

**JEFFREY AXELRAD'S PRESENTATION FOR FDA TASK FORCE
APRIL 14, 200 PUBLIC MEETING REGARDING IMPORTATION OF PRESCRIPTION
DRUGS**

I appreciate the opportunity you are providing to discuss the serious monetary liability issues that would attend non-manufacturers' importation of drugs into the United States.

My experience may be helpful to the Task Force's consideration of tort liability issues. For more than three decades, I was an attorney at the U.S. Department of Justice. Most of the time, I was defending the United States in tort claims. For twenty-five years, I was the Torts Branch Director at the U.S. Department of Justice responsible for most litigation under the Federal Tort Claims Act, including medical and medicine-related claims and litigation. Currently, I am an Adjunct Professor at George Washington University Law School and also am a consultant to PhRMA. My views, however, are entirely my own.

The Notice of Public Meeting asks "[w]hat, if any liability concerns would exist for entities in the U.S. pharmaceutical distribution system if importation of drugs from Canada or another country were permitted?" The answer to this question is that very substantial liability concerns would exist for any entity in the U.S. pharmaceutical distribution system that facilitated such importation, specifically those entities would subject themselves to the full panoply of state tort law remedies associated with the sale of drugs. In that regard, an importing party may not be able to prove that a defect was

the responsibility of a manufacturer. Importation might well bar an importing entity from establishing a direct causal link between the manufacture of a drug by a U.S. manufacturer and the drug's subsequent alleged cause of an injury to an individual. The importing entity consequently may well be solely responsible for any damages suffered as well as for litigation costs. At a minimum, the importing entity would likely be embroiled in litigation claiming that it is liable to pay a share of the damages.

This conclusion follows from established tort law principles. The "black letter" law is that "[o]ne engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect."ⁱ Product sellers have the same legal responsibility as manufacturers under strict liability. Any seller or distributor of a drug falls within these principles.ⁱⁱ These principles apply to establish a viable theory of liability if and when a seller or distributor partially or wholly causes a stale, counterfeit or mislabeled prescription drug to reach a customer and the customer is harmed. Obviously, the Food and Drug Administration would consider whether it is feasible to guard against harm to our citizens from importation of stale, counterfeit and/or mislabeled prescription drugs. My point is somewhat different: It is that persons selling or distributing imported drugs not only need to exercise care to ensure that they are not a part of any "chain" that results in distribution of imported stale, counterfeit or mislabeled drugs but also that they could be strictly liable if they sold or distributed such a defective product. Liability for even one really "bad" outcome can amount to millions, as I learned all too frequently during my Department of Justice career.

Monetary liability of a seller or distributor of a stale, counterfeit or misbranded drug is straight-forward. That species of liability would not be the sole source of litigation that would arise from drug importation by non-manufacturers for sales and distribution. Sellers and distributors might also be liable for the consequences of good drugs that have rare, harmful effects on a small proportion of users.

A plaintiffs' lawyer would want to sue all potentially responsible parties if there were a potential product-liability claim. The original manufacturer of the drug would presumably deny knowledge of distribution starting in another country over which it lacked either sufficient knowledge or control. Moreover, it might be difficult to obtain jurisdiction over the foreign participants in the distribution chain in a suit filed in our country's judicial system. A prudent plaintiff's lawyer representing an injured individual would likely target the seller and distributor as a defendant or defendants

Joint and several liability principles add to the U.S. sellers' and distributors' liability. Although the law pertaining to joint and several tort liability varies from state to state, in many states, one liable defendant legally can be required to pay *all* of a plaintiff's damages, even if other defendants or absent, foreign parties are primarily responsible for the plaintiff's injuries. In a "worst case" scenario, a seller who is one percent responsible for an injury can be held legally liable to pay 100 percent of the damages.

If a defective imported prescription drug is sold, the seller may have to bear the burden of defending and potentially paying judgments in suits claiming a drug is defective, including inadequate warning or labeling defects, due to application of joint and several liability. Responsible sellers and distributors sensibly may shy away from

this substantial—potentially huge—liability. As a consequence, it is very possible that major sellers and distributors of imported medicines might be the least responsible sellers and distributors.

“Irresponsible” product sellers may not make a careful effort to provide adequate labeling and product information or guard against potentially stale or counterfeit drugs. Moreover, some sellers might be judgment-proof parties. All of this could create a domino effect of substantial tort liability against the only available and viable distributor or product seller defendant within the jurisdiction of the court.

For each of these reasons, liability concerns do exist. Clearly, the concerns are real and, at a minimum, very significant.

The Notice of Public Meeting also asks “[i]f liability concerns do exist, what liability protection do you believe should be implemented.” Tort reform proposals, for the most part, strive to strike a reasonable balance between the amount or quantum of damages and the right of an injured person to be compensated adequately for injuries. Some proposals seek to cabin-in liability without eliminating all tort liability. In order for sellers and distributors of imported drugs to be protected from the liabilities I have described, however, their tort liability would need to be eliminated. Tort law is largely state law created. Barring seller and distributor tort liability therefore would need to take the form of federal pre-emptive legislation. Assuming, for the sake of discussion, that no constitutional barrier would invalidate such legislation, federal legislation immunizing sellers and distributors from suit when they sell imported prescription drugs would be the surest way (and, at first blush at least, the only sure way) of protecting them from liability. Presumably, to avoid any such legislation being entirely irrational, all

prescription drug sales, not just imported prescription drug sales, would need to be immunized from suit.ⁱⁱⁱ

I want to be clear that I do not advocate the legislative proposal that I have just outlined in the abstract. The approach I have outlined would sometimes eliminate any and all effective tort remedies for injured persons. I am merely addressing the question the Notice of Public Meeting asks.

Thank you for permitting me to discuss imported drug tort liability issues at this public meeting.

ⁱ Restatement (Third) of Torts: Product Liability, § 1

ⁱⁱ Restatement (Third) of Torts: Product Liability, § 6 (e)

ⁱⁱⁱ An excellent discussion of federal preemptive tort reform legislation is included in Victor E. Schwartz & Leah Lorber, *The General Aviation Revitalization Act: How Rational Civil Justice Reform Revitalized an Industry*, 27 J. Ai. L. & Com. 1269 (2002)