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Victor E. Schwartz

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Hamilton Square
600 14th Street, N.W., Suite 800
Washington
D.C. 20005-2004
202.783.8400
202.662.4886 DD
202.783.4211 Fax
vschwartz@shb.com

Re: **Docket No. 2004N-0115:**
Prescription Drug Importation

To whom it may concern:

On behalf of the American Tort Reform Association (ATRA), enclosed please find two (2) copies of comments for filing in the above-referenced docket. These comments are submitted for consideration of the Task Force on Drug Importation and focus on liability issues raised by the proposed importation of prescription drugs from Canada. ATRA files these comments in response to the Food and Drug Administration's Notice of Public Meeting and Establishment of Docket published in the March 18, 2004 edition of the Federal Register.

Thank you for your consideration.

Sincerely,



Victor E. Schwartz, Esq.
General Counsel
American Tort Reform Association

Enclosure

Geneva
Houston
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NEW ORLEANS

HAMILTON SQUARE
600 14TH STREET, NW, SUITE 800
WASHINGTON, D.C. 20005-2004
TELEPHONE (202) 783-8400 ■ FACSIMILE (202) 783-4211

ORANGE COUNTY
OVERLAND PARK
SAN FRANCISCO
TAMPA
WASHINGTON, D.C.

Victor E. Schwartz
vschwartz@shb.com

IMPORTATION OF PRESCRIPTION DRUGS FROM CANADA: A PRESCRIPTION FOR LAWSUIT ABUSE

In December 2003, Congress amended Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 381 *et seq.*) to permit the importation of prescription drugs from Canada when certain certifications, registration requirements, and other safeguards are met. This provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Modernization Act"), Public Law 108-173, would become effective only if the Secretary of Health and Human Services (HHS) certifies to the Congress that importation of prescription drugs poses no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer.¹

States and consumers are attracted to the importation of prescription drugs from Canada because of anticipated cost savings. Yet, as HHS, the Food and Drug Administration (FDA), and health policy experts have recognized, the importation of prescription drugs carries substantial risks to consumers, including misbranding, adulteration, contamination, counterfeiting, and lack of adequate warnings or directions on usage. Furthermore, there is no guarantee that drugs imported through Canada did not come from other foreign countries. With rising demand from the United States, increased importation of unregulated foreign drugs by Canadian businesses for export to the United States may be a near certainty.

The importation of drugs from Canada may be a prescription for a lawsuit bonanza. If American consumers are hurt because of this risky policy, personal injury lawyers will sue everyone, except those who are actually responsible, namely the counterfeiters, those who tampered with the drugs, and fly-by-night companies operating outside the United States. Also ducking claims will be anonymous internet websites. These are not easy targets. They are likely to escape responsibility. When they can be found, the order forms of these businesses disclaim any liability and require injured consumers to consent to bring their claims to local Canadian courts subject to local Canadian law. For these reasons, personal injury lawyers will attack the available "deep pockets," namely domestic drug manufacturers, shippers, hospitals, pharmacies, pharmacists, doctors, and anyone else who participated in the chain of distribution. They will also sue state and local governments that purchase Canadian drugs for their employees or retirees, or those that have established programs facilitating purchases by state residents from abroad. States may be surprised to learn that the general immunity that protects them from tort lawsuits usually does not apply when they engage in this type of activity.

The relatively low savings compared to the potential risks to the public and legal costs to American businesses and state governments, raise serious questions as to whether importation of prescription drugs should move forward. Such legal costs could further increase the price of prescription drugs, hurt innovation, and result in a loss of jobs. If importation of prescription drugs from Canada is to proceed, then Congress must, at a minimum, reduce the potential for a flood of lawsuits against domestic employers, while protecting the ability of consumers to recover from foreign companies who are responsible for their injuries.

¹ Pursuant to Sections 1121 and 1122 of the Medicare Modernization Act, HHS Secretary Tommy G. Thompson, in consultation with other government agencies, is currently studying the safety and cost effectiveness of drug importation and a report is expected to Congress by the end of 2004.

I. IMPORTATION OF PRESCRIPTION DRUGS: NOT WHAT THE DOCTOR ORDERED

HHS and the FDA have both voiced strong concern for the safety of drugs that are imported from other countries without U.S. regulation.² As HHS Secretary Tommy G. Thompson told members of Congress, "Opening our borders to reimported drugs potentially could increase the flow of counterfeit drugs, cheap foreign copies of FDA approved drugs, expired and contaminated drugs, and drugs stored under inappropriate and unsafe conditions."³

In a speech before the National Press Club, FDA Commissioner Mark B. McClellan cautioned, "Buying long distance from sources we can't regulate is simply not the same as walking into a well-regulated pharmacy under the regulatory umbrella of Canada or another country with a very safe drug supply. People's health is put at risk when doctors and pharmacists, our 'learned' intermediaries, are replaced by storefronts and bogus Internet sites that are for private profit not public health."⁴ Commissioner McClellan went on to explain that Canada and the United States do not have integrated health systems and that even "the Canadian government itself has said repeatedly that it cannot assure the safety of drugs exported to the U.S."⁵

In testimony before Congress, William K. Hubbard, the FDA's Associate Commissioner for Policy & Planning, outlined some of the risks of importing prescription drugs, including:

- Foreign outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use.
- Some patients may unknowingly buy counterfeit copies of prescription drugs that contain inert ingredients, legitimate drugs that are outdated and have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent products that were improperly manufactured.
- Labeling may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer.

² See, e.g., Michelle Meadows, *Imported Drugs Raise Safety Concerns*, FDA CONSUMER MAGAZINE (U.S. FDA, Sept.-Oct. 2002), available at <http://www.fda.gov/fdac/features/2002/502_import.html>.

³ See HHS Press Release, *Secretary Thompson Determines that Safety Problems Make Drug Reimportation Unfeasible* (July 10, 2001), available at <<http://www.hhs.gov/news/press/2001pres/20010710.html>>.

⁴ Remarks by Mark B. McClellan, Commissioner, Food & Drug Admin., Speech Before Fifth Annual David A. Winston Lecture, Nat'l Press Club, Wash., D.C., Oct. 20, 2003, available at <<http://www.ncsl.org/statefed/health/McPresSpe.htm>>.

⁵ See *id.*

- Drugs may not have been packaged and stored under appropriate conditions to avoid degrading or tarnishing the product.
- If a consumer has an adverse drug reaction to an imported prescription drug or any other problem, they have little or no recourse either because the physical location or operator of the pharmacy often is not known or the seller is beyond the consumer's reach. In addition, as a condition of doing business, many of these foreign operators require the U.S. consumer to sign a document releasing the operator from all potential liability.⁶

Other health and policy experts have also expressed concern that the risks of drug importation from Canada may far outweigh the benefits of such a policy. Robert Goldberg, a senior fellow with the Manhattan Institute for policy research, points out that as demand for Canadian drugs grows, pharmacies in Canada will need to rely on foreign companies to fulfill American orders, such as those in China, Iran, and Saudi Arabia.⁷ This is a significant problem that has been largely overlooked in the current debate. Canada, with its population of less than 32 million, cannot possibly fill the demand for less expensive drugs from the over 280 million U.S. citizens. With money to be made on providing drugs to American consumers, individuals and businesses in Canada are likely to import drugs from across the sea. Since Canadian law does not regulate products brought in for the purpose of exportation, Canada may become but a rest stop on a super highway of potentially dangerous foreign drug products flowing into the United States.

II. WE CAN EXPECT LAWSUITS AGAINST AMERICAN EMPLOYERS AND LOCAL GOVERNMENTS

As discussed above, importation of prescription drugs carries or enhances many risks to consumers, including misbranding, adulteration, contamination, counterfeiting, and lack of adequate warnings or directions on usage, among others. Personal injury lawyers are likely to seek recovery for their clients from whoever they can. They will sue any entity or individual in the chain of distribution, including pharmaceutical manufacturers, foreign exporters, repackagers, importers, distributors, doctors, pharmacies, and pharmacists. They will also sue the state and local governments that facilitate the purchase of imported prescription drugs for their employees or citizens. As Joseph Bast, President of The Heartland Institute and publisher of *Health Care News*, astutely observed in concluding remarks at a recent symposium on drug importation:

⁶ See Statement of William K. Hubbard, Assoc. Comm'r for Policy & Planning, *Canadian Prescription Drug Re-Importation: Is There A Safety Issue?*, Before the Comm. on Gov't Reform, Subcomm. on Human Rights & Wellness, U.S. House of Representatives (June 12, 2003), available at <<http://www.fda.gov/ola/2003/Canadian0612.html>>.

⁷ See Robert Goldberg, *Small Gains, Enormous Risks*, in WHAT'S WRONG WITH IMPORTING DRUGS FROM CANADA 16-17 (Nat'l Symposium on Drug Importation, Oct. 23, 2003).

Litigation looms. If you work for the state of Illinois or are a retired state employee or if you're on Medicaid, under [Illinois] Governor Blagojevich's plan, you would be receiving drugs imported from Canada and not inspected by either Health Canada or the FDA. If one of those drugs is found to be counterfeit or contaminated or expired or in some other way a threat to your health, who do you hold accountable? Do you sue the guy who sold it to the state? Do you sue the state for allowing these drugs to be provided to you? Do you sue the original manufacturer for failing to prevent the fraud? It becomes very confusing, and in confusing situations, I have noticed that lawyers make tons and tons of money and victims typically get very little.⁸

Plaintiffs' lawyer typically use five legal theories against those that participate in the distribution of prescription drugs: strict liability, common law negligence, misrepresentation, breach of warranty, and violation of consumer protection statutes.⁹ They are likely to make such claims and come up with new and innovative legal theories to seek multi-million dollar awards. In any case, plaintiffs' lawyers will case their net wide and sue any company or government remotely associated with the imported drug that caused the injury. The legal cost of defending such suits will be high and the potential consequences of one successful lawsuit can be devastating.

A. Lawsuits Stemming from the Inflow of Counterfeit or Tampered-With Drugs

Since there will be more companies and individuals involved in the chain of distribution should prescription drug importation go forward, there will be greater opportunity for counterfeiting, tampering, or other abuse. It is likely that liability for the resulting injuries will not fall on the foreign company or criminal responsible, but on domestic companies and individuals that are within reach of American courts.

1. No Amount of Foresight Will Avoid Negligence Claims

When an injury occurs, personal injury lawyers may broadly contend that a manufacturer, foreign importer, distributor, doctor, pharmacy, or pharmacist, or a combination of those companies and individuals, breached a duty of care to the consumer by not taking sufficient steps to ensure their safety against the hazards of importing prescription drugs.

Claims for negligence may contend that a manufacturer should have done more to make its product uniquely identifiable so that consumers could verify whether the product was authentic, or that it should have taken some measure to make the product's packaging more

⁸ Joseph L. Bast, *The Pros and Cons of Drug Importation*, in WHAT'S WRONG WITH IMPORTING DRUGS FROM CANADA 55-56 (Nat'l Symposium on Drug Importation, Oct. 23, 2003).

⁹ See Gale D. Pearson, *Theories of Liability for a Pharmaceutical Product*, ATLA Winter 2003 Convention Reference Materials (Feb. 2003).

tamperproof. Others in the marketing chain are likely to be accused by plaintiffs' lawyers of being negligent by failing to discover evidence of counterfeiting or tampering, or by improperly storing the drugs. The importation of drugs from abroad, however, provides ample opportunity for criminals to navigate around the most rigorous of safeguards.

2. *Despite the Benefits of Prescription Drugs, Lawsuits May Contend They Are Unreasonably Dangerous*

Personal injury lawyers may also sue under a strict liability theory. Unlike negligence claims that center on what a company did or did not do, the focus of a strict liability claim is on the characteristics of the product itself. Lawsuits may contend that a drug's packaging, warnings, or instructions rendered it unreasonably dangerous to consumers. They might also claim that the drugs, if found to be counterfeit or tampered with, were defectively designed in that the product's markings or packaging did not ultimately guard against that criminal act.¹⁰ As discussed more fully on the following pages, such lawsuits may target not only manufacturers, but any entity within the chain of distribution of the prescription drug.

3. *Whether or Not the Technology is Available or Effective, Will Not Stop Costly Lawsuits*

Whether the technology to make a more tamper resistant or counterfeit-proof product is currently available, feasible, or cost-effective will not be a barrier to this costly round of litigation. Nor will the lack of any government regulation requiring the incorporation of such technology stop such lawsuits from being filed, even if the lawsuits are ultimately dismissed.

For example, handgun manufacturers have faced a barrage of lawsuits, none of which have been successful thus far, but the future of the litigation remains uncertain. Plaintiffs' lawyers have argued that the manufacturers should have incorporated safety features, such as trigger locks and owner-authorized technology.¹¹ These lawsuits claim that the failure to apply

¹⁰ See Restatement (Second) of Torts § 402A cmts. g, k (1965) (providing that whether a product is defective depends on whether it is in a "condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him" and recognizing there are inherently dangerous products, such as prescription drugs that are useful and desirable, and not defective just because there is "a known but apparently reasonable risk"); see also Restatement Third of Torts: Product Liability § 2 (providing that whether a product is defective or not is based on a "risk-utility" test, which evaluates whether "the foreseeable risk of harm could have been reduced or avoided by the adoption of a reasonable alternative design."); *Id.* § 6 (noting that a prescription drug is defective if, at the time of sale or other distribution, the drug is not reasonably safe due to defective design; or inadequate instructions or warnings, and that a retail seller or other distributor of a prescription drug may be held liable if, at or before the time of sale or other distribution of the drug, the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons).

¹¹ See, e.g., *Halliday v. Sturm, Ruger & Co.*, 792 A.2d 1145 (Md. 2002) (dismissing case after applying consumer expectations test); *Baker v. Smith & Wesson Corp.*, No. Civ. A. 99C-09-283-FS, 2002 WL 31741522 (Del. Super. Nov. 27, 2002) (dismissing case under "municipal costs recovery rule");

such technology rendered the handgun defective and should subject the manufacturer to liability for creating, essentially, a defective, or “unreasonably dangerous,” product. Trade associations are sometimes named as defendants in handgun lawsuits for “acting in concert” with the manufacturers.¹² In some cases, courts denied initial motions to dismiss these lawsuits for failure to state a claim, leading to discovery and other litigation costs. Some cases are still pending. Other courts have dismissed these cases at a very early stage.¹³

In February 2004, FDA suggested that the pharmaceutical industry incorporate new technologies to protect the drug supply.¹⁴ This report, which was not subject to the rigors of the notice and comment of a rulemaking, recommended the use of Radiofrequency Identification (RFID) tagging of products by manufacturers, wholesalers, and retailers by 2007. This technology, according to FDA, will provide the ability to track and trace the movement of every package of drugs and make counterfeiting extremely difficult and unprofitable. The FDA also recommends that manufacturers embed “authentication technologies” such as color shifting inks, holograms, fingerprints, taggants, or chemical markers in the product or its label. Are such measures effective? Is the technology available? Is the incorporation of such technologies cost-effective, or will they simply further increase the cost of prescription drugs? Personal injury lawyers will not wait until 2007 to raise these questions in lawsuits. They are likely to sue manufacturers, wholesalers, and retailers at the first instance that a tampered-with or counterfeit imported drug product hits the shelves and causes an injury in the United States.

B. Lawsuits Will Broadly Target the Entire Pharmaceutical and Biotechnology Industry

Lawsuits resulting from the importation of prescription drugs, whether based in negligence, strict liability, or both, are likely to broadly target the entire pharmaceutical and biotechnology industry.

Claims premised on negligence may use the legal principle of “joint and several liability” to go after a company that bears minimal responsibility for the entire amount of the damages. The rule of joint liability provides that when two or more persons engage in conduct

Order, City of Cincinnati v. Beretta U.S.A. Corp., Case No. A9902369 (Ohio Ct. Common Pleas, Hamilton Cty, Oct. 7, 1999) (dismissing case after finding that “the City’s complaint is an improper attempt to have this Court substitute its judgment for that of the legislature, something which this Court is neither inclined nor empowered to do”).

¹² See *Sills v. Smith & Wesson Corp.*, No. 99C-09-283-FSS, 2000 WL 33113806, at *8-*12 (Del. Super. Ct. Dec. 1, 2000) (finding sufficient minimum contacts under a claim of conspiracy to exert personal jurisdiction over non-resident trade associations including the Sporting Arms and Ammunition Manufacturers’ Institute, the National Shooting Sports Foundation, Inc., and the American Shooting Sports Council, Inc.).

¹³ See *Sills*, 2000 WL 33113806, at *4-*5 (examining several of such cases).

¹⁴ FDA, COMBATING COUNTERFEIT DRUGS: SAFE AND SECURE (2004); see also News Release, *HHS Takes New Steps to Protect Consumers from Counterfeit Drug Threats*, Feb. 18, 2004.

that might subject them to individual liability and their conduct produces a single, indivisible injury, each defendant will be liable for the total amount of damages.¹⁵ The principle underlying joint liability is that each defendant's wrongful conduct is substantial enough to pay for the plaintiff's injury, so the plaintiff should be fully compensated and should not suffer if one defendant is absent from the jurisdiction or bankrupt. Over the past two decades, the shortcomings of joint liability rules have become increasingly apparent. In many of its operations, it means that a defendant only minimally at fault bears a disproportionate burden.

In the strict liability context, courts have recognized that even when a defendant is not engaged in the distribution of a product in the same manner as a manufacturer, retailer, or lessor, it may be held liable when it "provide[s] the product to the public for use by the public, and consequently does play more than a random and accidental role in the overall marketing enterprise of the product in question."¹⁶ Moreover, where a party places a defective product in the "stream-of-commerce," creating a demand for that product for its own benefit, personal injury lawyers will claim it should be held strictly liable for any resulting injuries.¹⁷ For instance, the Illinois Supreme Court has recognized that "[t]he major purpose of strict liability is to place the loss caused by defective products on those who create the risk and reap the profit by placing a defective product in the stream of commerce, regardless of whether the defect resulted from the 'negligence' of the manufacturer."¹⁸ Courts have also ruled that "[e]ven parties who are not within the actual chain of distribution, but who play an integral role in the marketing enterprise of an allegedly defective product and participate in the profits derived from placing the product into the stream of commerce, are held liable under the doctrine of strict liability."¹⁹ Courts in several states recognize that "the imposition of strict liability hinges on whether the party in question has *any participatory connection*, for personal profit or other benefit, with the injury-causing product and with the enterprise that created consumer demand for and reliance upon the product."²⁰

¹⁵ See *Coney v. J.L.G. Indus., Inc.*, 454 N.E.2d 197 (Ill. 1983).

¹⁶ *Tauber-Arons Auctioneers Co., Inc. v. Superior Ct.*, 161 Cal. Rptr. 789, 792 (Cal. App. Ct. 1980) (quoting *Garcia v. Halsett*, 82 Cal. Rptr. 420, 423 (Cal. Ct. App. 1970)); see also *Bay Summit Community Ass'n v. Shell Oil Co.*, 59 Cal. Rptr.2d 322, 330 (Cal. App. Ct. 1996) (ruling that a defendant that is involved in marketing a defective product may be held strictly liable if the defendant received a financial benefit from its activities, its conduct was a necessary factor in bringing product to the consumer market, and defendant had a substantial ability to influence the distribution process).

¹⁷ See *Kasel v. Remington Arms Co.*, 101 Cal. Rptr. 314, 324-25 (Cal. Ct. App. 1972).

¹⁸ *Liberty Mutual Ins. Co. v. Williams Machine & Tool Co.*, 338 N.E.2d 857, 860 (Ill. 1975).

¹⁹ *Bittler v. White & Co.*, 560 N.E.2d 979, 981 (Ill. App. Ct. 1990) (citing *Connelly v. Uniroyal, Inc.* 389 N.E.2d 155 (Ill. 1979) (doctrine of strict liability applied to defendant despite the fact that its only link to the chain of distribution was its authorization of the use of its trademark, which appeared on the allegedly defective tire)).

²⁰ *Id.* (quoting *Kasel v. Remington Arms, Inc.*, 101 Cal. Rptr. 314, 323 (Cal. Ct. App. 1972) (internal quotations omitted) (emphasis added)).

C. Lawsuits Will Target State and Local Governments

Private employers, such as drug manufacturers, shippers, hospitals, and pharmacies, are not the only potential defendants in these lawsuits. Personal injury lawyers may target another deep pocket defendant: state and local governments. As a former director of the U.S. Department of Justice's Torts Branch recognized in a recent column in *The Legal Times*, "A plaintiff's attorney may want to add or substitute a state or municipality to permit addition of viable theories to the complaint, and to eliminate defenses that manufacturers may possess but that governments could not assert."²¹

State and local governments view the importation of foreign drugs as a quick fix to budgetary problems and an easy way to please their constituents with cheaper medications. It does not appear that governments have fully considered the potential liability costs of distributing or facilitating the distribution of drugs to its citizens. Legal experts note that the modest savings gained by a drug import program "could be dwarfed easily by a single judgment in a negligence or product liability suit."²²

Several mayors and a handful of governors, as in Boston and New Hampshire, have established programs to import prescription drugs for government employees, retirees, city employees and retirees, and Medicaid recipients, despite the clear illegality of such actions under federal law. Others, such as Illinois, are considering taking this route. Some state and local governments, including Minnesota and Wisconsin, have financed and developed Internet websites that encourage their residents to order imported drugs by providing links to Canadian websites. Thousands of residents are placed at risk by these programs.

Due to the characteristics of this activity as a businesslike function for which injuries may result from the day-to-day challenges in ensuring that the drugs are safe and unadulterated, the state's actions may result in forfeiting the immunity it ordinarily enjoys from civil lawsuits. Generally, a state's sovereign immunity protects it from liability in personal injury cases unless the law provides an exception to this rule. This immunity is often extended by the state to political subdivisions. Although laws vary from state to state, courts often find that this immunity does not apply in two situations. First, many jurisdictions find that state and local governments are not immune from liability when engaged in a commercial activity. Courts rule time and time again that when the government engages in an activity that is traditionally provided by the private sector, it loses its immunity from suit. For example, state and local governments are subject to lawsuits when they operate municipal parking garages,²³

²¹ Jeffrey Axelrad, *Watch Out for Canadian Drugs!*, LEGAL TIMES, Mar. 1, 2004, at 53.

²² *Id.*

²³ See, e.g., *Elsev v. City of Norfolk*, Slip Op., 2003 WL 22135699 (Va. Cir. Ct., Sept. 15, 2003); *McDermott v. Calvary Baptist Church*, 1999 WL 73981 (Feb. 5, 1999, Conn. Super. 1999); *Stringfield v. City of Hackensack*, 171 A.2d 361 (N.J. Super. App. Div. 1961).

day-care centers and preschool programs,²⁴ airports,²⁵ hospitals,²⁶ convention centers and coliseums.²⁷ Even when not seeking to make a profit, the government loses its immunity when it provides rental housing or acts as a landlord,²⁸ or operates railroads.²⁹

Second, states are subject to lawsuits arising out of the implementation of public programs. Some jurisdictions, instead of distinguishing between commercial and governmental activities, recognize that state and local governments are subject to liability for injuries related to the day-to-day operations of their programs.³⁰ While a government may be immune from lawsuits that attack its “discretionary” public policy choices,³¹ once it makes a decision, the government is subject to ordinary rules of negligence in the implementation of the program. For example, if a government decides to engage in a prescription drug importation program, then it is obligated to use due care to make certain that the program is safe for those who use it.³² The government is also liable if it fails to warn participants of the potential dangers.³³ Even when a state or local government claims that it was engaging in a policy decision, as the Iowa Supreme Court recently recognized, “[i]t takes more than a mere label of ‘policy’ to rise to the level of a legitimate policy-based consideration [and thereby qualify for immunity].”³⁴

²⁴ *Schulz v. City of Brentwood*, 725 S.W.2d 157 (Mo. App. Ct. 1987).

²⁵ *See Wendler v. City of Great Bend*, 316 P.2d 265 (Kan. 1957).

²⁶ *See Carroll v. Kittle*, 457 P.2d 21 (Kan. 1969).

²⁷ *See Pierson v. Cumberland County Civic Ctr. Comm’n*, 540 S.E.2d 810 (N.C. App. 2000); *City of Wichita v. U.S. Gypsum Co.*, 72 F.3d 1491 (10th Cir. 1996).

²⁸ *See Fisher v. Housing Auth. of City of Kinston*, 573 S.E.2d 678, 681 (N.C. App. Ct. 2002); *Miller v. State*, 467 N.E.2d 493, 496 (N.Y. 1984); *Muses v. Housing Auth. of City & County of San Francisco*, 189 P.2d 305 (Cal. App. 1948).

²⁹ *See People v. Superior Ct. of City & County of San Francisco*, 178 P.2d 1, 5 (Cal. 1947).

³⁰ Discretionary functions involve “planning,” rather than activities that are “operational” or “ministerial,” in nature. *See, e.g., Angnabooguk v. State*, 26 P.3d 447, 457-58 (Alaska 2001); *Nusbaum v. Blue Earth County*, 422 N.W.2d 713, 719 (Minn. 1988); *see also Norman v. Ogallala Pub. Sch. Dist.*, 609 N.W.2d 338, 346 (Neb. 2000) (ruling that a teacher’s decisions involving the welding class, including decisions regarding supervision, materials, and clothing to be worn during the welding class, were not basic policy decisions, but were discretionary acts at an operational level).

³¹ *Board of Comm’rs of County of Harrison v. Lowe*, 753 N.E.2d 708, 716 (Ind. App. 2001) (Discretionary functions involve “formulation of basic policy decisions characterized by official judgment or discretion in weighing alternatives and choosing public policy” and “the conscious balancing of risks and benefits”); *Holmquist v. State*, 425 N.W.2d 230, 232 (Minn.1988) (recognizing that discretionary functions involve “the evaluation of factors such as the financial, political, economic, and social effects of a given plan or policy”).

³² *Lewis v. State*, 256 N.W.2d 181 (Iowa 1977) (holding that a state is obligate to use due care to make certain that a highway meets the standard of reasonable safety for the traveling public) (citing *State v. Webster*, 504 P.2d 1316, 1318-19 (Nev. 1972)).

³³ *See Stanley v. State*, 197 N.W.2d 599 (Iowa 1972) (ruling that the government can be held liable if it fails to warn motorists of construction on a public highway and an accident results).

³⁴ *Graber v. City of Ankeny*, 656 N.W.2d 157, 166 (Iowa 2003) (ruling that because the city “failed to show any broad-sweeping economic, political, or social considerations were at the heart of its

If a state engages in the sale, distribution, or facilitation of the purchase of drugs from Canada, then personal injury lawyers are likely to argue that it has forfeited its immunity and can be subject to lawsuits for any injuries related to the program. They may claim that in taking on this function, the government engages in a business enterprise³⁵ because the distribution of pharmaceuticals is not a product or service “traditionally” provided by the state or local governmental units.³⁶ They may argue that in purchasing or selling pharmaceuticals from foreign countries, state and local governments compete with private pharmacies at home by undercutting their prices.³⁷ They may contend that the purchase and importation of drugs is not a type of activity that can be solely undertaken by government or even that which the government has some special expertise or function.³⁸ In those jurisdictions recognizing a state’s immunity when performing “discretionary functions,” personal injury lawyers may argue that this immunity is lost if, in importing or facilitating the importation of foreign medications, the state’s actions violate federal or state laws or regulations.³⁹ Importation of prescription drugs, even if authorized by Congress, may conflict with other federal and state laws or regulations regarding licensing of pharmacists, sale and distribution of prescription drugs, and labeling requirements.⁴⁰

decision on how to time this traffic signal,” it could not claim immunity); *see also Hawkeye Bank v. State*, 515 N.W.2d 348 (Iowa 1994) (ruling that the state is not entitled to discretionary function immunity for negligent supervision of students).

³⁵ *See Gillespie v. City of Los Angeles*, 250 P.2d 717, 721 (Cal. Ct. App. 1952).

³⁶ *See Pierson v. Cumberland County Civic Center Comm’n*, 540 S.E.2d 810, 813 (N.C. App. 2000); *Greene County Agr. Soc’y v. Liming*, 733 N.E.2d 1141, 1144 (Ohio 2000) (quoting Ohio Rev. Code § 2744(G)(1)(b) and ruling that a county agricultural society was not immune from suit in relation to its conducting of a livestock competition at a county fair because such “activities . . . are customarily engaged in by nongovernmental persons”).

³⁷ *See, e.g., Muses v. Housing Auth.*, 189 P.2d 305 (Cal. Ct. App. 1948).

³⁸ *See, e.g., Richards Irr. Co. v. Karren*, 880 P.2d 6 (Utah Ct. App. 1994).

³⁹ *Berkovitz*, 486 U.S. at 547-48 (ruling that the federal government’s “discretionary function” immunity did not apply when the FDA released an unsafe lot of polio vaccine, despite its mandatory policy of testing all lots for compliance with safety standards and preventing the public distribution of any lot that failed to comply); *see also Department of Transp. v. Neilson*, 419 So. 2d 1071 (Fla. 1982) (ruling that failure to comply with statutory standards and criteria for design, construction and maintenance of roadways subjects governmental entities to suit). Several courts have found that even when municipalities adopt safety procedures for their public transportation systems, they are subject to liability when a driver fails to protect a passenger in accordance with those rules and procedures. *See, e.g., Washington Metro. Area Transit Auth. v. O’Neill*, 633 A.2d 834, 839 (D.C. 1993); *see also Lopez v. Southern Cal. Rapid Transit Dist.*, 710 P.2d 907 (Cal. 1985).

⁴⁰ For example, Massachusetts law requires the pharmacist filling a prescription to package the drug in a container with a label showing the date of filling, the pharmacy name and address, the pharmacist’s initials, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, the name of the drug, directions for use and cautionary statements, the number of tablets or capsules in the container, and, if the purchaser is elderly or visually impaired, a large type label. *See Mass. Gen. Laws ch. 94C, § 21*. Massachusetts law, and the laws

Should a state lose its immunity, it may face lawsuits attempting to require it (and thus the taxpayers) to pay for injuries resulting from imported drugs. Plaintiffs' lawyers may claim that the state failed to use reasonable care to inspect the imported drugs and verify the authenticity and safety.⁴¹ Although the state governments are unlikely to have the resources to ensure the safety of the imported drugs, personal injury lawyers will argue that the state presented the program as safe to its employees and encouraged their participation in it. They may also allege that the state failed to adequately warn the public of the risks of counterfeiting, contamination, or adulteration associated with imported prescription drugs, or that the state directed its citizens to websites belonging to unreputable or irresponsible foreign companies.⁴² In addition, if the government undertakes a role in fulfilling the prescription medication needs of its employees, and its employees come to rely upon the government's stamp-of-approval of imported foreign drugs, then lawsuits might contend that the government is responsible for any resulting injuries.⁴³

Finally, just as with private companies, plaintiffs' lawyers can assert that the state or local government should be held strictly liable for injuries caused by drug product that is defective, regardless of the government's lack of involvement in the manufacturing process,

of other states, also prohibit the manufacture, distribution and sale of counterfeit drugs. *See* Mass. Gen. Laws ch. 94C, § 32G. Similarly, Iowa law places various licensing requirements on resident and nonresident pharmacists who sell prescription drugs to state residents, prohibits the adulteration or misbranding of drugs, and prohibits the sale or dispensing of counterfeit drugs. *See* Iowa Code §§ 126.3, 126.9, 126.10, 155A.1 *et seq.* There are also various federal legal requirements for the labeling of drugs, and it is illegal to introduce or deliver into interstate commerce any drug that is adulterated or misbranded, or to sell or dispense a counterfeit drug. *See* 21 U.S.C. §§ 331, 351, 352. In addition, under the Federal Food, Drug, and Cosmetic Act, the interstate shipment of any prescription drug that lacks required FDA approval is illegal. *See* 21 U.S.C. § 331(a).

⁴¹ *See Cross Brothers Meat Packers, Inc. v. United States*, 705 F.2d 682, 684-85 (3d Cir. 1983) (ruling that the federal government could be held liable when Department of Agriculture employees failed to properly monitor and inspect the plaintiff's meat, thereby resulting in an erroneous grading of the product).

⁴² *See Neilson*, 419 So. 2d at 1078 (recognizing that the government's failure to warn of a known danger is a negligent omission for which it may be held liable).

⁴³ *See* Restatement (Second) of Torts §§ 323, 324A; *see also* *Patentas v. United States*, 687 F.2d 707, 715 (3rd Cir. 1982) (recognizing that "detrimental reliance has frequently been the reason for injury when a government agent acted as a good samaritan" and that the government may also be liable if it increases the risk of harm to an individual); *Baran v. City of Chicago Heights*, 251 N.E.2d 227, 227 (Ill. 1969) (recognizing that "when a city creates a hazardous condition and someone is injured as a consequence it must respond in damages, just as others are required to do"); *Snyder v. Curran Township*, 657 N.E.2d 988, 993 (Ill. 1995) (once the instant defendant acted on the determination that the curve in the roadway was of sufficient severity to warn motorists by erecting a right reverse turn sign, defendant had a duty to erect it in a non-negligent manner); *Hanley v. City of Chicago*, 2003 WL 21839562, (Ill. App. Ct. June 30, 2003) (ruling that once city embarked on repair of pothole, it had duty to perform repair in a reasonably safe and skillful manner).

simply because of its role in placing the product in the “stream-of-commerce.” The federal government is not subject to strict liability,⁴⁴ and some states may have similar protection. Under modern product liability law, however, plaintiffs’ lawyers can make similar claims against the state as negligence actions for failure to warn and defective design.⁴⁵

B. It Only Takes One Successful Lawsuit to Devastate an American Employer or State or Local Government

Not only is there a high cost in defending against these lawsuits, it only takes one successful claim to result in extraordinary liability for an American company or a state or local government. If a batch of counterfeit drugs or tampered-with imported drugs hits the market, and people are injured, then a single product recall, settlement, or verdict can run into the billions of dollars. The Tylenol poisonings and the recent dilution of prescription drugs by a Missouri pharmacist remind us of the potential injuries that can result from tampered-with drugs and the extraordinary cost that falls on businesses that are not responsible for the acts of criminals, but are within reach of personal injury lawyers. The importation of prescription drugs increases the risk to consumers and, with it, the potential liability of American businesses.

1. We All Remember the Tylenol Poisonings

Consider, for example, the 1982 Chicago-area Tylenol poisonings, which resulted in a nationwide poisoning scare in which seven persons became sick and died after taking cyanide-laced Tylenol. Johnson & Johnson, the product’s manufacturer, immediately pulled thirty-one million bottles of the product from the shelves, at an extraordinary loss to the company, and worked to create tamper-proof packaging. In an eight-year highly-publicized product liability case, the families of three individuals who died sued Johnson & Johnson. Although it was a demented individual who was never caught that was responsible for the poisonings, Johnson & Johnson opted in 1991 to enter into a confidential settlement to avoid going through a long and expensive trial.⁴⁶

Four years later, 23-year-old Diane Elsroth died suddenly after taking two Extra-Strength Tylenol capsules from a sealed bottle in New York.⁴⁷ Investigators later determined that her death was a result of ingesting cyanide. The killer was able to make the packaging appear as if it were safely sealed, and the impregnation of the poison was believed to have

⁴⁴ See *Dalehite v. United States*, 346 U.S. 15, 44-45 (1953).

⁴⁵ See generally Restatement Third, Torts: Products Liability § 2 & cmts. i (inadequate instructions or warnings), p (misuse, modification, and alteration), and o (liability of nonmanufacturer sellers for defective design and defects due to inadequate instructions and warnings) (1998).

⁴⁶ See Edward Walsh, *Tylenol Maker, Families Settle in Cyanide Deaths*, WASH. POST, May 14, 1991, at A3.

⁴⁷ See *Death Laid to Tainted Tylenol A&P Pulls Drug From Shelves in 24 States*, WASH. POST, Feb. 11, 1986, at A3.

occurred en route to the area stores or in the stores themselves. The manufacturer, and the retailer, Great Atlantic & Pacific Tea Co. ("A & P"), were sued by the administrator of Ms. Elsroth's estate.⁴⁸ In Ms. Elsroth's case, the court found that although the retailer might be under a duty to its patrons to reasonably secure the store, the sophisticated tampering involved was likely to have taken place off the A & P premises, with the contaminated product then returned to the store's shelves by the wrongdoer. The court recognized that "short of eliminating over-the-counter shopping, no practical, feasible, affordable way of ensuring against this kind of tampering has been suggested by the parties or imagined by this court." With respect to the manufacturer, the court found that after previous instances of tampering, Johnson & Johnson had redesigned its packaging to make it extremely difficult to tamper with the product in such a way as to conceal to the average person that tampering had occurred. The court dismissed the case because the product was "reasonably safe," and the plaintiff had presented no evidence to indicate how it could be made safer. Nevertheless, the defending companies incurred substantial legal costs, not because they had acted negligently or produced an unreasonably dangerous product, but because someone outside of their control tampered with their product.

When drug products change hands many times on their way to consumers in the United States, the potential for incidents of tampering dramatically rises. The Tylenol copycat case demonstrates that no amount of security can ensure against tampering. The additional risk created by the government's adoption of a drug import policy is likely to fall on manufacturers, retailers, and others who had nothing to do with the criminal tampering, while those responsible evade the courts.

2. *A Drug Tampering Case Resulting in the Second Highest Verdict in the United States in 2002, a String of Lawsuits, and Millions in Settlement Costs.*

A more recent example of the extent of liability for injuries resulting from tampering occurred in Missouri. In 2001, FBI investigators and the FDA discovered that Robert R. Courtney, a Kansas City pharmacist, had diluted 158 chemotherapy medication prescriptions for 34 patients for his own profit. After pleading guilty, he was sentenced to thirty years in prison, fined \$25,000, and ordered to pay \$10.5 million in restitution.⁴⁹ In a later civil lawsuit, a jury awarded \$2 billion against Courtney, a largely symbolic verdict that was the second largest in the United States in 2002.⁵⁰ The company that insured Courtney and his two pharmacies,

⁴⁸ See *Elsroth v. Johnson & Johnson*, 700 F. Supp. 151 (S.D.N.Y. 1988).

⁴⁹ See Mark Morris, *Courtney Sentenced to 30 Years in Prison for Diluting Medications*, KANSAS CITY STAR, Dec. 6, 2002.

⁵⁰ See Dan Margolies, *Insurer to Pay \$35 Million; Settlement Will Go to Courtney Victims*, KANSAS CITY STAR, Nov. 26, 2003. In October 2002, the court reduced the verdict to \$225 million in compensatory damages and \$300 million in punitive damages.

Pharmacists Mutual Insurance Co., paid \$35 million to settle the case even though it believed that its coverage did not extend to the acts of criminals.⁵¹

Hundreds of victims of the pharmacist also filed civil lawsuits against Eli Lilly and Co. and Bristol-Myers Squibb Co. The lawsuits alleged that the manufacturers knew or had reason to know that a single pharmacist was engaged in a dilution scheme simply because they had access to sales data showing that he sold greater quantities of drugs than he purchased. Rather than incur substantial legal fees and adverse publicity, and risk an extraordinary verdict, the companies opted to settle the claims in February 2003. Although the settlement was confidential, the Kansas City Star reported that arbitrators assessed \$48.55 million against Eli Lilly and \$23.55 million against Bristol-Myers Squibb for a total settlement of \$72.1 million.⁵² The case against the companies had substantial factual and legal weaknesses. The companies, however, decided to settle the cases because “under [Missouri] law, even if a jury had found the drug companies only 1 percent at fault, they could have been forced to pay 100 percent of any damages awarded by the jury.”⁵³

Again, the potential for what happen in the dilution case to reoccur is magnified when prescription drugs are being imported from foreign countries; far out of view of U.S. regulation. As in the Missouri case, pharmacies, insurers, manufacturers and others will be left holding the liability bag. The dilution case also demonstrates the potential for astronomical awards and the unfairness of joint and several liability, which may require an employer that a jury finds to have even the slightest degree of responsibility to pay the entire amount of a billion dollar verdict while the more responsible party is beyond the reach of the court or otherwise cannot pay the judgment.

III. SUGGESTIONS FOR ADDRESSING LIABILITY

HHS, FDA, and many experts agree that importation of prescription drugs comes with substantial risks to consumers – risks that are created or greatly exacerbated by state and local governments in adopting such policies and beyond the means of domestic companies to control. Should Congress move forward with authorizing the importation of prescription drugs, fairness dictates that it consider measures that would ensure that American employers are not held liable beyond their responsibility. While none of these steps alone will solve the problem, each would address an aspect of unfairness that is likely to result from adopting a prescription drug importation policy.

⁵¹ See *id.*

⁵² See Dan Margolies, *Courtney Victims to Get About \$71 Million in Settlement Money From Drug Makers*, KANSAS CITY STAR, Feb. 9, 2003.

⁵³ *Id.*

A. Elimination of Joint and Several Liability

Recognizing the problems that may flow from application of full joint liability, a substantial majority of states have abolished or modified the traditional doctrine.⁵⁴ As the new Restatement of Torts (Third) explains, “[t]he clear trend over the past several decades has been a move away from joint and several liability.”⁵⁵ As of this writing, sixteen states had entirely abolished joint liability and replaced it with pure several liability, under which each defendant is liable for its proportionate share of fault for the harm.⁵⁶ Four states have eliminated joint liability for noneconomic damages.⁵⁷ Fourteen states have abolished joint liability in cases where the defendant’s comparative responsibility is below some threshold level.⁵⁸ Some states

⁵⁴ See Restatement (Third) of Torts: Apportionment of Liability § 17 cmt. a (2000) (surveying state joint liability laws) [hereinafter “Restatement”].

⁵⁵ Restatement § 17 Rptrs.’ Note cmt. a.

⁵⁶ See Alaska Stat. § 09.17.080 (2003); Ariz. Stat. § 12-2506 (2003); Ark. H.B. 1038 (signed by Gov. Mar. 26, 2003); Colo. Rev. Stat. § 13-21-111.5 (2003); Ind. Code Ann. § 34-51-2-8 (2003); Idaho Code § 6-803 (2003) (exempting cases arising out of a violation of state or federal law related to hazardous waste or an action arising out of the manufacture of medical devices or pharmaceutical products); *Brown v. Keill*, 580 P.2d 867 (Kan. 1978); Ky. Rev. Stat. Ann. § 411.182 (2003); *Prudential Life Ins. Co. v. Moody*, 696 S.W.2d 503 (Ky. 1985); La. Civ. Code Ann. Arts. 1804, 2323- 2324 (2003); Mich. Comp. Laws §§ 600.6304(4), 600.6312 (2001) (exempting certain medical malpractice claims and criminal conduct involving gross negligence or the use of alcohol or drugs); N.D. Cent. Code § 32-03.2-02 (2003); *Anderson v. O’Donohue*, 677 P.2d 648 (Okla. 1983) (abolishing joint liability where plaintiff was at fault); Or. Rev. Stat. § 18.485 (2003) (exempting cases resulting from violation of federal or state statute regarding spill, release, or disposal of hazardous waste); arising out of a violation of state or federal law related to hazardous waste or an action arising out of the manufacture of medical devices or pharmaceutical products); *McIntyre v. Balentine*, 833 S.W.2d 52 (Tenn. 1992); Utah Code Ann. § 78-27-40 (2003); Wyo. Stat. Ann. § 1-1-109 (2003).

⁵⁷ See Cal. Civ. Code § 1431.2 (2003); Iowa Code Ann. § 668.4 (2003); Miss. Code Ann. § 85-5-7(8) (2003); Neb. Rev. Stat. § 25-21, 185.10 (2003); Ohio Rev. Code Ann. § 2307.22 (2003). Cf. N.Y. Civ. Prac. L. & R. §§ 1601-1602 (2003) (joint liability abolished for noneconomic damages for defendants less than 50% at fault, except in where defendant acted with reckless disregard for the safety of others, unlawfully released hazardous substances, and in product liability actions where the manufacturer of the product is not a party to the action, jurisdiction over the manufacturer could not be obtained, and liability would have been imposed on the manufacturer through strict liability, among other statutorily defined exemptions).

⁵⁸ See, e.g., Fla. Stat. Ann. § 768.81 (2003) (if plaintiff is at fault, joint liability is abolished for: (a) any defendant found 10% or less at fault; (b) economic damages in excess of \$200,000 for any defendant found to be more than 10% but less than 25% at fault; (c) economic damages in excess of \$500,000 for any defendant found at least 25% but no more than 50% at fault; (d) economic damages in excess of \$1 million for any defendant found more than 50% at fault. If plaintiff is not at fault, joint liability abolished for: (a) any defendant found to be less than 10% at fault; (b) economic damages in excess of \$500,000 for any defendant found at least 25% but not more than 50% at fault; (c) economic damages in excess of \$1 million for any defendant found at least 25% but not more than 50% at fault; and (d) economic damages in excess of \$2 million for any defendant found more than 50% at fault. Joint liability does not apply to any defendant who is found to be less at fault than the plaintiff.); Iowa Code Ann. § 668.4 (2003) (joint liability abolished for economic damages for defendants less than 50% at fault); Minn. S.F. 872 (joint

provide other limits on joint liability.⁵⁹ That leaves just a distinct minority of seventeen jurisdictions that have yet to abolish or modify their joint liability rules.⁶⁰

Congress should examine the approaches taken by the states to abolish or modify joint and several liability in cases involving injury from a drug imported from Canada or from other foreign countries. In cases of tampering or counterfeiting, some potential defendants, such as the original manufacturers and the pharmacy dispensing the product, have absolutely nothing to do with the individuals creating the harm. These defendants should not be held liable for the pain and suffering caused by those who tamper with or counterfeit prescription drugs. A manufacturer, product seller or a state should not bear the liability costs of wrongful, intentional acts committed by others.

B. Preemption of State Product Liability Lawsuits Against Manufacturers

Rather than allow lawsuits to proceed against those who manufacture or distribute imported prescription drugs, Congress should consider providing that compliance with FDA safety standards with regard to the labeling, design, and distribution of prescription drugs precludes product liability acts against the parties under state law. If the product meets applicable regulatory standards or requirements, then the law might provide that the imported prescription drug is not defective. Congress might require importers to provide an additional warning of the enhanced risks of using imported prescription drugs on its packaging and labeling to qualify for such protection.

liability abolished for defendants less than 50% at fault (signed by Gov. May 19, 2003); Miss. Code Ann. § 85-5-7(8) (2003) (abolishing joint liability for economic damages for defendants found less than 30% at fault; defendants found 30% or more at fault are liable only to the extent needed for the plaintiff to recover 50% of his or her economic damages); Mont. Code Ann. § 27-1-705 (2003) (joint liability abolished for defendants less than 50% at fault); N.H. Rev. Stat. Ann. § 507:7-e (2001) (abolishing joint liability for defendants less than 50% at fault); Ohio Rev. Code Ann. § 2307.22 (2003) (abolishing joint liability for defendants found to be less than 50% at fault); Pa. S.B. 1089 (signed by Gov. June 19, 2002) (abolishing joint liability for defendants found to be less than 60% at fault); Tex. H.B. 4 (signed by Gov. June 13, 2003) (abolishing joint liability for defendants found to be less than 50% at fault); Wisc. Stat. Ann. § 895.045(1) (West 2002) (abolishing joint liability for defendants found to be less than 51% at fault).

⁵⁹ See Conn. Gen. Stat. Ann. § 52-572h (2003) (defendants in negligence actions generally liable only for percentage of fault); Ga. Code Ann. § 51-12-33 (2003) (joint liability can be disregarded if the plaintiff is partially at fault); Mass. Gen. Laws Ann. Ch. 231B §§ 1-2 (2003) (each defendant liable to the extent of that defendant's proportionate share of the entire common liability; thus in a two defendant case, each defendant is liable up to 50% of the judgment); Mo. Stat. § 537.067 (2003) (joint liability limited to two times defendant's percentage of fault if plaintiff was at fault); S.D. Codified Laws Ann. §§ 15-8-15.1 (2003) (joint liability limited to two times defendant's percentage of fault for any defendant found to be less than 50% at fault).

⁶⁰ Full joint liability continues to apply in Alabama, Delaware, District of Columbia, Hawaii, Illinois, Maine, Maryland, Nevada (for product liability cases); New Jersey (for asbestos cases); New Mexico (for strict liability cases); North Carolina; Rhode Island, South Carolina, Vermont, Virginia, Washington, and West Virginia (except in medical malpractice cases).

This form of federal preemption, which provides a “regulatory compliance defense,”⁶¹ relies on the primacy of federal law under the Supremacy Clause of the United States Constitution to displace competing state law, including state common law.⁶² While some courts may recognize a regulatory compliance defense without explicit legislation in certain circumstances, in many cases, the court will simply permit the jury to consider a defendant’s compliance with the federal standard in determining liability, rather than preclude such lawsuits. Courts rarely consider compliance with FDA standards as conclusive on the issue of defectiveness.⁶³

Should Congress choose not to act, the FDA should consider using its authority to preempt state tort law. This power, known as “administrative preemption,” may be exercised by a federal agency when Congress expressly or impliedly authorizes it to preempt state law.⁶⁴ Although administrative preemption has been used most often to preempt state statutes and administrative regulations, it can also be invoked to preempt state common law doctrines. Courts will often look to and pay great deference to the federal agency’s own interpretation of its governing statute’s preemptive effect. Such deference recognizes that the FDA is staffed with policy experts who are charged with ensuring the safety and effectiveness of the nation’s drug supply. The FDA is in a better position than the courts to hold hearings, solicit comments from all stakeholders, and adopt safety standards that reflect the learning gained from this process. For example, the FDA might take the position that compliance with its anti-counterfeiting and anti-tampering guidelines, preempts inconsistent state lawsuits grounded in negligence, strict liability, or other legal theories.

⁶¹ For useful resources and background on the regulatory compliance defense, see generally Richard C. Ausness, *The Case for a “Strong” Regulatory Compliance Defense*, 55 Md. L. Rev. 1210 (1996); Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 Geo. L.J. 2167 (2000).

⁶² U.S. Const. art. VI, cl. 2. Article VI states in pertinent part: “This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”

⁶³ See *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 70-71 (Mass. 1985) (“compliance with FDA requirements, though admissible to demonstrate lack of negligence, is not conclusive on this issue, just as violation of FDA requirements is evidence, but not conclusive evidence, of negligence”).

⁶⁴ See, e.g., *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 699-700 (1984) (holding that FCC regulations with respect to television cable operators preempt state law prohibiting advertising of alcoholic beverages); *Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 178 (1978) (holding that Department of Transportation regulations on oil tanker safety preempt state tanker safety law).

C. Elimination of Punitive Damages

Congress should also consider eliminating punitive damages in situations where someone other than the defendant is responsible for the counterfeiting or tampering that resulted in an injury. Tort law exists, at least in part, to compensate injured individuals when someone else's wrongful act is responsible for their injuries. Tort law is also supposed to deter wrongful conduct and encourage socially responsible behavior by holding individuals responsible for the injuries that they have caused. In the litigation resulting from counterfeit or tampered with prescription drugs, the second of these two rationales is substantially reduced.

Punitive damages, as their name suggests, exist to punish defendants. The theory behind punitive damages is that in some instances, if a defendant engages in highly morally objectionable conduct, the civil justice system should impose additional damages against the defendant to punish the conduct in question and deter similar conduct in the future. Punitive damages awards do not compensate victims for injuries that they have suffered. Injured parties are compensated with two types of compensatory damages: economic (*i.e.* awards for lost wages or bills) and non-economic (*i.e.* awards for pain and suffering). Because punitive damages do not compensate the victims, they are considered a "windfall recovery."

Punitive damages could continue to be available in an action against an individual who produced counterfeit drugs or tampered with a product. Manufacturers, distributors, or resellers of prescription drugs may have been careless or negligent, but their behavior pales when compared with the culpability of the actual party who caused the harm. Their conduct does not and should not create a basis for punishment.

D. Stop Disclaimers of Liability

Although state and local governments are establishing programs to facilitate and encourage the purchase of prescription drugs from Canada, they are, at the same time, disclaiming any liability associated with the products that it is bringing into the United States.

For example, the State of Minnesota's website, "Minnesota RX Connect," provides the following disclaimer: "The State of Minnesota makes no warranty, express or implied, of merchantability and fitness for a particular purpose, and accepts no legal liability, with respect to any product offered, or pharmaceutical care provided, by the pharmacies listed on this website."⁶⁵ The website also states that "The State of Minnesota cannot guarantee the transaction or your safety." While the website notes that "there are no guarantees when you buy your medications from your local pharmacy either," the state goes on to concede that "there are some additional risks that arise when you purchase medications via the Internet or mail order." Nevertheless, the state disclaims liability for this additional risk that the state created by facilitating the importation of the Canadian drugs.

⁶⁵ <http://www.state.mn.us/cgi-bin/portal/mn/jsp/content.do?programid=536902438&agency=Rx>.

The State of Wisconsin's prescription drug importation website goes further than Minnesota. It literally has pages of disclaimers. The primary disclaimer provides:

Important Information About the Legality of Purchasing Medications from Canada

There are certain unavoidable risks inherent with the purchase of medication. As with all important purchases you make, education about your needs and the product to be purchased will best minimize these risks. The State of Wisconsin has exercised its discretionary authority to visit the physical locations of the web site pharmacies listed on this site, and is confident that the prescription medications listed by these pharmacies on this web site will be dispensed in a safe manner.

However, the State of Wisconsin currently does not license these pharmacies, which are otherwise licensed by the relevant provincial authorities in Canada. Furthermore, while the United States Food and Drug Administration has implemented a personal use importation policy that results in enforcement discretion on the importation of drugs from Canada, it is the federal government's position that applicable federal law currently prohibits such importation. The user of this web site assumes sole responsibility for any decisions made based upon visiting this web site, including the purchase of any and all prescription medications from the Canadian pharmacies listed herein. The State of Wisconsin, as well as its officers and employees, makes no representation as to the legality of the importation or reimportation of pharmaceuticals from Canada, and it expressly disclaims any and all liability from such importation or reimportation or the use of any products so acquired.⁶⁶

The state then provides several paragraphs of "legal notices," including another general disclaimer of liability, a disclaimer of warranties and accuracy of data, a disclaimer of endorsement, a disclaimer for external links, a disclaimer of duty to continue provision of data, and restrictions on choice of law that may govern resulting lawsuits.

The result of such disclaimers is to further shift liability from those who have facilitated the risky purchase of Canadian drugs to those who did not willingly participate in this program. Congress should consider prohibiting states that decide to engage in this dangerous business from disclaiming liability for the enhanced risk of injury and lawsuits created by their actions. Alternatively, Congress might provide the same level of protection to manufacturers, distributors, and retailers so that they are not unfairly hit with lawsuits spurred by state and local government importation programs.

⁶⁶ State of Wisconsin, Prescription Drug Resource Center, Ordering Information, <http://drugsavings.wi.gov/section.asp?linkid=25&locid=2>.

Canadian pharmacies and internet services that fill orders of prescription drugs from U.S. residents have similar disclaimers of liability.⁶⁷ In addition, they may provide that disputes may only be resolved under the laws of a far-away Canadian province and under the jurisdiction of Canadian courts.⁶⁸ Consider just a portion of the disclaimers provide by MedCenter Canada: “American’s Source for Affordable Medications”:

The Client *releases and discharges The Providers, and all of their officers and directors, agents, and employees from any and all liability, claims or causes of action* with respect of the use or application of the Ordered Product by the Client, including, but not limited to undesired side effects. The Client confirms the release in the preceding sentence *also benefits and protects any Canadian Physician* retained by the Providers to lawfully issue the prescription in Canada as directed by the Client’s Doctor. The Client agrees that *child protective packaging may not be used* by the Providers and the Client releases and discharges the Providers and all of their officers and directors, agents and employees *from any and all causes of action with respect to errors or omissions by the company* or agency responsible for transporting the Ordered Product to the Client. . . . The Provider and Client hereby *submit to the jurisdiction of Manitoba and agree that any dispute shall be heard by the Courts in Manitoba, Canada*, including, but not limited to any claims of negligence and/or malpractice. Further, the Client agrees that the *laws of Manitoba, Canada shall apply in such a proceeding*, agrees to these provisions on the basis that the Client understands that he/she is actively doing business in Manitoba, Canada pursuant to the laws, policies and privileges of Canadian law including but not limited to the laws of Manitoba, Canada and that the Client is benefiting from such laws, policies and privileges by participating in this program. The Client acknowledges that the *Ordered Product may not be returned for a refund or an exchange*.⁶⁹

⁶⁷ See, e.g., Discount RX Mart, <http://www.discountrxmart.com/policies.shtml> (providing a “comprehensive limitation of liability” that states that the company “will be held harmless out of any controversy that may arise between its members and its affiliated pharmacies or partner companies” for “all damages of any kind”).

⁶⁸ See, e.g., http://www.crossborderpharmacy.com/au_ourpolicies.html (providing that disputes are to be decided under the laws of the Province of Alberta and the laws of Canada under the non-exclusive jurisdiction of the courts of the Province of Alberta); <http://www.canadadrugs.com/policies/Terms+of+Sale/84/> (providing that disputes are to be decided under the laws of the Province of Manitoba and the laws of Canada, and are subject to the exclusive jurisdiction of Manitoba courts).

⁶⁹ <http://www.medcentercanada.com/orderform.pdf> (emphasis added).

Longstanding fundamentals of product liability law for over forty years prohibit disclaimers of liability in personal injury cases. For example, the Supreme Court of New Jersey has recognized that “an express disclaimer of implied warranties that ordinarily accompanied a sale “gave little and withdrew much.”⁷⁰ It found that such disclaimers, in personal injury cases, “is so inimical to the public good as to compel an adjudication of its invalidity.”⁷¹ The Uniform Commercial Code also provides that court may refuse to enforce such disclaimers.⁷²

Any federal law that permits the importation of prescription drugs should require foreign exporters to agree to submit to the jurisdiction of United States courts. Otherwise, U.S. citizens who are injured by a drug provided by a Canadian company or otherwise have a dispute with that company may be left without a practical remedy, but to sue domestic businesses within the chain of distribution.

V. CONCLUSION

The Medicare Modernization Act’s authorization of the importation of prescription drugs from Canada may substantially increase the flow of counterfeit drugs, contaminated, or adulterated drugs into the United States. Consumers, who are being assured by some government officials that the program is safe, may be harmed. Personal injury lawyers are not likely go after those responsible for these injuries – the criminals who tampered with or counterfeited the drugs, the fly-by-night foreign companies, or those who may have improperly stored them drugs abroad. Those companies may be beyond the reach of U.S. law and are not likely to have resources to pay a judgment. Instead, plaintiffs’ lawyers may sue any private or public entity, or individual, that participated in or facilitated the chain of distribution. Congress should consider enacting liability protections, such as eliminating joint and several liability and providing a regulatory compliance defense with regard to such lawsuits, and eliminating punitive damages. Congress should also consider acting to ensure that parties responsible for exporting prescription drugs into the United States are subject to the jurisdiction of our laws and courts.

⁷⁰ See *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69, 85 (N.J. 1960).

⁷¹ *Id.* at 95.

⁷² See U.C.C. §§ 2-302 (providing that courts may refuse to enforce or limit enforcement of unconscionable terms), 2-316 (providing limitations on exclusion or modification of warranties).