The Medicine Equity and Drug Safety Act of 2000: Releasing Gray Market Pharmaceuticals

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As increased pharmaceutical prices became a political focal point amidst a contentious 2000 presidential campaign, Congress sought a compromise between agitated American consumers and a healthy pharmaceutical lobby. The resulting Medical Equity and Drug Safety Act of 2000 seeks to lower domestic pharmaceutical prices by allowing pharmacists and wholesalers to import U.S. pharmaceuticals that are sold abroad by U.S. companies at lower prices.

This Article analyzes two aspects of the new legislation: whether the law is compatible with existing intellectual property rights regarding patent holder control of the imports of patented goods and a critical analysis of the public policy and economic reality of instituting such a plan as envisioned by the Act. While implementation of the law is contingent on the as of yet unsecured approval of the Secretary of Health and Human Services, it is unlikely that this issue will dissipate in the near future.

I. INTRODUCTION

In November 1999, Democratic Senate candidate for the state of Montana, Brian Schweitzer, organized a bus trip to Canada for a group of elderly Montanans.[1] The "Run for the Border" was not a pleasure trip but, rather, a chance to take advantage of cheaper pharmaceutical prices. The powerful image of beleaguered elderly fleeing their own country to purchase life-sustaining drugs made for a popular campaign base, and

1. *See* David Foster, *National Debate Over Escalating Costs Hits Home in Montana Senate Race*, ST. LOUIS POST-DISPATCH, May 19, 2000 at A6.

within a month Schweitzer was on another trip to Canada and planning a large-scale trip to Mexico.[2] By the fall of 2000, popular recognition of pharmaceutical price differentials, increasingly referred to as "price gouging" by pharmaceutical companies, and pressure from consumer groups, including Ralph Nader's Consumer Project on Technology and Doctors without Borders, compelled Congress to act.[3] The result, The Medicine Equity and Drug Safety Act of 2000 (MEDSA),[4] was a piecemeal compromise aimed at lowering pharmaceutical prices by allowing wholesalers and pharmacists to buy U.S.-approved drugs abroad and resell them in the United States, passing the discounted foreign prices along to the consumer. MEDSA, if implemented, may effectively reverse a thirteen-year policy of allowing pharmaceutical patent holders *de facto* control over third parties who seek to profit by reimporting U.S.-made pharmaceuticals purchased abroad.

It does not take a high-profile campaign to illustrate that there is an opportunity for arbitrage in the pharmaceutical industry among our foreign neighbors. In fact, the price differential is quite drastic. For example, a three-month supply of Tamoxifen, the most widely prescribed breast cancer drug, costs $298 in the United States, but only $26 in Canada.[5] Likewise, the popular antidepressant drug, Prozac, sells at a seventy percent discount above the forty-ninth parallel.[6] These price differences are exaggerated even further in third world countries, where foreign customers pay as little as nine percent of the U.S. price for AIDS drugs.[7]

Many reasons exist for these price differentials, including national price regulation, consumer demand for certain pharmaceuticals, and the internal structure of each nation's health care system.[8] From country to country, these factors, separate or combined, compel the industry to price accordingly, resulting in a patchwork of drastically inconsistent pricing for identical products among various nations.

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2. *See id.*

3. *See* Robert Lenzer & Thomas Kellner, *The Effects Could Be Devastating*, FORBES, Nov. 27, 2000, at 156, 161.

4. H.R. Rep. No. 106-948, at 38 (2000). MEDSA was passed as section 745 of Public Law 106-387, "making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 2001." *Id.* Section 745 amends chapter VIII of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 381, by adding § 804. Hereinafter MEDSA will be cited as 21 U.S.C. § 384.

5. *See* Lenzer, *supra* note 3, at 164, 166.

6. *See id.*

7. *See id.* at 161.

8. *See* JOHN F. CALFEE, PRICES, MARKETS AND THE PHARMACEUTICAL REVOLUTION 1-3 (2000).

For several reasons these price differentials remain, despite third parties who seek to subvert the pricing techniques by purchasing products in a low cost country for resale in a higher price country. In the United States, Congress expressly banned the resale of foreign-purchased pharmaceuticals by statute in 1987.[9] In other countries that do not expressly ban resale, pharmaceutical companies include contract provisions with the first sale of the drugs to foreign distributors that expressly forbid the resale of products in other territorial regions. Another reason that price differentials remain is that importers seeking to profit by reselling foreign-purchased drugs were also prohibited by the sheer logistics of shipping, repackaging, and relabeling the drugs, as well as complying with each country's diverse regulatory standards.

The express intent of MEDSA is to encourage the resale of foreign-purchased drugs in the United States.[10] It seeks to accomplish this goal by reversing the 1987 U.S. ban on reimported pharmaceuticals, and by specifically prohibiting pharmaceutical companies from entering into contracts that restrict resale by distributors. Though the Act, as it is now written, does not address the logistical difficulties inherent in repackaging and relabeling, bills pending before the 2001 Congress seek to include language within MEDSA, which would compel pharmaceutical companies to provide U.S.-approved labels to foreign distributors seeking to resell drugs in the United States.[11]

This Article will identify and evaluate the effect of MEDSA on intellectual property rights held by pharmaceutical companies, and analyze the public policy arguments for and against encouraging the resale of foreign-purchased pharmaceuticals in the United States. Part I introduces the history and content of MEDSA, including the law's status at the time this Article was written. Part II identifies possible conflicts between MEDSA and the rights of pharmaceutical companies as patent holders. Part II also evaluates the legal significance of the MEDSA prohibition on contractual restrictions to resale. Both discussions conclude that, while there is no clear line of authority regarding this subject within the scope of patent law, courts appear to favor reducing restrictions to international trade over protecting patent holders' specific pricing regimes. Part III evaluates the public policy implications of encouraging the resale of foreign-purchased pharmaceuticals. Part III concludes that without sufficient empirical evidence regarding the cost of regulating the safety of the resold drugs and without practical data

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9. *See* Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293. *See* 21 U.S.C. § 381(d) (2000) [hereinafter PDMA].

10. *See* 21 U.S.C. § 384(a) (2000).

11. *See* 107 Bill Tracking S. 215; 107 Bill Tracking H.R. 58.

regarding possibly prohibitive logistical hurdles to resale, the effect of MEDSA on U.S. consumers is unclear.

II. THE HISTORY AND CONTENT OF MEDSA

In the 1980s, the market for pharmaceuticals purchased abroad and resold in the United States was a campaign issue for considerably different reasons. A 1986 report entitled *The Multimillion Dollar Market in Reimported Pharmaceuticals* recorded over $10 million worth of pharmaceuticals reentering the United States.[12] At the time, safety, not value, prompted the study. The Report documented health risks caused by counterfeit and improperly stored and mislabeled pharmaceuticals which slipped by customs officials.[13] Congress responded by enacting the Prescription Drug Marketing Act of 1987.[14] The Act expressly banned the reimportation of pharmaceuticals manufactured in the United States and sold abroad by anyone other than the drug maker.[15]

During the interim period preceding MEDSA, technological and internal structural developments in the pharmaceutical industry created a significant increase in the development of newer and better drugs.[16] These developments came at the price of significant investments in research and development (R&D). This cost was passed on to the consumer who, in an era of unprecedented economic growth, was able to bear this expense. Collaterally, the public was concerned about the viability of Medicare and social security. Anticipating an increase in Medicare recipients as the "baby boomer" generation retires, several public advocates pointed out that these entitlement programs did not sufficiently cover pharmaceutical expenses.[17] Instead of addressing the entitlement programs themselves, Congress opted to pressure the pharmaceutical companies to adjust their pricing techniques by manipulating the supply of pharmaceuticals sold in the United States.

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12. *See* STAFF OF HOUSE COMM. ON ENERGY & COMMERCE, 99TH CONG., UNCERTAIN RETURNS: THE MULTIMILLION DOLLAR MARKET IN REIMPORTED PHARMACEUTICALS 1 (Comm. Print 1986) [hereinafter *The Report*].

13. The Report states that over a six-month period between September 1985 and March 1986, over $10 million worth of pharmaceuticals reentered the United States. Of these, many were found to be counterfeit, mislabeled, improperly stored and subjected to laboratory analysis. *Id.* at 1.

14. *See* PDMA, *supra* note 9, at 58. The PDMA created an amendment to the Federal Food, Drug and Cosmetic Act, at 21 U.S.C. § 381 2000. The relevant provision of the amendment states, "Except as provided in paragraph (2), no drug subject to section 353(b) of this title which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug." 21 U.S.C. § 381(d)(1) (2000).

15. *See* 21 U.S.C. § 381(d)(1).

16. *See* CALFEE, *supra* note 8, at 2.

17. *See* H.R. Rep. No. 106-948, at 39 (2000).

Congress, by enacting MEDSA in October 2000, intended to strike a balance between protecting consumers from adulterated products cited in the 1987 law, and increasing competition in the market by encouraging the resale of pharmaceuticals purchased abroad. Within the findings preceding the amendment Congress stated: "Americans should be able to purchase medicines at prices that are comparable to prices for such medicines in other countries, but efforts to enable such purchases should not endanger the gold standard for safety and effectiveness that has been established and maintained in the United States."[18]

Several proposals of MEDSA-like legislation were submitted to the 2000 Congress.[19] While these provisions were hotly debated preceding the final draft, the resulting language of the act was pushed through the committee stage at an expedited rate.[20] The final version of MEDSA appeared as a relatively small section within the Agricultural, Rural Development, Food and Drug Administration, and Related Agencies appropriation bill.[21]

MEDSA amends Chapter VIII of the Federal Food, Drug, and Cosmetic Act.[22] The amendment can be found at Section 384(a) and states, "The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import into the United States covered products."[23] "Covered product" means a prescription drug, except as limited by the Controlled Substances Act and the Public Health Service Act.[24]

This language would presumably displace section 381(d) of the Federal Food, Drug, and Cosmetic Act,[25] which embodies the 1987 ban. To date, however, MEDSA remains inactive pursuant to subsection (l). This subsection requires the Health and Human Services (HHS) Secretary to demonstrate to Congress that the implementation of the amendment will "(1) pose no additional risk to the public's health and safety; and (2) result in a significant reduction in the cost of covered

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18. *Id.*

19. *See* Adriel Bettelheim, *GOP Eager to Show Voters Progress in Cutting Drug Costs*, CONGRESSIONAL Q. WKLY., Sept. 16, 2000, at 2131.

20. *See* 146 CONG. REC. S10,686 (daily ed. Oct. 18, 2000).

21. For the text as it appears in the appropriations bill, see H.R. Rep. 106-948. At this time, the section of Public Law 387 which contains MEDSA is not available for placement on GPO Access. MEDSA is an Incorporated by Reference (IBR) Bill. The Office of the Federal Register, National Archives and Records Administration has the bill and is waiting to release it until after they receive all associated appendices.

22. *See* 21 U.S.C. § 381 (2000).

23. 21 U.S.C. § 384.

24. *See id.* § 384(k)(1)(A).

25. *Id.* § 381(d).

products to the American consumer."[26] Outgoing HHS Secretary Donna Shalala refused to enable the amendment. The *Washington Post* reported that Shalala, in a letter to President Clinton, stated that the law is "unworkable and would not lower costs."[27] As of the date of this Article, HHS Secretary designee Tommy Thompson has only agreed to reconsider the decision to implement MEDSA.[28]

If implemented, MEDSA would require the Health and Human Services (HHS) Secretary to establish an extensive regulatory framework intended to provide safeguards to ensure that the imported pharmaceuticals do not pose a public health risk.[29] The amendment would also allow imports from only a limited number of countries and economic areas.[30] Additionally, the law includes what has come to be called the "non-discrimination" clause. The provision states that manufacturers are prohibited from entering into contracts with distributors, which include provisions that prevent the sale or distribution of pharmaceuticals.[31] If MEDSA is implemented, the plan will be limited to five years following the effective date of implementation.[32]

The expressed intent of MEDSA presents a host of legal and policy questions that will inevitably be addressed if the act is implemented. The act may be criticized for impeding pharmaceutical patent holders' right to control the importation of their patented product. The act may restrict patent rights that allow the patent holder to expressly limit the use of the patented product. Furthermore, MEDSA's broad pronouncement of encouraging the resale of foreign-purchased drugs may have questionable public policy effects.

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26. *Id.* § 384(l).

27. Marc Kaufman, *Shalala Rejects GOP Drug Practice Law, Plan Won't Have Money, She Says*, WASH. POST, Dec. 27, 2000 at A1.

28. *See* Wash. D.C. Congressional Press Release, New HHS Secretary Designee Agrees to Reconsider Implementation of Prescription Drug Plan at Senate Confirmation Hearing, (Jan. 19, 2001).

29. *See* 21 U.S.C. § 384(b)–(e). Included among these provisions are requirements for recording of the name, the dosage form, the date of shipment, and the amount of active ingredient within the product. The amendment also requires information pertaining to the manufacturer of the pharmaceutical, testing data, and information that could facilitate the tracking of the importer. *Id.*

30. *See* 21 U.S.C. § 384(f). These countries include Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and members of the European Union and the European Economic Area. This list may, however, be expanded or reduced at the HHS Secretary's discretion. *Id.*

31. *See* 21 U.S.C. § 384(h). This provision may pose substantive constitutional problems. *See infra* Part II.A.

32. *See* 21 U.S.C. § 384(m).

III. THE EFFECTS OF MEDSA ON PATENT LAW

The effects of MEDSA on intellectual property and U.S. trade policy were not fully measured during the drafting of this legislation. The law states that within two years of implementation, the HHS Secretary must complete a report that includes consultation with the United States Trade Representative (USTR) and the Commissioner of Patents and Trademarks to evaluate the effect of encouraging the resale of foreign-purchased pharmaceuticals on trade and patent rights under federal law.[33]

During the Senate Conference Report, Senator Orrin Hatch stated, "[I]n some respects, this non-discrimination clause is a major assault on intellectual property rights. It hardly sends a strong signal to our knowledge-based industries that form the backbone of the new high-technology economy."[34]

Whether the provision is a "major assault" on intellectual property rights depends on whether federal patent law provides a right to patent holders that allows them to restrict further resale of their patented products after the patented product is first sold abroad. Unfortunately, the patent statute does not directly answer this question, nor is the case law clear on this issue.

Before proceeding, it is important to clarify the vocabulary that many courts and commentators use to describe transactions involving the resale of foreign-purchased goods. This situation is referred to as either "parallel trade" or trade in "gray market" goods.[35] These terms are best illustrated in a hypothetical.

U.S. pharmaceutical Company *A* has a long-standing relationship with Canadian Distributor *B*. Distributor *B* is Company *A*'s authorized distributor of the pharmaceutical products which were manufactured in FDA-approved labs. Distributor *B* is *authorized* when Company *A*, through a contractual agreement, establishes an exclusive territory outside of which Distributor *B* is prohibited to sell the products. The Canadian-bound products are labeled and packaged in accordance with Canadian law with the intent of reaching Canadian end-users. The FDA-approved drugs are sold in Canada at a steep discount because Canadian

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33. *See id.* § 384(i)(1).

34. *See* 146 CONG. REC. S10, 669, 687 (daily ed. Oct. 18, 2000) (statement of Sen. Hatch).

35. *See* Claude E. Barfield, Mark A. Groombridge *Parallel Trade in Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185, (1994-96)(1999); *see also* Robert J. Staaf, *The International Gray Market: The Nexus of Vertical Restraints, Price Discrimination and Foreign Law*, 19 U. MIAMI INTER-AM. L. REV. 37, 39 (1987).

pharmaceutical prices are affected by differences in national economic, social, legal, or regulatory regimes.[36] Importer *X* determines that after subtracting the cost of repackaging, relabeling, and reshipping she can still turn a profit by purchasing the drugs at the Canadian price and reselling to U.S. wholesalers and pharmacists below the U.S. price set by pharmaceutical Company *A*.

Importer *X* is engaged in "parallel trade" and the products that reach the U.S. wholesalers and pharmacists after the skillful turnaround are considered "gray market" goods. It is important to distinguish the above scenario from situations in which foreign distributors seek to import drugs that were manufactured without the consent of the patent holder. It is clear that U.S. patent holders have rights against the importation of counterfeit drugs as well as rights against anyone who reproduces the patented product.

Patent rights may arise, however, when Company *A* sues Importer *X* for infringing on *A*'s exclusive right to import his patented product. Section 271 of the Patent Act states that, "whoever without authority . . . offers to sell, or sells any patented invention, within the United States or *imports into the United States* any patented invention during the term of the patent therefor, infringes the patent."[37]

Extending the right of patent holders against third parties who seek to import patented goods into the United States appears, facially, to restrict parallel trade. The patent law provision restricting imports is limited, however, by two doctrines: the first-sale doctrine and the principle of exhaustion. The first-sale doctrine is based on the premise that monopoly rights granted to patent holders are limited in that patent holders may not restrict alienation of the patented product beyond the first sale of that product. The patent system was designed to balance the goal of sustaining a competitive marketplace with a desire to encourage innovators to invent new products and share the benefits of those inventions with the public. Extending legal rights to control goods beyond their first sale, however, is unnecessary to accomplish the incentive function, and may unduly interfere with competition and the free movement of goods in the marketplace. Though not codified within the Patent Act, this principle is well established in U.S. case law.[38]

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36. *See* PATRICIA M. DANZON, PRICE COMPARISONS FOR PHARMACEUTICALS: A REVIEW OF U.S. AND CROSS-NATIONAL STUDIES 27-28 (1999).

37. 35 U.S.C.A. § 271(a) (West Supp. 1996) (emphasis added).

38. *See* United States v. Univis Lens, Co., 316 U.S. 241, 249 (1942); Adams v. Burke, 84 U.S. (17 Wall.) 453, 456 (1873) ("When the patentee, or the person having his rights, sells a machine or instrument whose sole value is in its use, he receives the consideration for its use . . . and he parts with the right to restrict that use."); Bloomer v. McQuewan, 55 U.S. 539 (1852).

United States courts use the term exhaustion of intellectual property rights interchangeably with the first-sale doctrine. Exhaustion refers generally to the idea that when the patented product is released, or authorized to be released, into the stream of commerce, any further rights to the product are exhausted. Regarding domestic sales and distribution of patented products, these concepts are clearly established rules of law.[39] Internationally, however, U.S. courts have provided little guidance with regard to two factual scenarios. First, because of possible perceived territorial limitations of intellectual property rights among various nations, it is not clear whether a first sale of a product outside of the United States will effectively exhaust the rights of the holder of a U.S. patent.[40] Second, several cases suggest that a patent holder may have the right, pursuant to federal patent law, to contract out of the effects of exhaustion by imposing contractual limitations on further sales of the product.[41]

A. Territorial vs. International Exhaustion

By encouraging parallel imports, MEDSA may encounter constitutional problems with regard to possible conflicts with federal patent law. Because patent law is derived from express constitutional provisions, courts may find that facilitating parallel trade is unconstitutional. For reasons elaborated below, this outcome is doubtful.

To succeed in a constitutional challenge to MEDSA, the challenger must convince the court to adopt a "territorial" or "domestic" exhaustion theory, which would limit the effects of exhaustion to goods manufactured and initially sold within the territory of the United States. The rationale supporting the territorial argument is that each nation's intellectual property law regime provides a separate right to control the patented product within its geographical area.

Currently, pharmaceutical companies must register their patents in accordance with the local patent laws in each country in which the product is sold. For example, Company *A* may properly register a valid patent for the drug in question with the Patent and Trademark Office (PTO), but the company may not assert its U.S. patent rights against an

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39. *See supra* note 38.

40. *See* Margreth Barret, *The United States' Doctrine of Exhaustion: Parallel Imports of Patented Goods*, 27 N. KY. L. REV. 911, 964-65 (2000) (arguing that while there are inconsistent rulings on the subject, the territoriality argument should fail); *see also* Barfield, *supra* note 35, at 197 (finding that U.S. patent law is territorial in scope).

41. *See* Mallinckrodt, Inc. v. Mediapart, Inc., 976 F.2d 700 (Fed. Cir. 1992) (holding that the patentee could restrict purchasers of its patented medical device to a single use, and hold those who reused the device in violation of the restriction liable for patent infringement).

infringing party when that infringement occurs in Canada. Company *A* must file for Canadian patent protection separately and pursue all claims of Canadian infringement in Canadian courts.

The territorial limitations of the patent system regarding foreign infringement are well established in the case law. The Supreme Court in *Brown v. Duchesne*[42] stated:

> [The Patent Acts] do not, and were not intended to, operate beyond the limits of the United States; and as the patentee's right of property and exclusive use is derived from them, they cannot extend beyond the limits to which the law itself is confined. And the use of it outside of the jurisdiction of the United States is not an infringement of his rights, and he has no claim to any compensation for the profit or advantage the party may derive from it.[43]

The restrictive scope of the patent laws was also expressed in *Dowagiac Manufacturing Co. v. Minnesota Moline Plow, Co.*[44] In *Dowagiac*, the Court stated that patent infringement "cannot be predicated [on] acts wholly done in a foreign country."[45]

Though the territorial scope is well established, it is unclear how this rule affects the principle of exhaustion. Those who oppose encouraging parallel trade argue that because patent law only extends to the border of any one country, that country should not recognize the first sale of patented products abroad as exhausting the patent holder's right against imports of that product. The Supreme Court's decision in *Boesch v. Graff*[46] is frequently cited as authority for this position.

Boesch, a late nineteenth-century case, involved a U.S. patent holder who sold lamp burners in Germany. Though the U.S. patent holder could exclude others from the sale of the patented invention in the United States, he was forced to compete with a German manufacturer in Germany.[47] The German manufacturer could sell the product free of liability under the corresponding German patent due to a "prior use" law.[48] Defendant Boesch purchased the lamp burners from the German manufacturer and attempted to export them to the United States. The Court found that the specific issue inherent in the case was "whether a dealer residing in the United States can purchase in another country articles patented there, . . . and import them to and sell them in the United

42. 60 U.S. 193 (1856).
43. *Id.* at 195-96.
44. 235 U.S. 641 (1915).
45. *Id.* at 650.
46. 133 U.S. 697 (1890).
47. *See id.* at 700.
48. *See id.* at 701.

States, without the license or consent of the owners of the United States patent."[49] The court found that a purchaser could not rely on the rights provided by a foreign law to usurp the rights of a U.S. patent holder.[50]

By manipulating this foreign-U.S. law distinction, plaintiffs in *Gordon V. Griffin Keystone Mushroom Farm, Inc.*,[51] succeeded in convincing a federal district court that they should benefit separately from the protection of an Italian patent and a U.S. patent. The plaintiff owned U.S. and Italian patents on an identical composting device. The plaintiff licensed the patent to an Italian agent and to an unrelated U.S. agent. The defendant purchased three devices from the Italian agent and imported them into the United States. Two devices were sold and the defendant retained the use of one device. The court, citing *Boesch*, held that the defendant infringed upon the plaintiff's U.S. patent, despite the foreign sale.[52] Notwithstanding criticism that such a finding would enable the patent holder to receive a double recovery on the patent, the court stated:

> If the plaintiff had arranged for ownership of the Italian and American patents to be vested in two different persons, . . . the facts here would presumably create a right under *Boesch* and *Daimler Manufacturing Co. v. Conklin* to two different royalties one due the Italian patentee from [licensee], the other owing to the American patentee from the defendant for use and/or sale here.[53]

The *Griffin* holding has been criticized for misconstruing the true intent of the *Boesch* decision and for not properly distinguishing several intermediary cases holding that when a patent holder or licensee of the patent makes an *unrestricted* sale of the patented good, the sale, regardless of where it occurs, exhausts the U.S. patent.[54]

Central to these intermediary holdings is the patent holder's consent to the first sale. The court in *Holiday v. Mattheson*,[55] an important lower court decision five years before *Boesch*, found that once a patent holder had made an unrestricted sale of the patented goods within a foreign country, he could no longer restrict the transfer of that good. "[U]nless by the conditions of the bargain the monopoly right is impressed upon the thing purchased; and if the vendor sells without reservation or

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49. *Id.* at 702.
50. *Id.* at 703.
51. 453 F. Supp. 1283 (E.D. Pa. 1978).
52. *See id.* at 1283.
53. *Id.* at 1286.
54. *See* Barret, *supra* note 40, at 198-99.
55. 24 F. 185 (S.D.N.Y. 1885).

restriction, he parts with his monopoly so far as it can in any way qualify the rights of the purchaser."[56]

Following this principle, the court in *Curtiss Aeroplane & Motor Corp. v. United Aircraft Engineering Corp.*,[57] dealing with the resale of U.S.-patented airplanes into the United States after an unrestricted first-sale in the United Kingdom, stated: "If the thing sold contains inventions of several United States patents owned by the vendor, the article is freed from each and all of them, and if the vendor has divided his monopoly into different territorial monopolies, his sale frees the article from them all."[58]

Again, these cases seem to suggest, as several commentators have hypothesized, that the United States abides by a modified international exhaustion policy.[59] Commentators have characterized international exhaustion in the United States as modified because U.S. patent holders may have the right to restrict resale of the product by contract.[60] A pure international exhaustion policy would mean that any sale of a patented product would exhaust the rights of the patent holder no matter where the sale occurred. The reasoning is that the patent holder's publicly funded incentive to innovate is contained in her right to control the first sale. It can be assumed that if the patent holder decided to make that first sale abroad, she has obtained sufficient benefit to maintain an incentive to invest in creative efforts. Regardless of whether the good is protected by intellectual property rights in the foreign country, the U.S. intellectual property owner's decision to sell abroad suggests that it finds the sale beneficial.

The trend toward international exhaustion in the United States is also supported by recent cases involving trademarked and copyrighted goods.[61] Recent U.S. court decisions concerning trademark rights have provided for conditioned international exhaustion.[62] In regard to the Lanham Act section 42[63] and the Tariff Act section 526,[64] the Court found that as long as the U.S. owner itself, or an affiliated business entity, put the goods bearing the mark into the market abroad, its rights to

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56. *Id.* at 185.
57. 266 F. 71 (2d Cir. 1920).
58. *Id.* at 78.
59. *See* Barret, *supra* note 40 at 916; 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.03[2][a][iv] (1998).
60. *See* Barret, *supra* note 40, at 916.
61. *See* Quality King Distrib., Inc. v. L'Anza Research Int'l, Inc., 523 U.S. 135 (1998).
62. *See* K-Mart Corp. v. Cartier, Inc., 486 U.S. 281 (1988) (regarding the Tariff Act); Weil Ceramics and Glass, Inc. v. Dash, 878 F.2d 659 (3d Cir. 1989), *cert. denied*, 493 U.S. 853 (1989).
63. 15 U.S.C. § 1124 (1994).
64. 19 U.S.C. § 1526 (1994).

restrict importation into the United States of those products were exhausted.[65] The Court provided an exception where imported trademarked goods differ materially from their U.S. counterparts.[66] In such cases, the Court reasoned, consumers may be misled as to the quality and origin of the imported products.

The Copyright Act of 1976 codifies the exhaustion doctrine at section 109(a)[67] and gives copyright holders the right to prohibit the unauthorized importation of copies at section 602(a).[68] In *Quality King Distributors, Inc. v. L'Anza Research International, Inc.*,[69] the plaintiff sought to prohibit defendants from importing into the U.S.-copyrighted goods purchased from authorized distributors abroad. The Court found that the right to restrict imports was a limited right, which is exhausted after the first sale of the product, domestically or abroad.[70] The Court specifically stated that, "[W]hether or not we think it would be wise policy to provide statutory protection for such price discrimination is not a matter that is relevant to our duty to interpret the text of the Copyright Act."[71]

The Court's reluctance to directly address the effects of parallel importing in *Quality King* is also reflected in U.S. trade policy. Parallel importation of goods protected by intellectual property rights was the subject of an inconclusive debate in the Uruguay Round of the Negotiations on the General Agreement on Tariffs and Trade (GATT). The result of these discussions, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),[72] suffers from the same ambiguity regarding exhaustion as does the U.S. Patent Act regarding exhaustion. Section 28 of the TRIPS agreement states that patent holders shall have the right to prevent third parties from importing the patented product.[73] However, section 6 of the agreement states, "For the purposes of dispute settlement under this Agreement, subject to the provisions of Article 3 and 4 above nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."[74] Several commentators have suggested that this inconsistency regarding exhaustion is endemic of the general lack of consensus and

65. *K-Mart*, 486 U.S. at 294.
66. *Id.* at 296.
67. 17 U.S.C. § 109(a) (1994).
68. *Id.* § 602.
69. 523 U.S. 135 (1997).
70. *See id.* at 145.
71. *Id.* at 153.
72. *See* 33 I.L.M. 81 (1994) [hereinafter TRIPS].
73. *See id.* at 94.
74. *Id.* § 6.

decisionmaking procedures necessary to evaluate the distinct economic justifications for exhaustion.[75]

The international lack of consensus reflects the U.S. national division on this matter. While the U.S. courts and international agreements remain in a holding pattern concerning the issue of international exhaustion, it is doubtful that the pharmaceutical industry can defeat parallel imports by arguing that foreign first sales are beyond the reach of the exhaustion doctrine. Thus, the underlying intent of MEDSA should not be thwarted by judicial oversight, at least not on these grounds.

B. Contractual Restrictions on the Right of Importation

In the alternative, opponents of parallel imports may argue that the "non-discrimination" clause within MEDSA violates a patent holder's right under federal patent law to restrict further resale of the patented product. The MEDSA provision states: "No manufacturer of covered products may enter into a contract or agreement that includes a provision to prevent the sale or distribution of covered products imported pursuant to subsection (a)."[76]

Recently a federal court, following an extensive line of authority, held in *Mallinckrodt, Inc. v. Medipart, Inc.*,[77] that patent holders could restrict future use and resale through contracts and licensing agreements. These restrictions, the court found, were enforceable through the patent laws. The court reasoned that patent law is based on the right to exclude others from using or selling the patented product and that "[t]his right as any other right to exclude may be waived in whole or in part."[78]

The Federal Circuit expanded on this logic in *B. Braun Medical, Inc. v. Abbott Lab.*[79] Here the court justified the limitation on the first sale doctrine by stating:

> The theory behind [the first-sale doctrine] is that in such a transaction, the patentee has bargained for, and received, an amount equal to the full value of the goods. This exhaustion doctrine, however, does not apply to an expressly conditioned sale or license. In such a transaction, it is more reasonable to infer that the parties negotiated a price that reflects only the value of the "use" rights conferred by the patentee.[80]

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75. *See* Vincent Chiappetta, *The Desirability of Agreeing to Disagree: The WTO, TRIPS, International Exhaustion and a Few Other Things*, 21 MICH. J. INT'L L. 333, 335 (2000).
76. 21 U.S.C. § 384(h) (2000).
77. 976 F.2d 700 (Fed. Cir. 1992).
78. *Id.* at 703.
79. 124 F.3d 1419 (Fed. Cir. 1997).
80. *Id.* at 1426.

By allowing patent holders to restrict use and resale, the court merely recognized an existing line of authority than has been employed in addressing parallel import suits. The language "without restrictions" or "subject to restrictions" was recorded as early as *Adams v. Burke*.[81]

Adams not only lays out the foundation for the first-sale doctrine, but it also states that the patent holders rights are exhausted if the good "passes without limit of the monopoly" and is "open to the use of the purchaser without further restriction."[82] The court in *Dickerson v. Matheson*,[83] dealing with a foreign first sale of a U.S. patented product, held that the purchaser acquires unrestricted ownership in the article subject to the patent holder's restrictions on use and monopoly.[84] *Curtiss*, a later Second Circuit decision, built on the *Matheson* decision stating, "[T]he agreements [between patent holder and purchaser] will be searched in vain for any restrictions or condition as to the right to use or vend."[85]

Restrictions on resale in the United States are generally upheld if the sale was made on the express condition that the product was not to be resold in the United States and there was adequate notice of the restriction. Courts applying this rule have found that even when the product has passed through several intermediaries, the restriction is still enforceable if the notice of the restriction is affixed to the product.[86] In *Dickerson v. Matheson*, the defendant sought to insulate himself from the prohibition on resale by purchasing the product through a series of agents.[87] The court held that knowledge of the restrictions stated on invoices was imputed through defendant's agents.[88]

Licensing agreements have made restrictions on resale more complicated. In *Sanofi, S.A. v. Med-Tech Veterinarian Products, Inc.*,[89] the plaintiff, a French pharmaceutical company, authorized the U.S. patent for a drug for veterinary use in the United States.[90] The plaintiff sold the product in Europe and established an exclusive licensing agreement with a U.S. firm.[91] The defendant purchased the drug in Europe for import in the United States and both the plaintiff

81. 84 U.S. 453 (1873).
82. *Id.* at 456.
83. 57 F. 524 (2d Cir. 1893).
84. *Id.* at 527.
85. Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng'g Corp., 266 F. 71, 77 (2d Cir. 1920).
86. Dickerson v. Matheson, 84 F. 192, 194-95 (8th Cir. 1897).
87. *See id.* at 194.
88. *See id.* at 195.
89. 565 F. Supp. 931 (D.N.J. 1983).
90. *See id.* at 934.
91. *See id.*

manufacturer and its licensee filed suit.[92] The court held that the French manufacturer's rights against the defendant were exhausted by the foreign sale but that the licensee's rights had not been exhausted.[93] According to the court, the exclusive licensing agreement was so strong that not even the French manufacturer could sell its products in the United States without approval from the exclusive U.S. licensee.[94]

These cases suggest that U.S. patent law operates under a limited international exhaustion doctrine, but it is unclear how integral the right of these contractual limitations are to the overall purpose of the patent system. Critics have argued that the purpose of the patent system is not to ensure the patent holder's monopoly rights in connection with all sales.[95] These commentators suggest that the patent system provides a more general purpose: to provide an incentive to invent by giving the inventors the means of profiting from their inventions, while ensuring that those incentives do not unnecessarily interfere with free competition.[96] The purpose is not, however, to ensure that patent holders extract the greatest possible benefit from their inventions.

Implementation of the patent system, while constitutionally mandated, rests in the hands of Congress. Congress must weigh conflicting social values to determine the structure of the patent system. Providing increased competition in one area of patent protection through the enactment of MEDSA will probably not subvert the true intent of the patent system. In *Mallinckrodt*, the "court" limited its allowance of restricted sales contracts by stating that such restrictions are "subject to patent, contract, antitrust, and any other applicable law, as well as equitable considerations such as are reflected in the law of patent misuse."[97] Prohibitions on restricting the importation of foreign-purchased drugs will most likely fall within these exceptions without conflicting with the underlying purpose of constitutionally mandated patent law principles.

IV. PUBLIC POLICY IMPLICATIONS OF ENCOURAGING THE RESALE OF FOREIGN-PURCHASED PHARMACEUTICALS

Encouraging parallel trade will probably not be countered by successful constitutional opposition, but the effects of such a policy may be criticized for insufficiently weighing the economic and social effects.

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92. *See id.*
93. *See id.* at 940-41.
94. *See id.*
95. *See* Barret, *supra* note 40, at 912.
96. *See id.* at 912-13.
97. Mallinckrodt, Inc. v. Mediapart, Inc., 976 F.2d 700, 703 (Fed. Cir. 1992).

The fact that the importation of foreign-purchased goods is identified by two different terms, gray market and parallel trade, is evidence that many economists and policy analysts hold divergent normative views on this subject. "Gray market," a term derived from black market, connotes a negative effect on the domestic market.[98] The term "parallel trade," however, is used by many to refer to the benefits of lowering barriers to trade and encouraging a free market.[99]

The effects of parallel trade are felt internationally and across a wide variety of industries. Industries that are particularly affected by the unauthorized market are those that deal in goods protected by intellectual property rights.[100] Copyrighted books, audio and video recordings, goods bearing trademarks, and patented products, particularly pharmaceuticals, are principally influenced.[101]

Estimates of the size of this market in the United States ranged from $5.5 to $7 billion in the mid-1980s.[102] This volume is not only evidence of the size and sophistication of parallel trade, but also illustrates the perceived threat to those who have established exclusive distribution networks.[103] Parallel trade is estimated to account for roughly ten percent of pharmaceutical sales in the European Union (EU),[104] and surveys suggest that the effect in Asian markets is of growing concern.[105]

Putting aside the specific health considerations wedded to the pharmaceutical industry, many argue, and Congress appears to agree, that if there is no safety risk to the consumer from parallel imports, foreign-purchased drugs should not be denied reentry into the United States.

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98. *See* Hugh C. Hansen, *Protection of Intellectual Property Rights at the Border: Continuing Battle Over "Parallel Imports,"* 536 PLI/Pat 39 (1998).

99. *See id.* When the authorized goods and the unauthorized goods are both imported, then the term "parallel imports" makes sense as indicating two separate lines of importation. This term is not always accurate, however, as sometimes the authorized goods, and even occasionally the unauthorized goods, are not imported. *Id.* at 42. For purposes of efficiency and because of its relatively neutral meaning, parallel imports and parallel trade will be used to refer to U.S.-produced goods purchased abroad and imported into the United States.

100. *See* William Richelieu, *Gray Days Ahead?: The Impact of* Quality King Distributors, Inc. v. L'Anza Research International, Inc., 27 PEPP. L. REV. 827, 829 (2000).

101. *See id.*

102. *See* Andrew Ruff, *Releasing the Grays: In Support of Legalizing Parallel Imports*, 11 UCLA PAC. BASIN L.J. 119, 120 (1992).

103. *Id.*

104. *See* Barfield, *supra* note 35, at 194 (demonstrating that parallel trade within the European Union (EU) among EU member nations is only restricted by private contracts).

105. *See id.* The survey data indicated that "thirty percent of U.S. exporters in Asia stated that their local distributors were experiencing problems with lower-priced parallel imports." *Id.*

A. The Case for Parallel Trade

Former Washington Senator Slade Gordon, during the Senate Conference Report, stated:

> [W]e face a situation in which American pharmaceutical manufacturers that are benefiting from huge tax subsidies through research and development tax cuts, and benefiting from the immense research that we do in the National Institutes of Health, nevertheless, sell their products outside of the United States in Canada, in Europe, and in Latin America for prices half or less the price they charge for those drugs in the United States. That is outrageous. It is a form of discrimination without any justification whatsoever.[106]

By characterizing territorial price discrimination as anticompetitive behavior, those applauding the new law base their support on the assumption that contractual agreements between manufacturers and authorized dealers creating territorial restraints are necessarily anticompetitive.[107] These territorial restraints, or vertical territorial restraints, occur when a firm at one stage of production imposes contractual limitations to take effect at a subsequent stage of production.[108] These restraints are criticized because they allow pharmaceutical companies to segment the world into territorial markets within which the companies, critics argue, charge "whatever the market will bear."[109] When patent protection and the perceived inelastic demand for pharmaceutical products are added to territorial market segmentation, critics argue pharmaceutical manufacturers can make disproportionately high profits.[110] With these increased revenues the companies can effectively raise costs to smaller rivals and make entry by newcomers more difficult. Once the market is reduced to a few key players, the remaining companies may collude to set artificially high prices within a specific market.

Several commentators have argued that parallel trade, such as that envisioned in MEDSA, could effectively check these monopolistic barriers and create a more responsive free market.[111] By using parallel

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106. 146 CONG. REC. S10, 669, 670 (daily ed. Oct. 18, 2000) (statement of Sen. Gordon).

107. *See* Ruff, *supra* note 102, at 120.

108. *See* Micheal K. Vaska, *Conscious Parallelism and Price Fixing: Defining the Boundary*, 52 U. CHI. L. REV. 508, 511 (1998).

109. *See* Senator Dorgan's statement: "The lack of competition in the U.S. marketplace has created a situation in which the big drug companies can charge American consumers the maximum the market can bear. And if their 18 percent profit margins are any indication, that is exactly what the drugmakers are doing." 146 CONG. REC. S10, 669, 683.

110. *See id.*

111. *See* Ruff, *supra* note 102, at 120; *see also* Jamie S. Gorelick & Rory K. Little, *The Case for Parallel Importation*, 11 N.C. J. INT'L L. & COM. REG. 205 (1986).

imports to compete with collusive pricing regimes, unauthorized importers resist economies of scale or start-up and advertising costs because the authorized dealer has done the work for them.[112] If competition from parallel imports is successful, proponents argue, one can assume that supplier cartels have driven prices up to a point where it is feasible to pay import tariffs and transportation costs and still be able to compete with the cartel's price. Importers will arbitrage this retail difference until the cartels drop their prices back down to competitive levels.

This rationale, while economically sound in the abstract, suffers from a lack of empirical evidence. There is a significant dispute among legislators and pharmaceutical companies as to the accuracy of recorded price differentials among foreign countries. Congress has relied on two sources of comparative pricing information, a 1992 U.S. General Accounting Office (GAO) report entitled *Prescription Drugs: Companies Typically Charge More in the United States than in Canada*,[113] and a 1994 report entitled Prescription Drugs: Companies Typically Charge More in the United States than in the United Kingdom.[114] The 1992 report indicated that a market basket of 121 identical prescription drugs available from the same manufacturer would cost wholesalers thirty-two percent more in the United States than in Canada.[115] The 1994 report showed that prescription drug pricing in France, Germany, Sweden, and the United Kingdom is lower and has a much slower rate of growth compared to the same drugs in the United States.[116]

The methodology of both GAO studies has been criticized for sampling only the most popular drugs with the highest rate of return.[117] Along with unrepresentative sample sizes, the reports are also disputed for not taking into account various other margins of error. These critics state that the price differential is upward biased and atypical.[118]

A second crucial assumption within this analysis is that third party distributors, after transportation costs, costs incurred by conforming to health and safety requirements, and extracting the realization of a profit

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112. *See* Ruff, *supra* note 102, at 150.

113. *See* DANZON, *supra* note 36, at 29-32 (citing GAO-HRD-92-110).

114. GAO-HEHS-94-29.

115. *See* DANZON, *supra* note 36, at 29.

116. *See Examining the Accessibility of Affordable Prescription Drugs, The Price Differentials for Identical Prescription Drugs in the International Marketplace, and Drug Quality and Safety: Hearing of the Comm. on Health, Education, Labor, and Pensions*, 106th Cong. (2000) (statements of Senate Byron L. Dorgan).

117. *See* DANZON, *supra* note 36, at 2.

118. *See id.* at 2-3.

on the exchange, will pass a considerable savings on to consumers. The legislative history surrounding the passage of the Prescription Drug Marketing Act of 1987 generally dismissed the possibility of higher domestic pharmaceutical prices in the wake of banning the importation of foreign-purchased pharmaceuticals.[119] The Committee Report stated:

> Consumers will be spared from currently existing health and safety risks and will not have their prescription drug costs increased as the result of this bill because the benefit of the lower wholesale prices available in this diversion market are absorbed by middlemen and are not passed on to the ultimate consumer.[120]

This concern was also raised in the MEDSA conference report. Senator Orrin Hatch, skeptical of consumer price benefits, stated:

> [O]ne of my chief concerns about [MEDSA] . . . is whether consumers will get any substantial benefit when a new phalanx of middlemen get their piece of the action for bringing these drugs into the United States. I am not convinced that consumers will get much in the way of savings. And, what little benefit they get will come at what cost?[121]

If parallel trade only nominally affects the consumer price of pharmaceuticals, it will be difficult to justify the extensive regulatory framework that is envisioned by MEDSA to protect the public against counterfeit or adulterated pharmaceuticals that may enter the United States posing as U.S.-made imports. Unfortunately, there are no reports that adequately balance the real effects of these concerns. The question remains to be answered: will prices actually fall for U.S. pharmaceutical consumers, or will the implementation of MEDSA simply be a windfall for middlemen reimporters?

B. In Defense of Pharmaceutical Price Differentials

Domestic consumers characterize distribution schemes that result in differential pricing as collusive or anticompetitive, but this facial analysis may improperly weigh the particular circumstances inherent within the pharmaceutical market. First, the pharmaceutical industry may be more competitive than initially suspected. Second, vertical restraints on trade resulting in differential pricing may allow the pharmaceutical industry to maximize profits, therefore encouraging innovation and entry into new markets more effectively than a uniform international price.

Proponents of price restrictions argue that, due to the inelastic demand of their product, pharmaceutical companies can charge whatever

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119. *See id.*
120. H.R. Rep. No. 100-76, at 10 (to accompany H.R. 1207).
121. 146 CONG. REC. S10 (daily ed. Oct. 18, 2000) (statement of Sen. Hatch).

the market will bear. Recent developments in technology and research, however, have revealed more intense and more rapid competition within the industry. Specifically, the period of one-brand dominance for an innovative drug has shortened considerably.[122] For example, whereas the first beta blocker for heart disease, which was introduced in 1965, did not meet competition for thirteen years, the first protease inhibitor for HIV (Invirase) developed in the mid 1990s, encountered market competition within a few months.[123] New classes of cholesterol-reducing drugs, antidepressants, and treatments for adult-onset diabetes have also developed at accelerated rates by competing firms.[124] These new technology factors counter the notion that the industry is dominated by monolithic or even collusive powers that "set" prices.

Critics of pharmaceutical pricing schemes also argue that allowing companies to contractually limit the resale of their products outside of a specific area increase and enforce the perceived anticompetitive nature of the pharmaceutical industry.[125] Debates concerning the economic viability of these contractual arrangements, popularly known as vertical territorial restraints, first arose in the 1960s and early 1970s. Efficiency or "Chicago School" theorists, including Robert Bork and Richard Posner, argued that without vertical restraints, third parties could free-ride on producers' pre-sale marketing and post-sale services.[126] The free rider problem inhibited producers from providing these services at an ultimate cost to the consumer exceeding short-term price benefits. Distributors with exclusive territorial agreements, however, were induced to provide better and more extensive services without the fear of a competitor taking a free ride on these investments. The effects of free riding that concern the pharmaceutical industry are a reduction in research and development costs and the ability of pharmaceutical companies to monitor the safety of their products.

Along with the free-rider problem, several commentators have argued that vertical restraints on trade resulting in differential pricing can effectively maximize a companies' entry into new markets by allowing distributors to charge more to consumers who are less effected by price increases and charge less to those who are more susceptible to higher

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122. *See* CALFEE, *supra* note 8, at 20.

123. *See id.*

124. *See id.*

125. *See* Ruff, *supra* note 102, at 122; *see also* Gorelick & Little, *supra* note 111, at 209.

126. *See, e.g.*, Robert Bork, *The Rule of Reason and the Per Se Concept: Price Fixing and Market Division* (pt. 2), 75 YALE L.J. 373 (1966); Richard A. Posner, *The Next Step in the Antitrust Treatment of Restricted Distribution: Per Se Legality*, 48 U. CHI. L. REV. 6 (1981).

prices.[127] This rationale is known as "Ramsey pricing" after economist Frank Ramsey.[128] "Price discrimination," in light of this argument, is simply recognizing each consumer's demand across various geographical areas and charging for pharmaceuticals accordingly. For example, when Company *A* sells its pharmaceuticals abroad, it can reach a larger customer base by pricing according to local demand than by pricing according to international demand. International demand would include the average consumer in the highest income nation who is willing to pay $100 for a particular product and the average consumer in a lower income country who may only be willing to purchase the drug for $50. The international price, considering these demands, would fall somewhere between $100 and $50. The consumer in the lower income country would be unwilling to purchase the drugs at the international price and Company *A* would leave that market.[129] By pricing according to local demand and relying on vertical restraints, Company *A* can serve the consumer in the lower income country by pricing slightly above marginal cost. Company *A* can still recoup its long-term investments by selling at a higher price to consumers in the highest income country without fearing that the lower priced goods will make their way into the highest income country's market. In the abstract, allowing vertical restraints will allow higher total revenue and a higher rate of investment in R&D, leading to a greater flow of innovative drugs to more people.[130]

The distribution system within the pharmaceutical industry is particularly reliant on vertical restraints on trade. Several economic factors are found within the pharmaceutical industry that justify this conclusion. These factors include the high ratio of sunken joint R&D costs, within the industry, price distortions created by public authorities that drive prices below average fixed costs and the ability of

127. *See* DANZON, *supra* note 36; Barfield, *supra* note 35, at 223-24. It is interesting to note that for most of the twentieth century vertical restraints were per se illegal under judicial interpretation of the antitrust laws. *See* Benjamin Klein & Kevin M. Murphy, *Vertical Restraints as Contract Enforcement Mechanisms*, 31 J.L. ECON. 265, 265 (1988). It was not until 1977 that the Supreme Court, in *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36 (1977), discarded the per se rule in favor of a rule of reason regarding vertical restraints. The change in attitude opened the doors to vertical restraints across a variety of industries.

128. *See* Barfield, supra note 35, at 249 (citing F.P. Ramsey, *A Contribution to the Theory of Taxation*, ECON. J. 47-61 (1927)).

129. Several commentators have stated that a uniform price could compel pharmaceutical companies to pull out of lower income markets completely to protect their market share in more price inelastic markets. See *Barfield*, *supra* note 35, at 249 The implications of this possibility have concerned international policy analysts who must determine the relative value of encouraging foreign direct investment into these areas while balancing the effects of increased free trade. *See id.*

130. *See* DANZON, *supra* note 36, at 41.

unauthorized distributors to undercut information and service activities.[131] These considerations are explored in the following section.

1. The Cost of Research and Development

R&D accounts for upwards of thirty percent of total costs in the pharmaceutical industry.[132] The R&D cost per new chemical entity brought to market in the United States is estimated between $359 and $500 million.[133] This cost includes the risk factor inherent in the trial and error method of drug development. Also, capital costs and foregone interest income are incurred because pharmaceutical companies must wait as long as fifteen years between the initiation of R&D and the launch of a successful product.[134]

These R&D costs are spread across the industry. The R&D of any one manufacturer draws from a large pool of innovation developed by the collective efforts of all members of the industry. Without the ability to differentially price products according to local demand, parallel trade may decrease the industry's total net revenue, threatening R&D expenditures.

Critics of the "threat to R&D" argument find that, while in the abstract the case for differential pricing may appear as an impediment to innovation, empirical evidence may not reflect this danger to the industry.[135] Testifying before the Senate on June 13, 2000, Senator Byron Dorgan argued that pharmaceutical companies, in the face of decreasing prices, could just as easily cut back on promotional budgets, which are equivalent to approximately two-thirds of R&D spending. "Personally, I find it disappointing that, when faced with the possibility of a reduction in revenues, however small first and only place that the industry has identified for cutbacks is in their spending on research and development."[136]

The threat to R&D investment is also tempered by the uncertainty of any real effects on consumer prices caused by increased parallel trade. As discussed above, if the effect on prices is merely nominal, it is unlikely that the pharmaceutical industry will pause in its efforts to innovate and compete with other players in the field.

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131. *See* Barfield, *supra* note 35, at 247-58.
132. *See* PATRICIA DANZON, PHARMACEUTICAL PRICE REGULATION 5 (1997).
133. *See id.*
134. *See* Barfield, *supra* note 35, at 247.
135. *See* Barret, *supra* note 40, at 976-79.
136. *See Hearing of the Comm. on Health, Labor, and Pensions*, *supra* note 116.

2. Price Distortions Created by Public Authorities

Determining the international demand for any particular pharmaceutical is complicated by differences among national regulatory policies and health care systems.[137] Within the United States, pharmaceutical pricing is affected by government discounts, insurance, and managed care demands, as well as the effect of prescribing physicians who are frequently not influenced by the price of drugs they prescribe.[138] Internationally, different countries have widely different approaches to regulating the sale and distribution of pharmaceuticals.[139] These complications cast doubt as to whether encouraging parallel trade will result in a seamless adjustment to the domestic price of pharmaceuticals.

A brief look at Canadian and Mexican regulatory schemes may be helpful to identify the collateral effects of parallel trade. Pharmaceutical pricing in Canada is affected by several government-related factors that are absent or curtailed in the United States. Commentator Patricia Danzon points out four significant factors affecting pharmaceutical prices:

> First, [compared to the United States] there is lower exposure to product liability in Canada. Second, Canada's federal government controls the prices of new products, and post-launch price increases are not permitted to exceed the rate of increase of the consumer price index (CPI). Third, until recently . . . [i]f a manufacturer did not accept the government's price, the government could force the manufacturer of a patented product to license a generic producer to manufacture the product, even though that nullified the patent protection. [Though this threat has been lifted by NAFTA, the residual effect may prevent catch-up price increases.] Fourth, in addition to the federal government's controls, some provincial governments in Canada operate other control mechanisms, . . . which may constrain prices below the price permitted by the federal controls.[140]

Most significant among these factors are the direct local and federal price regulations. These price ceilings do not represent the true demand among consumers for any particular product, and the distortions may force pharmaceutical companies to look elsewhere to recoup deep-sunk costs. Responding to foreign price controls, Senator Hatch stated, "We must be especially wary of price control regimes in other countries that may set prices at levels inadequate to reflect their citizens' fair share of

137. *See* DANZON, *supra* note 36, at 2-3.
138. *See id.*
139. *See id.*
140. *Id.* at 27-28.

the R&D costs."[141] If parallel trade substantially affects prices within the United States, it may be argued that foreign nations are exporting their price regulations to the United States. Even though Congress has created price controls in many areas of the health care system, it remains consistently reluctant to impose such control over the pharmaceutical industry. Consequently the United States remains perhaps the only large nation that does not manipulate drug prices in one way or another.[142] Again, this concern turns on the assumption that parallel trade will substantially affect prices.

While Canadian law imposes strict pricing standards, Mexican law represents the opposite extreme by imposing little to no regulation.[143] This hands-off approach, however, also compels pharmaceutical companies to downwardly adjust pricing because consumers have a more elastic demand for the goods. Several factors contribute to this increased elasticity of demand. First, Mexico has lower real wages and per capita incomes. Per capita spending on health care in 1997 in Mexico was $391 compared with $3925 in the United States.[144] Second, Mexico did not adopt comprehensive patent protection laws until 1991.[145] Before this, U.S. pharmaceutical companies competed directly with unauthorized copies of their patented drugs sold at greatly reduced prices. Finally, these factors are supported by the fact that most pharmaceuticals sold in Mexico do not require prescriptions. Without the physician intermediary, Mexican consumers are more responsive to prices than U.S. consumers.[146]

Exporting discounted Mexican products may compel pharmaceutical companies to curtail their involvement in the Mexican market to protect their more profitable market in the United States. This worst case scenario is unlikely with respect to the majority of drugs on

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141. 146 CONG. REC. S10, 687 (daily ed., Oct. 18, 2000) (statement by Sen. Hatch).

142. Even though Congress has created price controls in many areas of the health care system, it has remained consistently reluctant to impose such control over the pharmaceutical industry; consequently, the United States remains the only large nation that does not manipulate drug prices in one way or another. *See* CALFEE, *supra* note 8, at 37.

143. Though the new law does not specifically allow reimportation from Mexico, several commentators have argued that because the law is vague regarding the chain of distribution, it may be possible that U.S.-made drugs could be exported to an authorized country, and then back into the United States. *See* 146 CONG. REC. S10, 669 (giving the statement of Sen. Harkins concerning fears that several intermediate distributors may circumvent the country exclusion provision); *see also* 21 U.S.C. § 384(f) (2000) (providing the country limitation is subject to the HHS Secretary's discretion).

144. *See Danzon*, *supra* note 37, at 32.

145. *See id.* at 33.

146. *See id.* at 34.

the Mexican market, but it may pose a risk to specific pharmaceuticals that carry high profit margins.

These ancillary effects of parallel trade (i.e., the exportation of price controls and possible abandonment of markets in lower income nations) should be thoroughly explored before MEDSA is implemented.

3. Vertical Restraints and Self Regulation

It has been long held that vertical restraints on distribution have facilitated the ability of producers to increase information and services to consumers.[147] These services may be in the form of warranties or manufacturers' guarantees, but may also exist as quality controls.[148] Within a closed and closely monitored distribution network, pharmaceutical manufacturers can ensure that consumers receive drugs that are free from the risks of adulteration or counterfeiting.[149]

The most debated issue regarding MEDSA is the possible consumer health risks created by allowing reimported pharmaceuticals. MEDSA provides broad general guidelines for the HHS Secretary to adopt safety measures to ensure that the resold pharmaceuticals pose no health risks. It is unclear, however, whether these provisions will protect the U.S. public or threaten the internal safety mechanisms already in place within the pharmaceutical industry.

MEDSA states that records regarding the reimported pharmaceuticals are to be provided and maintained by the HHS Secretary.[150] These records include the name of the product and the amount of its active ingredient(s).[151] The records must also include the date it was shipped, the quantity of the shipment, points of origin and destination for the product, the price paid for the product, and the price for which it is sold.[152] A product coming directly from the first foreign recipient of the product from the manufacturer it must be accompanied by documentation stating that the product was statistically sampled and tested and that it meets all U.S. labeling requirements.[153] A product not coming directly from the first foreign recipient of the product from the manufacturer requires accompanying documentation regarding sampling and testing, including complete data derived from all tests necessary to assure that the product is in compliance with established specifications

147. *See Bork*, *supra* note 126; *Posner*, *supra* note 126.
148. *See Bork*, *supra* note 126.
149. *See supra* note 68.
150. 21 U.S.C. § 384(c) (2000).
151. *Id.* § 384(c).
152. *Id.* § 384(d).
153. *Id.* § 384(d)(6).

and standards.[154] The HHS Secretary also has the authority to expand these requirements as he or she sees fit; furthermore, the Secretary may suspend the importation of any product upon "discovery of a pattern of importation of such products or by such importers that is counterfeit or in violation of any requirement pursuant to this section."[155]

Critics have opined that these provisions are logistically inadequate to ensure the safety of U.S. consumers.[156] The broad reporting and testing requirements may overwhelm U.S. customs.[157] Repackaging and relabeling requirements may allow for a high margin of error.[158] Furthermore, allowing restricted parallel imports may increase criminal activity in this area.[159]

Despite these concerns, Commissioner of U.S. Customs Raymond Kelly, during testimony before the House Commerce Committee, stated that the Customs department endorses MEDSA.[160] Commissioner Kelly's testimony, however, also recognized increased safety threats coming from Internet drug companies that ship pharmaceuticals by mail and the increasing threat of counterfeit drugs mixed into legitimate drug shipments.[161] Several letters recorded in the Congressional Record point to safety issues inherent in MEDSA.[162] These letters state that the FDA is substantially behind in its inspection of foreign drugs currently shipped into the United States.[163] The letters also point out concerns with increased criminal activity pursuant to the implementation of MEDSA and possible problems associated with future industry call backs, which may be difficult with attenuated distribution systems.[164]

Success of MEDSA also relies on proper funding of implementing agencies and on providing proper oversight of their duties. MEDSA provides for an initial $23 million in spending to support the new regulatory scheme.[165] The total cost of fully implementing the provisions, however, has been estimated at over $100 million.[166]

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154. *Id.* § 384(d)(7).
155. *Id.* § 384(g).
156. Barfield, *supra* note 35, at 254-55.
157. *See id.*
158. *See id.*
159. *See id.*
160. *See Testimony on Counterfeit Drugs: Hearing Before the House Comm. on Commerce*, Oct. 3, 2000 (statement of commissioner Raymond Kelly).
161. *See id.*
162. *See* 146 CONG. REC. S10, 669, 685-87 (daily ed., Oct. 18, 2000).
163. *See id.*
164. *See id.*
165. *See id.* at 685.
166. This number combines the $23 million in startup funding with an additional $90 million for succeeding years. *See id.*

Without more empirical data regarding the feasibility of establishing the proposed regulations, it is difficult to determine whether the new system can monitor pharmaceutical distribution as well as the industry. This limitation, if for no other reason, should cause Congress and the new HHS Secretary to pause before implementing the program.

V. CONCLUSION

It is uncertain whether the reimportation of pharmaceuticals will survive as a potent political issue during the 107th Congress. As an abstract political promise in the heat of a well-fought campaign, MEDSA may have looked like a step toward lower priced health care in October, 2000. The truth is that the outcome of such a plan seems to be less certain.

Though not implemented, the fact that MEDSA was passed into law is a telling sign of where the U.S. Congress stands regarding parallel trade. In light of several recent court opinions touching on this issue and the international climate regarding parallel trade, MEDSA will remain an example of the erosion of domestic apprehension toward parallel trade. Therefore, without significant judicial opposition to the reimportation of foreign purchased pharmaceuticals, the issue will turn on the uncertain effects of MEDSA on U.S. consumer pricing for pharmaceuticals.

With numerous variables fluctuating across the two-year implementation period, it is difficult, at best, to determine the overall cost-benefit trade-off of MEDSA. Central to the unresolved dispute is the lack of empirical data that may predict both the outcome regarding the market price of pharmaceuticals, and whether the contemplated regulatory scheme will ensure safe products. The safety issue will most likely carry the day, as it did in 1987.