the incidence of unsafe products would be reduced to 1 out of 5000. This is a good outcome for safety, but if it involves a doubling of costs the product regulators (and the public) may prefer the status quo. If, on the other hand, the increase in cost is small, regulators may prefer the new regime. This simply reflects the fact that the regulator wants safety to be improved only when the marginal reduction in costs imposed by unsafe products exceeds the marginal cost of the safety improvements.

In short, regulators wish to increase safety up to the point where the marginal cost of safety exceeds the marginal benefit. It can do so by forcing producers to internalize the full social harm caused by unsafe products. This will normally not yield perfect safety, and the incidence of unsafe products will vary depending on the cost of improving safety. Consistent with this observation, we avoid arguments about absolute levels of safety and reject arguments that call for increase safety regardless of cost. We focus instead on ways that producers of potential hazardous products can be made to internalize the full social cost of harm from those products.

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<sup>53</sup> For simplicity we assume that any increase in costs is passed through to consumers, so that both the cost and benefits of increased safety are felt by Americans. If the producer has a degree of market power this pass through will normally be only partial, creating an incentive for the importing country (here, the United States) to demand excessive levels of safety because some of the costs will be borne by the foreign firm.

## 2. *The Domestic Baseline*

In this paper we are interested in how regulators can address the challenges of regulating imports. There are obviously important and contentious questions about how domestic production should be regulated. It would, however, take us far afield to wade into this debate in any detail, and doing so is not necessary for our own analysis.

To illustrate the particular issues affecting the regulation of imports, therefore, we simply assume that existing domestic regulations, including the level of regulation and the manner in which it is carried out, are optimal. 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 – but rather because it allows us to emphasize the ways in which imports differ from domestic production.<sup>54</sup> By assuming that existing regulation accurately reflects the marginal cost and marginal benefit of safety-enhancing measures by domestic producers we are able to isolate the ways in which the regulation of imports may fail to be optimal.

We are comfortable with this assumption in part because the conclusions of our analysis can easily be adjusted to take account of alternative views about domestic regulation. For example, if one believes that the United States engages in excessive regulation of domestic activity, the fact that imports are able to avoid some relevant regulations is cause for celebration and there may be no policy response needed. If, instead, one believes that the United States regulates domestic production too little, then one should be even more concerned about how imported products regulated.

### *B. Substitutes for the Production Lever*

As discussed in Part I, the most obvious problem with simply applying existing regulatory schemes to imports and domestic production alike is that the production lever works poorly for imports. When regulation relies on this lever, then, domestic production will be affected more than imports. Assuming, as we do throughout this paper, that regulation is chosen because it suits the

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<sup>54</sup> See Andrew T. Guzman, *Is International Antitrust Possible?*, 73 N.Y.U. L. Rev. (1998); Andrew T. Guzman & Stephen Choi, *Portable Reciprocity: Rethinking the International Reach of Securities Regulation*, 71 SO. CAL. L. REV. 903 (1998); Kenneth A. Bamberger, *Private Actors in the Domestic Governance of Global Terror Risk*, in GLOBALIZATION COMES HOME: HOW THE UNITED STATES IS BEING TRANSFORMED BY GLOBALIZATION (B. Crawford and M. Bertho, eds.) (forthcoming 2008); Bamberger, *Regulation as Delegation*, *supra* note 10.

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: (i) product-based regulation by a foreign government; (ii) third-party regulation by a relevant industry group or certifying organization; and (iii) regulation by the domestic private actors engaged in outsourcing, motivated by outcome-based regulation. The first two of these approaches are familiar and will only be described briefly. The third approach offers a strategy for dealing with some of 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.

### 1. *Regulation by Foreign Governments*

#### a) *The Potential for Relying on Foreign Governments*

As applied by American regulators, the production lever often fails to reach imports because production takes place abroad. This suggests the most obvious substitute for that lever – the relevant foreign government. As long as the regulatory objectives in the two states (the United States and the foreign state in question) are compatible, and as long as the regulation in the foreign states 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.

This approach is expressly used by U.S. regulators 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 then only from establishments certified by the foreign government.<sup>55</sup>

Congress has, further, authorized this regulatory method in the pharmaceutical context, although it has not been adopted administratively. Specifically, the Medicare Prescription Drug,

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<sup>55</sup> Once eligibility is established, however, the Animal and Plant Health Inspection Service animal health restrictions determine the specific types of products that can be imported from the country. *See generally* USDA Food Safety and Inspection Service, Eligible Countries, Products and Certified Establishments [http://www.fsis.usda.gov/Regulations & Policies/Eligible Foreign Establishments/index.asp](http://www.fsis.usda.gov/Regulations%20&%20Policies/Eligible%20Foreign%20Establishments/index.asp).



Improvement and Modernization Act of 2003,<sup>56</sup> which created a prescription drug benefit for seniors and people with disabilities, authorizes the Secretary of HHS to promulgate regulations allowing importation of prescription drugs into the United States 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.”<sup>57</sup> Such authority creates an exception from the mandates of the “closed” system established by the Food Drug and Cosmetics 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 convened to assess the issue suggested that the import of drugs be permitted from countries that “have a regulatory system equivalent to the U.S.,”<sup>58</sup> 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.”<sup>59</sup> 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.”<sup>60</sup> The Secretary has, accordingly, not acted on this authorization, instead taking action to stop importation of drugs whose manufacture it does not regulate directly.<sup>61</sup>

Finally, the European Union has adopted a strategy of relying on regulation by foreign governments for the protection of consumer privacy. Specifically, its Privacy Directive,<sup>62</sup> as a general matter, permits the transfer of personal data to parties in non-European

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<sup>56</sup> Pub. L. 108-173.

<sup>57</sup> Pub. L. 108-173, § 804(l)(1).

<sup>58</sup> HHS Task Force Report, *supra* note \_\_ at 10

<sup>59</sup> *Id.* at xi.

<sup>60</sup> *Id.*

<sup>61</sup> See, e.g., *United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238, 1252 (N.D. Okla. 2003) (supporting FDA finding that storefront pharmacy was illegally importing drugs from Canada); *Vermont v. Leavitt*, 405 F. Supp. 2d 466 (D. Vt. 2005) (prohibiting state from importing drugs from Canada).

<sup>62</sup> Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 On The Protection Of Individuals With Regard To The Processing Of Personal Data And On The Free Movement Of Such Data.

Union nations only if those countries' privacy protection regimes are considered "adequate."<sup>63</sup>

Preliminary measures along these lines have, too, been pursued by U.S. regulators. In 2007, senior HHS officials met with senior Chinese officials and developed two agreements, one on food and feed,<sup>64</sup> the other on drugs and medical devices.<sup>65</sup> Both agreements focused on registration, certification and verified compliance. Through the food and feed agreement, China's State Food and Drug Administration (SFDA) 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.<sup>66</sup> In addition, the SFDA agreed to notify the FDA within 24 hours whenever it determines that a product exported to the U.S. could cause serious adverse health consequences.<sup>67</sup> Through the drugs and medical devices agreement, the two countries agreed on a framework for information sharing and regulatory cooperation.<sup>68</sup>

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<sup>63</sup> See *id.*, Art. 24. Exceptions to the Directive's transfer restriction include: (a) the data subject has unambiguously given his consent to the data transfer; (b) the transfer is necessary for the performance of a contract between the data subject and the controller or the implementation of precontractual measures at the data subject's request; (c) the transfer is necessary for the conclusion or performance of a contract in the interest of the data subject between the controller and a third party; (d) the transfer is necessary or legally required in the public interest or for legal claims; (e) the transfer is necessary to protect the vital interests of the data subject; or (f) the transfer is made from a register, which according to laws or regulations, is intended to provide information to the public and which is open to the public or any person who can demonstrate legitimate interest.

<sup>64</sup> 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>.

<sup>65</sup> 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>.

<sup>66</sup> Agreement on Food and Feed, *supra* note \_\_; see also U.S. Gains Access to Chinese SFDA Inspection Information, International Pharmaceutical Regulatory Monitor, Vol. 36 No. 1, January 15, 2008.

<sup>67</sup> *Id.*

<sup>68</sup> Agreement on Drugs and Medical Devices, *supra* note \_\_. Paradoxically, some have noted that the certification regime detailed in the MOU's may actually lead to a reduction in border inspections of Chinese products, a measure that the U.S. has declined to implement with regard to imports from Canada and Mexico. While the proposed 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

CPSC officials also negotiated a Memorandum of Understanding with the Chinese government, covering certain targeted products including children's toys, clothing, fireworks and cigarette lighters.<sup>69</sup>

*b) 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 regards to specific jurisdictions, there are obvious limits to this approach. As a practical matter, many foreign states will employ regulatory standards that are significantly less stringent than those of the United States, or systems that are inept, corrupt or perhaps even non-existent, and therefore cannot operate as adequate regulatory substitutes. This is, to date, largely the regulatory situation with respect to production in China, the world's largest exporter of manufactured goods,<sup>70</sup> and with regards to India, which 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.<sup>71</sup> As these systems 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.

Moreover, differing domestic political contexts suggest that there will often be at least some differences between the regulatory priorities and goals of different states, so even close allies of the United States with broadly similar concerns and objectives, will adopt different regulatory standards and will enforce them differently. The HHS Task Force on drug imports, for example, noted, in rejecting the import of drugs whose manufacture the FDA did not oversee,

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U.S. inspectors could waive inspections on the basis of certifications. U.S.-China Food Safety Deal Could Give China Preferential Treatment, *INSIDE US-CHINA TRADE*, Vol. 7 No. 50, December 19, 2007.

<sup>69</sup> Memorandum of Understanding between the U.S. Consumer Product Safety Commission (CPSC) and The General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ), available at <http://www.cpsc.gov/CPSCPUB/PREREL/prhtml04/04124mou.html>.

<sup>70</sup> 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* (Sep. 5, 2006), available at <http://www.manufacturingnews.com/news/06/0905/art1.html>.

<sup>71</sup> See Forbes.com, *India Controls 44 Percent of Outsourcing* (June 12, 2005), [http://nasscom.org/artdisplay.asp?Art\\_id=4406](http://nasscom.org/artdisplay.asp?Art_id=4406) (reporting for the main infotech trade body that revenues for Indian companies reached US\$17.2 billion in the year ended March 2005).

concerns that Japanese law permits the import of expired medical products, their re-packaging as “new,” and their export to other countries—activities that would be illegal under U.S. law.<sup>72</sup>

Finally, competition among jurisdictions for business makes it extremely unlikely that reliance on regulation by foreign governments will ever become more than a context-specific substitute for domestic government regulation. The willingness to accept a foreign regulatory substitute necessarily leads to a certain degree of competition among jurisdictions. Both India and the United States, for example, represent potential locations for provision of business process services. Although there are many other factors that affect a firm’s decision about the location of 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. Whether one views this competition as good or bad depends in part on one’s assumptions about the political economy of regulation. Some may think that competition is good because it causes regulators to fully account for the burden of regulation on firms. Others may view this competition as harmful and a threat 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 United States 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.<sup>73</sup>

Regulation by a foreign jurisdiction, then, is likely to provide a better regulatory substitute when either (1) only a small share of production is exported and the rest is consumed internally, or (2) high standards are sustained by trade reciprocity, in which each jurisdiction realizes that if it fails to adequately regulate local production intended for export other jurisdictions will do the same. Reciprocity alters the choice set of each state—making it choose between mutual cooperation (full regulation) and mutual non-

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<sup>72</sup> HHS Task Force, *supra* note \_\_ at 10.

<sup>73</sup> For a similar argument in the context of antitrust and the regulation of competition policy see, Andrew T. Guzman, *Is International Antitrust Possible*, 73 N.Y.U. L. REV. (1998).

cooperation (reduced regulation for exported products).<sup>74</sup> Where neither of these situations exists, 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.<sup>75</sup>

## 2. *Third-Party and Self-Regulation*

### a) *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 takes a variety of forms but is widely used. More than 2700 municipal, city, and state governments within the United States mandate private safety certifications for certain types of products sold or installed within their jurisdictions.<sup>76</sup> The bulk of such certifications are provided by Underwriters Laboratories, a private firm founded over a century ago, that, through its 62 laboratory, testing and certification facilities serving customers in 99 countries, places over 21 billion certification “marks” on 72,000 manufacturers’ products each year.<sup>77</sup> 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 EU and US have negotiated a Safe Harbor agreement, administered by the U.S. Department of

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<sup>74</sup> See ANDREW T. GUZMAN, *HOW INTERNATIONAL LAW WORKS: A RATIONAL CHOICE ANALYSIS* 42-45 (2008) (discussing and analyzing reciprocity in international law).

<sup>75</sup> 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 paper. Inevitably, for example, this decision will be influenced by political concerns rather than simply the working 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 simply 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 jurisdiction complicated and difficult.

<sup>76</sup> See Harold Furchtgott-Roth, *et al.*, *The Law And Economics Of Regulating Ratings Firms*, 3 J. COMPETITION L. & ECON. 49, 88 (2007).

<sup>77</sup> See <http://www.ul.com/about/>.

Commerce, by which particular companies can self-certify annually that they meet the adequacy standard individually.<sup>78</sup>

Consistent with this notion of third-party oversight as a substitute for 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.<sup>79</sup> Some U.S. retailers have begun to rely on GlobalGap, a private standards organization organized by European food retailers, which certifies compliance of over 81,000 farms and plants in 76 countries with food industry safety guidelines.<sup>80</sup> 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 which monitor products and processes in those two countries.<sup>81</sup> In 2007, NASSCOM (the National Association of Software and Services Companies), the nonprofit group established by the Indian software and business process outsourcing industry,<sup>82</sup> established the Data Security Council of India (DSCI) after unsuccessful attempts at lobbying the Indian legislature to enact formal data protection legislation.<sup>83</sup> The DSCI is a self-regulatory initiative to develop standards and certification processes, enforced by disaccreditation and penalties, to ensure compliance with U.S. and European data privacy and security practices.<sup>84</sup>

Several current consumer protection proposals recognize the promise of private third-party regulation. The Interagency Working Group on Import Safety's September 2007 *Action Plan for Import Safety* included as two of its five proposals the verification of compliance by

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<sup>78</sup> See <http://www.export.gov/safeharbor/>.

<sup>79</sup> See generally Margaret M. Blair, *et al.*, *The New Role for Assurance Services in Global Commerce*, 33 J. CORP. L. 325 (2008) (discussing generally the emergence of a private-sector compliance and enforcement infrastructure in global commerce).

<sup>80</sup> See <http://www.globalgap.org>; John W. Miller, *Private Food Standards Gain Favor: Wal-Mart, McDonald's Adopt European Safety Guidelines*, WALL ST. J., B1 (March 11, 2008).

<sup>81</sup> See *id.*; *U.S. Pharmacopoeia-India Site Inaugurated at ICICI Knowledge Park, Hyderabad*, [www.usp.org/aboutUSP/media](http://www.usp.org/aboutUSP/media), Feb. 8, 2006; *U.S. Pharmacopoeia Inaugurates New Facility in Shanghai*, [www.usp.org/aboutUSP/media](http://www.usp.org/aboutUSP/media), Sept. 6, 2007.

<sup>82</sup> See NASSCOM, *About NASSCOM*, at <http://www.nasscom.in/Nasscom/templates/NormalPage.aspx?id=5365> (discussing trade organization).

<sup>83</sup> See NASSCOM, *Data Security Council of India (DSCI): A Self Regulatory Initiative in Data Security and Privacy Protection*, at <http://www.nasscom.in/Nasscom/templates/NormalPage.aspx?id=51973>.

<sup>84</sup> See *id.*; Moumita Bakshi Chatterjee, *Nasscom Working on Data Security Council*, THE HINDU (BUSINESS LINE) (Jun 11, 2007), available at <http://www.thehindubusinessline.com/2007/06/11/stories/2007061101150200.htm> (discussing standards, auditing and certification proposal).

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 U.S. for compliance with FDA standards.<sup>85</sup> These measures would be promoted, in part, by access to expedited import privileges for those who meet the certification requirements. The Senate version of 2008 legislation intended to strengthen the regulatory authority of the CPSC, moreover, would require safety certification of children's products by third party laboratories, or by proprietary labs upon CPSC approval.<sup>86</sup>

*b) The Limits of Third-Party 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 quite circumscribed. 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. Moreover, such “self-regulatory” apparati have historically proven most successful when there is a credible threat of government regulation to provide industry groups with an incentive to act. This government pressure is missing in many of the contexts involving extraterritorial activity with U.S. consumer protection implications.

For self-regulatory systems to function requires that government and consumers have a certain confidence in them. This is difficult to generate from scratch, making the establishment of such systems difficult, especially over short periods of time. Where they do not already exist, then, there is no easy way to develop them quickly. This challenge is made more acute by the fact that self-regulation normally requires at least some oversight by public authorities to ensure its proper functioning. Where these public authorities are unable or unwilling to engage in such oversight, self-regulation is likely to fail.

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<sup>85</sup> *Id.*

<sup>86</sup> Senate Passes Bipartisan Children's Safety Legislation Sponsored by Pryor, Stevens and Inouye, Congressional Documents and Publications, March 6, 2008. Differences between the House and Senate versions include provisions respecting the level of caps on civil penalties and whistleblower protections. Statement by Sen. Mark Pryor on CPSC Reauthorization, States News Service, December 19, 2007.

### 3. *Regulation by US participants in globalized trade*

So while both regulation by a foreign government and self-regulation can sometimes provide satisfactory substitutes for the sort of production-based regulation that is used for domestic production, in many circumstances those substitutes will not prove adequate.

Consider once again, the example of imported toys from China. The American regulatory system is frequently unable to reach Chinese firms that have neither a presence nor assets in the United States, so the production regulation lever is missing. The two substitutes discussed above—regulation by a foreign government and self-regulation—are also missing or, at least, highly imperfect. Despite evidence that China at least wants to improve its regulatory system,<sup>87</sup> and despite the fact that it obviously possesses the legal authority to do so, it is clear that the level of regulatory oversight of production in China fails to approximate the standards present in the United States. Indeed, if the domestic Chinese system were an adequate regulatory substitute the concern about Chinese imports and the resulting public debate would never have come about.

One possible solution would be to help build the missing structures in China through, for example, assistance in the development of administrative agencies and governance regimes. Though we support such efforts, they obviously do not address the short-term need to respond to immediate safety concerns. Even under a hopelessly optimistic view, it will 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. More broadly, though China is the focus of these concerns at the moment, it is not the only country with weak regulatory systems that is exporting to the United States. Many other countries, including many developing countries, are similarly unlikely to provide domestic regulatory oversight that can be considered an appropriate substitute for the American system.

Self-regulation similarly fails to meet the demand for reliable production processes in many instances. 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 has not generated

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<sup>87</sup> See Eric Lipton, *China Plans Greater Security of Food Exports*, New York Times, August 16, 2007; David Barboza, *China Steps Up Efforts to Cleanse Reputation*, New York Times, Sept. 5, 2007; *China Blacklists 400 Exporters*, CNNMoney.com, Aug. 4, 2007; TAN 64-69.



a simultaneous emergence of comprehensive self-regulatory mechanisms to govern production processes. Like reliance on foreign governments, reliance on self-regulation is sensible in some instances, but not all.

There remain, therefore, important categories of imports for which American authorities must find some additional way to respond when they only have access to the outcome lever of regulation and when neither regulation for foreign governments nor self-regulation are effective substitutes.

To address this set of imports we propose that domestic regulatory authorities 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. Thus in the case of toys Mattel, for example, would face legal obligations designed to provide it with sufficient incentives to address the safety risks associated with the toys it imports.

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 partners comply with safety norms required under relevant production-based regulations. The FDA relies on U.S. drug makers themselves to test ingredients they buy abroad.<sup>88</sup> Importers of foreign fish and fishery products into the United States are obligated to take “affirmative steps” to determine that their foreign suppliers are complying with U.S. HACCP requirements. 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.”<sup>89</sup>

These attempts have proven incomplete because of the 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

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<sup>88</sup> Kaufman, *supra* note \_\_\_\_.

<sup>89</sup> *Interagency Guidelines Establishing Standards for Safeguarding Customer Information*, 12 CFR Part 30.

“regulators” of foreign activities. They have failed, for example, to expend the resources necessary to properly monitor foreign supply chains.<sup>90</sup> In the face of competitive pressures, for example, the older practice of batch-testing of 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.”<sup>91</sup> American firms engaged in little oversight of the manufacturing of many of the millions of toys later recalled for safety violations.

U.S. food and drug companies have demonstrated a lack of knowledge of even of the identity of some of their suppliers, let alone participation in comprehensive monitoring and oversight.<sup>92</sup> This was the case, for example in the recent recall of fresh ginger packaged and distributed under the name of a large California firm. It turned out that the ginger was of unknown origin and was tainted with the banned pesticide aldicarb sulfoxide.<sup>93</sup> Similarly, the American pharmaceutical company Baxter was ignorant of the source of the fatal Chinese-produced ingredient it incorporated in its blood-thinning Heparin drug.<sup>94</sup> In the data protection context, firms’ implementation of affirmative steps to oversee foreign partners has proven 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.<sup>95</sup>

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<sup>90</sup> Deloitte Consulting, *Supply Chain’s Last Straw: A Vicious Cycle of Risk* (2007), available at [http://www.deloitte.com/dtt/cda/doc/content/us\\_consulting\\_suppchain\\_wp\\_090107.pdf](http://www.deloitte.com/dtt/cda/doc/content/us_consulting_suppchain_wp_090107.pdf).

<sup>91</sup> Parija B. Kavilanz, *Blame U.S. companies for bad Chinese goods*, CNNMoney.com (August 14 2007); see also Nicholas Zamiska and David Kesmodel, *Tainted Ginger’s Long Trip From China to U.S. Stores*, Wall St. J., Nov. 19, 2007, at A1 (documenting California firm’s failure to identify, let alone monitor, the supply chain that produced Chinese tainted ginger).

<sup>92</sup> See U.S. Department of Agriculture, Office of Food Safety and Technical Service, *Food and Agricultural Import Regulations and Standards Report (FAIRS)*, at [www.fas.usda.gov/itp/ofsts/us.html](http://www.fas.usda.gov/itp/ofsts/us.html) (1999).

<sup>93</sup> Nicholas Zamiska and David Kesmodel, *Tainted Ginger’s Long Trip From China to U.S. Stores*, Wall St. J., Nov. 19, 2007, at A1.

<sup>94</sup> See Gardiner Harris and Walt Bogdanich, *Drug Tied to China Had Contaminant*, F.D.A. Says, N.Y. TIMES (Mar. 6, 2008).

<sup>95</sup> See GAO *Privacy Outsourcing Report*, *supra* note \_\_, at 18; Ponemon, *Outsourcing Survey*, *supra* note \_\_ (while 56% of respondents experienced data loss or theft, only 55 percent of respondents say they evaluate the outsourcer’s data protection practices before engaging them or transferring information).

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 the capacity of other substitute regulators—such as foreign governments and other third-parties—quickly and effectively, this substitute should be explored more vigorously.

### III. THE REGULATORY PROPOSAL: IMPORTERS AS REGULATORS

The remainder of our analysis explains how it is possible to establish more appropriate incentives for private parties with the reach of the American regulatory system. Specifically, we argue that when existing regulatory structures fail to ensure satisfactory consumer protection levels for imported goods and outsourced data, U.S. regulators should impose additional outcome-based penalties for safety violations on the U.S. partners in international trade—penalties, therefore that discriminate between foreign and domestic activity.

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.

We make the case that a system of discriminatory penalties will cause 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

#### *A. The Case for Discriminatory Penalties*

##### *1. Who and What Should Regulators Target?*

Our proposal begins with a recognition of the limited tools and regulatory targets available to American regulators when dealing with imports. Because they are unable to use the production lever effectively, regulators must seek substitutes. The prior discussion has

described some of the possible substitutes for production-based regulation and has explained why none of them offers a satisfactory solution the problem of regulating imports.

What remains when these alternatives are either unavailable or their usefulness is exhausted are changes to the penalties that accompany outcome-based regulation.<sup>96</sup> This means, first, that the legal strategy adopted by the United States must target the parties that are within the reach of the domestic legal system. There is no sense, after all, assigning liability to foreign firms that cannot be reached.

In some situations, of course, the limited reach of the law will not present a meaningful constraint for regulators. Even foreign producers sometimes have a significant presence in the United States (think, for example, of foreign car manufacturers such as Toyota, Hyundai, and Volkswagen, which can easily be reached by the American legal system) or it may even be an American firm (think of foreign production facilities owned and operated by Ford Motor Company). In other situations, however, the producer or service provider will be beyond the reach of American law enforcement.

For a product to be distributed in the United States, however, requires that some entity or person within the United States be involved. There will normally be a party responsible for the importation of the product, one responsible for distribution, and one responsible for sale of the product, though a single party may play more than one of these roles. There may also be additional parties carrying out additional functions to get the product to market. For simplicity we refer to these parties as “importers and sellers.” With that term we mean to include the principal private parties in the chain of commerce from when the good or service arrives in the United States to the point at which it is sold to consumers. That term is also limited to parties that are within the reach of American legal authorities.

These importers and sellers, then, are the ones on whom the American system can credibly impose regulatory obligations and, if those obligations are not met, penalties. These parties are not chosen because they necessarily have some culpability for unsafe products or because they are ideally suited to promote safety. They are chosen instead mostly by default. If the United States is to impose legal rules that have an effect, those legal rules must be directed at one or more

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<sup>96</sup> Importantly we do not advocate changes to substantive safety requirements. Our focus instead is on the penalties assessed if stated requirements are not met.

parties within the jurisdictional reach of the United States and involved in the stream of commerce at some point prior to the final purchase by the consumer. Importers and sellers are sometimes the only parties that fit this description. These parties are able, however, to have an impact on activity earlier in the chain of production. They can demand certain behaviors from their business partners or can seek alternative partners. Importantly, appropriate regulatory obligations must be given to importers and sellers without regard to what they know or even what they should know. Making them responsible without regard to their own knowledge gives them a proper incentive to identify and investigate relevant risks and to take action to reduce those risks. If lack of knowledge allows the importers and sellers to avoid responsibility they can simply remain ignorant of important risks, leaving all potentially responsible parties beyond the reach of American law, and making regulatory efforts pointless.

A second feature of any regulatory strategy is that it must be based on actions and events that are observable to the U.S. system. Obviously if some of the production process takes place in the United States then that production is observable. But with respect to production that takes place abroad the regulatory system must focus on the product itself, or the outcome of the service—like a data breach involving U.S. consumer information—rather than any aspect of its production. For foreign production, then, our proposal limits itself to use of the outcome lever.

These constraints – regulating only those within the reach of American legal authorities and using only the outcome lever – are significant ones for the regulatory system and they make the task of addressing safety concerns more difficult. They are not, however, fatal to the system’s ability to do so. This is fortunate as it might otherwise be necessary for policymakers to choose between safety and international trade. We demonstrate below, however, that even when it is only possible to apply legal rules to parties with some presence in or connection to the United States, and even if only outcome-based regulation is available, an appropriately designed strategy can generate desirable incentives for producers, importers, and sellers. The key to such a strategy is to enlist American private parties to fill the role of *de facto* regulators of their foreign business partners.

## 2. *When Should Discriminatory Regulation be Used?*

Throughout this paper we have assumed that domestic regulatory approaches are optimal for the regulation of domestic production.<sup>97</sup> It is only when those approaches are unavailable that we believe a different policy response is needed. In other words, we do not advocate a general shift away from the status quo toward a system that relies exclusively on the outcome lever.

This raises the question of when we believe that regulators should use outcome-based regulation to enlist the regulatory capacity of domestic trade partners. With respect to imported products, the status quo approach will often be sufficient. In other contexts, however, existing strategies will fail to effectively impact imports.

The first, and simplest, point is that if it were possible to reproduce the regulatory system applied to domestic production simply by making importers and sellers responsible for compliance with regulatory requirements, addressing the problem of quality and safety in imports would be straightforward. Domestic authorities could use precisely the same regulatory mix of production and outcome regulation for imports as they do for domestic production, and a similar level of safety could be achieved.<sup>98</sup> 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, it is necessary to use different regulatory strategies for foreign and domestic producers, respectively. 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 is employed to improve safety outcomes. Put another way, this is the category—which includes drugs, food and data—in which it is the production lever that determines the level of safety of domestic products.

In this situation, once the firm has complied with the production regulation requirements, the products that it produces already have a low risk of being dangerous. Even if some potential outcome-based liability exists, the producer will only make additional investments in safety if the marginal cost of doing so is less than the marginal benefits. Because production-based regulation has already generated a fairly safe product, the risk that it will be subject to a

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<sup>97</sup> See Part II.A.2.

<sup>98</sup> In fact, 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.

penalty through the outcome-based liability regime is small, so the marginal benefit from increased safety is small, and the firm may conclude that there is no need to take any action in response to the outcome-based liability. Thus, it is the production lever that determines the safety of the final product.

Because the production lever operates less effectively, if at all, against foreign activity, however, regulators find themselves with a smaller toolkit that limits them to using the outcome lever. There is no choice but to find a way to make outcome-based liability in a way that compensates for the lost production lever.

The other context in which discriminatory regulation is needed is one in which goods and services are regulated only by means of the outcome lever but the outcome requirements are satisfied not only because of the possibility of legal action, but also because of the non-legal incentives in place. These are the economic or social factors that influence safety decisions but that are not enforced through legal action. They include reputational issues, ethical commitments of firms, industry group pressures, and so on. When those extra-legal incentives are lacking or work differently and compliance suffers once activity is moved outside U.S. borders, ensuring the requisite level of consumer safety may require that regulators increase the penalties associated with failures to satisfy outcome-based regulation.

### 3. *How Should Discrimination Regulation Work?*

In sum, regulators are often constrained as to the parties whom they can regulate (domestic parties) and the methods they can use (outcomes-based measures) in addressing the failure of regulation calibrated to domestic activity. Recognition of this fact leads to an important conclusion: *consumer protection sometimes requires outcome-based regulation that applies a different level of penalties for non-compliance when the product at issue is made abroad than when it is made in the United States.*

To see why this is so, recall that the 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, in turn, 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. They will, therefore, have weaker incentives to produce safe products, which would be expected to have a negative impact on safety.

To ensure appropriate levels of safety in imports, then, requires a different strategy than that used for American products. Regulators must find an alternative way to prevent hazardous products from entering the market. As already discussed, the one available tool is outcome-based regulation. The need to marshal outcome-based regulation as a substitute for production-based regulations means that the former must play a different (or perhaps additional) role in the regulation of imports than it does in the regulation of domestic production. In particular, among the products at issue here production-based regulation determines the level of safety present in domestic production but fails to do so for imports. It is up to outcome-based regulation to provide importers and sellers with an incentive to deliver safe products or, more accurately, to cause them to internalize the costs of unsafe products. Providing proper incentives to importers and sellers, then, requires that imports face different forms of outcome-based regulation. This fact follows directly from the observation that the safety of domestic production is determined by production-based regulation that cannot (fully) reach imports.

The policy result is that parties responsible for imported products must be provided with additional incentives to produce safe products, and this must be done through an increase in outcome-based liability. This, in turn, implies that the outcome-based liability for imports must depart from that provided to domestic production. In other words, outcome-based liability must discriminate between domestic and imported products.

It is important to understand that although the application of outcome-based regulation that we propose is discriminatory, the objective is to offset the fact that production-based regulation affects domestic production more than foreign production. In effect, discrimination in outcome-based regulation is intended to offset the unavoidable discrimination in the application of production-based regulation.<sup>99</sup> In this sense the difference between how outcome-based regulation treats foreign and domestic producers could be termed “corrective,” rather than discriminatory.

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<sup>99</sup> One could also eliminate production-based liability for domestic producers, but as we are assuming that this liability is an efficient way to achieve governmental objectives eliminating it would also present significant costs.



Once it is recognized that imported products must be regulated entirely through the outcome lever, the way in which importers and sellers become *de facto* regulators is a straightforward implication of familiar results from the literature on accident and administrative law. In the tort context, for example, the imposition of strict tort liability forces actors to internalize the full cost of defective or harmful products. Those actors then 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 is proposed here, though it is done in the context of the full range of outcome-based sanctions rather than only tort law. Domestic partners in trade should be subject to penalties for regulatory noncompliance regardless of the level of care they take, or their actual knowledge about product safety. These penalties, moreover, should be set so as to cause actors within the reach of domestic authorities to internalize the full social costs of increased risks to consumer welfare.

Setting penalties at this level, in turn, will provide the incentives for more accurate decisions regarding the risk of foreign activity. The potential of liability for products that fail to meet outcome requirements represents a cost to importers and sellers. It is also a cost over which they do not have direct control if they are not producing the product. Indeed, they may not even have knowledge of the relevant risks or production methods. The liability does, however, provide them with an incentive to manage their exposure to liability and, therefore, to either achieve some level of control over the quality of the product, or find a way to shift liability to the producer who does have such control. Thus, even if importers and sellers themselves do not know the quality of individual imported products, this liability scheme provides them with an incentive to take action to ensure that the quality is of a sufficiently high level to protect them from undue costs.

The importers or sellers will then take action to manage their exposure to liability. They must estimate the risk of liability with respect to a particular product and adjust their behavior to reflect that potential cost. More specifically, they have a range of options to reduce their exposure to liability and have an incentive to balance the costs and benefits of those alternatives. 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-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 adopts 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. In this way importers and sellers can generate enforcement through these contractual mechanisms that may be impossible for domestic regulatory authorities to achieve directly. The threat of legal sanctions might even spawn an industry of intermediaries that would certify the quality of certain products or suppliers, or an insurance industry that would 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.

Making a firm within the reach of American authorities also addresses the problem of fly-by-night foreign enterprises that engage in production until a problem arises and then simply close up shop only to appear later under a different name. U.S. based parties are much better situated than regulators to identify such parties and to either avoid doing business with them or find way to ensure that the product is a adequately high quality and safety. Once again, the private firm becomes a *de fact* regulator and adjusts its behavior to reflect the cost of unsafe products.

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, it will simply decline to participate in the process of bringing the product to market. It will instead seek other producers of the product, perhaps from the United States or other 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.

Setting administrative penalties appropriately, then, both aligns the interests of regulators and domestic partners in global trade, and enlists 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 their 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.

### *B. Implications of Discriminatory Regulation*

#### *1. The Cost of 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. It may be, for example, that in one country a producer cannot easily ensure that the paint it purchases for use in production is lead-free or that the storage facilities it rents for perishable goods will be kept at a constant temperature, whereas in another country these issues are easy to control. In the former situation the foreign producer will have difficulty ensuring safe inputs 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. That 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. Poorly functioning regulatory environments, of course, are 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.

But another possibility exists. 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,

As a result it is not possible (without more information) to predict the relative costs of increased safety in different countries. This point should not surprise us. The cost of increased safety is best viewed as simply another cost associated with production and sale of the product. 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).

It is possible, however, to predict the impact of the cost 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, but not on its level.

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 so. 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 a violation that is accompanied by payment of penalties and compliance. 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 reflecting this tradeoff between affordability and safety. When the cost of production and safety differ between two countries, there is no reason to think that the tradeoff between costs and safety should be made in the same way and so 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,<sup>100</sup> 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 (based on the likelihood of a tainted product and the 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.<sup>101</sup>

Imagine, for example, that two companies offer a medication to treat heart disease. The drugs are equally effective. One company produces the drug in China. The other company produces its drug in the United States. For both companies, there is a small risk that

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<sup>100</sup> Or perhaps even higher to reflect the fact that tainted products may not all be identified and penalized.

<sup>101</sup> 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.

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 a tainted product. The risk that the Chinese-made product is harmful is 1 in 3 million. For the American-made product it is 1 in 5 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 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.<sup>102</sup> But those same judgments must be made for any regulatory strategy. Once penalties are set to reflect those costs, however, the market can be left to determine which of the products suits the needs of consumers better.<sup>103</sup>

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. Decision 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.<sup>104</sup>

It may, alternatively, turn out that only one of the products survives. The social costs of harm may be large enough that the

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<sup>102</sup> Some disagreements about safety and imports relate to different views of social costs. We take no position on how such costs should be calculated.

<sup>103</sup> Again, this requires clear labeling of other efforts to inform consumers about the relative dangers of the two drugs.

<sup>104</sup> Tort law, for example, recognizes this trade-off explicitly. The “primary” test for design defect in tort, for example, 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.” Rest. (Third) of Torts: Prod. Liab. § 2, comment d (1998); *see also 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 . . .”).

foreign-produced product is not 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, for whatever reason, 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 products may come to be both safer and less expensive than domestic products.

## 2. *Do International Trade Rules Permit Discriminatory Regulation?*

Among the impacts of higher penalties for violations of outcome-based regulatory requirements is an increase in the price of imports. Importers and sellers facing higher expected costs from such a regime, deal with it in part by trying to reduce those costs – leading to efforts to improve the safety of the product – and in part by passing those cost along to consumers.<sup>105</sup> Raising the domestic price of imports obviously serves to make domestic production more competitive relative to imports. This raises the question of whether such rules would be permitted under existing international trade treaties and, in particular, the rules of the World Trade Organization (WTO).

The key WTO rule for our purposes is found in Article III.4 of the General Agreement on Tariffs and Trade (GATT). This rule prohibits states from imposing on imports regulations that are “less favourable than that accorded to like products of national origin.”<sup>106</sup> If a measure fails to meet this requirement, it is nevertheless permitted if it satisfies any of the several exceptions available. The exception of interest in the case of our discriminatory regulation proposal can be found in Article XX(d) of the General Agreement on Tariffs and Trade (GATT).<sup>107</sup>

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<sup>105</sup> 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.

<sup>106</sup> General Agreement on Tariffs and Trade, art. III.4.

<sup>107</sup> 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, where the other exceptions might apply the reasoning would be quite similar to the discussion of GATT XX(d).

We begin with an analysis of GATT Article III, known as the national treatment obligation. The discriminatory liability regimes 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.<sup>108</sup> Imports and domestic products may be treated differently as 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 of 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 that our proposal is inconsistent with the requirements of GATT Article II.4.

The single most important argument justifying discriminatory outcome-based regulation relies on need to get producers to internalize the cost of harmful products so that they invest in safety up to the point where the marginal cost of increased safety is equal to the marginal benefit. Taking this as the objective of the legal system in dealing with both imported and domestic production yields the proposed discriminatory policy.

It is not the goal of having the cost of harm internalized that is problematic for the trading rules, but rather the fact that outcome-based liability imposes larger penalties on imports even if safety levels are at the same level as for domestic products. Imagine, 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. Without this discrimination, we explain in Part III.A, imports have a weaker incentive to provide safe products.

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<sup>108</sup> WTO Appellate Body report, *EC – Asbestos*, para. 100; WTO Appellate Body Report, *Korea – Various Measures on Beef*, paras. 135-36.



The problem from the perspective of Article III.4 can be seen if we imagine a foreign producer that 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.

The discriminatory regulation is saved, however, by the exceptions in GATT Article XX. Article XX provides a list of “general exceptions” to the substantive requirements of the GATT. Among them is Article XX(d) which provides an exception for measures “necessary to secure compliance with laws or regulations which are not inconsistent with the provisions” of the GATT.<sup>109</sup> The discriminatory regulation is intended to secure compliance with laws or regulations governing safety and quality. These rules are quite clearly legal under the GATT, so Article XX(d) is relevant to our inquiry. What remains is to determine if the requirements of that exception are satisfied.

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 balancing of relevant factors, including (i) the relative importance of the interest the regulation seeks to protect; (ii) the extent to which the measure contributes to compliance with the regulation; and (iii) the impact on international trade.<sup>110</sup>

The central thrust of this paper has been that regulators have almost no choice in the tools they use to address the safety of imports.<sup>111</sup> Furthermore, we advocate discriminatory regulation only when other, less trade distorting alternatives are unavailable or ineffective, including regulation by a foreign state and self-regulation. We also propose the use of discriminatory regulation only where

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<sup>109</sup> GATT article XX(d).

<sup>110</sup> WTO Appellate Body Report, *Korea – Various Measures on Beef*, paras. 162-63.

<sup>111</sup> 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.

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.<sup>112</sup> Moreover, not only have we shown that discriminatory regulation serves the goal of promoting compliance with relevant safety requirements, when it is used 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-factors balancing test mentioned above, then, is satisfied by our proposed system of discriminatory regulation because 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.”<sup>113</sup> Rather than providing a detailed discussion of the relevant case law on point here, it is suffice to say that our proposed system of discriminatory regulation is unlikely to be problematic under either of these requirements. 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.

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

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<sup>112</sup> WTO Appellate Body report, *Ec – Asbestos*, para. 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.”).

<sup>113</sup> GATT Article XX.

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 of the rules of international trade. Using the language of the WTO, discrimination in penalties would not be “necessary” in that context.

To meet the requirements of the WTO the outcome-based penalties imposed on foreign products must be calibrated to reflect the social harm from dangerous products. Larger penalties would trigger concerns that the measure is a “disguised restriction on international trade” or is not “necessary.”

### *3. Other Objections and Concerns*

Establishing different outcome-based liability regimes for domestic products and imported products raises a host of questions. Considering a few of the practical implications of this system of liability based where a product is made illustrates these issues. 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. 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 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. This same problem exists for any form of regulation that relies on sanctions or penalties, of course, 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 as 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.

The concerns are legitimate ones, but they are problems that come up in this or other areas 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

When production and data services are outsourced, these functions can evade both domestic regulatory obligations, and extra-legal pressures to increase consumer safety. In particular, they can avoid measures that protect consumers by preventing unsafe products before they are ever completed, or data breaches before they ever occur. Foreign producers, accordingly, 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 many, if not all, of the benefits of offshore outsourcing.

Where alternate mechanisms are unavailable for preventing the production of unsafe goods, then, the domestic firms that benefit from foreign activity should be forced, instead, to internalize the domestic costs of their activity through increased penalties for the violation of consumer protection norms. In this manner their superior capacity for oversight, monitoring, risk shifting, and decisionmaking 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. They will be permitted to compete on the cost of safety—to the benefit of the U.S. consumer—but not its level.