

**IN SEARCH OF A GOVERNMENT THAT
WILL GOVERN: SENATE BILL 812 AND
“REIMPORTING” PRESCRIPTION
MEDICATION FROM CANADA**

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America’s senior citizens pay more for prescription medication than those of any other nation, both because the United States places no price controls on prescription medication, and because the strong U.S. economy can withstand such differential pricing. As a result, many American seniors are turning to Canadian pharmacies to provide their medication. In this note, Abraham N. Saiger examines Senate Bill 812 (S. 812), the Greater Access to Affordable Pharmaceuticals Act, which would allow U.S. citizens to reimport low-cost prescription drugs from Canada. Mr. Saiger argues that S. 812 is unlikely to resolve the problems that it was designed to address because it is unsafe, economically unsound, and will not create adequate pressure to force the pharmaceutical industry to drive down prices. He ultimately concludes that S. 812 will never become law because no one will be willing to certify its safety. Mr. Saiger posits that S. 812 is not a valid solution to the problem of expensive prescription medication and recommends instead that reimportation proposals such as S. 812 be forgotten in lieu of privatizing the U.S. prescription health care system.

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I. Introduction

The United States of America is the wealthiest country in the world¹ thanks in no small part to today's senior citizens.² The wealth and power that generation has cultivated and grown has paid handsome dividends, but has taken its toll as well. The strong and secure U.S. market created by America's seniors made possible innovations in science and technology, especially in the field of medical research.³ The tangible benefits of these innovations include life-enhancing and life-prolonging prescription medications.⁴ Paradoxically, precisely because the U.S. market and economy is so strong, the senior population in America pays more for prescription medications than any other population on earth.⁵ The result is that many of America's seniors are driven to Canadian pharmacies by a U.S. government that fails to address their medical needs, and continued to fail in the summer of 2002.

This note focuses on Senate Bill 812 (S. 812), or the Greater Access to Affordable Pharmaceuticals Act,⁶ and Senate Amendment 4300, drafted by Senator Byron Dorgan (D-N.D.) (the Dorgan Amendment⁷), allowing for wholesale commercial reimportation of prescription medication from Canada. Part II of this note discusses the background of this issue, namely, internal and external conditions in the pharmaceutical medicine industry and how S. 812 purports to address them. Part III analyzes S. 812 and "reimportation" in the context of gray markets and price differentiation and price controls, and finds that S. 812 is unlikely to resolve the problems it is designed to address. Part IV recommends that reimportation proposals be taken off the table, and that Congress privatize the U.S. prescription health care system. Part V concludes that S. 812 will never become law, rather the U.S. Senate will continue to avoid making hard decisions

1. CENT. INTEL. AGENCY, CIA WORLD FACT BOOK 2003, at <http://www.cia.gov/cia/publications/factbook/index.html>.

2. See Robert L. Bartley, *Trade Warriors: Baby-Boomers Toy with Matches*, WALL ST. J., Mar. 17, 1993, at A14.

3. See Jonathan Rauch, *Taking Stock*, ATLANTIC ONLINE, Jan.-Feb. 2003, at <http://www.theatlantic.com/issues/2003/01/rauch.htm>.

4. See Jerry Stanton, Comment, *Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L L. 149, 162 (2000).

5. See 146 CONG. REC. S7194 (daily ed. July 19, 2000) (statement of Sen. Jeffords).

6. S. 812, 107th Cong. (2002).

7. 148 CONG. REC. S6969 (daily ed. July 17, 2002).

until this crisis for the elderly and for the nation is unfixable, and the stakes of making a clear decision are too high. At that point, it will be too late to craft an operational plan, and Congress will be forced to take drastic and destructive measures that could have been avoided.

II. Background

A. The Current State of Affairs

The senior population in America pays more for prescription medications than any other population.⁸ And, there is no denying that pharmaceutical prices are higher in the United States than in any other country.⁹ Comparative studies show that for every dollar spent on pharmaceutical medication in the United States, the same drugs cost only sixty-five cents in Switzerland, sixty cents in Sweden, sixty-four cents in the United Kingdom, fifty-one cents in France, and forty-nine cents in Italy.¹⁰ Senator Mark Pryor (D-Ark.) compared U.S. prices for the five most popular drugs for seniors—Lipitor (Pfizer), Celebrex (Pharmacia and Upjohn), Zocor (Merck), Prilosec (Astra/Merck), and Prevacid (TAP Pharmaceuticals)—to prices in other industrial nations, namely Canada, France, the United Kingdom, Italy, and Japan.¹¹ Senator Pryor found that uninsured seniors in the United States paid approximately 128% more for Prilosec, 131% more for Prevacid, 129% more for Celebrex, 101% more for Lipitor, and 72% more for Zocor.¹² While Senator Pryor's study focused on the most successful flagship drugs, Senator Dorgan conducted similar research and found that the average brand name drug in Canada is 38% cheaper than in the United States.¹³

8. See 146 CONG. REC. S7194 (daily ed. July 19, 2000) (statement of Sen. James Jeffords).

9. See *id.*

10. See *Talk of the Nation: Obstacles to Reimporting Prescription Drugs from Abroad as a Way to Lower Pharmaceutical Drug Prices in the United States* (NPR radio broadcast, Jan. 2, 2001), 2001 WL 4189807 [hereinafter *Talk of the Nation*].

11. MARK PRYOR FOR U.S. SENATE, PRESCRIPTION DRUGS ARE MORE EXPENSIVE IN ARKANSAS THAN IN CANADA, EUROPE, AND JAPAN 4 (July 2002) [hereinafter PRYOR].

12. *Id.* at 8.

13. Press Release, Office of Sen. Dorgan (D-N.D.), U.S. Consumers Pay Substantially Higher Prices for Their Medications than Consumers in Canada and Other Countries (on file with The Elder Law Journal).

Pharmaceutical spending in the United States increased dramatically over the last ten years.¹⁴ As a percentage of health care spending, prescription drug spending increased from 5.6% in 1993 to 7.9% in 1998.¹⁵ The cost of drugs rose 19.1% in 1999,¹⁶ and continued to rise in 2001—increasing nearly 19% to more than \$132 million.¹⁷ Additionally, the number of prescriptions written every year is expected to double in the next ten years, possibly exceeding 4.5 billion prescriptions per year as early as 2004.¹⁸ This simultaneous increase in drug prices and drug usage necessarily places a heavy burden on the U.S. health care system.

Ballooning drug prices are especially problematic for the elderly, whose ranks are growing, whose incomes are often fixed, and whose need for prescription drugs is higher than the general population.¹⁹ According to the most recent estimates from the Congressional Budget Office (CBO), Medicare beneficiaries accounted for about 40% of the more than \$100 billion spent on prescription drugs in the United States.²⁰ Despite talk of reforming and modifying Health Maintenance Organizations (HMOs), socializing medicine, health care, or prescription benefits, or privatizing Social Security, Medicare and prescription benefits, little has been done.²¹ The plight of Amer-

14. See *Examining Prescription Drug Importation: A Review of a Proposal to Allow Third Parties to Reimport Prescription Drugs: Hearing Before the House Subcomm. on Health of the Comm. on Energy & Commerce*, 107th Cong. 65 (2002) (prepared statement of Elizabeth A. Wennar, President and CEO, United Health Alliance).

15. Gail Shearer, *Prescription Drugs for Medicare Beneficiaries: 10 Important Facts*, <http://www.consumersunion.org/health/drugdc400.htm> (Apr. 14, 2000).

16. CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURE AMOUNTS AND AVERAGE ANNUAL PERCENT CHANGE BY TYPE OF EXPENDITURE: SELECTED CALENDAR YEARS 1980–2011, at <http://www.cms.hhs.gov/statistics/nhe/projections-2001/ta.asp> (last modified July 17, 2002).

17. See Bruce B. Fallik, *Beyond Co-Pays*, *WORLDATWORK J.* Apr. 1, 2003, 2003 WL 19186227.

18. *Id.*

19. See Eric Schmidt, *Politics Stalls Congressional Action on Medicare Drug Benefits*, *N.Y. TIMES*, Feb. 27, 2000, at A35. This problem is especially acute among the uninsured elderly, who face a formidable two-tiered pricing system that seeks to capture profits from individuals that it lost in negotiations with insurance providers. See FED. TRADE COMM'N, *THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE*, at <http://www.ftc.gov/reports/pharmaceutical/drugexsum.htm> (last visited Feb. 23, 2004).

20. *Administration's FY 2003 Budget Proposal for Prescription Drugs: Hearing Before the S. Comm. on Fin.*, 107th Cong. 71 (2002) (statement of Dan L. Crippen, Director, Cong. Budget Office).

21. See Jennifer Rak, Note, *An Rx for Reform: A Medicare Prescription Drug Benefit*, 12 *HEALTH MATRIX* 449 (2002).

ica's growing senior population, however, has worsened²² and will continue to deteriorate as the baby-boomer generation begins to retire and to put more and more pressure on the Medicare system.²³

B. Causes

There are several reasons why U.S. seniors pay more than anyone else for prescription medications, but patents and profits are at the core. Prescription medications are patented goods and are therefore entitled to various government protections.²⁴ These protections are intended to fuel confidence in inventors and encourage them to innovate and create new products,²⁵ as well as reward useful innovation with a brief monopoly window for exploitation by the inventor.²⁶ It is not clear, however, that patent protection has its intended effect in the area of prescription medication. In fact, the first half of S. 812 attempts to supplement and amend the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, which created patent protection for pharmaceutical medications.²⁷ A related area of concern for those who sell patented materials around the world is the desire to keep each market isolated from the others in order to maximize profits in each market.²⁸ This market segregation is especially critical in the pharmaceutical industry and has been the subject of litigation on numerous occasions.²⁹ Whether this type of market segregation is fundamental to the pharmaceutical industry's innovation is the subject of heated debate, as

22. See *id.* (explaining many of the deficiencies with current Medigap policies, and detailing the program's failure to adequately meet seniors' needs in the way of prescription medication costs).

23. See *id.*

24. 35 U.S.C. § 154(a)(2) (2000).

25. See, e.g., *id.* § 102(a)-(f) (requiring that inventions be a novel item that applicant created).

26. See Am. Soc'y of Int'l Law, *General Agreement on Tariffs and Trade—Multilateral Trade Negotiations (The Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods*, [Dec. 15, 1993], 33 I.L.M. 81, 93-96 [hereinafter TRIPS].

27. See *Hearing on Generic Pharmaceuticals: Hearing on S. 812 Before the S. Comm. on Commerce, Sci. & Transp.*, 107th Cong. (2002) [hereinafter *Hearing on Generic Pharmaceuticals*] (testimony of Dr. Greg Glover, Pharm. Research & Mfrs. of Am.), 2002 WL 735406.

28. A. Bryan Baer, *Price Controls Through the Back Door: The Parallel Importation of Pharmaceuticals*, 9 J. INTELL. PROP. L. 109, 126 (2001).

29. See *Hearing on Generic Pharmaceuticals*, *supra* note 27 (statements of Sen. Byron Dorgan including a request for patent extension that was based on ability to crush up and sprinkle the drug on apple sauce).