

CALIFORNIA WESTERN INTERNATIONAL LAW JOURNAL

VOLUME 36

FALL 2005

NUMBER 1

INTERNATIONAL DRUG IMPORTATION: ISSUES IN PUBLIC POLICY, PATIENT SAFETY, AND THE PUBLIC HEALTH

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This issue of the California Western International Law Journal memorializes the proceedings of the First Annual San Diego Health Policy Conference, *International Drug Importation: Issues in Public Policy, Patient Safety, and the Public Health*. Leaders from medicine, law, public policy, academia, and patient care groups gathered together on June 3-4, 2005 to discuss the issue of international drug importation from their stakeholder perspectives. The conference drew attendees from around the world, including representatives from in-

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dustry, European patient care groups, law enforcement, and other important bodies to vigorously and rigorously debate the concerns surrounding drug importation.

In the first piece, *Over the Virtual and Geographic Borders: Understanding Importation and Counterfeit Drugs*, I attempt to contextualize the debate on drug importation. I provide some information on the traditionally safe U.S. system, but also outline some breaks in protection that have resulted in counterfeit drugs being produced and imported into this country. I also try to review some incentives that lead to the problem of counterfeit drugs and the movement of international crime and terrorist organizations into this area, including ease of production, exceedingly small penalties, illicit Internet sales, and a porous domestic gray market system that allows for fake drugs to enter into the medicine supply. This environment may create systems issues that, without deeper inspection, may allow our heretofore relatively safe domestic supply to become tainted with an influx of fakes, resulting in nontreatment, wrong treatment, or harm associated with the fake materials used, including death. Importantly, consumers must be their own last barrier to harm and use tools, such as the Partnership for Safe Medicines SAFE DRUG checklist, which may be instrumental in saving lives.

We then move to the health care provider perspective. Physicians are key stakeholders in the debate on drug importation. Edward Langston, a practicing physician and a pharmacist, Member of the American Medical Association Board of Trustees, Commissioner of the Joint Commission on Accreditation of Healthcare Organizations, and a professor at the Purdue School of Pharmacy provides his perspective in the piece *The Quality Quandary*. Dr. Langston notes the incredible number of prescriptions written in the United States—over three *billion* each year. The focus of the physician, however, is that the medications being provided to their patients are both safe and affordable. Yet on a practicing physician level, many challenges are created by importation. The Internet, the difficulty with the FDA regulating drugs from Canada and other countries, and an open distribution chain create safety risks that may result in harm to patients. Dr. Langston calls for implementation of technological solutions for tracking and tracing medicines, as well as authenticity verification, before importation is broadly accepted.

Ms. Arlene Luu then provides us with the nursing perspective. As a nursing clinical case manager in the emergency department, as well as a public health nurse, she and those in similar positions are often the first to see patients who may have been subject to therapeutic fail-

ure due to prescription drugs. In her piece, *Medication Use, Safety, and Nursing Culture: A View of Potential Counterfeits from the Front Lines*, Ms. Luu notes that although it is the function of the nurse to detect and educate patients about the potential for counterfeit drugs, nurses and other providers rarely consider counterfeits as a possibility when patients experience therapeutic failure. This is a critical awareness issue, and requires attention both for the purpose of treating patients, as well as educating them to the risks of purchases from over the border, the Internet, and other unreliable markets.

Canada has been the focus of much discussion regarding drug importation. Yet the shrillness of the debate here has muted the perspectives of those on the other side of the border. Tim Gilbert, founder and partner of Gilbert's LLP, has been extensively involved in the ongoing policy initiatives involving prescription drugs both in Canada, as well as the United States. With his associate Sana Halwani, they review and clarify some of the issues in their piece, *Confusion and Contradiction: Untangling Drug Importation and Counterfeit Drugs*. They first note that drugs used in Canada, as well as the United States, are manufactured around the world, so the term "importation" is as limited as it is broad. In addition, they point out that most of the problems surrounding counterfeits are at the manufacturing or wholesale level, creating alternative issues of detection and protection. They also note that counterfeit medicines are truly a worldwide problem. Hence, the question of medicine safety is not, in fact, an importation issue, but instead a highly difficult, complex problem of international regulation and harmonization that requires cooperation and technical savvy. Devising such a system, coupled with necessary enforcement, can address the international problem of counterfeits.

Of course, many in Canada make a significant living off of selling drugs through mail order pharmacies, and are scrupulous in their activities. These individuals are perhaps being tarred with too broad a brush when the discussion of importation and counterfeits is raised. In this vein, the comments of Andy Trozsok, a registered pharmacist in Canada, and the President of the Canadian International Pharmacy Association, are instructive. Mr. Trozsok, who has testified in front of the U.S. Congress on Canadian drug importation, notes that Canada's regulatory system is as strong as, if not stronger than, the U.S. system, and mail order activities over the border may be a partial solution to the high costs of brand name drugs in the United States. He indicates that those who oppose importation have no evidence, or are self-interested parties in the debate. Hence, he believes that importation

from Canada into the United States is a viable solution and serves the public interest here as well.

Although the debate between the provider and Canadian policy levels are essential to understand, as noted by Tim Gilbert and Sana Halwani, the key player in the movement and authentication of pharmaceuticals are the wholesalers in this country. This perspective is often unheard in the give-and-take debate on this issue. However, Robert P. Giacalone, both an attorney and a pharmacist for Cardinal Health, one of the largest wholesaler distributors in the country, provides this tremendously important perspective in his piece, *Drug Wholesaling and Importation: Challenges and Opportunities?*. In this paper, Mr. Giacalone details the drug distribution supply in the United States and indicates the practical nature of the limits and benefits of technological solutions, including a heretofore unpublished evaluation of radio-frequency identification tags done by Cardinal Health. He concludes that present regulatory structures and limitations of current technology cannot support importation at this time, and introduction of medicines into the U.S. drug supply from foreign non-manufacturing sources may undermine the integrity of the pharmaceutical supply chain in this country.

Importation is not a new issue. Border importation, particularly across the United States-Mexico border, has been going on for decades. Indeed, it has been estimated that Americans buy \$800 million worth of medicines and import them across this border each year. Professor Marv Shepherd, the Director for Pharmacoeconomic Studies at the College of Pharmacy of the University of Texas, has been studying the drug importation phenomenon for years and is the leading authority in this area. In his paper, *Drug Quality, Safety Issues and Threats of Drug Importation*, he notes that drug products are entering the United States from all areas of the world. He observes the significant problems associated with rogue pharmacy Web sites that ship any and all sorts of drugs to Americans without a prescription, the limited information on just who is buying these drugs and who is servicing them, and the poor quality and quality control associated with these purchases and sales. On the other hand, he notes that, in fact, there are some sites that are legitimate and high quality. Yet the epidemiology of these nontraditional purchases is unknown, including hospitalization and deaths associated with counterfeit drugs. He concludes that without this information, policymakers cannot make informed decisions about the appropriate means to address the risks of importation, and hence, drug importation is not a viable alternative at this juncture.

Of course, medicines are not the only goods that are counterfeited. Counterfeiting products has a long and extensive history. James Cooper, California Western School of Law Institute Professor of Law and Assistant Dean of Mission Development, provides us with some of the context of counterfeiting in his piece, *Piracy 101*. He notes that there are significant implications associated with pirated goods; public health and safety are, of course, impacted, but, echoing others, he notes the connection between organized crime and terrorist groups and the counterfeiting and sale of goods around the world. He calls for coordination of regulatory structures and law enforcement across borders, and better enforcement of intellectual property protections to support the relevant domestic and international interests.

The key stakeholder associated with importation—and, of course, the potential for counterfeit drugs—is the patient. Additionally, patients must also shoulder the burden for the costs of pharmaceuticals. Therefore, their voice must be heard in the debate on the appropriateness of drug importation.

Patients who have suffered disease can reasonably be considered critical representatives of the patient population because they have lived the phenomenon of disease and its treatment. William P. Bro, CEO and President of the Kidney Cancer Association, is one such person. He provides his real life insights in his piece, *Importation of Prescription Drugs and Risks to Patient Safety*. Mr. Bro, a cancer survivor, notes that imported drugs outside the realm of FDA jurisdiction create risks to patients, particularly with sensitive disease states. The issues associated with importation, including counterfeits, poor quality, untested ingredients, as well as unsupervised use, result in risks too high for the patient at the current time. He concludes that a personal importation system would create more risks to Americans and should be scrutinized carefully before implementation.

Another important patient care perspective is provided by Dr. Rene Rodriguez, President of the Interamerican College of Physicians & Surgeons, whose patient care base is the underserved Latino population. In his piece, *Drug Importation and the Hispanic Physician*, he, like Dr. Langston, emphasizes the need for physicians to play a role in the drug importation debate. Dr. Rodriguez, however, points to an important concern regarding importation: that the attendant risks associated with importation, including counterfeits, will be shouldered by the poor and the vulnerable patient. These patients would be subject to the imported “somewhat regulated” drugs, whereas more affluent patients would be provided with the fully regulated, domestic versions. Hence, the minority patient with limited income will be re-

quired to take the risk of imported medicines due to their lack of resources. This is an unacceptable result, particularly as evidence mounts indicating the disparities in health care outcomes for minority and underserved poor patients in this country.

Finally, other patient groups, including the American Association of Retired Persons, do favor importation. In his comments entitled *Prescription Drug Importation Beyond Canada*, State Director of AARP, Michael Moreno, outlines this position. He notes that AARP has a longstanding interest in ensuring prescription drug coverage for the vulnerable patient. He describes the activities of AARP to investigate the safety of drug importation from Canada and the important assessment made to make sure Canadian-purchased drugs are safe. He indicates that the regulatory structure in Canada, plus safety provisions, can result in appropriate and effective importation, such as under the Dorgan-Snowe importation bill currently being considered in Congress.

Overall, the issue of drug importation is a challenging one. However, having all stakeholder groups together and memorializing their thoughts will provide those involved in the policymaking debate essential information about the pros and the cons of this policy choice. The conference *International Drug Importation: Issues in Public Policy, Patient Safety, and the Public Health* and its proceedings will hopefully provide some important information toward that end.