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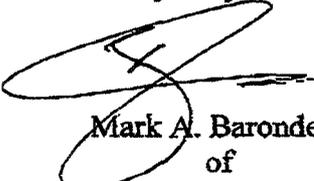
Re: **Docket No. 2004N-0115:**  
**Prescription Drug Importation**

To Whom It May Concern:

As a sufferer of Multiple Sclerosis and a citizen concerned about the above referenced issue, I am enclosing a copy of comments for filing in the above-referenced docket. These comments are submitted for consideration by the Task force on Drug Importation and focus on the issue of liability raised by the proposed importation of prescription drugs from Canada. I am filing 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.

Very truly yours,

  
Mark A. Barondess  
of  
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2004N-0115

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May 27, 2004

**EXPANDING PRESCRIPTION DRUG IMPORTS FROM CANADA WILL  
EXPOSE PHARMACEUTICAL MANUFACTURERS, DISTRIBUTORS,  
DISPENSERS, AND OTHERS IN THE DISTRIBUTION CHAIN TO  
INCREASED TORT LIABILITY**

This memorandum evaluates the civil liability risks that entities within the pharmaceutical distribution chain (pharmacists, wholesalers, importers, manufacturers, and others) could face, should the import provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 take effect. For the reasons discussed below, if recipients of imported Canadian drugs were injured by those products, individuals and plaintiffs' attorneys would almost certainly attempt to bring suit against the entities involved in the drug distribution chain under a range of potential tort theories. Whatever the merits of such claims, the litigation that can be anticipated would impose a potentially substantial burden on defendants, and would tie up significant judicial resources in the courts. It is thus critical that legal protections be considered to limit the potential for unmeritorious suits. Even if legal protections are adopted, however, it is difficult to conceive how they would eliminate inappropriate litigation and defense costs that entities in the pharmaceutical distribution chain would likely face if new imports from Canada or elsewhere are legalized.

**Drugs Imported from Canada May Pose Serious Dangers to Patients**

FDA recently announced the results of a series of spot examinations of courier and mail shipments of foreign drugs to U.S. consumers that revealed surprising numbers of

unapproved or counterfeit drugs, products that pose potentially serious safety problems.<sup>1</sup> During the November 2003 operation, FDA and the U.S. Customs and Border Protection Agency examined 1,982 parcels and discovered 1,728 unapproved drugs, including controlled substances, potentially recalled drugs, “foreign versions” of FDA-approved drugs, and improperly labeled drugs. Approximately 80 per cent of the 1,006 parcels shipped through mail facilities were shipped from Canada. Many of those drugs were actually manufactured elsewhere.

It is a common misperception that all drugs imported from Canada can be safely substituted for their American counterparts. In actuality, FDA’s examinations reveal serious safety concerns about a number of Canadian imports. This is not because drug manufacturers are selling products into Canada that are less safe than those sold in the United States. Rather, imports may be stored, repackaged, or shipped in a way that compromises the product, may be outright counterfeits, may differ in some material and non-obvious way from the U.S. version such as in its preservatives or release profile, or may otherwise fall outside the distribution controls that apply to products in domestic commerce.

For example, FDA found in its sweep that Canadian-manufactured isotretinoin, a drug for severe acne, was shipped without any assurance that a physician would monitor its use. Sales of isotretinoin in the U.S. are subject to a strict risk management plan to prevent serious risks, such as birth defects, associated with the drug. The operation also detected shipments from Canada of certain drug products used to treat asthma and chronic obstructive pulmonary disease.

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<sup>1</sup> FDA’s press release describing the results of these examinations is available at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html>.

Shortly after the operation, several lots of the Canadian versions of the drugs were recalled in Canada because of concerns the product's delivery system might not function properly, and FDA announced a consumer alert for the import of the drugs. The FDA-approved product sold in the U.S. was not subject to the recall.

As these examples show, Canadian drug imports can pose real and serious health risks to patients taking them. The expanded distribution chain increases the likelihood that imported drugs will suffer mishandling en route to their final consumer, leading to a higher incidence of impotent, subpotent, superpotent, or even toxic drugs. Imported drugs are more likely to be counterfeit versions of their U.S. counterparts. They may bear labeling or warnings that comply with foreign requirements but are inadequate under FDA's standards. They may contain formulation differences that are not clear to physicians, pharmacists, or patients. In each case, patient harm may result, and in this day and age lawsuits inevitably will follow against those entities involved in the manufacturing, importing, distributing, prescribing, or dispensing of the imported drugs.

#### **Tort Liability for Injuries Suffered by Patients Using Canadian Drugs**

Patients could be harmed by imported Canadian drugs in a variety of ways. Harm could occur, for example, if a legitimate FDA-approved product is counterfeited, and the imported counterfeit contains the wrong amount of active ingredient, no active ingredient, or a toxic substitute. Harm could occur if a legitimate product has been stored, shipped, or handled by third parties in a way that introduced contaminants or affected its stability and purity. Harm could occur where the potency of a foreign drug is not the same as that of the FDA-approved drug for which it is intended to substitute, resulting in an over- or under-dose, or where the imported product causes side effects or drug-to-drug interactions that would not be expected with

the FDA-approved version. Consumer confusion resulting from labeling differences or dosing differences between U.S. and foreign products could result in medication error. None of the parties associated with the drug's manufacture, import, distribution, and eventual delivery to the patient may have been able to take action to avert the harm. Nonetheless, in each case such parties could face the burden of defending suits alleging injury arising from the imported products.

The risk of lawsuits arising from imported drugs exists today. The risk would become exponentially greater once Canadian imports are legalized, both because the volume of imports can be expected to grow substantially and because individuals injured by the Canadian drugs would presumably no longer be engaging in an activity that was at base illegal. Among the conceivable tort theories a plaintiff might allege are negligence, strict liability/breach of implied warranty of merchantability, failure to warn, and fraud/misrepresentation/unfair trade practices. Each is addressed in turn.

**A. Negligence**

Negligence is the failure of a responsible person to exercise the degree of care required to discharge the duty resting on him. *See, e.g., Nelson v. Massachusetts Port Authority*, 771 N.E.2d 209, 211 (Mass. App. 2002). The elements of a negligence action are a legal duty of reasonable care owed by defendant to plaintiff, a breach of that duty, and injury proximately caused by that breach. *See id.; Swett v. Village of Algonquin*, 523 N.E.2d 594, 597 (Ill. App. 1988). A defendant is held to the standard of care that a reasonable person would exercise under similar circumstances. Whether that standard of care creates a legal duty turns on a number of considerations, including the foreseeability and likelihood of injury, the burden of guarding against injury, and the consequences of placing that burden on the defendant. *Swett*, 523 N.E.2d

at 597; *Cottam v. CVS Pharmacy*, 764 N.E.2d 814, 819 (Mass. 2002). Plaintiffs can seek to impose a duty of care on a defendant when a product is used as intended, or even when a product is used in a manner that is not intended but that is foreseeable.

Plaintiffs could try to invoke negligence against manufacturers, importers, other distributors, physicians, or pharmacies. A plaintiff might attempt to establish, for example, that given FDA's longstanding insistence that such drugs are unsafe, injury to patients who use imported drugs was foreseeable and perhaps even likely, thus creating in the "reasonable manufacturer/importer/distributor/doctor/pharmacy" a duty of care to potential patients. Once imports are legalized, plaintiffs might allege that knowledge of the risks presented by Canadian imports creates a duty for these entities and individuals to take steps to prevent the foreseeable dangers, including by warning the patient of the potential risks.

Plaintiffs could conceivably seek to assert additional negligence theories against importers and others directly involved in the imports. For example, a plaintiff might argue that importers and distributors negligently transported drugs from Canada into and throughout the United States, subsequently leading to patient harm. Importers and distributors are particularly susceptible to a claim that they were negligent in failing to recognize and investigate problems with the drugs at their Canadian source, such as improper handling and storage and incomplete recordkeeping practices.

Pharmacies might also face negligence claims. The legalization of imports from Canada will make it more common for imported drugs to enter the drug distribution streams that culminate in brick-and-mortar pharmacy sales. A plaintiff injured by such a drug might try to attribute the harm he or she suffered to the pharmacy where he or she purchased the drug, on the theory that the pharmacy had an obligation to ensure it provided only safe drugs (*i.e.*,

unadulterated, properly labeled drugs of the correct potency). To the extent imported drugs pose a known risk to patients, a plaintiff might allege that a pharmacy was negligent if it failed to take adequate steps to ensure the quality and integrity of the drugs it dispenses. Similarly, plaintiffs might argue that pharmacies have a duty to identify any differences between the foreign import version of the drug and the version in U.S. commerce, and perhaps also to identify ways the imported product deviates from the approved foreign import version. It is unlikely a pharmacist will have ready access to detailed information about the dozens of foreign versions that might be sold of the thousands of FDA-approved drugs a pharmacy ordinarily sells. Some information about foreign variances could be trade secret. To minimize the risk of litigation, however, pharmacies might have to devote significant resources to due diligence activities.

These broad and malleable negligence theories could create substantial exposure to suits from personal injury attorneys against those involved in importing drugs from Canada. Even where the linkage between legitimate sales to Canada and eventual harm to a plaintiff in the U.S. is attenuated, commercial entities in the distribution chain present attractive “deep pockets” and would thus be required to defend against such claims, however speculative. The burden of mounting a defense in court against even speculative charges can be substantial, and there is the specter that our courts might be clogged with a new species of tort actions.

**B. Strict Liability/Breach of Implied Warranty of Merchantability**

The tort theory of strict liability is nearly identical to the contract theory of breach of implied warranty of merchantability. *See, e.g., Garcia v. Edgewater Hospital*, 613 N.E.2d 1243, 1249 (Ill. App. 1993). Each theory may be premised upon an inherent defect in a product or upon the defendant’s failure to warn. This section addresses liability for product defect; failure to warn is discussed below.

A plaintiff may recover in a strict liability action if he or she proves that an injury resulted from an unreasonably dangerous condition of the product, which condition existed at the time the product left the control of the manufacturer or seller. *See, e.g., Johnson v. Danville Cash & Carry Lumber Co.*, 558 N.E.2d 626, 629-30 (Ill. App. 1990). The rule of strict liability “encompasses the commerce chain in its entirety, including manufacturers, distributors, retailers, and lessors.” *Id.* at 629 (citation omitted). Manufacturers are held to be in a position to institute quality control or other measures to keep defective products from the marketplace, and they are held strictly liable for injury simply on the basis of permitting a defective product to enter the stream of commerce. *See, e.g., Nelson v. Nelson Hardware*, 160 Wis. 2d 689, 705 and n.6 (1991). Other sellers are also subject to strict liability for the sale of an unreasonably dangerous product but on a different theory; among other reasons, courts have noted that “imposition of liability may impel a retail seller to purchase only from other sellers or manufacturers who, under threat of liability as a matter of law, will correct or prevent the manufacture of dangerously defective products.” *Id.* at 707.

Based on similar arguments, a plaintiff could also allege a breach of implied warranty of merchantability. Although this is a contract theory, a plaintiff may recover non-economic damages for personal injury. *Federal Ins. Co. v. Village of Westmont*, 649 N.E.2d 986, 989 (Ill. App. 1995). To recover under this theory, a plaintiff must establish a sale of goods, that the seller of the goods is a merchant with respect to goods of that kind, and that the goods were not of merchantable quality. M.G.L. c. 106, § 2-314; 810 ILCS 5/2-314; *Garcia*, 613 N.E.2d at 1249; *Chapman v. Bernard's Inc.*, 167 F. Supp. 2d 406, 414 (D. Mass. 2001). If a consumer were injured by an imported drug, he or she might seek to hold each party that played a role in delivering the pharmaceutical strictly liable. For example, the consumer might allege

that the dangerous conditions presented by the foreign drug were inherent in the foreign distribution and U.S. import scheme, and thus existed and were known at the time the manufacturer introduced the drugs into that scheme or the time a downstream party purchased the drugs for resale. In other words, a manufacturer might face strict liability charges from patients who can show they have been injured by Canadian drugs, regardless of the actual cause of the injury (e.g., improper handling by an importer that rendered the drug subpotent after it left the manufacturer's control). A retail pharmacy might face a lawsuit claiming that it should have recognized the safety flaws in a distribution chain that flows through foreign sources.

Downstream parties in the pharmaceutical distribution chain face an even greater potential risk of liability under an implied warranty of merchantability theory, because they more neatly fit the definition of a "merchant." For example, in *Garcia, supra*, the court found that a hospital's provision of mitral valves was a "sale," independent of the service of performance of mitral valve replacement surgery, that rendered the hospital subject to liability for breach of implied warranty of merchantability. Pharmacies may also face claims under this theory; they are extensively regulated by governmental entities, staffed by highly qualified, licensed professionals who hold themselves out to the public as having specialized knowledge and skills, and sell drugs directly to their ultimate consumers. Finally, even though manufacturers do not sell drugs directly to patients, a plaintiff might claim that a U.S. manufacturer selling into Canada fits the definition of a "merchant" and seek to prove a breach of the implied warranty of merchantability. Even if such a claim ultimately proves unsupportable, the defendant may bear substantial expense in defending against it.

**C. Failure to Warn**

A failure to warn of a product's dangerous propensities can give rise to a claim of strict liability, breach of implied warranty of merchantability, or negligence. Under a strict liability theory, the manufacturer's or other seller's failure to warn of the danger posed by the product renders it unreasonably dangerous. *See, e.g., Schultz v. Hennessy Industries, Inc.*, 584 N.E.2d 235, 242 (Ill. App. 1991); *Anderson v. Heron Engineering Co.*, 198 Colo. 391, 398 (1979). The implied warranty of merchantability includes an assurance that the product is reasonably safe for its ordinary purposes. Consequently, the manufacturer, distributor, or seller of a product known to be unreasonably dangerous may be obligated to warn those who foreseeably will come in contact with the product. *Cocco v. Deluxe Systems, Inc.*, 516 N.E.2d 1171, 1175 (Mass. App. 1987). Under these two theories, the focus is on the adequacy of the warning. *Werckenthein v. Bucher Petrochemical Company*, 618 N.E.2d 902, 908 (Ill. App. 1993). By contrast, under a negligence theory, the focus is on the particular defendant's knowledge and conduct. *Werckenthein v. Bucher Petrochemical Company*, 618 N.E.2d 902, 908 (Ill. App. 1993).

A plaintiff predicated a products liability action upon a failure to warn must demonstrate that the defendant knew or should have known of the danger that caused his or her injury. *Schultz*, 584 N.E.2d at 242; *see also Cocco*, 516 N.E.2d at 1175. The purpose of a warning is to apprise people coming into contact with a product of dangers of which they are unaware so that they may take appropriate precautions to protect themselves. *Vallejo v. Mercado*, 580 N.E.2d 655, 662 (Ill. App. 1991).

Particularly with respect to Canadian drugs that FDA has specifically identified as potentially dangerous, plaintiffs might seek to make out an argument for failure to warn, with

regard to pharmacies. In general, the “learned intermediary” doctrine relieves pharmacists of the duty to warn about possible dangers of prescription drugs, for the patient’s physician is deemed to be in the best position to provide any applicable warnings to the patient about the drug. However, courts in a number of states have refused to extend the protections of the learned intermediary doctrine to pharmacists who had specific knowledge of a particular danger to the patient. In *Happel v. Wal-Mart Stores, Inc.*, 737 N.E.2d 650 (Ill. App. 2000), the court held that the pharmacy, which was aware of the patient’s drug allergies, owed a duty to disclose either to the patient or her physician that the prescribed drug was contraindicated. Similarly, in *Cafarelle v. Brockton Oaks CVS, Inc.*, 1996 Mass. Super. LEXIS 421 (Mass. Super. 1996), the court concluded that the pharmacy had a duty to warn the patient and her prescribing physician that the patient may have overused the medication. Plaintiffs could cite these cases to support a claim that where a pharmacy dispenses Canadian drugs known to be potentially problematic, it has a duty to warn the patient of the particular harm that users of those drugs might incur.

Doctors and other health care professionals may similarly face liability claims. A court may conclude that a health care provider acted negligently in failing to warn patients about the dangers of filling prescriptions through non-traditional sources, including Internet pharmacies. Medical professionals are generally not held strictly liable in tort, but are expected to apply a reasonable standard of medical care under the circumstances. *See, e.g., Hoven v. Kelble*, 79 Wis. 2d 444, 456 (1977). Given the heightened attention paid to these issues in recent years, however, a plaintiff might feel emboldened in an argument that reasonable medical practice requires a warning to patients. For example, the House of Delegates of the American Medical Association has adopted for its members a policy on the appropriate use of the Internet in prescribing medications that takes into account the spread of pharmaceutical sales by

illegitimate Internet sites. *See* AMA House of Delegates Policy H-120.956. A plaintiff consumer might argue that, given the level of attention devoted to this issue by the federal government, media, and professional associations, “ordinary care” by a doctor or other health care provider includes giving adequate warnings to patients about the potential risks of imported drugs.

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In sum, the distribution chain that supplies drugs that are subsequently imported into the United States from Canada contains a wide range of parties that could be exposed to liability claims under a number of tort theories. Most such claims could be expected to fail on the merits. However, the fact remains that each party faces substantial litigation risks given the realities of our current tort system, no matter the merit of any of these claims. These suits would be expected to add to the burden on the court system. In addition, the defendants likely would pass a portion of their defense costs to consumers, reducing the potential savings to be obtained from legalized drug imports.

#### **Liability Protections**

In light of the liability risks described above, it is imperative that the implementation of any change to the U.S. import laws be accompanied by liability protections for parties in the distribution stream. From the pharmacist’s perspective, the risk of liability will make insurance and contractual indemnification provisions essential. The costs of such protection will undoubtedly be passed along to patients, the ultimate consumers in this stream of commerce. Smaller pharmacies unable to secure adequate insurance may be forced to cease their operations, thereby reducing market competition and patient choice. Without liability protection,

of course, increased liability and litigation may also depress pharmaceutical innovation and skew drug development decisions in undesirable ways.

**A. Immunity and Liability Waivers**

The logical starting place for liability protections is some sort of statutory immunity for products that are sold into Canada for the Canadian market and are not intended by the manufacturer to enter U.S. commerce. It is likely that drugs that were in full compliance with Canadian requirements when they left the manufacturer's possession, intended for sale only to Canadian consumers, will be reimported into the United States against the manufacturer's wishes. In such cases, there is no good basis for the manufacturer to face potential liability. A rule of immunity could, for example, provide that manufacturers are immune from liability for injuries caused by imported drugs, unless the plaintiff can establish that the drug did not comply with the applicable foreign law. Congress could also consider legislative action to provide pharmacies protection from liability where a pharmacy supplies an approved foreign import version of a drug, or where the pharmacy provides a specified disclosure to patients receiving the imported version.

Statutory immunity would have obvious limitations. First, it would not prevent the filing of lawsuits, and companies would thus face some burden of defending claims even if they could be dismissed at a preliminary stage of the litigation. Second, it is not clear in practice whether there will be any meaningful way to determine whether an individual patient received a drug imported from Canada or not. Third, it is not clear the U.S. court system is equipped to adjudicate questions of compliance with foreign regulatory standards. Fourth, any exception created in the immunity, such as for cases of noncompliance with applicable foreign law, will

invite arguments from plaintiffs' attorneys and reduce the effectiveness of the intended immunity.

Other models of immunity or liability protections also exist, but each has its weaknesses. For example, Congress could provide that parties may only face liability for Canadian imports for negligence or gross negligence, with no strict liability or breach of implied warranty of merchantability. However, as discussed above, there would remain the difficulties of determining whether an injury arose from a Canadian or U.S.-sourced product. Additionally, plaintiffs' lawyers would predictably cast claims in terms of negligence, and parties would thus be forced to defend themselves and incur litigation expenses regardless of the facts.

Some states creating websites to facilitate Canadian drug imports by their employees and/or residents have attempted to waive liability for any personal injury that may arise from drugs obtained via pharmacies listed on the sites. In addition, a number of Canadian pharmacy websites require American consumers to agree to a waiver of liability. Whether a court would accept such a waiver of liability is doubtful: "Traditionally the law has looked carefully and with some skepticism at those who attempt to contract away their legal liability for the commission of torts. (Prosser & Keeton, Torts (5th ed. 1984) pp. 482-483.)" *Gardner v. Downtown Porsche Audi*, 180 Cal. App. 3d 713, 716 (1986); *see also, e.g., Rose v. National Tractor Pullers Ass'n*, 33 F.Supp.2d 757, 763 (W.D. Wis. 1998) ("The Wisconsin Supreme Court has held consistently that exculpatory contracts 'are not favored by the law because they tend to allow conduct below the acceptable standard of care.'") (citation omitted). There is, therefore, some possibility a court would conclude that enforcing an exculpatory clause is against the public interest.

In making that assessment, “the courts consider whether the party seeking exoneration offered services of great importance to the public, which were a practical necessity for some members of the public.” *Seigneur v. National Fitness Inst., Inc.*, 132 Md. App. 271, 284 (2000). Each party in the pharmaceutical distribution stream, from manufacturer, to distributor, to doctor and pharmacy, and perhaps extending to State governments operating pharmacy referral services, arguably meets this definition. Courts will also consider whether “the bargaining power of one party to the contract is so grossly unequal so as to put that party at the mercy of the other's negligence.” *Id.* at 282-283. A court might conclude that the consumer purchasing imported drugs is generally not a sufficiently sophisticated purchaser to understand the full effect of the waiver of liability. Rather than permit this decision to be made in each jurisdiction as litigation develops, Congress should consider establishing clear rules regarding the use of liability waivers.

#### **B. Federal Preemption**

Some important relief for expanding liability could be provided separate and apart from creating Canada-specific protections, were Congress to enact legislation establishing the adequacy of FDA-mandated warnings for liability purposes and preempting contrary state laws. FDA imposes extensive requirements for manufacturers to label drug products with warnings. However, this requirement often does not preempt state tort law that may give rise to a claim that a drug product inadequately warned patients of the risks they may incur by using a particular product. *See, e.g., Caraker v. Sandoz Pharms. Corp.*, 172 F.Supp.2d 1018, 1035 (S.D.Ill. 2001) (holding that FDCA was not intended to preempt state law creating a cause of action for failure to warn). Congressional action to clarify that FDA approval of a drug warning establishes its adequacy would reduce exposure to civil liability on this basis for manufacturers and others in

the distribution chain, and potentially offset the expanded liability risks companies would face due to newly authorized Canadian imports.

**C. Proportionate Liability and Punitive Damage Limitations**

To further reduce liability concerns, Congress could take action to substitute proportionate liability for the current system of joint and several liability. Particularly in light of the complexity of the drug import system, it is unfair to assign full joint liability to a party that played a relatively minor role in bringing a foreign drug to its final point of sale to the consumer. A federally mandated proportional system of liability would standardize state laws on joint and several liability and ensure that defendants in an action are only responsible for their relative share of any damages. A proportional system of liability would also sharpen the focus of litigation on the actual damages suffered by plaintiffs.

Congress should also take legislative action to formalize judicial limits on the award of punitive damages. Under recent Supreme Court jurisprudence, it has become clear that constitutional due process imposes a limit on punitive damage awards and requires a clear nexus between a defendant's bad behavior and a compensable injury suffered by the named plaintiff. *See State Farm Mutual Automobile Insurance Co. v. Campbell*, 123 S.Ct. 1513 (2003) (reversing, on Fourteenth Amendment grounds, an award of punitive damages by the Utah Supreme Court that was 145 times the compensatory damages in the case). To reduce the uncertainty and risk associated with state court litigation, Congress should enact legislation to eliminate or cap punitive damages against any party engaged in the legitimate importation of prescription drugs.

**Conclusion**

For the reasons discussed above, implementation of laws to permit drug imports from Canada or elsewhere will potentially expose a variety of entities in the pharmaceutical distribution chain to new and serious liability risks. Some steps can be taken to address these risks, but none provides a clear and adequate solution.