



Potential Health Plan Liability for Participation in Prescription Drug Importation Programs

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I. Introduction

According to a recent report issued by the U.S. Department of Health and Human Services (HHS) Task Force on Prescription Drug Importation (HHS Task Force Report), nearly 5 million shipments of unapproved prescription drugs entered the U.S. in 2003 from Canada through Internet sales and from travel to Canada by American consumers.¹ Astonishingly, these unapproved shipments comprised roughly 12 million prescription drug products valued at nearly \$700 million. And, the HHS Task Force Report estimates that an equivalent amount (or approximately another 12 million) of prescription drugs have entered the U.S. from other countries, mostly through the mail and courier services.²

To establish and sustain this obviously lucrative drug importation business requires the participation of various entities, including foreign pharmacists and pharmacies, certain regulators, patients, and the group health plans through which many individuals obtain prescription drug coverage. Within this framework, group health plans (particularly self-funded group health plans) and their third-party administrators (TPAs) are becoming significant players.³ Indeed, group health plans inevitably have paid for some share of the estimated 24 million unapproved prescription drug imports, leading many group health plans and their TPAs to question the extent of their liability if a member is injured as a result of taking an unapproved drug.⁴

To be sure, there appears no likely end in sight to the desire to locate a cheaper version of those often highly-priced prescription drugs needed to maintain or regain health, given: (1) the increasing age of the U.S. population; (2) the corresponding increase in prescription drug utilization; and (3) the growing need of group health plans to aggressively seek ways to stem their ever increasing prescription drug costs.⁵ In

fact, without some external intervention, 2005 is likely to be a banner year for what has become the open and notorious convention of flouting the law to import prescription drugs into the U.S.

Indeed, with the pursuit of cost savings at a fever pitch, it is unlikely patients or their group health plans will discontinue their quest for alternative product venues—at least not until external pressure comes to bear. And from where might this external pressure come? Certainly, Canada and those other countries from which prescription drugs are routinely imported (and which to date have provided their tacit approval of this practice) could effectively shut down importation channels by closing their borders. In fact, as of the time of this writing, the Canadian Health Minister is expected to make recommendations to the Prime Minister's cabinet regarding legislation that essentially would end the over \$700 million a year Canadian pharmaceutical export business by: (a) explicitly prohibiting Canadian physicians from countersigning U.S. prescriptions without first conducting an in-person patient examination; (b) prohibiting prescriptions for foreigners not present in Canada; or (c) creating a list of commonly used drugs taken by Canadians that may not be exported.⁶

External pressure could also come from within our borders through actions taken by drug manufacturers to limit the supply of drugs sent to certain targeted foreign pharmacies, thereby reducing the availability of drugs for importation. Indeed, Pfizer, GlaxoSmithKline, and, more recently, Merck have reportedly undertaken such actions. External pressure also could come in the form of civil or criminal actions by federal regulators and/or through patient lawsuits borne out of the unwitting consumption of misbranded or adulterated drugs. Indeed, given the conflicting forces of: (1) increasing demand from large influential group health plans to support/facilitate prescription drug importation; and (2) the

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surprising unanimous chorus of rebuke such programs have received from federal regulators, health plans—as third-party administrators for self-funded group health plans, or as insurers to such plans under fully insured contracts—have begun to consider seriously their exposure for cooperation/participation in the importation trade.

Although both the current legal framework and the appetite of regulators to penalize participants taking part in these legally unsupported—but intensely popular—programs leave much of this “liability” inquiry to speculation, health plans are asking in earnest, “If external pressure to stop the continued importation of drugs comes in the form of civil/criminal actions or lawsuits, might the focus of these actions be directed at my Plan?” This article examines some potential theories of health plan liability for participation in those various importation arrangements designed to furnish Americans with access to, and reimbursement for, prescription drugs imported from outside U.S. borders.

II. The Role of Health Plans in Importation Arrangements

There are various business models now employed by group health plans to facilitate the importation of prescription drugs. Among the more common designs are the following: (a) credentialing certain foreign pharmacies (principally those in Canada) to serve as participating pharmacies in the group health plan’s participating retail pharmacy network; (b) establishing a limited formulary of popularly prescribed brand named medications that will be reimbursed if obtained from foreign (e.g., Canadian) pharmacies (e.g., brand named cholesterol lowering medications or COX-2 inhibitors); (c) providing members access to the Web sites of certain foreign pharmacies for which the group health plan has undertaken a limited quality review (i.e., “group health plan-recommended” pharmacies);⁷ (d) providing members access to the Web sites of “group health plan-recommended” foreign pharmacies with the elimination (or reduction) of the standard prescription drug co-payments for those members who obtain their drugs from these designated pharmacies; or (e) a combination of the above.

These business models typically are advanced by large self-funded group health plans and are linked to health plans through the health plans’ role as their TPA. In fact, at this point in the development of formal employer-sponsored importation programs, it is largely the self-funded group health plans of substantial size and influence that are driving the expansion of these programs and the involvement of health plans (as TPAs). However, it is not outside the realm of possibility that these same health plans might implement some of these models to stem the costs of pharmaceutical products offered in connection with their insured products. Indeed, any of these models also might be employed by insurers through insurance contracts negotiated with group health

plans as a means of reducing the insurer’s healthcare costs, and, correspondingly, the group health plan’s premiums.⁸

In either situation, health plans might feel compelled by group health plans—either to respond to competitive pressure or, when serving as TPAs, to implement the prescribed benefit design—to participate in/implement importation programs. And this participation might take shape in many ways, but most often will be in the form of paying claims submitted by foreign pharmacies, credentialing such pharmacies as participating providers, or providing Web site access information to certain pharmacies. Thus, in considering potential liability implications for health plans, we evaluate health plans exposure to legal and/or regulatory actions arising out of their roles as TPAs and as insurers.

III. Legal Framework

A. Existing Federal Prohibitions

Measuring a health plan’s exposure to liability for participating in importation arrangements must be undertaken against the backdrop of federal law that: (1) requires certain regulatory approvals of prescription drugs before they can be distributed in the U.S.; and (2) prohibits virtually all prescription drug importation by anyone other than the original manufacturer of the drug.

Under existing federal law, the Food and Drug Administration (FDA) has regulatory jurisdiction over prescription drugs, and all such drugs are subject to examination by the FDA when being imported or offered for import into the U.S. The standards governing approval of both domestic and imported products for distribution into the U.S. market are established in the federal Food, Drug & Cosmetic Act (FDA Act).⁹ The FDA Act includes several provisions that collectively operate to bar most importation arrangements by prohibiting both the importation of drugs that have never been approved for use in the domestic market, as well as unapproved, foreign-made versions of FDA-approved drugs. Furthermore, the FDA Act prohibits introducing into interstate commerce an unapproved new drug,¹⁰ a misbranded drug,¹¹ or an adulterated drug.¹² When considered together, these provisions clearly prohibit virtually all importation arrangements.

The FDA has rightfully asserted in response to several states’ importation programs that “[a]ny state law that legalizes imports in contravention of the [FDA Act] would be preempted by federal law.”¹³ Despite numerous declarations denouncing importation as a threat to health and safety, many states continue to largely disregard the FDA’s position by actively facilitating the importation of prescription drugs both for state health plan members and for residents of the state.¹⁴ As noted in Section II (The Role of Health Plans in Importation Arrangements), these programs vary by jurisdiction, ranging from hosting Web sites that link plan members to Canadian pharmacies to conducting on-site inspections of the

Canadian pharmacies and licensing these pharmacies under state law. Even though the FDA has uniformly denounced state efforts to implement importation programs, it has taken no decisive action to end them.

B. Potential Congressional Action

Importation and reimportation have been political flash points on Capitol Hill for many years, simultaneously generating both bipartisan support and highly partisan opposition. For example, in 2000, Congress enacted the “Medicine Equity and Drug Safety Act” (or “MEDS Act”),¹⁵ which, among other things, would have allowed U.S. pharmacists and wholesalers to reimport FDA-approved prescription drugs manufactured in the U.S. that were exported to certain countries designated by the FDA.

In order for the MEDS Act to become effective, the Secretary of HHS was required to certify the safety and cost savings of the reimported drugs. In a letter to President Clinton, then-Secretary of HHS Donna Shalala stated that she could not provide this requisite certification. Similarly, following the change in administrations in 2001, then-Secretary of HHS Tommy Thompson also declined to certify the MEDS Act reimportation program due to safety concerns.

The passage of the Medicare Modernization Act of 2003 (MMA)¹⁶ rekindled the importation debate by including a provision that would amend § 804 of the FDA Act to require the Secretary of HHS to promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the U.S., and to establish waiver criteria to enable certain individuals to import Canadian pharmaceuticals.¹⁷ As with past legislative efforts to legalize importation, the MMA conditioned implementation of the importation provision on the Secretary’s certification to Congress that its implementation would pose no additional risk to the public’s health and safety and result in a significant reduction in the cost of covered products to the American consumer.¹⁸ To date no certification has been made, and in light of the conclusions of the HHS Task Force Report (see below), it appears highly unlikely that any certification will be forthcoming.

The HHS Task Force Report is a product of the MMA requirement that the Secretary of HHS, in connection with appropriate government agencies, conduct a study on the importation of prescription drugs into the U.S. That study, which resulted in the creation of the HHS Task Force Report, provides significant insight as to the current administration’s stance against legalizing importation. Key findings of the Report are as follows:

- The current system of drug regulation in the U.S. has been very effective in protecting public safety, but is facing new threats. It should be modified only with great care to ensure continued high standards of safety and effectiveness of the U.S. drug supply;

- There are significant risks associated with the way individuals are currently importing drugs;
- It would be extraordinarily difficult and costly for “personal” importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs;
- Overall national savings from legalized commercial importation will likely be a small percentage of total drug spending, and developing and implementing such a program would incur significant costs and require significant additional authorities;
- The public expectation that most imported drugs are less expensive than American drugs is not generally true;
- Legalized importation will likely adversely affect the future development of new drugs for American consumers;
- The effects of legalized importation on intellectual property rights are uncertain but likely to be significant; and
- Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities.

Although the HHS Task Force Report attempts to identify (and admonish) various key players fueling the importation trade, notably missing from the HHS Task Force Report is any significant discussion specifically related to a group health plan’s/health plan’s liability for financing prescription drugs imported by its members. The HHS Task Force Report, which includes an entire chapter entitled “Liability Issues Related

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to Importation,” limits the liability analysis to entities within the pharmaceutical distribution system (e.g., manufacturers, distributors, doctors, and pharmacists). The HHS Task Force Report does note, however, that a new cause of action could arise against state and other governmental entities for their roles in endorsing the importation of drugs that cause injury.¹⁹ Furthermore, the HHS Task Force Report notes that “[p]erhaps the largest source of additional liability and/or litigation risk under a drug importation system would be an increase in the number of injuries and poor disease outcomes if imported drugs are, as a class, less safe and effective.”²⁰ Based on these findings, it appears fairly certain that, like his predecessors, current HHS Secretary Mike Leavitt will refuse to certify that establishing a national importation system would pose no additional risk to the public’s health and safety and result in a significant reduction in the cost of covered products to the American consumer.

Even if certification from the Secretary of HHS is not forthcoming, by no means is the HHS Task Force Report the final chapter of the importation saga. In fact, currently underway on Capitol Hill are two legislative efforts that, if signed into law, would permit limited importation of prescription drugs.²¹ At the political forefront of U.S. importation reform is Congressman Gil Gutknecht, whose bill entitled the “Pharmaceutical Market Access Act of 2005” would allow individuals, pharmacists, and wholesalers access to FDA-approved prescription drugs from FDA-approved facilities in twenty-five industrialized countries.²² According to Congressman Gutknecht, “[t]his is a new day in the debate over affordable pharmaceuticals. We have joined forces with members of the Senate to say that this is an idea whose time has come.”²³ Several senators agree, and are working on bipartisan legislation that, if passed, would legalize certain types of importation and significantly change the way prescription drugs are distributed in the U.S.²⁴ Demonstrating their bipartisan solidarity, Senators Byron Dorgan and Olympia Snowe issued a joint statement indicating that “[w]e are determined to pass drug importation legislation in the Senate this year in order to put downward pressure on prescription drug prices.”²⁵ Furthering this commitment, the two senators secured a pledge from Senate Majority Leader Bill Frist and the new Chairman of the Health, Education, Labor and Pensions Committee, Senator Mike Enzi, to hold a hearing on their importation legislation within ninety days.²⁶ Thus, despite the current administration’s opposition to legalize importation, bipartisan support exists in both houses of Congress that could change U.S. importation policy.

IV. Theories of Health Plan Liability

As the discussion under Section III (Legal Framework) clearly suggests, while current federal law regarding the impermissibility of prescription drug importation is clear, the willingness of regulators to initiate enforcement actions beyond stern written denunciations of this practice is not. In addition, given the attention this issue has garnered in Congress, the jury is

still out concerning whether federal law ultimately might be amended to expressly permit certain types of importation activities and, correspondingly, limit parties’ exposure to some enforcement actions. In view of the shifting legal landscape, it is difficult to predict an entity’s exposure to civil or criminal liability. Efforts to comprehend liability issues become even more challenging and speculative when one attempts to isolate the risk of a support player—such as that of the group health plan’s TPA—for its role in a prescription drug importation program.

What does seem fairly certain, however, is that potential legal consequences—however doubtful now—only will become more acute over time as the likelihood that prescription drugs entering the U.S. through formal (albeit legally proscribed) importation programs might produce adverse health consequences for members. Moreover, because TPAs will be one of the few players in the importation trade located within the borders of the U.S. (and, therefore, subject to the jurisdiction of U.S. courts and U.S. regulators), TPAs—despite what some might deem their nominal role—will fall squarely within the line of fire. Thus, in this admittedly uncertain world of liability, the following discussion attempts to begin to identify some of the legal challenges that might be advanced by a regulator or an aggrieved party against a health plan for its role (principally as a TPA) in facilitating prescription drug importation. This discussion, however, is certainly not exhaustive, and we are hopeful that with an understanding of the types of importation programs currently in play, the legal framework now underlying these programs, and the prospect of legislative changes, health plans will have adequate information to begin to evaluate their own potential legal risks should they choose to initiate or participate in such programs.

A. FDA Enforcement

Despite numerous declarations voicing safety concerns, the FDA, because of inadequate funding and staffing, is unable to effectively enforce the provisions of the FDA Act that make importation illegal.²⁷ Some have argued that this lax enforcement has indirectly encouraged both the escalation of personal importation and an increase in those group health plans willing to promote importation arrangements.

Under the FDA’s regulatory procedures manual relating to personal importation, the FDA generally will not seize a non-compliant FDA product at the U.S. border when the purpose and quantity demonstrate that the product is clearly for personal use.²⁸ For prescription drugs, this generally means that the quantity may not exceed what one person might take in approximately three months. However, the FDA does not take this same lenient view with respect to commercial shipments. In fact, the FDA’s regulatory procedures manual clearly states that “[c]ommercial and promotional shipments are not subject to this guidance” and that the guidance (relating to personal importation) is “not intended to create or modify any

rights, privileges, or benefits on or for any private person.”²⁹ Notwithstanding this stricter standard, commercial shipments sent via courier have nonetheless grown exponentially.³⁰

The skyrocketing demand for less expensive pharmaceuticals, increasingly from Internet-based foreign pharmacies, prompted a request to the FDA for guidance regarding the potential liability of various parties to an importation arrangement, including sponsors and/or administrators of employer-sponsored group health plans in the following factual scenario:³¹

- A health plan’s sponsor amends a health plan to include coverage for prescription drugs purchased outside of the U.S.
- The health plan’s administrator publicizes this change to plan members.
- A health plan member in the U.S. obtains a valid prescription from a licensed U.S. physician and forwards the prescription to Expedite-Rx, a company that performs technological services for SPC Global Technologies, Ltd. (SPC), a claims processing company.
- Expedite-Rx receives the prescription, performs certain data entry services and forwards the prescription, along with ancillary patient-protective information, to a licensed pharmacy in Canada.
- In Canada, a Canadian doctor rewrites the prescription.
- A Canadian pharmacy then fills the prescription and ships the drugs directly to the patient in the U.S.
- Neither the employer, SPC, nor Expedite-Rx handles the drugs.
- Expedite-Rx consolidates the plan and patient co-pays and forwards the payment to the Canadian pharmacy.
- The plan will not cover Cipro, “quack” drugs, or controlled substances from a source outside of the U.S.

Declining this request for an advisory opinion, in part because “potential liability is a very fact-specific inquiry,” the FDA cautioned, “any party participating in this kind of import plan does so at its own legal risk.”³² Perhaps more informative is the FDA’s position that if it “were to take enforcement action in this scenario, our highest enforcement priority would not be actions against consumers.”³³

The FDA’s not so implicit warning was that its highest enforcement priority would be against the commercial parties to the importation arrangement, as opposed to individual consumers. This position was underscored in March 2003 when the FDA sent the store manager of Rx Depot, an Oklahoma-based storefront operation that facilitated prescription drug importations, a warning letter stating that it: (a) violated the FDA Act; (b) posed a significant risk to public health; and (c) misled the public about the safety of the drugs obtained through Rx Depot.³⁴ An injunction order against Rx Depot and its affiliates became permanent with the entering of a consent decree on August 20, 2004.³⁵

Following the FDA’s August victory, the FDA on November 29, 2004, through the U.S. Attorney’s Office for the Southern District of New York, filed a civil complaint against Canada

Care Drugs, Inc. (Canada Care), a former affiliate of Rx Depot, for illegally importing prescription drugs into the U.S.³⁶ On December 16, 2004, the U.S. District Court for the Southern District of New York issued a preliminary injunction enjoining Canada Care and certain other named defendants from causing the importation of drugs, receiving commissions from the importation of drugs, and advertising or promoting any importation service.³⁷

From a health plan’s perspective, these cases provide ample notice that the FDA’s highest enforcement priority is on commercial parties involved in importation arrangements. Unlike typical health plans, Rx Depot and Canada Care derived revenue principally by facilitating the illegal importation of prescription drugs. But, given the FDA’s strain on resources, it is not surprising that FDA focused its enforcement efforts on these “maverick” commercial entities that openly and notoriously flouted existing federal prohibitions. Having established the viability of using the judicial process to uphold existing federal proscriptions on importation, the FDA may begin to focus its enforcement authority on more mainstream entities in order to send a clear message that illegal importation arrangements will not be tolerated.

B. State Law Enforcement

Although several states actively are facilitating importation programs, none are likely to directly regulate importation in large part because federal law generally pre-empts state laws that either conflict or interfere with the FDA’s comprehensive regulatory scheme. For those states that are reluctant to implement, or affirmatively disfavor, importation, they are unlikely to be sympathetic to any entity offering such programs to its citizens. As such, they might use the array of existing state laws to stem such programs.

States are vested with inherent authority to regulate issues involving the health, safety, and welfare of their citizens, and it is not unlikely that certain activities relating to importation (including the act of importing itself) may run afoul of these state laws, which would likely withstand pre-emption under the existing federal statutory/regulatory regime. For example, many state consumer protection laws generally prohibit “deceptive trade practices.” In Illinois, for example, deceptive trade practices are defined to include (among other things) an act that:

- causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services; and
- causes likelihood of confusion or of misunderstanding as to affiliation, connection, or association with or certification by another.³⁸

Under these definitions, a health plan conceivably could be held liable if its efforts to encourage the importation of prescriptions drugs lead members to believe that the prescrip-

tions obtained were FDA-approved, or certified as safe and effective. Furthermore, the mere representation that: (1) a Web site link takes a member to a legitimate off-shore pharmacy (e.g., a Canadian pharmacy); or (2) that drugs are coming from a particular country (e.g., Canada) might be materially false misrepresentations, given that the FDA has repeatedly warned that a pharmacy's representation that it is a Canadian pharmacy oftentimes is not true, and that drugs, while purporting to be from Canada, might have been transhipped from a distributor of unknown or dubious origins.

The extent of a health plan's efforts to steer members to foreign pharmacies also may give rise to potential liability for violating a state's pharmacy practice act. For example, in Illinois, the "practice of pharmacy" is broadly defined to include (among other things) "participation in drug selection, drug monitoring, drug utilization review, evaluation, administration, interpretation, application of pharmacokinetic and laboratory data to design safe and effective drug regimens." Based on this broad definition, a state might attempt to establish that a health plan is engaged in the practice of pharmacy if it actively participates in drug selection by establishing a limited formulary of popularly prescribed brand named medications that will be reimbursed if obtained from foreign (e.g., Canadian) pharmacies (e.g., brand named cholesterol lowering medications; brand named COX-2 inhibitors).

C. Member Claims

Depending on the nature of the importation program and the role of the TPA, a cause of action might lie against a TPA/health plan for breach of contract, fraud/misrepresentation, and negligence, among other possible theories.³⁹

Included within the scope of obligations a TPA typically is required to undertake on behalf of its self-funded group health plan is to provide a network of "credentialed" providers. This obligation is often set forth both in the Administrative Services Only contract with the group health plan, and in general statements made to plan members in enrollment, marketing, and other documents they might receive. In its most basic sense, parties generally understand "credentialing" as the process by which the health plan obtains, verifies, and assesses a provider's—here a pharmacy's/pharmacist's—qualifications to provide prescription drug dispensing and management services. In the prescription drug world, members generally understand a pharmacist's credentials to be indicators that he/she holds the qualifications needed to practice the profession of pharmacy and is therefore worthy of the trust of patients, of other healthcare professionals, and of society as a whole.

Included among a health plan's traditional credentialing criteria is a requirement that the pharmacy/pharmacist: holds current and unrestricted licenses and registrations in the

respective state(s) of practice; holds a valid and unrestricted Drug Enforcement Agency certificate; maintains appropriate amounts of professional liability insurance; and agrees to submit to a variety of prospective and retrospective auditing processes. To further this effort, a health plan's typical credentialing process might include evaluating the pharmacy's application for network participation, undertaking primary source verification of its representations, and conducting an on-site and/or file review to ensure the pharmacy maintains processes and safeguards that help maintain the integrity of the products dispensed or shipped to members.

For those importation programs that have come to the attention of the FDA, the FDA has issued written communications to these programs that: (a) repeatedly affirm the FDA's concern about Americans purchasing drugs from foreign countries, and warn that purchasers cannot assume pharmaceutical products from other countries meet the quality, efficacy, and safety standards of FDA-authorized products; (b) put the importation program on notice that the FDA does not assure the quality, safety, and efficacy of products purchased outside the U.S.; and (c) federal law prohibits virtually all prescription drug importation by anyone other than the original manufacturer of the drug.

Despite being armed with information from the FDA concerning the risks associated with, and the illegality of, importing prescription drugs from other countries, and despite knowledge that foreign pharmacies generally have not undergone the same rigorous credentialing process as domestic pharmacies, health plans and others that promote importation programs do not typically choose to affirmatively disclose these pertinent facts to their members. On the contrary, some programs actually appear to vouch for the safety and reliability of the imported drugs from certain designated foreign pharmacies.

Moreover, even where there is no explicit "representation of efficacy" by the health plan, one might argue that where the health plan is providing links to the Web sites of off shore pharmacies that can be used to the same degree as those pharmacies in the health plan's U.S. network, members are reasonable in concluding: (1) that the pharmacies will dispense drugs that are safe and effective; and/or (2) that the health plan has undertaken the same laborious process of verifying the qualifications and processes of the off shore pharmacy. In the case where a health plan establishes a limited formulary of popularly prescribed brand named medications that will be reimbursed if obtained from foreign pharmacies, members also might quite logically conclude that the health plan has undertaken reasonable due diligence to ensure that minimal quality standards for dispensing and shipment are being employed. If any of these factors prove untrue, a host of legal actions might result, not the least of which might be actions for breach of contract, fraud/misrepresentation, and negligence, among others.

While health plans, like certain Canadian pharmacies and state players with importation programs, might seek to limit their liability by having members execute a disclaimer of liability for injuries the member might sustain from using imported drugs, the success of such efforts to foreclose member lawsuits is highly questionable. In its letter to Boston Mayor Thomas M. Menino regarding the city's plan to encourage its employees to seek pharmaceuticals from abroad, the FDA noted that under the Boston plan, the city would accept "no legal liability, with respect to any product offered, or pharmaceutical care provided, by [the contracted Canadian pharmacy]."⁴⁰ Moreover, the FDA noted that the contracted Canadian pharmacy would require patients to sign an acknowledgement that the pharmacy is "not responsible for any...damage whatsoever and howsoever caused, arising out of or in connection with the use of the site...including personal injury."⁴¹

The HHS Task Force specifically called into question whether disclaimers of personal injury would be enforced. Although the analysis was rooted in a discussion of sovereign immunity, the HHS Task Force noted that the Uniform Commercial Code permits courts to disregard these disclaimers under fairly discretionary standards with respect to private parties.⁴² Interestingly, the Report noted that even if courts were to enforce these clauses, "the result would most likely not be a reduction in tort liability, but simply a shift in liability from the state to private parties involved in the transaction."⁴³ However, under compelling public policy considerations, courts might be unwilling to give legitimacy to such disclaimers obtained in connection with programs established in clear contravention of federal law, particularly if the individual has not been fully apprised of the illegality of the program and

the health and safety risks potentially attendant to drugs imported in connection with the program.

V. Conclusion

As the search for affordable prescription drugs continues to be a major healthcare issue, the prescription drug importation business appears to offer an alluring solution. So, one can certainly understand why those who pick up a major portion of the tab for prescription drugs—individuals and group health plans—are struggling mightily to find a way to reconcile the current legal proscriptions with what appears to be a viable answer. Health plans—as TPAs and insurers—are thrust in the middle of this quagmire as they try to respond to competitive and business pressures to meet the needs of their customer base. However, under the current legal framework, importation programs are not without risks, and health plans should carefully consider the potential legal consequences should they choose to initiate or participate in such programs.

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End Notes

- 1 The HHS Task Force Report, at 7; available at <http://www.hhs.gov/importtaskforce/Report1220.pdf>. According to a recent Wall Street Journal article, Americans bought \$1.1 billion of prescription drugs in 2004 from Canada. Christopher Conkey, *States' Bid for Cheaper Medicine Sputters*, Wall St. J., Feb. 14, 2005, at A4.
- 2 *Id.* The Food and Drug Administration (FDA) has warned that although some prescriptions may originate in countries that effectively regulate pharmaceuticals (*e.g.*, certain member countries of the European Union), many pharmaceuticals originate from countries lacking significant uniform and formalized quality controls (*e.g.*, Mexico). Furthermore, because some drugs are "transshipped" to the U.S. from the country of origin through another country having more onerous quality controls (*e.g.*, from the Bahamas through Canada to the U.S.), consumers may not be able to assess their level of risk, or may assume inaccurately that their level of risk is far less than it actually is. See generally "Imported Drugs Raise Safety Concerns," FDA Consumer Magazine (Sept. – Oct. 2002), available at http://www.fda.gov/fdac/features/2002/502_import.html. See also Chapter 1 of the HHS Task Force Report, at page 18, § III/B/2: "Risks of Buying Drugs From Some Internet Pharmacies."
- 3 In this article, we refer to the employer-sponsored health plan as the "group health plan," and to the group health plan's TPA or insurer as the "health plan."
- 4 "Importation and "reimportation" are often used interchangeably, but are indeed distinct concepts. "Reimportation" refers to prescription drugs that are manufactured in the U.S. and exported to another country, and then "re-imported" back to the U.S. Conversely, "importation" is the process under which drugs are manufactured outside the U.S. (in facilities that may or may not meet FDA regulations) and then are shipped to the U.S. This article addresses the implications of prescription drug importation on health plan liability.
- 5 For example, to address severe budgetary limitations and to respond to member costs concerns, several state and local governments (*e.g.*, Wisconsin, Vermont, North Dakota, Kansas, Oklahoma, Missouri, Illinois, Minnesota, New Hampshire, Rhode Island, the city of Boston, New York's Westchester County, and Caldwell County, North Carolina) have implemented various importation programs.
- 6 See <http://www.cbsnews.com/stories/2005/01/06/health/main665204.shtml>.
- 7 For example, Wisconsin has adopted this approach, and on its Web site provides: "[t]his website gives our citizens the ability to buy certain prescriptions at significantly lower prices from pharmacies that have been visited and found to be safe, reputable, and reliable by inspection on behalf of several state governors." See <http://drugsavings.wi.gov/>.
- 8 As TPAs, health plans contract with group health plans to administer the benefit established by group health plan for its members, and these administrative activities typically may include contracting with a

- network of credentialed providers, undertaking utilization management, and adjudicating and paying members' claims. It is the group health plan, and not the TPA, that determines the benefit to be offered to its members, including the contours of any pharmacy benefit program. For those group health plans to which the health plan provides an insured product, the health plan is at risk for the healthcare costs incurred by the group health plan's covered members. However, although a health plan typically might offer its standard benefit design for its insured products, health plans often negotiate with group health plans (particularly those with significant member populations) to establish the exact scope of the benefit plan, including, for example, the reach of the prescription drug benefit formulary (and, these negotiated benefit designs are reflected in the premiums to be charged the insured group health plan).
- 9 See 21 U.S.C. § 381(a). In response to concerns that drugs were being "re-imported" into the U.S. in a manner that could compromise safety, Congress passed the Prescription Drug Marketing Act of 1987 (as an amendment to the FDA Act) to allow pharmaceuticals manufactured in the U.S. that are sent abroad to be imported back to the U.S., but only by the original manufacturer. 21 U.S.C. § 381(d).
 - 10 21 U.S.C. §§ 331 and 355.
 - 11 21 U.S.C. §§ 331, 352, and 353.
 - 12 21 U.S.C. §§ 331 and 351.
 - 13 Letter to Patrick C. Lynch, Attorney General of Rhode Island, from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA (Jan. 28, 2005), available at www.fda.gov/oc/opacom/hottopics/importdrugs/lynch012805.html.
 - 14 As noted in footnote 5, importation programs are not limited to states and some cities also are facilitating such programs. For example, the city of Boston developed a "Meds by Mail" program that encourages its employees to seek prescription drugs from Total Care Pharmacy of Calgary, Alberta. See Letter to The Honorable Thomas M. Menino, Mayor of Boston, from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA (Aug. 4, 2004), available at www.fda.gov/oc/opacom/hottopics/importdrugs/menino0804.html.
 - 15 Pub. L. No. 106-387.
 - 16 Pub. L. No. 108-173.
 - 17 See MMA § 1112.
 - 18 *Id.*
 - 19 *Id.*
 - 20 The HHS Task Force Report, at 99.
 - 21 Several attempts to legalize importation have been made, but to date none of these efforts have been implemented. For example, the "Safe Importation of Medical Products and Other Rx Therapies Act of 2004," referred to as the "Safe IMPORT Act," would have permitted (among other things) limited importation by individuals, pharmacies, and wholesalers, in addition to imposing significant safety controls (e.g., labeling, tracking, and container requirements) and licensure requirements for Internet pharmacies. See S. 4293, 108th Cong. (2004).
 - 22 In July 2003, the U.S. House of Representatives passed H.R. 2427, the "Pharmaceutical Market Access Act of 2003" (referred to as the "Gutknecht Bill"), which would (among other things) allow limited importation by pharmacists, wholesalers, and qualifying individuals. See H.R. 2427, 108th Cong. (2004). Although this bill died at the conclusion of the 108th Congress, Rep. Gutknecht reintroduced this bill to the 109th Congress on January 26, 2005.
 - 23 See Press Release, "Gutknecht Introduces Rx Market Access Bill," (Jan. 26, 2005), available at www.gil.house.gov/newsroom/statements/stateJAN05/012605pd.htm.
 - 24 Senators Dorgan, Snowe, Kennedy, and McCain sponsored the "Pharmaceutical Market Access and Drug Safety Act of 2004," S. 2328, 108th Cong. (2004), which would permit (among other things) importation. A similar bill is expected to be reintroduced to the 109th Congress.
 - 25 See Press Release, "Dorgan and Snowe Secure Commitment for Hearing on Their Bi-Partisan Drug Importation Legislation," (Jan. 25, 2005), available at dorgan.senate.gov/newsroom/record.cfm?id=230885.
 - 26 *Id.* As of the date this article was written, this hearing has not been scheduled. To view the HELP Committee's schedule, see help.senate.gov/calendars/all.html.
 - 27 See generally the HHS Task Force Report, at Chapter 2: "Limits on Resources and Authorities." See also the HHS Task Force Report, at Chapter 5: "Agency Resources Associated with Drug Importation Activities."
 - 28 Regulatory Procedures Manual, Chapter 9, Subchapter Coverage of Personal Importations. Despite its lax personal importation policy for many drugs, the FDA does maintain a list of drugs on an "FDA Import Alert," which, according to the FDA, "alerts FDA field personnel to the possible importation of these drugs, provides guidance as to their detention and refusal of admission into the United States, and also advises United States Customs personnel to refer any attempted importation to the local FDA field office." See FDA News, "FDA Strengthens Controls, Issues Consumer Alert on Importing Certain Prescription Drugs" (Dec. 9, 2002), available at www.fda.gov/bbs/topics/NEWS/2002/NEW00856.html.
 - 29 *Id.*
 - 30 See *supra* note 1.
 - 31 See Letter to Robert P. Lombardi, from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA (Feb. 12, 2003), available at www.fda.gov/ora/import/kullman.htm.
 - 32 *Id.*
 - 33 *Id.*
 - 34 According to the FDA, Rx Depot was running a storefront operation that sent U.S. prescriptions, credit card information, and paperwork (including a "Patient Profile" and "Release & Limited Power of Attorney") to a Canadian pharmacy, which obtained a prescription from a medical doctor in Canada, and then shipped the prescription drugs directly to the U.S. consumer. See Letter to Harry Lee Jones, Store Manager, Rx Depot, from David J. Horowitz, Director, Office of Compliance, Center for Drug Evaluation and Research, FDA, (Mar. 21, 2003), available at www.fda.gov/foi/warning_letters/g3888d.pdf.
 - 35 See FDA News, "FDA Takes Action Against Company for Illegal Importation of Unapproved, Potentially Unsafe Drugs," (Dec. 1, 2004), available at www.fda.gov/bbs/topics/news/2004/NEW01142.htm.
 - 36 *Id.*
 - 37 See FDA Talk Paper, "Court Halts Illegal Importation of Prescription Drugs," (Dec. 27, 2004), available at www.fda.gov/bbs/topics/ANSWERS/2004/ANS01337.html.
 - 38 815 ILL. COMP. STAT. 510/2(a) (2005).
 - 39 We do not examine in this article whether a member's state law claims under any of these theories might survive pre-emption under the Employee Retirement Income Security Act of 1974 (ERISA), as amended, 29 U.S.C. §§ 1001 et seq. The ERISA pre-emption provisions are codified at 29 U.S.C.A § 1104(a) (providing that ERISA supercedes any state law that "relates to" an employee benefits plan) and 29 U.S.C.A § 1132(a) (the "implied pre-emption" provision).
 - 40 See Letter to The Honorable Thomas M. Menino, *supra* note 14.
 - 41 *Id.* According to the FDA, "no properly licensed American pharmacy of which [it was] aware requires such a disclaimer and, indeed, both the FDA and pharmacies in this country stand behind the quality of the legal drugs sold in the United States."
 - 42 The HHS Task Force Report, at 107. The Report notes that courts have disregarded disclaimers of tort liability in order to protect unsophisticated parties. See Uniform Commercial Code (UCC) § 2-302 (providing that courts may refuse to enforce unconscionable contracts); UCC § 2-316 (limiting exclusions and changes in warranties).
 - 43 *Id.*