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U.S. Federal Court Order Closes Pharmacy Offering Drugs From Canada

The ongoing battle between the Food and Drug Administration and pharmacies, including Internet pharmacies, selling Canadian drug products to American residents took an important turn on November 6 with the decision of the court in *United States v. Rx Depot, Inc., et al.*, Case No. 03-CIV-0616-EA (M) (N.D. Okla.). In that case, Judge Claire Eagan issued a preliminary injunction shutting down Rx Depot, Inc. and Rx Canada, Inc. (together, “Rx Depot”), two U.S. companies whose business was to arrange for the purchase of pharmaceuticals for U.S. residents from Canadian pharmacies. The occurrence of an enforcement action in an area in which the FDA has been quick to talk but relatively slow to act may significantly affect the operations of the literally hundreds of Internet pharmacies currently selling to U.S. consumers unapproved products or unapproved versions of approved products sourced from abroad. In addition, while issued in the somewhat forgiving context of a request by the Government for injunctive relief, Judge Eagan’s opinion offers a number of findings that would be of assistance in actions by private plaintiffs to prevent unlawful Internet sales of foreign drugs.

The case arose after FDA had advised Rx Depot in warning letters that its operation violated federal law.¹ The defendants were Rx Depot and individuals associated with its ownership and management. Following a hearing, the court issued its preliminary injunction on November 6, along with comprehensive Findings of Fact (“Findings”) and Conclusions of Law (“Conclusions”).

The evidence revealed that Rx Depot operated both an Internet pharmacy and dozens of store-front “pharmacies” in which consumers could order Canadian

drug products. In all cases, the Rx Depot operations would collect U.S. prescription information, medical histories, and payments. The medical information was transmitted to Canadian doctors, who wrote prescriptions that were filled by Canadian pharmacies.² Findings ¶¶12. The court characterized the relationship by saying that the Rx Depot entities were “essentially sales agents for Canadian pharmacies,” obtaining commissions of between 10-12% of the original sales and retaining a share of refill orders. Findings ¶¶13, 14.

The court made specific and notable findings about the importation of Canadian pharmaceuticals into the U.S. Although Rx Depot said that it took steps to ensure that it sold only approved Canadian stock and avoided products where extensive shipment might create a health risk, the court concluded that a threat to public health was nevertheless presented:

[D]rugs imported from foreign countries by someone other than U.S. manufacturers do not have the same assurance of safety and efficacy as drugs regulated by [FDA]. Because the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S. manufacturer or authorized distributor, their quality is less predictable than drugs obtained in the United States. For instance, the drugs may be contaminated, counterfeit, or contain erratic amounts of the active ingredient or different excipients. Also, the drugs may have been held under uncertain storage conditions, and therefore be outdated or subpotent.

Id. ¶18. The court also noted that the Canadian shipments often exceeded the quantities prescribed by U.S. doctors and did not contain U.S.-approved package inserts. *Id.* ¶¶19, 20.

The evidence included specific findings as to products supplied by Rx Depot in response to undercover purchases by the FDA. In one instance, the investigators’ prescriptions specified the drug Serzone[®] (Bristol-Myers Squibb), but what they received in response to their order was an unapproved generic APO-Nefazodone. The court observed that the quantity provided was in excess of that specified in the U.S. prescription, and that both the label and the product inserts provided with the order gave less information than would have been provided had the prescription been filled in the U.S. Findings ¶¶ 22-29.

The court concluded that Rx Depot’s activities violated the Federal Food, Drug, and Cosmetic Act. Specifically, it found violations of 21 U.S.C. §321 through the company’s importation of unapproved products into the U.S., and its importation of U.S.-made drug products while not being the products’ manufacturer. So that there would be no doubt as to its holding, the court stated that the United States “has conclusively shown that the relevant statutory provisions explicitly prohibit exactly what the defendants continue to do.” Conclusions ¶12.

Issuance of a preliminary injunction does not follow automatically from a violation of federal law, and the court reviewed the factors to be considered in deciding whether to proceed. Although the

standards applicable to granting injunctions requested by the Government are less demanding than in a private action, the court made a number of findings that might also facilitate an injunction in a private case. Specifically, courts in private cases will balance the interests of both parties in deciding whether to issue an injunction. The court found in this case that Rx Depot's interest in continuing operations was not legally cognizable: "[D]efendants would suffer only the 'harm' of being ordered to refrain from illegal activity. . . . [Rx Depot has] no vested interest in an illegal business activity." Conclusions ¶16. The court also evaluated the public interest in entering the injunction, and concluded that it was bound by the findings that accompanied enactment of the Prescription Drug Marketing Act, Pub. L. 100-293, §2, 102 Stat. 95 (1989). Those findings stated that the unrestricted reimportation of drugs "created an unacceptable risk that counterfeit, adulterated, misbranded, subpotent or expired drugs will be sold to American consumers." Conclusions ¶17. The court also rejected as insubstantial the interests of U.S. consumers who are able to obtain drugs less expensively in Canada. "This Court is not unsympathetic to the predicament faced by individuals who cannot afford their prescription drugs at U.S. prices. However, the defendants are able to offer lower prices only because they facilitate illegal activity found by Congress to harm the public interest." Conclusions ¶18.

The effects of the court's issuance of an injunction are apt to be felt immediately, but to what practical end is unclear. Internet pharmacies have proliferated in large part because of the absence of litigation against them by the United States and by private parties whose intellectual property and commercial rights may have been injured. Still, even a dramatic reduction in the number of such enterprises would still leave many in operation and easily accessible to American consumers. Whether that situation changes may well turn on the pace and success of enforcement actions in the future. In that regard it is good to bear in mind that various theories may be used against the illegal importation of drugs depending on the facts. Patent claims may exist, including ones under recent Federal Circuit law where patented products have lawfully been first sold overseas. Even in the absence of patent protection, theories of trademark infringement and unfair competition may exist, both as to counterfeit goods and goods not lawfully sold in this country.

This advisory is for informational purposes only and is not intended as legal advice. For further information, or a copy of the court's Findings, Conclusions, and Order in United States v. Rx Depot, Inc., please contact James B. Kobak, Jr., Chair of the Antitrust Practice Group and member of the Intellectual Property and Pharmaceuticals and Healthcare Practice Groups at (212) 837-6757, kobak@hugheshubbard.com.

¹ At least one state pharmacy board had also initiated an enforcement action against Rx Depot, taking the position that the company's operations violated state pharmacy licensing requirements.

² The court stated that evidence produced at the hearing was to the effect that issuance of the Canadian prescriptions under the circumstances presented may violate Canadian law. Findings ¶12 n.1.