## University of Florida Journal of Law & Public Policy

Volume 16 | Issue 1

Article 4

2005

# What's at Stake in Pharmaceutical Reimportation: The Costs in Terms of Life Years, Lives, and Dollars

Joseph H. Golec

John A. Vernon

Follow this and additional works at: https://scholarship.law.ufl.edu/jlpp

#### **Recommended Citation**

Golec, Joseph H. and Vernon, John A. (2005) "What's at Stake in Pharmaceutical Reimportation: The Costs in Terms of Life Years, Lives, and Dollars," *University of Florida Journal of Law & Public Policy*: Vol. 16: Iss. 1, Article 4.

Available at: https://scholarship.law.ufl.edu/jlpp/vol16/iss1/4

This Article is brought to you for free and open access by UF Law Scholarship Repository. It has been accepted for inclusion in University of Florida Journal of Law & Public Policy by an authorized editor of UF Law Scholarship Repository. For more information, please contact kaleita@law.ufl.edu.

## ESSAY

## WHAT'S AT STAKE IN PHARMACEUTICAL REIMPORTATION: THE COSTS IN TERMS OF LIFE YEARS, LIVES, AND DOLLARS

#### Joseph H. Golec\* & John A. Vernon\*\*

| I.   | INTRODUCTION  |
|------|---|
| П.   | The Conflict between Short-Term and Long-Term<br>Consumer Interests |
| III. | Implications for R&D Investment and   Consumer Health   141         |
| IV.  | QUANTIFYING THE ECONOMIC COSTS OF<br>PHARMACEUTICAL REIMPORTATION   |
| V.   | CONCLUSION  |

#### I. INTRODUCTION

Recent policy debates over the reimportation of pharmaceuticals from Canada and Europe have not quantified the potential long-term effects of such a policy.<sup>1</sup> Because Canadian and European drug prices are currently regulated<sup>2</sup> while U.S. prices are not,<sup>3</sup> the reimportation of drugs from such markets effectively imports foreign price controls. As a result, the

<sup>\*</sup> Associate Professor of Finance, University of Connecticut School of Business; Ph.D. 1987, Washington University; B.A. 1980, Trinity College.

**<sup>\*\*</sup>** Assistant Professor of Finance, University of Connecticut School of Business; Ph.D. 2003, University of Pennsylvania; Ph.D. 2000, City University of London; B.A. 1992, Duke University. This Article formed the basis for Vernon's testimony before the U.S. Senate Committee on Health, Education, Labor, and Pensions on May 20, 2004.

<sup>1.</sup> See, e.g., Tech Central Station, Milton Friedman and the Reimportation Debate (transcript of Jan. 27, 2004 debate), at http://www.techcentralstation.com/020204D.html (last visited Sept. 3, 2004); American Enterprise Institute for Public Policy Research, Unrestricted Prescription-Drug Importation from Canada and Elsewhere (Oct. 2003) (transcript of Oct. 2, 2003 debate), at http://www.aei.org/events/filter.,eventID.634/summary.asp.

<sup>2.</sup> Patricia M. Danzon, Making Sense of Drug Prices, REGULATION, Spring 2000, at 56-57.

<sup>3.</sup> John A. Vernon, Drug Research and Price Controls, REGULATION, Winter 2003, at 22.

profitability of pharmaceutical research and development (R&D) investment will fall.<sup>4</sup> And because expected profitability is the primary determinant of firm R&D investment in the pharmaceutical industry,<sup>5</sup> R&D spending and new drug discoveries will fall as well.<sup>6</sup> But by how much will R&D spending fall, and how much will this cost future generations in terms of forgone years of life? This Article addresses and attempts to answer these questions.

Industry critics claim pharmaceutical companies earn excess profits that are more than enough to fund their R&D in the face of reimported drugs.<sup>7</sup> These critics expect little, if any, effect on R&D and new drug discoveries.<sup>8</sup> Conversely, pharmaceutical executives assert that pharmaceutical innovation will be decimated by reimportation.<sup>9</sup> However, consumer groups and industry critics typically focus on the huge profits earned by successful new drugs and ignore the costs of failed research,<sup>10</sup> while pharmaceutical firms seldom publicize their strategies for coping with price regulation.<sup>11</sup> Canada and European countries offer a patchwork of price regulations<sup>12</sup> and reimportation has been legal there for many years. This Article uses the European experience as a template to benchmark the likely effects of legalized reimportation on the United

5. Henry G. Grabowski & John M. Vernon, *The Determinants of Pharmaceutical Research and Development Expenditures*, 10 J. EVOLUTIONARY ECON. 201, 201-02 (2000); Vernon, *supra* note 3, at 22-23; Vernon, *supra* note 4.

6. Grabowski & Vernon, *supra* note 5, at 201-15; Vernon, *supra* note 3; Vernon, *supra* note 4.

7. See Public Citizen, Statement on "International Drug Parity Act of 1999" (H.R. 1885): Safe Drug Reimportation Law Could Save Consumers Billions, CONGRESS WATCH, June 9, 1999, at www.citizen.org/congress/reform/archives/106congress/reimport/articles.cfm?ID=1008 (last visited Sept. 17, 2004).

8. KATHERINE GREIDER, THE BIG FIX: HOW THE PHARMACEUTICAL INDUSTRY RIPS OFF American Consumers (Public Affairs Reports) 43-61 (2003).

9. John K. Iglehart, An Industry Under Siege Mounts Counter Attack, 23 HEALTH AFF. 7-8 (2004).

10. GREIDER, supra note 8, at 43-61.

11. For insight into the activities of major pharmaceutical firms in Britain, see The Association of the British Pharmaceutical Industry, Department of Health Discussion Paper: The Pharmaceutical Price Regulation Scheme (Sept. 2003), *at* http://www.abpi.org.uk/information/pdfs/PPRS-ABPI-Response-To-DOH.pdf (last visited Aug. 24, 2004).

12. PATRICIA M. DANZON, PHARMACEUTICAL PRICE REGULATION: NATIONAL POLICIES VS. GLOBAL INTERESTS 15-29 (1997).

<sup>4.</sup> Firms undertake R&D investment because of expected future returns from these efforts. As profits fall, so will the level of R&D because it is no longer as attractive an investment. See, e.g., John A. Vernon, Examining the Link Between Price Regulation, Re-importation, and R&D Investment, 13 HEALTH ECON. (forthcoming 2004), available at http://www3.interscience.wiley. com/cgi-bin/fulltext/108561688/PDFSTART (last visited Oct. 26, 2004).

States. The expected costs are not devastating, but they are substantial and should be weighed carefully against the benefits.

The legalization of pharmaceutical reimportation from Canada and Europe could significantly diminish the incentives to invest in the risky business of pharmaceutical R&D.<sup>13</sup> A decline in R&D, or even a decline in the growth of R&D, will result in fewer future drug discoveries.<sup>14</sup> Indeed, the threat of reimportation may have already affected pharmaceutical firms' R&D decisions. Because R&D investment is long-lived, forward-thinking firms make investment decisions today based upon expectations of profitability well into the future.<sup>15</sup> The average growth rate in total R&D for 2002 and 2003 was 5.6% compared to 13.4% over the last 33 years.<sup>16</sup> A similar decline in R&D growth occurred in response to the threat of price regulation during the Clinton Administration even though the health care reform act<sup>17</sup> never passed.<sup>18</sup>

Recent evidence documents the tremendous value generated by medical research, especially pharmaceutical R&D,<sup>19</sup> and this evidence concludes that the United States may already be under-investing in R&D.<sup>20</sup> While the reimportation of price-regulated pharmaceuticals from abroad could generate short-term economic benefits for U.S. consumers,<sup>21</sup> the long-term costs are substantial. Furthermore, the European experience with reimportation shows that the benefits can be small due to additional

16. PhRMA, supra note 13.

<sup>13.</sup> For insight into just how expensive and risky is the business of pharmaceutical R&D, see Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003); PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PROFILE PHARMACEUTICAL INDUSTRY 2-4 (2004) [hereinafter PhRMA], *at* http://www.phrma.org/publications/2004-03-31.937.pdf (last visited Oct. 26, 2004).

<sup>14.</sup> Joseph H. Golec & John A. Vernon, *Pharmaceutical Reimportation: The European Experience — What the United States Can Expect*, MANAGED CARE, June 2004, at 26-29.

<sup>15.</sup> RICHARD A. BREALEY & STEWART C. MYERS, PRINCIPLES OF CORPORATE FINANCE 311-36 (2003).

<sup>17.</sup> Joseph Golec, Shantaram Hegde & John Vernon, *Pharmaceutical Stock Price Reactions* to Price Constraint Threats and Firm-Level R & D Spending, Univ. of Conn., Dep't of Fin. Working Paper.

<sup>18.</sup> Frank R. Lichtenberg, *Public Policy and Innovation in the U.S. Pharmaceutical Industry, in* PUBLIC POLICY AND THE ECONOMICS OF ENTREPRENEURSHIP 83, 97-107 (Douglas Holtz-Eakin & Harvey S. Rosen eds., 2004).

<sup>19.</sup> FRANK R. LICHTENBERG, SOURCES OF U.S. LONGEVITY INCREASE, 1960-1997, (Nat'l Bureau of Econ. Research, Working Paper No. 8755, 2002).

<sup>20.</sup> KEVIN M. MURPHY & ROBERT H. TOPEL, MEASURING THE GAINS FROM MEDICAL RESEARCH (2003).

<sup>21.</sup> For example, short-term economic benefits for consumers include saving dollars on prescription drugs, which could be spent on other items such as food, clothing, or shelter.

inspection costs, repackaging costs, import costs and sufficient profit for the importer.<sup>22</sup>

Part II of this Article describes the economic basis for the conflict between short-term and long-term consumer interests and how the price outcome impacts a pharmaceutical firm's investment decision. Conflict resolution in favor of short-term interests (reimportation) reduces pharmaceutical prices, particularly for high-margin drugs that are likely to attract the greatest reimportation.<sup>23</sup> Pharmaceutical firms will respond by devoting fewer resources to new pharmaceutical R&D.<sup>24</sup> Part III uses earlier empirical work to estimate how much they will cut R&D.<sup>25</sup> Given the productivity of R&D, this leads to fewer new pharmaceutical and biotechnology products.<sup>26</sup> Because the cost of the number of new drugs not researched or developed is relatively intangible, in Part IV these economic costs are restated in terms of human life years lost. Human life years lost are the years of life future generations will not enjoy because some drugs are not developed or are delayed in being produced. While such estimates are contingent upon a number of assumptions, the human costs of reduced health status of future generations are put on equal footing with the human benefits of greater drug affordability to current consumers.<sup>27</sup> Part V concludes that reimportation has the potential to impart significant economic costs on society.

#### II. THE CONFLICT BETWEEN SHORT-TERM AND LONG-TERM CONSUMER INTERESTS

Firms allocate resources to R&D activities based on their expected returns and costs.<sup>28</sup> The degree to which a firm can appropriate the economic value of a new invention or pharmaceutical product plays a central role in the expected returns to R&D.<sup>29</sup> New pharmaceutical and

22. PANOS KANAVOS ET AL., THE ECONOMIC IMPACT OF PHARMACEUTICAL PARALLEL TRADE IN EUROPEAN UNION MEMBER STATES: A STAKEHOLDER ANALYSIS, (London Sch. Econ. & Pol. Sci., Special Research 2004).

23. DANZON, supra note 12, at 46-64.

24. Grabowski & Vernon, supra note 5; Vernon, supra note 3; Vernon, supra note 4.

25. Vernon, supra note 4.

26. DiMasi et al., supra note 13.

27. Without translating these costs into life years lost and dollars, it is difficult to appreciate what nonresearch or developed drug innovations will mean to society. Thus, for the purposes of this Article "equal footing" refers to a more tangible measure of these costs, which can be more readily appreciated.

28. BREALEY & MYERS, supra note 15, at 311-36.

29. Grabowski & Vernon, supra note 5; Vernon, supra note 3; Vernon, supra note 4.

biotechnology products are information products much like books or computer software. The fixed costs of discovery are substantial: firms spend more than ten years and hundreds of millions of dollars to obtain *information* about a new chemical or biological structure.<sup>30</sup> But once approved for marketing the marginal manufacturing cost of a new pill is often quite small.<sup>31</sup> From a short-term perspective, price should be set low to reflect low marginal manufacturing cost.<sup>32</sup> However, this entirely ignores the fixed costs of discovery.<sup>33</sup> From a long-term perspective, low prices eliminate the incentive for creation of the product in the first place.<sup>34</sup>

The creation of property rights via limited-time patents is an attempt to balance the short-term and long-term economic forces.<sup>35</sup> A higher price for a limited time reduces the availability or affordability to current customers but provides a profit incentive for innovators to provide new pharmaceuticals.<sup>36</sup> This fundamental tradeoff was made famous by Nobel laureate Kenneth Arrow:

Information is a commodity with peculiar attributes, particularly embarrassing for the achievement of optimal allocation. In the first place, any information obtained, say a new method of production, should, from the welfare point of view, be available free of charge (apart from the cost of transmitting information). This insures [sic] optimal utilization of the information but of course provides no incentive for investment in research. . . . In a free enterprise economy, inventive activity is supported by using the invention to create property rights; precisely to the extent that is successful, there is an underutilization of the information.<sup>37</sup>

Limited patent protection and the right of a manufacturer to price and distribute its product as it sees fit are attempts to balance short-term and long-term forces. Reimportation constrains a manufacturer's freedom to

35. *Id*.

<sup>30.</sup> DiMasi et al., supra note 13.

<sup>31.</sup> The True Cost of Drug Manufacturing, *at* http://www.prwatch.org/forum/archive/index. php/t-4282.html (last visited Aug. 24, 2004).

<sup>32.</sup> This is a basic principle of welfare economics.

<sup>33.</sup> DiMasi et al., supra note 13.

<sup>34.</sup> Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention, in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609-25 (Nat'l Bureau Econ. Research ed., 1962).

<sup>36.</sup> This assertion is derived from basic investment theory. See BREALEY & MYERS, supra note 15, at 311-36.

<sup>37.</sup> Arrow, supra note 34, at 616-17.

price and distribute its product.<sup>38</sup> Reimportation also makes patents much less valuable and reduces the number of new innovations.<sup>39</sup>

This tradeoff is represented diagrammatically in Exhibit 1. Here, lower prices (shown to the left of the socially optimal price) reduce costs to current customers but stifle innovation and increase long-term costs to future consumers. From a societal perspective, the objective is to minimize the sum of the two costs. Limited patents provide the balance mechanism and reimportation upsets the balance in favor of the short-term.

## Exhibit 1:

#### The Tradeoff Between Short-Run and Long-Run Costs



**Economic Costs** 

Unfortunately, in policy debates, the short-term is often given the heaviest weight.<sup>40</sup> This is not entirely surprising due to the fact that the short-term benefits and costs are more tangible and immediately

<sup>38.</sup> Golec & Vernon, supra note 14.

<sup>39.</sup> Id.

<sup>40.</sup> Sally C. Pipes, President and CEO, Pacific Research Institute, Drug Importation — The Year's Hottest Policy Debate, Speech Presented to Eli Lilly Corporation (Oct. 14, 2003), *at* http://www.pacificresearch.org/pub/sab/entrep/speech\_sally\_reimportation.html (last visited Aug. 24, 2004).

recognizable than long-term benefits and costs. Moreover, it is difficult to anticipate which medicines or innovations will be sacrificed in the future to pay for greater access to today's medicines.

#### III. IMPLICATIONS FOR R&D INVESTMENT AND CONSUMER HEALTH

There are two mechanisms through which reimportation can impinge upon a firm's decision to invest in pharmaceutical R&D: 1) an expectedprofitability effect; and 2) a supply-of-funds effect. The expectedprofitability effect is the idea that greater expected profit margin encourages greater investment.<sup>41</sup> The supply-of-funds effect represents that internally-generated cash flows provide cheaper funds than funds raised in the capital markets where firms must pay fees to issue new securities.<sup>42</sup> Internal funds generated from cash flows are a particularly important determinant of pharmaceutical R&D investment.<sup>43</sup>

These two effects play a major role in a firm's decision to allocate resources to pharmaceutical R&D.<sup>44</sup> Exhibit 2<sup>45</sup> is useful in illustrating the causal links between the legalization of reimportation and the costs of such a policy in terms of consumer health and life years lost. It is critical to note that this sequence assumes the legalization of reimportation is enforced on a large scale and that firms are not able to circumvent the system through,

42. For example, firms typically pay issuance costs of between three and ten percent of the value of the funds raised when they bring equity securities to market but they do not pay issuance costs for internally-generated equity. For more details on issuance costs and other reasons why internal funds are a cheaper source of finance see R. Glenn Hubbard, *Capital-Market Imperfections and Investment*, 36 J. ECON. LITERATURE 193 (1998).

43. Grabowski, supra note 41; Grabowski & Vernon, Determinants, supra note 41; Grabowski & Vernon, New Look, supra note 41.

44. Scherer, supra note 41; Giaccotto et al., supra note 41; Frank R. Lichtenberg, Probing the Link Between Gross Profitability and R&D Spending, 20 HEALTH AFF. 221-22 (2001).

45. This detail model is from an earlier publication. See Vernon, supra note 4.

<sup>41.</sup> Henry G. Grabowski, The Determinants of Industrial Research and Development: A Study of the Chemical, Drug, and Petroleum Industries, 76 J. POL. ECON. (1968); Henry G. Grabowski & John M. Vernon, The Determinants of R&D Expenditures in the Pharmaceutical Industry, in DRUGS AND HEALTH (Robert Helms ed., 1981) [herinafter Grabowski & Vernon, Determinants]; Henry G. Grabowski & John M. Vernon, A New Look at the Returns and Risks to Pharmaceutical R&D, 36 MGMT. SCI. 804 (1990) [hereinafter Grabowski & Vernon, New Look]; F.M. Scherer, The Link between Gross Profitability and Pharmaceutical R&D Spending, 20 HEALTH AFF. 216 (2001); Carmelo Giaccotto et al., Explaining Pharmaceutical R&D Growth Rates at the Industry Level: New Perspectives and Insights (AEI-Brookings Joint Ctr. For Reg. Stud., Related Publication 03-31), at http://www.aei.brookings.org/admin/authorpdfs/page.php?id=312 (last visited Oct. 26, 2004).

for example, restricting exports to foreign markets or altering dosages in drugs. Thus, the assumption is reimportation will result in foreign prices prevailing in the U.S. market. Estimates in this Article detail the long-term economic costs associated with the attainment of the reimportation policy objective.

#### Exhibit 2

#### Likely Sequence of Events Following the Legalization of Reimportation



Exhibit 2 illustrates how estimates of reimportation costs require one to capture the effects of two sequences of events.<sup>46</sup> Estimates are provided for the sequences labeled Sequence A and Sequence B in Exhibit 2, and then are combined.<sup>47</sup> This results in an estimate of the long-term costs of reimportation not provided in earlier studies.

## IV. QUANTIFYING THE ECONOMIC COSTS OF PHARMACEUTICAL REIMPORTATION

This Article relies on recent research that measures the significant difference in U.S. and non-U.S. pharmaceutical profit margins and links the expected decrease in profit margin to a drop in R&D to quantify the magnitude of Sequence A.<sup>48</sup> All things remaining equal, legalized reimportation would drive U.S. profit margins down to levels found outside the United States causing R&D investment to decline by between 23-32%.<sup>49</sup> This range is consistent with two other recent studies that attempted to answer the same question while employing different methods.<sup>50</sup> We select –25% as a conservative estimate. Besides being at the lower end of the range, –25% is conservative because reimportation is expected to be greatest for high-margin price-regulated drugs for which price spreads between the United States and, for example, Canada, are greatest. These types of drugs capture the lion's share of R&D spending;<sup>51</sup> therefore, the effect on R&D could easily be greater.

Taking the approach of the earlier model, the effect is measured as a one-time 25% decline in R&D. This assumes that R&D spending is entirely flexible and can be immediately adjusted. This is the simplest

<sup>46.</sup> The link between regulated prices and lower profit margins and lower profitability is supported by numerous studies of the elasticity of demand for pharmaceuticals, in which demand elasticity has consistently been found to be inelastic. See N. Edward Coulson & Bruce C. Stuart, Insurance Choice and the Demand for Prescription Drugs, 61 S. ECON. J. 1146-57 (1995).

<sup>47.</sup> LICHTENBERG, *supra* note 19; FRANK R. LICHTENBERG, THE IMPACT OF NEW DRUG LAUNCHES ON LONGEVITY: EVIDENCE FROM LONGITUDINAL, DISEASE-LEVEL DATA FROM 52 COUNTRIES, 1982-2001 (Nat'l Bureau of Econ. Research, Working Paper No. 9754, 2003); Vernon, *supra* note 4.

<sup>48.</sup> John A. Vernon, *The Relationship Between Price Regulation and Pharmaceutical Profit* Margins, 10 APPLIED ECON. LETTERS 467 (2003); Vernon, *supra* note 4.

<sup>49.</sup> This is a smaller decline than found in Vernon's *Drug Research and Price Controls*, which considered a longer time period and used a different model specification; thus, it may be reasonable to view this estimate as conservative. Vernon, *supra* note 3.

<sup>50.</sup> Giaccotto et al., supra note 41; John Vernon, Simulating the Impact of Price Regulation on Pharmaceutical Innovation, 1 PHARMACEUTICAL DEV. & REG. 55 (2003).

<sup>51.</sup> DiMasi et al., supra note 13, at 172.

approach but an equivalent result could be produced by allowing for an initial effect and then allowing delayed effects to spread over a few following years. Alternatively, the long-term growth rate in R&D spending could be reduced (it is held fixed in the calculations below). However either of these methods would be equivalent to a one-time drop of 25%.<sup>52</sup>

Using a figure for R&D spending in 2003 of \$33.2 billion,<sup>53</sup> an immediate 25% decline would cut it to \$24.9 billion. Total R&D by the pharmaceutical and biotechnology firms listed on the Compustat database for 2003 is about \$60 billion.<sup>54</sup> The \$33.2 billion figure is conservative because it includes only Pharmaceutical Research and Manufacturers of America member companies (33 companies), and excludes smaller, high-R&D firms.<sup>55</sup> These smaller firms could be more affected than larger firms because they rely on external funding to pay for their R&D.<sup>56</sup> Such funding will not be forthcoming if new and innovative products cannot be priced high enough to earn market-required returns.<sup>57</sup>

The full effect of Sequence A is not just the one-time drop. The smaller research base from which future innovations can be developed must also be considered. A measure of the total foregone R&D due to reimportation should be the sum of the lowered R&D for each year in perpetuity.<sup>58</sup> A proper estimate of this sum requires estimating future differences and discounted to present value. To do this effectively, add the annual differences between \$33.2 billion growing at 7.5% annually and \$24.9 billion growing at 7.5% annually in perpetuity.<sup>59</sup> This calculation employs the commonly-used model of the discounted present value of a growing perpetuity.

Future foregone R&D dollars should not be treated the same as current forgone R&D dollars. Therefore, discount future foregone R&D at an 11% annual rate so that forgone R&D in the far future adds less to the sum of foregone R&D. This discount rate is conservative because reliable

- 52. Vernon, supra note 3; Vernon, supra note 4.
- 53. PhRMA, supra note 13, at 39.
- 54. Standard and Poors Compustat Files (June 2004 data pull).
- 55. PhRMA, supra note 13, at 39.

56. Most small biotech firms do not have positive cash flows (Standard and Poors Compustat Files).

57. This is because investors require an expected rate of return on their investments. With reimportation or price controls many biotechnology investments will not generate the expected rate of return necessary to compensate potential investors for the riskiness of the investments and funds will not be forthcoming.

58. This result comes from the well-known, constant-growth perpetuity model in finance.

59. Scherer, *supra* note 41, at 217 (estimating that R&D investment by PhRMA members grew at an average annual inflation-adjusted rate of 7.5% between 1962 and 1996).

estimates for the pharmaceutical industry range from 9% to 11%.<sup>60</sup> Given these figures, the cumulative value of foregone R&D is \$237 billion. This is the estimate of the Sequence A effect. The result does not depend upon a specific discount rate or a specific growth rate of R&D. The sole requirement is that the difference between the two rates be equal to 3.5 percentage points.<sup>61</sup> If this difference was only 2.5%, for example, because of a 10% discount rate, the Sequence A effect increases foregone R&D to \$332 billion.

The more difficult question to answer is what the decline in R&D will mean for new drug innovation. The answer depends on two factors: the marginal productivity of R&D and the time horizon considered. Recent work maps the relationship from "lost" R&D investment into "lost" life years — i.e., Sequence B.<sup>62</sup> Specifically, estimates of pharmaceutical R&D productivity show that to gain one life year, the cost in R&D expenditures is between \$1,345 and \$4,500.<sup>63</sup> While these estimates are historical productivities, it seems reasonable to use these approximations in the absence of information on future productivities. Although future productivities could be higher or lower, discounting in the perpetuity model will reduce the effect that productivities in the far future have on our final result. Based upon a figure of \$3,000 R&D per life year, the \$237 billion in forgone R&D investment translates into 79 million life years lost. Using, for example, a life expectancy of 77.2 years in the United States for 2001 as reported by the Center for Disease Control,<sup>64</sup> this cost translates into slightly more than one million lost lives.

One further step is to translate these "human" costs into a dollar value. This value can be compared to the dollar value of the short-term benefits. We present a range of dollar costs in Exhibit 3 based upon estimates of the dollar value of a human life. Although estimating the value of a human life is common for actuaries, we assume that settling on any one figure could be controversial. Consequently, we show results for a range of \$50,000 to

<sup>60.</sup> DiMasi et al., *supra* note 13, at 153; Stewart C. Myers & Lakshmi Shyam-Sunder, *Measuring Pharmaceutical Industry Risk and the Cost of Capital, in* COMPETITIVE STRATEGIES IN THE PHARMACEUTICAL INDUSTRY 208, 222 (Robert M. Helms ed., 1996).

<sup>61.</sup> The pharmaceutical industry has managed robust growth for many years. The industry might not age like some other industries because demand for the product increases with income and wealth, both of which rise over time. But if growth were to slow because of industry aging, risk would fall as well. Therefore, discount rate and the growth rate could move one for one, maintaining the 3.5 percentage point difference.

<sup>62.</sup> LICHTENBERG, supra note 19; LICHTENBERG, supra note 47.

<sup>63.</sup> LICHTENBERG, supra note 19; LICHTENBERG, supra note 47.

<sup>64.</sup> See Centers for Disease Control and Prevention Web Site, at http://www.cdc.gov/nchs/ fastats/lifexpec.htm (last visited Oct. 26, 2004).

\$150,000 for one life year. Recent studies have used \$160,000 and \$150,000. Thus, \$100,000 is conservative.<sup>65</sup> We present results assuming \$50,000 to provide a symmetric lower bound. We also offer estimates based upon a range of one-time R&D decreases of between 20% and 30%. As previously noted, 25% is conservative but we offer a range for comparison.

## Exhibit 3

## The Range of the Dollar Cost of Reimportation by Life-Year Value and One-Time R&D Decrease (in Billions)

|                             | Assumed Value of One Life Year |           |           |
|-----------------------------|--------------------------------|-----------|-----------|
| One-Time<br>R&D<br>Decrease | \$50,000                       | \$100,000 | \$150,000 |
| 30%                         | \$4,743                        | \$9,486   | \$14,229  |
| 25%                         | \$3,950                        | \$7,900   | \$11,850  |
| 20%                         | \$3,166                        | \$6,333   | \$9,500   |

Settling on a 25% R&D decrease and a value of \$100,000 per life year, a conservative estimate of the cost of reimportation is \$7.9 trillion. Clearly, any figure in the table represents substantial costs imposed on society. These costs should be weighted carefully against the benefits. If the costs of legalizing importation exceed the benefits, then such a policy will make society worse off.

#### V. CONCLUSION

This Article provides estimates of the costs of legalizing reimportation of pharmaceuticals and focuses on these long-term costs to future consumers because they are given less attention in policy debates compared to the short-term benefits enjoyed by current consumers. From

65. MURPHY & TOPEL, supra note 20; LICHTENBERG, supra note 19.

Medicare to Social Security to tax cuts, the political system often supports short-term benefits with less regard to long-term costs.<sup>66</sup>

Measuring the economic benefits gained from legalizing pharmaceutical importation is beyond the scope of this Article. Nevertheless, the current evidence from Europe, where reimportation has been encouraged and grown significantly in the 1990s, shows that European consumers have not greatly benefited.<sup>67</sup> A comprehensive study of European reimportation shows that most of the margin between the high-priced importing countries and low-priced exporting countries is eaten up by the costs and profits of the firms doing the reimporting.<sup>68</sup> Furthermore, they find unintended cost of shortages in exporting counties.<sup>69</sup> That is, some consumers in exporting countries are no longer supplied because the new drug export companies take supplies from their country to sell abroad at higher prices.<sup>70</sup>

The size of the potential benefits in the United States is unknown, but at a minimum it is clear that the combined costs of exportation by the original manufacturer and reimportation by another firm is wasteful to society. This Article provides documentation of large economic costs of reimportation through its effect on research and development. At a cost of 79 million life years lost or \$7.9 trillion in dollar terms, which is equivalent to almost three quarters of one year's U.S. GNP, the hurdle for economic support for reimportation is quite high.

<sup>66.</sup> Edward J. Kane, Dynamic Inconsistency of Capital Forbearance: Long-Run vs. Short-Run Effects of Too-Big-To-Fail Policymaking (Aug. 15, 2000) (paper presented at 8th Central Banking Seminar of the International Monetary Fund), *available at* http://www2.bc.edu/~kaneeb/Dynamic. pdf (last visited Sept. 9, 2004).

<sup>67.</sup> KANAVOS ET AL., supra note 22.

<sup>68.</sup> Id.

<sup>69.</sup> Id.

<sup>70.</sup> Id.

.