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Importers as Regulators: Product Safety in a Globalized World

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In the wake of scandals involving lead toys, toxic toothpaste, poisonous pet food, and other dangerous products in recent years, policymakers have proposed a variety of strategies that purport to address safety concerns. Though many of these proposals would have salutary effects on consumer product safety, they do not provide, either individually or collectively, a full solution to the problem. This chapter offers a different proposal for addressing the challenges that global production poses for state-centered regulation of import safety. We argue that regulators should structure administrative penalties to make private importers regulate the foreign manufacturing processes from which they benefit.

Specifically, we make the case that where U.S. regulators expect a threat to consumer protection from foreign goods and services, they should augment the legal penalties imposed against foreign and domestic partners in international trade that are within the reach of American authorities. 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. Trade in domestic goods and services would not trigger the same penalties because these products face regulation of the production process that, in principle, achieves the desired level of safety.

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A more extended discussion of this proposal appears at *Keeping Imports Safe: A Proposal for Discriminatory Regulation of International Trade*, 96 Cal. L. Rev. 1405 (2008).

The goal of this enhanced regulation is to motivate American firms (or others within the reach of the American legal system) trading in imported goods and services to take into account the safety of those products. To get these firms to assess the effectiveness of the legal, social, and economic forces that are at play in the production and marketing of these items, and to supplement those forces as necessary to protect consumer safety. Increased penalties for harmful products can ensure that private parties internalize the costs of reduced consumer safety and, therefore, balance it against the savings available through lower production costs.

Our proposal is designed in response to the particular reality of regulation in the presence of global trade. Domestic authorities have a wide range of tools available to regulate domestic producers, but only a subset of those are available to deal with global production. This fact distinguishes the regulation of domestic products from the regulation of imported products. To the extent that domestic production is regulated using tools that are unavailable for foreign production, an alternative regulatory strategy is needed for imported goods.

It is useful to divide the available regulatory options into two categories. The first focuses on "outcomes"— characteristics of the final product or service affecting its level of safety. These regulations typically set safety standards, and create an apparatus for inspecting finished products; coordinating recalls; forcing disclosure to affected consumers; and imposing administrative penalties through enforcement actions. Importantly, this form of regulation requires no information beyond what can be gleaned from the product itself. We refer to this approach as "outcome-based regulation" or the "outcome lever."

The second type of regulation constrains firm behavior during the process of production, seeking to increase safety by addressing the way in which goods and services are made. When outcome-based laws mandating the safety of U.S.-made goods prove insufficient—when, for

example, noncompliance is difficult to detect through *ex post* inspection or before consumer harm has actually occurred; or when harm may become apparent only long after use of the product—the production process itself is regulated. Specifically, regulators can mandate that private firms adopt internal procedures and assessments intended to prevent risks before they occur, or they oversee production processes directly through inspection, monitoring, reporting and licensing, to ensure a high level of safety before goods ever leave the plant or reach the market. We refer to this approach as "production-based regulation" or the "production lever."

One could debate the relative merits of outcome-based and production-based regulation in the domestic context. Our task in this chapter, however, is different. We are interested in how best to regulate foreign production, given the existing choices regarding the regulation of domestic production.

The central dilemma facing regulators thinking about imported products is that production regulation is largely unavailable. This is so because 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 regulate the process by which imports are produced comparably to the way they govern domestic production. Regulators cannot easily place themselves, in a figurative sense, in a foreign producer's delivery bay to keep an eye on the inputs being purchased, on the factory floor to monitor production, or in the information processing center to ensure that sensitive personal data is kept secure. Thus, in the very context that policymakers might ordinarily turn to production-based regulation, the production lever is

largely unavailable.[2]

Importers, on the other hand, are well-positioned to monitor the safety of their products. Though they are often not themselves the producers of those products, given appropriate incentives they are in a position to demand assurances about safety and to choose their business partners with safety in mind. Providing importers with appropriate incentives ensures that they will compete with one another to sell products that are not only inexpensive, but also safe.[3]

I. IDENTIFYING THE REGULATORY PROBLEM

A. Two Modes of Domestic Consumer-Safety Regulation

1. Outcomes Regulation

The most pervasive form of government involvement in the regulation of domestic goods and services uses the outcome lever. This form of regulation includes a variety of instruments, including rules requiring or prohibiting particular outcomes, inspections of finished products, *ex post* agency enforcement actions, and the imposition of penalties. The Consumer Product Safety Commission (CPSC), for example, promulgates regulations governing outcomes—such as those limiting the use of lead paint and setting standards for toys intended for young children.[4] It possesses the authority to bring civil and criminal enforcement actions against those who violate

[2] To be sure, importing countries could articulate requirements intended to govern the extraterritorial production of goods but mechanisms for enforcing such mandates (such as foreign government oversight or third-party certification) will in many contexts prove unreliable or underdeveloped regulatory substitutes (Bamberger & Guzman 2008: 1422-1429).

[3] This chapter addresses the regulatory challenges facing the United States, but it should be noted that the general argument applies equally well to any importing country that uses outcome-based regulation to improve the safety of its domestically-produced goods.

4. For example, the CPSC in 1978 banned the sale of paint containing in excess of 0.06% lead intended for consumer use, and banned toys and other articles intended for use by children that uses paint with a lead content in excess of 0.06% (16 C.F.R. pt. 1303 (1978)), a limit that was lowered further in 2008 (Consumer Product Safety Improvement Act (2008)).

specific legal mandates (FDCH Regulatory Intelligence Database (2004); FDCH Regulatory Intelligence Database (2001)); and it can impose penalties of up to $15 million on companies that fail to inform the agency when they discover unsafe toys on the market (Consumer Product Safety Improvement Act of 2008, § 217(a)(1)(B)).

After the finding of a violation or an increased risk of consumer harm, outcome regulation may also require ameliorative measures. For example, the CPSC has a program designed to encourage the reporting of unsafe goods and coordinate their recall. Alternatively (or perhaps in addition), responsible parties may be forced to publicize the risk they have created, as is the case in the thirty-eight states with laws requiring notification of data breaches to affected consumers (Berinato 2008; Schwartz & Janger 2007). The outcome lever, moreover, operates at all levels of government; various forms of food safety testing, for example, are carried out by both federal and state officials (*e.g.*, Sparks 2007). And the governance of outcomes extends beyond administrative regulation: tort law, too, may impose liability for physical harms actually caused by unsafe products or behavior (Keeton *et al.* 1984: 677-724).

The success of these formal legal mandates frequently rests in part on the presence of a variety of social and economic factors promoting compliance. These include the normative commitments of firms (Bardach & Kagan 1984: 64-66), advocacy of consumer-protection groups, threat of more comprehensive government regulation, operation of standards bodies, and, perhaps most importantly, reputational constraints. These forces serve to encourage compliance by domestic manufacturers with both legal mandates and voluntary standards promulgated by groups such as the American National Standards Institute and the American Society for Testing and Materials (*e.g.* ASTM Standard).

For a number of reasons, however, policymakers may conclude that in a given context the

outcome lever is insufficient to achieve consumer-safety objectives. Performance outcomes may be difficult to identify in advance or to assess contemporaneously (Bamberger 2006: 388-391). This is the case, for example, if the harm from a defective product is observable only after a long period of time (as with certain health effects), or the harm is diffuse and difficult to associate with specific products (as with some environmental effects). Similarly, outcome-based measures may be difficult to implement if product failures are themselves hard to observe (as with information databases that are inadequately secured).[5]

Non-legal incentives for compliance with consumer-protective outcomes, moreover, may vary by context. The same informational difficulties that undermine outcome regulation's direct efficacy can undermine social safety norms and reputational mechanisms. Furthermore, if it is difficult for consumers or consumer groups to assign blame for unsafe products—perhaps because it is difficult to observe each step in a long supply chain—the incentive effect of these informal mechanisms is weakened. If consumers have difficulty identifying the risks posed by products, and if organization of consumer groups is difficult (perhaps because a product is used in small amounts by a large number of geographically-diverse consumers), these problems will be exacerbated (Gunningham, et al. 2004).

2. Production Regulation

For any of these reasons, policymakers may decide that production-based approaches—alone or in concert with outcome-based approaches—should be employed to reduce the incidence of harmful or defective products,[6] or achieve a given level of consumer protection

[5] Cary Coglianese has discussed those contexts in which outcomes are "undesirable to rely upon as the sole basis for a regulatory standard" (Coglianese 2002).

6. It is possible to debate the desirability of using production-based regulation either in general or in specific cases. For the purposes of

more efficiently (Coglianese 2002).

The case of food and drugs provide an illustration. In this context, regulators govern and monitor the process of product manufacture extensively. The United States Department of Agriculture (USDA) and the FDA's Hazard Analysis and Critical Control Point (HACCP) programs governing food safety compel firms to assess food-safety hazards and to identify points in the production process at which they can be eliminated, minimized, or reduced to an acceptable level (U.S. Department of Agriculture 1996; U.S. Food and Drug Administration 1995; Coglianese & Lazer 2003: 696-698). They also establish procedures to measure and address risks at those points through corrective action. And those same agencies have developed programs for testing and inspecting during the production process in order to ensure safe outcomes, such as the USDA's on-site inspections of meat processing facilities (Federal Meat Inspection Act 2000; Poultry Products Inspection Act 2000), and the FDA's quality-control inspections of drug manufacturing plants (*Code of Federal Regulations*, title 21, sec. 210.1).

Indeed, as the Department of Health and Human Services's 2004 Task Force on Drug Importation has described, "[a] fundamental principle of drug regulation is that quality cannot be tested into a product," but must instead be "built into the product through the manufacturing process." (U.S. Department of Health and Human Services 2004). 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 (U.S. Department of Health and Human Services 2004).

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this chapter, however, we simply take the use and effectiveness of this form of regulation as given. We do so because reviewing the full debate about the merits of production-based regulation would serve only to distract from the focus of this chapter.

B. Challenges for Product Safety Regulation in a Globalized World

1. Challenges for Regulating Outcomes

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 jurisdictional problems. Even when a plaintiff can obtain an American court judgment, it may be difficult or even impossible to enforce (Clarke 2004).

Moreover the volume of imports and the challenges inherent in *ex post* testing limit the efficacy of inspecting geared towards measuring compliance with outcome-based regulation. Approximately 9.1 million imported food shipments enter the United States annually (Kaufman 2007). But in 2006, the FDA visually inspected only 115,000 shipments, and sent 20,000 samples for laboratory analysis (Barrionuevo 2007). Toys—87% of which are produced overseas (Public Citizen 2007)—currently undergo no testing at all by regulators. The compromise of consumer data takes place entirely abroad. And no technology exists to test completed drugs effectively at the border, a reality underscored by the recent incident in which nineteen patients died from contamination of Heparin, a blood thinner produced by drug manufacturer Baxter International (Harris & Bogdanich 2008). While routine testing indicated that the manufactured product contained a "Heparin-like" ingredient, it did not detect the counterfeit element, which proved fatal before its recall. Indeed, even if the means existed, the task of testing pharmaceutical imports would be, in the words of U.S. Department of Health and Human Services, "logistically impossible" and "prohibitively expensive. (U.S. Department of Health and Human Services 2004: 21)"

Moreover, extra-legal incentives for compliance by foreign parties may not exist or may not

operate in the same way as in the domestic context. Local safety norms may be different in foreign states, and local consumer groups may not exist or may not be concerned with exports. The producing firm may also face slight or nonexistent reputational constraints because it is several links in the supply chain—and possibly thousands of miles—away from consumers. Certainly, a brand name product may suffer negative reputational consequences when a hazardous product finds its way to the market, and even a supplier that is invisible to consumers may suffer if intermediaries or sellers recognize that the supplier's products are unsafe. Yet when supply chains stretch across countries and continents, these reputational effects are muted at best. For example, a supplier's reputation may not spread from buyers in one country to another, and purchasers may not be able to observe whether a new supplier is the same or different from an existing supplier with a poor reputation.

2. Challenges for Regulating Production

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

Imported drugs and food illustrate the way in which foreign production disables the production lever. In the drug context, manufacturers in India and China supply an ever-

increasing share of the U.S. drug market, particularly generic and over-the-counter medications. India exported $800 million worth of 350 varieties of antidepressants, heart medications, antibiotics, and other drugs to the United States in 2006. This was up from just eight generic drugs a decade ago. Chinese manufacturers, in turn, sold $675 million in drug ingredients and products in 2006, a figure that more than doubled in five years (Kaufman 2007). Drug industry analysts trace 20% of finished generic and over-the-counter drugs to India and China, as well as more than 40% of the active ingredients in American-made medications (*id.*).

All drug-ingredient manufacturers, whether foreign or domestic, ostensibly face the same regulatory regime. They must register drug ingredients and other information with the FDA. The FDA both approves new drugs and regulates the manufacture and distribution of brand-name and generic medicines (*Code of Federal Regulations*, title 21, secs. 207.20 & 207.37) by providing minimum good manufacturing guidelines and conducting quality-control inspections (*Code of Federal Regulations*, title 21, sec. 210.1). However, because FDA regulators do not have the authority to enter foreign factories unannounced, as they do in the United States, they must schedule inspections in advance through an American-based agent of the foreign company (*Code of Federal Regulations*, title 21, sec. 207.40). And, due to resource constraints, foreign inspections are dramatically less frequent than those conducted in the United States. In 2006, for example, the agency performed thirty-two quality-assurance inspections in India, fifteen in China and 1,222 in the United States (Kaufman 2007). Moreover, some of the inspections conducted abroad were related to the initial drug approval, rather than to manufacturing procedures, and others involved inexpensive HIV/AIDS drugs that would not be sold in the United States.

Similar practical constraints limit the exercise of the production lever to ensure the use of safety-enhancing processes in the foreign production of food. For example, foreign processors

that ship fish or fishery products to the United States are formally required to operate in conformance with the FDA's seafood HACCP Regulations (U.S. Food and Drug Administration 1995). But FDA inspection trips to foreign countries simply cannot ensure worldwide compliance. The chance of any one processor being subject to administrative inspection is extremely low, and regulators change targets, and even countries, year by year. Accordingly, should an inspection take place it is virtually certain that it will be a long time before any further inspections occur (U.S. Food and Drug Administration, CFSAN/Office of Seafood 2005). With regard to manufactured goods, the CPSC lacks broad jurisdiction to test a product's safety before it reaches the market (U.S. Consumer Product Safety Commission).

II. Seeking Regulatory Solutions

The discussion in the prior section frames a challenge for public regulators. While the outcome lever remains an important part of the regulatory system, it is insufficient to achieve consumer safety objectives and, in any event, is weaker in the context of imports than in the context of domestic production. The production lever, used domestically to address the shortcomings of the outcome lever in the domestic context, is severely disabled when it comes to foreign production. How, then, should the importing countires go about providing their consumers from unsafe imports?

Many of the legislative proposals approach the problem by attempting to bolster domestic regulators' ability to extend the traditional outcome or production levers they use domestically to foreign activity as well. This section explores those, and raises concerns as to both their cost and efficacy. It then suggests, instead, that rather than rely entirely on attempts to extend regulators' formal territorial reach, policymakers should seek to foster the creation of surrogate regulators

who can exercise the traditional regulatory functions more effectively.

A. Legislative Proposals for Addressing the Global Challenge for Product Safety: State-Regulator Centered Approaches

Several recent policy proposals have suggested enhancing both outcome-based inspections and the production-based component in U.S. regulation of foreign activity (*Agence France-Presse* 2007). One option is to increase post-production inspections. This could certainly yield benefits in some important contexts, but provides at most an incomplete response. Approximately $2 trillion of products were imported into the United States in 2006, from more than 150 countries (U.S. Census Bureau 2008). More than 825,000 importers brought shipments into the United States through more than 300 ports, border crossings, and postal facilities (Barrionuevo 2007). Furthermore, the value of imports is increasing over time (*id*.). A system of inspections could never achieve the scale and scope necessary for the comprehensive regulation of such an enormous volume of imports.

A second option would seek to extend the reach of American production-based regulation. These 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 (*MQN Weekly Bulletin* 2008). 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 (Kaufman 2008). More generally, the FDA has explored requiring inspections of foreign plants before foreign-manufactured active drug ingredients are allowed in FDA-approved

prescription medication (U.S. House Committee On Energy And Commerce 2008). And the Interagency Working Group on Import Safety convened by President George W. Bush[7] has similarly called for an increased presence overseas in order to inspect goods before they enter the United States, and to integrate inspections of processes into the regulatory framework (Interagency Working Group on Import Safety 2007a; Interagency Working Group on Import Safety 2007b).

One problem with such proposals is the sheer size that a program of extraterritorial inspections and regulations would have to achieve to be effective. The resources required to achieve an important presence in all the places from which the United States imports products and services are simply not available.[8] Even if the United States were to focus only on China, an effective regulatory team in that country would need a much larger staff than would be required for similar tasks here in the United States. This is so both because China is much larger than the United States, and because its political, social, and economic context is different. There is, moreover, reason to believe that American inspectors and officials operating in China would be less effective than those operating domestically simply because they would lack the language and cultural skills to navigate Chinese society and to understand local business practices. This

[7] 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 Department of Homeland Security, the Director of the Office of Management and Budget, the United States Trade Representative, the Administrator of the Environmental Protection Agency, and the Chairman of the Consumer Product Safety Commission. The Food and Drug Administration, Customs and Border Protection, and the Food Safety and Inspection Service were active participants in the Working Group as well (Import Safety Website).

[8] Janet Woodcock, the head of the FDA's Center for Drug Evaluation and Research, concludes:"It's very difficult to see how we could actually cover the entire globe" (Reuters, 12 June 2008).

phenomenon is evidenced in the case of the 2008 deaths arising from Heparin blood thinner, in which FDA inspectors thought they had inspected the Chinese plant that manufactured the fatal contaminant, but later learned that they had been taken to a different pharmaceutical plant with a similar name (Kaufman 2008).

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

Furthermore, even if American authorities were to discover a violation of a production standard abroad, they often would have difficulty enforcing any relevant sanction. To begin with, if a would-be violation concerns products that have not yet entered the United States, there may not have been any violation of American legal requirements, even if as a practical matter the products were destined for the United States.[9]

All of these problems make it easier and cheaper for foreign producers to ignore American laws. Production-based regulation is poorly designed to reach production outside the United States. Attempts to extend it will remain too expensive to represent practical solutions, not to mention the political and diplomatic constraints on any effort to extend American regulatory requirements abroad. Turning to outcome-based alternatives is also likely to be a poor solution. Whatever reason motivated regulatory authorities to use production-based rather than outcome-based regulation for domestic production applies to foreign production, and makes it unlikely

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

that an outcome-based solution is available.

Reduced regulatory effectiveness lowers the cost borne by producers when unsafe products find their way to store shelves and consumers. This, in turn, reduces firms' incentives to comply with U.S. standards. The lower the expected sanction for conduct inconsistent with American requirements, the less reason they have to adjust their behavior. The obvious result is that, unless some substitute for American production-based regulation is present, imported products will be less safe than comparable goods made within the United States.

B.Developing a Substitute for the State: A Mechanism for Making Importers Regulate

The remainder of our analysis explains how it is possible to establish more appropriate incentives for private parties within the reach of the American regulatory system. When foreign production escapes regulatory obligations that domestic production must satisfy, or avoids extra-legal pressures to increase safety, foreign producers will produce less safe products, all else equal. In other words, they will be able to compete and reduce costs by reducing the safety of their products.

Before describing our proposal in detail, it is worth noting that not all imported products represent a safety concern. It is true that American production-based regulation works poorly for foreign production, but that production must take place somewhere, and the relevant local authorities may have regulatory measures in place that ensure adequate levels of safety. As long as regulatory practices in the foreign state ensure a level of safety that is comparable to that sought by American regulation, the foreign practices can serve as a fully adequate substitute for American efforts. Where this is the case – where foreign regulators are achieving the same results as American authorities achieve for products made in the United States – our proposal for

enhanced penalties would not apply. These products should continue to be regulated as they currently are.

Where, on the other hand, existing regulatory structures fail to ensure satisfactory consumer-protection levels for imported goods, existing regulatory strategies fall short. As described previously, regulators in importing countries seeking to protect their consumers from unsafe foreign goods face significant obstacles.

Domestic regulators, however, do retain important regulatory tools. First, even when regulators cannot exercise power over foreign parties, the activity of concern almost always involves some entity in the role of importer, outsourcer, distributor, or seller within the reach of the importing country's law. These parties may not be those most culpable for consumer harm, and may not be optimally situated to promote safety. Yet they are the ones on whom the importing country's system can credibly impose regulatory obligations and penalties, and are involved in the stream of commerce at some point prior to the final purchase by the consumer. They are also typically in a better position than the regulator to ensure appropriate safety levels.

Second, regulators retain the ability to use the outcome lever to observe, regulate, and punish outcomes in the form of services or finished products that threaten or cause harm to citizens within their borders. Third, they retain control over rules governing liability for violations of outcome restrictions, and—perhaps most importantly—over associated penalties.

Our proposal operates within these confines. In its simplest terms, it suggests that regulators should use liability standards and penalties directed against American parties (or at least parties within reach of the U.S. legal system) to achieve appropriate levels of safety. U.S. partners in international trade should be subject to *additional* outcome-based regulatory penalties for safety and other consumer protection violations beyond those imposed on those who engage in purely

domestic activity.[10] This system of discriminatory penalties should be structured to ensure that U.S. partners in international trade 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. These additional obligations would be "strict" regulatory obligations on importers and sellers in the sense that they would operate without regard to what the party in questions knows, should have known, or even could have known about the process of production and service provision.

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

At root, our proposal is a fairly straightforward application of the existing literature on tort law and its behavioral effects, combined with the recognition that imported products often must be regulated entirely through the outcome lever. In the tort context, for example, the imposition of strict liability forces actors to internalize the full cost of defective or harmful products.

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

Penalties, moreover, should be set at the level necessary to ensure that the costs of harmful behavior are internalized by relevant actors. Those actors then have an incentive to take action to reduce this risk up to the point where the cost of further reductions exceeds the benefit of reduced liability.

The same strategy of strict liability is proposed here, although in the context of outcome-based sanctions. Those participants in the stream of commerce that are within the reach of American authorities and that bring imported products to market should be subject to penalties for regulatory noncompliance regardless of the level of care they take, or their actual knowledge about product safety.[11] The associated penalties, moreover, should be set at levels that force actors within the reach of domestic authorities to internalize the full social costs of increased risks to consumer welfare. Specifically, penalties should make up for the discount provided by engaging in more harmful behavior while escaping the domestic costs of safety they would otherwise face under domestic regulation.

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

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

quality is of a sufficiently high level to protect them from undue costs.

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

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

Focusing on firms within the reach of American authorities also addresses the problem of

fly-by-night foreign enterprises, which engage in production until a problem arises and then simply close up shop only to appear later under a different name. Domestically-based private parties are much better situated than regulators to identify and avoid such operators.

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

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

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

II. TWO POSSIBLE CONCERNS

A. International Trade Rules

Importers and sellers facing higher expected costs from our proposed system of discriminatory regulation will try to reduce costs by improving safety, but they may also pass these costs along to consumers by raising prices.[12] Raising the domestic price of imports obviously serves to make domestic production more competitive relative to imports. This discrimination between domestic and foreign producers raises the question of whether our proposed system would be permitted under existing international trade treaties and, in particular, the rules of the World Trade Organization (WTO).

We begin with an analysis of Article III of the General Agreement on Tariffs and Trade (GATT). This rule, known as the national treatment obligation, prohibits states from imposing regulations on imports that are "less favourable than that accorded to like products of national origin."[13] If a measure fails to meet this requirement, it is nevertheless permitted if it satisfies any one of several available exceptions. The exception of interest in the case of our discriminatory regulation proposal can be found in Article XX(d) of GATT, which provides an exception for measures "necessary to secure compliance with laws or regulations which are not inconsistent with the provisions" of the GATT.[14]

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[12] 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.

[13] General Agreement on Tariffs and Trade (GATT), art. III.4.

[14] *Id.* at art. XX(d). One could also advance arguments about exceptions provided by Article XX(b) and the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), both of which address health and safety concerns. We omit these because

The discriminatory liability regime we propose distinguishes products based on whether they are produced domestically or abroad, which immediately makes them suspect under Article III. Mere differences in treatment, however, are not enough to conclude that a measure is inconsistent with Article III.[15]119 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 on foreign producers would be a violation of Article III.4. And while it makes more sense to examine the production and outcome-based liability schemes together, even if one does so, it is likely our proposal is inconsistent with the requirements of Article III.4.

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

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the exception in GATT XX(d) is more appropriate for this situation and, in any event, to the extent the other exceptions might apply the reasoning would be quite similar to the discussion of GATT XX(d).

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

products.

Imagine that a foreign producer chooses to mimic the quality control and inspection system required of American producers. Suppose that this foreign producer puts these systems into place and achieves the same level of safety (at the same cost) as do American producers. Now imagine that an unsafe product makes it to the market despite these safety efforts. If the product is from the American producer the penalty will be smaller than if it is from the foreign producer. The foreign producer, then, even if it behaves in exactly the same way as the American producer, faces a higher cost from unsafe products. This amounts to discrimination in contravention of Article III.4. Our proposed discriminatory regulation is saved, however, by the already mentioned Article XX(d). Our proposal is intended to secure compliance with laws or regulations governing safety and quality, and the latter are quite clearly consistent with the provisions of the GATT. The question is whether such measures are "necessary." The question of whether the discriminatory penalties are "necessary" to secure compliance invokes a well-developed GATT jurisprudence. In general, the relevant WTO cases have concluded that the necessity of a measure under GATT XX(d) must be judged based on a balancing of relevant factors, including (1) the relative importance of the interest the regulation seeks to protect; (2) the extent to which the measure contributes to compliance with the regulation; and (3) the impact on international trade.[16] The central thrust of this article has been that regulators have almost no choice in the tools they use to address the safety of imports.[17] Furthermore, we advocate discriminatory regulation only when other, less trade distorting alternatives are unavailable or ineffective, including regulation by a foreign government and self-regulation. We also propose the use of discriminatory regulation only where existing regulatory structures aimed at domestic producers are unable to provide appropriate incentives to foreign producers. A system of discriminatory regulation, then, should be used only when it is the only practical response

[16] Appellate Body Report, *Korea–Various Measures on Beef, supra* note 119, at ¶¶ 162- 63.

[17] 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.

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.[18] Moreover, we have shown both that discriminatory regulation serves the goal of promoting compliance with relevant safety requirements, and that it is the only way to ensure that foreign producers internalize the full cost of harm from dangerous products. In this sense, the measure contributes directly to compliance with relevant safety regulations. The three-factor balancing test mentioned above, then, is satisfied by our proposed system of discriminatory regulation: the measure at issue addresses an interest of vital importance, contributes directly to compliance with relevant safety regulations, and is the least trade restrictive alternative available to decision makers. The exception provided by Article XX(d) requires, in addition to the above, that the relevant measure not be a means of "arbitrary or unjustified discrimination between countries where the same conditions prevail" or be a "disguised restriction on international trade."[19] Suffice it to say that the use of discriminatory regulation as we have described it does not constitute an abuse of the GATT Article XX(d) exception of a sort likely to cause difficulty under the "chapeau" of Article XX, as these provisions are called. The regulation is neither arbitrary nor unjustified; as discussed prior, it is only utilized when no other alternatives are available.[20] Finally, to meet the requirements of the

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

[19] GATT, *supra* note 118, at art. XX.

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

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

B. Financially Weak Firms

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 so their exposure to liability would be quite limited.

This is a reasonable concern, but it is not unique to this proposal. In fact, the same problem exists for any regulation that relies on sanctions or penalties, including regulation of domestic production. It is perhaps somewhat more acute in the context of imports because production may require a certain scale and sufficient assets to reduce the risk that a firm is damage-proof but an importer has no such needs. On the other hand, the distribution of products within the United States often requires a large entity, as does the sale of products under familiar brand names. These concerns are legitimate ones, but they are problems that come up in this or other regulatory contexts under existing rules. Where they have come up, they have not proved fatal to the enactment and effective use of regulation. Notice, furthermore, that whatever challenges these concerns pose, and even if they prevent the application of a perfect regulatory regime, they do not change the fact that a system of discriminatory liability provides better incentives for

foreign producers than is the case under the status quo.

C. Baker's Import Safety Warranties

Tom Baker, also writing in this volume, has proposed a system under which importers of goods thought to pose a potential danger would face a statutory obligation to warrant that those products do not contain undisclosed harmful substances. Breach of that warranty would trigger liability. Importers would also be required to post a bond equal to the value of the goods to increase the likelihood that they will have the ability to pay any penalties incurred.

We do not have the space in this chapter to respond fully to Bakers proposal, but it is worth noting how similar it is to our own, at least in terms of its general effect. His proposal and our own seek to hold importers and sellers accountable for unsafe imports – in both cases seeking a party in the supply chain that is within the reach of American authorities. Both proposals also serve to increase the exposure of imports to domestic liability. Our proposal would increase the sanctions imposed on imports that prove to be unsafe. Baker's proposal would do essentially the same thing, but relies on warranties made by importers rather than increased sanctions.

To be sure there are differences between the proposals. Baker's reliance on a bond posted by importers, for example, imposes a cost on every importer. Our own proposal, because it relies on ex post liability rather than an ex ante bond, imposes costs only in the event of a violation. Baker's proposal also requires the construction of a new regulatory system and the associated private markets required to providing the bonds that importers would require. On the other hand, the bonding system greatly reduces the problem of how to deal with importers that lack the resources to pay the sanctions they incur under our system.

Though we naturally have a preference for our own proposal over Baker's, the more important point is that both proposals adopt essentially the same strategy of forcing importers to

bear the risk of harmful products. Adoption of this general approach would represent a significant and healthy change from the approaches currently being explored. For this reason, rather than debating the relative merits of our proposal as compared to Baker's we prefer to think of them together as representing a more sensible and productive way to increase the safety of imported goods.

CONCLUSION

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

This Chapter has explained why conventional regulatory strategies are insufficient to address the challenges of importing products from foreign jurisdictions. When goods and services are provided abroad, producers and suppliers can evade American regulatory obligations and extra-legal pressures to increase consumer safety. In particular, they can avoid measures that protect consumers by preventing unsafe products before production is completed. Accordingly, foreign producers will not internalize the cost of harmful products as fully as their American counterparts, and will, therefore, invest less in ensuring the safety of their products.

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

A liability scheme aimed at parties within the reach of American authorities can help

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

To be sure, implementation of our proposal would require some delicate judgments about which products from which countries should be subject to the higher liability scheme. Yet from the perspective of American consumers, our proposal has the great advantage of ensuring appropriate levels of safety while at the same time encouraging healthy competition among domestic and foreign producers and suppliers, competition that should be focused on improving quality and lowering price, but doing so without compromising safety.

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