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David M. Ermer

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# PRESCRIPTION DRUG IMPORTATION AND REIMPORTATION

By David M. Ermer\*

The interstate shipment of any prescription drug (including importation and exportation) that lacks required FDA approval is illegal.

The U.S. Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., creates a closed prescription drug manufacturing and distribution system in the United States to preserve a safe public drug supply, free from counterfeit and other adulterated medications.<sup>1</sup> The U.S. Food and Drug Administration (FDA), which is responsible for the safety of the nation's drug supply, must approve for marketing all prescription drugs distributed in the United States. Those prescription drugs must bear FDA approved labeling and packaging.<sup>2</sup> They also must be manufactured at a domestic or foreign facility registered with the FDA, which routinely inspects those plants, whether foreign or domestic, for good manufacturing practices.<sup>3</sup> Drug wholesalers and pharmacists must be state licensed.<sup>4</sup> The interstate shipment of any prescription drug (including importation and exportation) that lacks required FDA approval is illegal.<sup>5</sup>

Prescription drugs are often manufactured in the United States and then exported to foreign countries for sale there. Once exported, drugs may only be reimported to the original manufacturer in the United States.<sup>6</sup> While the United States generally does not regulate prescription drug prices, foreign countries may do so.<sup>7</sup> For example, in Canada, the Patented Medicine Prices Review Board (PMPRB) "limits the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, under prescription or over the counter, to ensure they are not excessive."<sup>8</sup> As a result of these price regulations and other factors, such as U.S. patent laws, prescription drugs tend to be priced lower in foreign countries than in the United States.<sup>9</sup>

The PMPRB reported that manufacturers' prices for patented drugs were 69 percent higher in the United States as compared to Canada in 2001.<sup>10</sup> A study published in the *Annals of Internal Medicine* concluded, "[b]rand name medications are often substantially less expensive when purchased from Canadian internet pharmacies instead of from major online U.S. drug chain pharmacies."<sup>11</sup>

State and local governments faced with rapidly increasing prescription drug costs for their Medicaid and employee benefit programs have considered controlling those costs for themselves and their citizens by reimporting U.S.-manufactured prescription drugs from Canada and other countries. For example, Illinois has created the I-

SaveRx program.<sup>12</sup> Minnesota created the Minnesota RxConnect program earlier in this decade to help control prescription drug costs.<sup>13</sup> The FDA, however, opposed both programs on safety grounds.<sup>14</sup> Where other state and local governments challenged the FDA's position in court, the FDA has prevailed.<sup>15</sup> Nevertheless, the FDA has refrained from enforcement actions against similar state-run prescription drug programs.<sup>16</sup>

Congress entered the fray in 2000 when it passed the Medicine Equity and Drug Safety (MEDS) Act. The law permitted the reimportation of prescription drugs originally manufactured in the United States if the U.S. Department of Health and Human Services (HHS) Secretary determined that reimportation would be safe and would significantly reduce costs. However, both Donna Shalala, President Clinton's last HHS Secretary, and Tommy Thompson, President Bush's first HHS Secretary, declined to make those determinations.<sup>17</sup>

In 2003, Congress replaced the MEDS Act with a provision in the Medicare Prescription Drug and Modernization Act, which authorizes the HHS Secretary to:

1. Promulgate regulations permitting pharmacists and wholesalers to import drugs from Canada into the United States, [and]
2. Grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices under such circumstances as the Secretary determines to be appropriate.<sup>18</sup>

Similar to the MEDS Act, implementation of this law remained contingent on the HHS Secretary certifying to Congress that importation would be safe and cost-effective.<sup>19</sup> The Act also required HHS to prepare a study on the issue for Congress.<sup>20</sup>

Both Secretary Thompson and his successor, Michael Leavitt, have declined to issue this certification. In a 2004 report, the Congressional Budget Office agreed with HHS's position when it concluded that:

Permitting the importation of foreign-distributed prescription drugs would produce at most a modest reduction in prescription drug spending in the United States. H.R. 2427, for example, which would have permitted importation from

\* David M. Ermer is the Managing Partner of the Gordon & Ermer law firm, Washington, D.C., [www.gordon-ermer.com](http://www.gordon-ermer.com).

a broad set of industrialized countries, was estimated to reduce total drug spending by \$40 billion over 10 years, or by about 1 percent. Permitting importation only from Canada would produce a negligible reduction in drug spending.<sup>21</sup>

When Vermont challenged HHS's inaction under the federal Administrative Procedure Act, the federal district court sided with the HHS Secretary.<sup>22</sup> Currently, a stalemate exists between the federal government and the state governments that are operating drug importation programs without FDA approval. Although the FDA has criticized these programs, it has not taken any action to shut them down. In contrast, the FDA successfully used the courts in 2003 to shut down an American-based business, Rx Depot, which had been operating 85 storefronts in the United States to distribute prescription drugs purchased from a Canadian pharmacy.<sup>23</sup>

Will Congress take further action to resolve this stalemate? At the conclusion of its final session in October 2006, the 109th Congress did add a provision to the Homeland Security Fiscal Year 2007 appropriations law that permits individuals to import up to a 90-day supply of prescription drugs (excluding controlled substances and biological products) purchased in Canada.<sup>24</sup> This action did not directly affect American mail-order and internet purchases from Canadian pharmacies. However, also in October 2006, U.S. Customs and Border Protection announced that it would no longer seize prescription drugs that Canadian pharmacies send to U.S. residents.<sup>25</sup> The Senate in December 2006 approved the President's nomination of Dr. Andrew von Eschenbach as FDA Commissioner.<sup>26</sup> Senate action on that nomination stalled for several months due to the FDA's opposition to prescription drug importation, among other legislator concerns.<sup>27</sup>

Time will tell whether the Democrat-controlled 110th Congress will break the stalemate. On January 10, 2006, Senators Byron Dorgan (D-ND) and Olympia Snowe (R-ME) as well as Representatives Rahm Emmanuel (D-IL) and Jo Ann Emerson (R-MO) introduced bipartisan drug importation legislation.<sup>28</sup> If such legislation were to pass, the Administration's opposition to the plan could lead to a Presidential veto. In any event, the prescription drug manufacturers may hold the ultimate trump card because they control the drug supply upon which re-importation is dependent.

1 See Testimony of R. Lutter on Pharmaceutical Supply Chain Safety before the House Criminal Justice, Drug Policy, and Human Resources Subcommittee (July 11, 2006), available at <http://www.hhs.gov/asl/testify/t060711.html> (last visited Feb. 11, 2007).

2 See 21 U.S.C.A. §§ 351(a), (d), 352, 355 (2006).

3 See *id.* at §§ 351 (a), (h), 360.

4 See *id.* § 353(c).

5 See *id.* § 331.

6 See *id.* at §§ 331(t), 381(d)(1). The Secretary of the U.S. Dept. of Health and Human Services may authorize an exception to this rule for emergency use of the reimportation drug.

7 See U.S. GOVT. ACCOUNTABILITY OFFICE, HIGHLIGHTS: PRESCRIPTION DRUGS: AN OVERVIEW OF APPROACHES TO NEGOTIATE DRUG PRICES USED BY OTHER COUNTRIES AND U.S. PRIVATE PAYERS AND FEDERAL PROGRAMS, Rep. No. 07-358T (Jan. 12, 2006) available at <http://www.gao.gov/highlights/d07358thigh.pdf> (last visited Feb. 11, 2007).

8 See Frequently Asked Questions, Patented Medicine Prices Review Board, <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=272#1> (last visited Feb. 11, 2007).

9 See CRS REPORT FOR CONGRESS, IMPORTING PRESCRIPTION DRUGS: OBJECTIVES, OPTIONS, AND OUTLOOK, at 7-8 (Aug. 4, 2004), available at <http://www.senate.gov/~hutchinson/RL32511.pdf> (last visited Feb. 11, 2007).

- 10 See David Gross, *Prescription Drug Prices in Canada*, AARP ISSUE BRIEF (2003), available at <http://www.aarp.org/research/health/drugs/aresearch-import-725-IB62.html> (last visited Feb. 11, 2007).
- 11 See Bradley S. Quon, et al., *A Comparison of Brand Name Drug Prices between Canadian Internet Pharmacies and Major U.S. Chain Drug Pharmacies*, 143 ANNALS INT. MED. 397, 397 (2005).
- 12 See How I-SaveRx Works, I-Save Rx website, [http://www.i-saverx.net/how\\_works.htm](http://www.i-saverx.net/how_works.htm) (last visited Feb. 11, 2007). I-SaveRx obtains its drugs from a Calgary, Alberta provider called Pegasus Health Services Ltd. According to the website, "Pegasus has established relationships with an extensive network of licensed pharmacies in Canada, United Kingdom, Australia, and New Zealand."
- 13 See Minnesota RxConnect website, <http://www.state.mn.us/portal/mn/jsp/home.do?agency=Rx> (last visited Feb. 11, 2007). Minnesota RxConnect provides a prescription drug pricing comparison service as well as access to several Canadian pharmacies, two of which have British affiliates.
- 14 See Letter from Lester M. Crawford, Acting Commissioner of Food and Drugs, to Rod Blagojevich, Governor of Illinois (June 3, 2004) available at <http://www.fda.gov/oc/opacom/hottopics/importdrugs/GovB63.pdf>; see also Letter from William K. Hubbard, Acting Commissioner for Policy and Planning, to Tim Pawlenty, Governor of Minnesota (Feb. 23, 2004) available at <http://www.fda.gov/oc/opacom/hottopics/importdrugs/pawlenty022304.html> (last visited Feb. 11, 2007).
- 15 *E.g., Montgomery County v. Leavitt*, 445 F. Supp. 2d 505 (D. Md. 2006); *Vt. v. Leavitt*, 405 F. Supp. 2d 466 (D. Vt. 2005).
- 16 See 21 U.S.C. § 384 (Supp. 2001).
- 17 See Letter from Tommy Thompson, U.S. Dept. of Health and Human Services Secretary, to James Jeffords, U.S. Senator (July 9, 2001) available at <http://www.fda.gov/oc/po/thompson/medsact.html> (last visited Feb. 11, 2007).
- 18 See FEDERAL FOOD, DRUG, AND COSMETIC ACT, Pub. L. No. 108-173, § 1121(a), codified at 21 U.S.C.A. § 384 (2006).
- 19 See *id.* at § 384(1).
- 20 See The U.S. Dept. of Health and Human Services Task Force website, <http://www.hhs.gov/importtaskforce/> (last visited Feb. 11, 2007).
- 21 See CONG. BUDGET OFFICE, ECONOMIC AND BUDGET ISSUE BRIEF: WOULD PRESCRIPTION DRUG IMPORTATION REDUCE U.S. DRUG SPENDING?, available at <http://www.cbo.gov/showdoc.cfm?index=5406&sequence=0> (last visited Feb. 11, 2007).
- 22 See *Vermont v. Leavitt*, 405 F. Supp. 2d 466 (D. Vt. 2005).
- 23 See *United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238 (N.D. Okla. 2003). The Court subsequently entered a permanent injunction against Rx Depot.
- 24 See DEPT. OF HOMELAND SECURITY APPROPRIATIONS ACT OF 2007, 120 Stat. 1355, Pub. L. No. 109-295, § 535 (2006).
- 25 See *U.S. Customs Offers Stop Seizing Mailed Prescription Drugs Purchased from Canada*, available at <http://www.medicalnewstoday.com/medicalnews.php?newsid=53411> (Oct. 6, 2006) (last visited Feb. 11, 2007).
- 26 See 152 Cong. Rec. S11404-29, 11447-51 (Dec. 7, 2006).
- 27 See Christopher Lee, *Senate Approves FDA Chief*, WASH. POST, Dec. 8, 2006, A37, available at <http://www.washingtonpost.com/wp-dyn/content/article/2006/12/07/AR2006120701706.html> (last visited Feb. 11, 2007).
- 28 See S. 242, 110th Cong. (2007) (introduced in the House), available at <http://dorgan.senate.gov/documents/newsroom/drugimportation.pdf> (last visited Feb. 11, 2007); see also Press Release, Significant Bipartisan Drug Importation Legislation Introduced in the Senate (Jan. 10, 2007) available at [http://www.house.gov/apps/list/press/il05\\_emanuel/RX\\_Jan1107.html](http://www.house.gov/apps/list/press/il05_emanuel/RX_Jan1107.html) (last visited Feb. 11, 2007).