

# Rethinking Global Pharmaceutical Policy

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## Chapter 5: Differential Pricing

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If each drug manufacturer charged each consumer of its products no more than the amount that that consumer was able and willing to pay, then what we have been calling the “access problem” would disappear. All consumers throughout the world would be able to obtain the vaccines and medicines they need. By increasing sales of drugs to poor populations in developing countries, the same strategy would also help, at least modestly, to solve the “incentive problem,” because it would expand markets for drugs that address neglected diseases and thus would increase manufacturers’ willingness to conduct research in those areas. Manufacturers would be happy, because their profits would increase. We would be happy, because an enlarged set of vaccines and medicines would now be accessible to everyone.

Unfortunately, full implementation of this seemingly straightforward approach is impossible, for reasons that will soon become apparent. Partial implementation of the approach is feasible, but could have serious negative side effects.

The thesis of this chapter is that, despite these risks, we should strive to increase the use of this general strategy with respect to pharmaceutical products. Our defense of this approach begins with a brief review of the economic theory associated with differential pricing. We then examine the degree to which pharmaceutical firms already employ this practice and the factors that influence their behavior. Finally and most importantly, we identify a set of legal and institutional reforms that could enable greater use of this technique by pharmaceutical firms, while preventing them from employing it in ways we would find pernicious.

### A. The Theory and Practice of Differential Pricing<sup>1</sup>

The most straightforward form of differential pricing consists of charging different consumers different prices for access to the same good or service. A classic illustration is the pricing strategy of many private colleges and universities in the United States. Typically, they charge very high tuitions, but then award needs-based scholarships to students whose families cannot afford to pay that much.<sup>2</sup> The net result: the cost of attending those institutions varies with students’ wealth and income.

A more subtle form consists of charging different consumers different prices for different versions of the same good or service when the price gap is larger than can be

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<sup>1</sup> This section is adapted from William W. Fisher, III, “When Should We Permit Differential Pricing of Information?,” *UCLA Law Review* 55 (2007). For other general treatments of this topic, see Michael J. Meurer, “Copyright Law and Price Discrimination,” *Cardozo Law Review* 23 (2001); George Norman, *The Economics of Price Discrimination* (Northampton, Mass.: Edward Elgar Publishing, 1999); Louis Philips, *The Economics of Price Discrimination* (Cambridge: Cambridge University Press, 1983).

<sup>2</sup> See Richard Vedder, “Why Does College Cost So Much?,” *Wall St. J.*, August 25, 2005, at A10.

explained by differences in the costs of the versions. The classic illustration of the latter variant is the pricing of business-class and coach tickets on airlines. The magnitude of the premium that airlines charge for the former cannot be explained on the basis of the extra costs associated with a wide leather seat, better food, and more attentive service.

Ordinarily, four conditions are necessary to make differential pricing feasible and profitable. First, the firm must have market power. In other words, there must exist no readily available, equally satisfactory substitutes for the good or service the firm is selling. Otherwise, customers from whom the firm seeks to extract a high price will defect to competitors.<sup>3</sup>

Second, the firm must be able to prevent – or at least limit – arbitrage. In other words, it must be able to prevent customers to whom it sells goods or services at a low price from reselling them, either directly or with the aid of intermediaries, to customers from whom the firm is seeking to extract a high price.

Third, the value that different customers place upon the firms' product or service must vary. Otherwise charging them different prices would be pointless.

Fourth, the firm must be able to differentiate the customers who are able and willing to spend more from the customers who are able and willing to spend less. There are three main ways in which such differentiation can be achieved. In what economists refer to as “first-degree” price discrimination, the firm gathers information about individual buyers and attempts to charge each one the most that he or she is able and willing to pay for the good or service in question. In “second-degree” price discrimination, the seller does not know how much buyers are able and willing to pay, but induces them to reveal their resources or preferences through their purchasing decisions. Among the varieties of second-degree discrimination are volume discounts; “versioning” (exemplified by the aforementioned differentiation by airlines of coach and business-class service and by the customary price differential between hardcover and paperback copies of books<sup>4</sup>); and temporal price discrimination (exemplified by the “windowing” system through which most Hollywood movies traditionally were marketed<sup>5</sup>). Finally, in “third degree” price discrimination, the seller does not know the purchasing power of individual buyers, but is able to separate its customers into groups using a criterion that operates as a rough proxy for wealth or eagerness. Classic forms of third-degree discrimination are: student discounts; senior discounts; and geographic price discrimination.<sup>6</sup>

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<sup>3</sup> For analysis of a rare exception to the generalization that market power is a precondition for price discrimination, see Michael Levine, "Price Discrimination without Market Power," *Yale Journal on Regulation* 19 (2002).

<sup>4</sup> See Sifronis K. Clerides, "Book Value: Intertemporal Pricing and Quality Discrimination in the U.S. Market for Books," *International Journal of Industrial Organization* 20 (2002).

<sup>5</sup> A more extensive discussion of the “windowing” system may be found in William W. Fisher, III, *Promises to Keep: Technology, Law, and the Future of Entertainment* (Stanford University Press, 2004), 67-69.

<sup>6</sup> Among the myriad examples of geographic discrimination are the “region coding” system employed by the manufacturers and distributors of digital versatile discs (DVDs) and blu-ray discs, which enables them to charge different prices in different parts of the world (see [http://en.wikipedia.org/wiki/DVD\\_region](http://en.wikipedia.org/wiki/DVD_region); Hugh Bennett, *The Authoritative Blu-ray Disc (BD) FAQ: X. Copying Deterrents and Content Protection*,

Differential pricing usually benefits the firms that engage in it. By separating the set of potential customers into subsets with different elasticities of demand, and then by selecting the profit-maximizing price for each subset, the firms are able to earn more than they could by offering all of their customers the same price. So long as the resultant increase in revenue exceeds the costs of instituting and administering the scheme, the firms plainly benefit.

Is differential pricing also socially beneficial? In other words, does it redound to the benefit of society at large? That question proves surprisingly difficult to answer. Most economists agree that it's impossible to say, in the abstract, whether differential pricing increases or decreases aggregate social welfare. Rather, whether it is socially beneficial depends upon the character of the markets that the firm seeks to keep separate – and that a ban on the practice would aggregate.<sup>7</sup> Take the simplest case: Suppose that a seller could, if we allow it, divide the universe of its customers into two groups and then charge a different profit-maximizing price in each. It turns out that permitting this conduct will usually (though not invariably) increase the size of the social pie if the seller's total output would, as a result, increase. That, in turn, is more likely to occur where (a) the sub-market with a higher reservation price is larger than the sub-market with a smaller reservation price; (b) the difference between the profit margins possible in the two sub-markets is large; and (c) the demand curves in the sub-markets are concave rather than convex.<sup>8</sup>

The foregoing generalizations – which are now familiar in the economics literature – must be qualified in several respects when the goods or services at issue are shielded by intellectual property rights – patents, copyrights, etc. (Because, as shown in Chapter 2, most new drugs fall into this category, these qualifications are of direct relevance to the subject before us.) The first and perhaps most important qualification is that the “dynamic effects” (meaning the stimulus to innovative activity that results from the increase in monopoly profits caused by differential pricing) may be sufficient to offset the welfare losses that are usually associated with diminished output.<sup>9</sup>

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EMEDIA, Aug. 28, 2006, <http://www.emedialive.com/articles/readarticle.aspx?articleid=11760>) and the sharp differences in the prices that publishers charge for textbooks in different countries (See Christos Cabolis et al., “A Textbook Example of International Price Discrimination” 95 *Economics Letters* 91 (2007), available at <http://www.econ.ucy.ac.cy/~sofronis/pub/TEIPD-EconLet.pdf>).

<sup>7</sup> A slide presentation explicating this generalization may be found at <http://cyber.law.harvard.edu/people/tfisher/PD.ppsx>.

<sup>8</sup> See Yong He and Guang-Zhen Sun, “Income Dispersion and Price Discrimination,” *Pacific Economic Review* 11, no. 1 (2006): 60; Keith E. Maskus, “Parallel Imports in Pharmaceuticals: Implications for Competition and Developing Countries,” (2001): 14; F.M. Scherer, “The Economics of Parallel Trade in Pharmaceutical Products,” (2001), [http://www.wto.org/english/tratop\\_e/trips\\_e/hosbjor\\_presentations\\_e/13scherer\\_e.doc](http://www.wto.org/english/tratop_e/trips_e/hosbjor_presentations_e/13scherer_e.doc); Richard Schmalensee, “Output and Welfare Implications of Monopolistic Third-Degree Price Discrimination,” *American Economic Review* 71, no. 1 (1981); Hal R. Varian, “Price Discrimination and Social Welfare,” *American Economic Review* 75 (1985); “Versioning Information Goods,” (1997), <http://www.ischool.berkeley.edu/~hal/Papers/version.pdf>; W. Kip Viscusi, *Economics of Regulation and Antitrust*, 2d ed. (1995), 290-97. In section B, below, we will address the significance of convex versus concave demand curves.

<sup>9</sup> See Jerry A. Hausman and Jeffrey K. MacKie-Mason, “Price Discrimination and Patent Policy,” *RAND Journal of Economics* 19, no. 2 (1988).; Gene M. Grossman and Edwin L.-C. Lai, “Parallel Imports and Price

The second complication arises from the fact that differential pricing often (though, again, not invariably) results in a progressive redistribution of wealth. The reason: because the occupants of the lower-margin sub-market are usually poorer than the occupants of the higher-margin market. If we assume (i) that the general principle of the diminishing marginal utility of wealth holds for most persons and (ii) that utility curves are randomly distributed within the population of pertinent consumers, then redistribution of wealth “downward” will increase social welfare.<sup>10</sup>

A third complication: If consumption of the good in question results in positive externalities in the weaker of the two sub-markets, then differential pricing may result in an increase in net social welfare even if it does not lead to an increase in total output.<sup>11</sup> To illustrate, suppose (plausibly) that Adobe charged students a lower price for access to Photoshop (a powerful graphics editing software program) than it charged other consumers. It is possible that the positive externalities associated with students’ use of the program (for example, the pleasure reaped by their friends when edited photos are shared with them, or the benefits reaped by their future employers as a result of their enhanced skills) exceed the positive externalities associated with nonstudents’ use. If so, then permitting Adobe to engage in this practice might advance social welfare.

The fourth complication pertains to the likely impact of legal prohibitions on differential pricing. Whether such bans are socially beneficial depends upon what else is permitted – i.e., on the pricing practices that sellers would employ if the ban were implemented.<sup>12</sup> Suppose, for instance, that movie studios, if forbidden to engage in overt third-degree differential pricing in the distribution of their movies, would continue to rely on the traditional “windowing” system. The latter – a form of “temporal” differential pricing – has substantial and well-known disadvantages from the standpoint of social welfare. Most importantly, it forces many consumers to wait long periods of time before they can watch films. Those harms may well be worse than the welfare losses caused by permitting more overt forms of differentiation.<sup>13</sup>

A final complication involves what are sometimes called “psychic externalities.” If a social or economic practice makes people unhappy or angry, the resultant disutilities must be considered in determining whether the practice on balance promotes social welfare.<sup>14</sup> Thus, in determining whether a particular form of differential pricing advances

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Controls," *ibid.* 39 (2008); Meurer, "Copyright Law and Price Discrimination.," Patrick Rey, "The Impact of Parallel Imports on Prescription Medicines," (2003), <http://cepr.org.uk/MEETS/WKCN/6/6613/papers/Rey.pdf>; Stefan Szymanski and Tommaso Valletti, "Parallel Trade, Price Discrimination, Investment, and Price Caps," *Economic Policy* (2005).

<sup>10</sup> This is an old – though still controversial – topic in utilitarian theory. We will address it in much more detail in Chapter 10.

<sup>11</sup> See Takanori Adachi, "Third-Degree Price Discrimination, Consumption Externalities and Social Welfare," *Economica* 72 (2005).

<sup>12</sup> See Sherwin Rosen and Andrew Rosenfield, "Ticket Pricing," *Journal of Law and Economics* 40 (1997): 367-69; Varian, "Versioning Information Goods".

<sup>13</sup> See Fisher, *Promises to Keep*, Chapter 4.

<sup>14</sup> For example, as Frank Michelman showed long ago, an interpretation of the “takings” doctrine that aspires to maximize allocative efficiency must take into account the “demoralization costs” arising out of the dismay

social welfare, one must take into account the extent to which members of the society (and not just potential purchasers of the good or service in question) believe that the practice is exploitative or unfair. Because this variable will turn out to loom large in the context of pharmaceutical pricing, we pause to consider it in more detail.

It turns out that the public at large has strong feelings concerning the legitimacy of differential pricing. Most often, those feelings are hostile. Seeking to extract maximum profit from each individual or each subset of customers is widely considered a form of “gouging” – charging whatever the market will bear – which in turn is generally thought to be immoral. Many anecdotes evince popular hostility toward gouging. (For instance, in 1999 a report that Coca-Cola was testing a vending machine that would increase the price of Coke when the outside temperature rose provoked strong resistance.<sup>15</sup>) Consumers are not the only people who react this way; the same attitude apparently shapes the behavior of sophisticated traders of wholesale goods. For example, a survey of buyers and sellers of bulk electricity found that “[a] price increase under conditions of increased demand was perceived to be significantly less fair than one caused by a shortage in supply.... This is noteworthy because these conditions have traditionally been regarded as normatively equivalent, representing price increases that ration off relatively excess demand.”<sup>16</sup> Social psychologists who examine people’s response to hypothetical scenarios have confirmed the ubiquity of this belief. Kahneman, Knetsch, and Thaler, for example, found widespread adherence to the view that “[i]t is unfair for a firm to exploit an increase in its market power to alter the terms of a reference transaction at the direct expense of a customer, tenant, or employee.... [A]n increase in demand unaccompanied by an increase in costs is not an acceptable reason to raise prices or rents. The opposition to exploitation of market power also entails strong rejection of excessive monopoly gains and of price discrimination.”<sup>17</sup>

More specific factors can either amplify or offset this general hostility to differential pricing. Versioning seems to elicit especially strong hostility. Reducing the quality of a product solely in order to offer it cheaply to poor customers, while maintaining the demand on the part of wealthy customers for the original version is widely considered “cruel and mean.”<sup>18</sup> Another factor that seems to increase consumers’ ire is secrecy.

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experienced by persons who witness uncompensated governmental regulations of private property and believe them to be unjust. See Frank Michelman, "Property, Utility, and Fairness: Comments on the Ethical Foundations of 'Just Compensation' Law," *Harvard Law Review* 80 (1967).

<sup>15</sup> One reader asked, “Would [the system] enable the machine to distinguish between the sun’s rays and a bucket of cold water thrown over it by thirsty Luddites outraged by such a blatant attempt to gouge the consumer on price?” The company quickly abandoned the plan. See John Willman, “Coca-Cola Warms to a New Style of Vending Machine,” *Financial Times*, October 28, 1999, at 1; James Wilson, “Luddites May Dispense with this Price Effect,” *Financial Times*, October 30, 1999, at 12.

<sup>16</sup> Peter R. Dickson and Rosemary Kalapurakal, "The Use and Perceived Fairness of Price-Setting Rules in the Bulk Electricity Market," *Journal of Economic Psychology* 15 (1994): 439.

<sup>17</sup> Daniel Kahneman, Jack L. Knetsch, and Richard Thaler, "Fairness and the Assumptions of Economics," *Journal of Business* 59 (1986): S286. For similar findings, see B. S. Frey and W. W. Pommerehne, "On the Fairness of Pricing – an Empirical Survey among the General Population," *Journal of Economic Behavior and Organization* 20 (1993); R.J. Shiller, M. Boycko, and V. Korobov, "Popular Attitudes toward Free Markets: The Soviet Union and the United States Compared," *American Economic Review* 81 (1991).

<sup>18</sup> The phrase, “cruel and mean” is derived from James Boyle’s condensation of Jules Deputit’s denunciation of versioning by railroads: “[T]he companies, having proved almost cruel to third-class passengers and mean

Charging different consumers different prices without acknowledging as much can provoke rage if the tactic comes to light.<sup>19</sup> Third-degree differential pricing, by contrast, usually raises few hackles – so long as it’s done openly and the criteria used to separate consumers into groups are seen as appropriate. No one protests, for example, when students or senior citizens are admitted to museums for less money than other visitors.

Difficult to reconcile with the foregoing observations is the fact that many people, when assessing the fairness of various pricing schemes, emphasize choice. As long as all consumers have equal access to all variants of a product, and thus the price they pay is determined by their own actions, they do not feel they are treated unfairly.<sup>20</sup> Plainly, this factor suggests they should be happy with versioning and unhappy with third-degree differential pricing, which places them into unequally treated boxes from which they cannot escape.

Finally, popular reactions to differential pricing – like popular reactions to many phenomenon – are heavily affected by the ways in which transactions are “framed.” In part, this involves the way in which unequal prices are described. For instance, a scheme that charges everyone a high standard price, but then gives some people a “discount” is perceived as less unfair than a functionally identical scheme that charges everyone a low standard price and then imposes on some people a “surcharge.” Such “framing” effects are

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to the second-class ones, become lavish in dealing with first-class passengers. Having refused the poor what is necessary, they give the rich what is superfluous.” See James Boyle, “Cruel, Mean, or Lavish? Economic Analysis, Price Discrimination, and Digital Intellectual Property,” *Vanderbilt Law Review* 53 (2000). (quoting Jules Dupuit, *On Tolls and Transport Charges* 23 (International Economic Papers No. 11, Elizabeth Henderson trans., 1962)). The most infamous modern example was the IBM LaserPrinter Series E, which was identical to the standard LaserPrinter except that it contained an additional chip that reduced its output from 10 pages a minute to 5. See Varian, “Versioning Information Goods”. 6. Many other examples of this general strategy are discussed in *ibid.*, 6-7.

<sup>19</sup> A good illustration is the popular reaction to Amazon.com’s brief experiment with “dynamic pricing” – another term for first-degree price discrimination. In the fall of 2000, Amazon began to adjust the prices of a few DVDs, depending on the status of the purchasers. It seems (although most Amazon representatives persisted in denying this) that repeat customers (who could be identified by the Amazon “cookies” on their computers) were quoted higher prices for the films than were new customers. When this practice was revealed on an online DVD Talk Forum, the response of most participants was fierce. “I will never buy another thing from those guys!!!,” declared one. Quoted in David Streitfeld, “On the Web, Price Tags Blur; What You Pay Could Depend on Who You Are,” *Washington Post*, September 27, 2000, at A1. In part, consumers were upset that Amazon had engaged in price discrimination at all. Paul Krugman, for example, observed: “[D]ynamic pricing is ... undeniably unfair: some people pay more just because of who they are.” Krugman, “What Price Fairness?,” *New York Times*, Oct. 4, 2000, at A35. But the flames were plainly fanned by the fact that Amazon had instituted the system surreptitiously. Fumed one contributor, “I find this extremely sneaky and unethical.... This is really really dishonest Amazon.” See Posting of Syndicate to <http://www.dvdtalk.com/forum/archive/index.php/t-62219.html> (Sept. 3, 2000, 16:50 EST). A few others have reacted in the same vein. See, e.g., Posting of Hal2000 to <http://www.dvdtalk.com/forum/archive/index.php/t-62219.html> (Sept. 4, 2000, 2:42 EST) (“[T]heir pricing practices qualify them as the shysters of the internet. These pricing practices are nothing less than opportunistic and deceitful.”); Posting of Count Zero to <http://www.dvdtalk.com/forum/archive/index.php/t-62219.html> (Sept. 4, 2000, 13:14 EST) (“This makes me so !MAD! . . . They can’t get away with this. Absolutely unforgivable!”).

<sup>20</sup> See J. Cox, “Can Differential Prices Be Fair?,” *Journal of Product and Brand Management* 10 (2001); Dickson and Kalapurakal, “Price-Setting in Bulk Electricity.”

also evident in the impact upon consumers' reactions of the ways in which pricing schemes are justified. For good reason, manufacturers try hard to find reasons other than variations in demand to explain why they engage in differential pricing.<sup>21</sup> A third aspect of "framing" is that consumers' views concerning the fairness of prices often depend on the baseline against which those prices are assessed. For example, a price change that increases a firm's profits is often seen as unfair, while a price change that maintains a firm's profits is seen as fair.<sup>22</sup>

To summarize: whether a particular differential-pricing scheme is socially beneficial depends upon a host of variables: the character of the markets that the manufacturer is seeking to differentiate; the degree to which the enhanced profits generated by the scheme stimulate socially beneficial innovative activity in the future; the degree to which the scheme results in progressive redistribution of wealth; whether the sub-markets that would be better served by adoption of the scheme offer opportunities for positive externalities; the characteristics of the marketing strategy that the manufacturer would employ if forbidden to use the scheme; and the degree (if any) to which the scheme, as framed, chafes popular suspicion of differential pricing.

The bottom line: differential pricing almost always benefits manufacturers. Sometimes it also benefits society at large;<sup>23</sup> sometimes not. With these general considerations in mind, we turn our attention to price discrimination with respect to drugs.

## B. Differential Pricing in the Pharmaceutical Industry

Recall that differential pricing ordinarily is possible only when a seller has four things: market power; the ability to control arbitrage; potential consumers who vary in their ability or willingness to pay; and the ability to distinguish among consumers on those axes.

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<sup>21</sup> For example, Doug Ivester, the CEO of Coca-Cola, sought (unsuccessfully, as it turned out) to persuade consumers that making the price of a soda vary with the ambient temperature made sense because the *benefit* of the product to a consumer varied with temperature: "In a final summer championship game when people meet in a stadium to enjoy themselves, the utility of a chilled Coca-Cola is very high. So it is fair it should be more expensive. The machine will simply make this process automatic." Willman, *supra*, at A1.

<sup>22</sup> See Daniel Kahneman, Jack L. Knetsch, and Richard Thaler, "Fairness as a Constraint on Profit-Seeking: Entitlements in the Market," *American Economic Review* 76 (1986). This popular attitude contrasts sharply with the principle that figures prominently in marketing classes in business school: When setting prices, pay no attention to cost (unless, of course, the highest price you can charge is less than your cost, in which case one should exit the market).

<sup>23</sup> Two examples: A careful study by Philip Leslie of discriminatory practices by Broadway theatres revealed that they resulted in a 5% increase in the theatres' profit and no significant offsetting adverse impact on consumer welfare. Phillip Leslie, "Price Discrimination in Broadway Theatre," 35 *RAND Journal of Economics* 520 (2004), available at <http://www.stanford.edu/~pleslie/broadway.pdf>. Similarly, Julie Mortimer's analysis of the evolving efforts of movie studios to differentiate consumer purchasers of DVDs from video stores that buy DVDs in order to rent them to individuals showed that the adoption of overt discriminatory practices by European studios (unhampered by a first-sale doctrine) resulted in substantial net welfare benefits, but that the subsequent development in the United States of a system of revenue-sharing contracts (that did not run afoul the first-sale doctrine) proved even better from a welfare standpoint. See Julie Holland Mortimer, *Price Discrimination and Copyright Law: Evidence From the Introduction of DVDs* (Harvard Inst. of Econ. Research, Working Paper No. 2055, 2004), available at <http://www.econ.yale.edu/seminars/apmicro/am03/mortimer-030508.pdf>

In the pharmaceutical industry, sellers typically are well positioned with respect to the first of these requirements. The manufacturers of patented pioneering drugs usually enjoy market power. By definition, there are no close substitutes for a pioneer, and a patent on a pioneer enables its owner to prevent anyone else from making or selling the drug at issue.<sup>24</sup> But as we saw in Chapter 2, drug manufacturers often enjoy market power even when their products are not pioneers. The clearest manifestation of that power is the capacity of the developers of me-too drugs to sell them for prices well above the costs of producing them.<sup>25</sup> Finally, as we also saw in Chapter 2, even the manufacturers of drugs whose patents have expired continue to enjoy significant market power, as shown by the fact that the prices of formerly patented drugs frequently remain stable when lower-priced generic equivalents become available. The explanation for this counter-intuitive phenomenon seems to lie in a combination of brand loyalty, sustained by aggressive marketing, and the high degree of risk aversion consumers exhibit in contexts implicating their health. In short, the manufacturers of many sorts of drugs enjoy more than enough market power to engage in differential pricing.

Drug manufacturers are in an equally strong position with respect to the third of the three requirements. There are few things people value more than a life-saving drug. As a result, each consumer's willingness to pay for such a drug is very close to his or her ability to pay.<sup>26</sup> In a world characterized by sharp inequalities of wealth, we would expect to find huge variations among consumers in the amounts they will spend – and we do. It is not just life-saving drugs that generate these variations; consumers' reservation prices even for less essential drugs are also highly variable.<sup>27</sup>

Divergence of consumers' ability and willingness to pay is of course not enough; it is also essential that the manufacturers be able to differentiate among those consumers. Once again, it turns out that drug manufacturers are well positioned; several techniques are readily available to them. A relatively simple one is to separate potential customers into subsets using a criterion that correlates in some way with their wealth (and thus their ability to pay). One such criterion is geography. By treating the residents of each country as a distinct market – and then charging higher prices in richer countries – drug manufacturers

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<sup>24</sup> To be sure, if the pioneer offers no health benefits, then the patent will not confer on its holder any market power. But such drugs are unlikely to survive regulatory approval. Even if they did, manufacturers are unlikely to invest the large costs (described in Chapter 3) necessary to secure their approval.

<sup>25</sup> Perhaps the best example of this phenomenon is the stability of the prices for depression drugs even after the pioneer (Prozac) was joined in the market by eight more drugs that are reasonably close therapeutic substitutes (Zoloft, Paxil, Celexa, Effexor, Effexor XR, Serzone, Remeron, and Wellbutrin). See Jie Chen and John A. Rizzo, "Pricing Dynamics and Product Quality: The Case of Antidepressant Drugs," *Empirical Economics* 42 (2012). Today, the companies that manufacture these drugs divide among themselves a global market that generates revenues of approximately \$20 billion per year. See Mary Anne Crandall, *The Expanding Market for Psychotherapeutic Drugs* (Norwalk, CT: Business Communications Company, Inc., 2003), 85-97.

<sup>26</sup> See Jayashree Watal, "Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India under the Wto Trips Agreement," *World Economics* 23, no. 5 (2000).

<sup>27</sup> See Ernst R. Berndt and Joseph P. Newhouse, "Pricing and Reimbursement in U.S. Pharmaceutical Markets," in *Oxford Handbook on the Economics of the Pharmaceutical Industry*, ed. Patricia M. Danzon and Sean Nicholson (Oxford University Press, 2012), 30.



can increase their profits sharply.<sup>28</sup> At least in theory, the manufacturers could subdivide their markets into much smaller geographic pieces. Provinces, states, cities, and even postal codes often differ radically in terms of the average income or wealth of their residents. By making corresponding adjustments in the prices they charge the residents of each unit, drug manufacturers could further enhance their profits. Another criterion that firms in other industries (bus companies, hotels, rental-car companies, and so forth<sup>29</sup>) have used as a rough proxy for wealth is age. Following their lead, drug manufacturers could easily offer their products at lower prices to senior citizens.

Third-degree discrimination schemes of these sorts by no means exhaust the manufacturers' options. Increasingly, they (or the intermediaries through which they sell) have access to rich sources of data that could enable them to engage in first-degree discrimination. This is especially true in developed countries, where the information systems pertaining to health care are rapidly becoming more comprehensive, integrated, and precise. Already those systems contain an extraordinary amount of information about each patient (occupation, insurance coverage, medical history and prognosis, tolerance for pain, penchant for obtaining "second opinions," names of close relatives, and so forth) that could be used to predict that patient's willingness and ability to pay for particular drugs. If the manufacturers (or the companies through which their products were distributed) could gain access to that data, they could institute differential pricing systems that would make the complex pattern of financial-aid awards that private colleges use to engage in differential pricing seem like child's play.

In sum, drug manufacturers interested in engaging in differential pricing are in great shape with respect to three of the four requirements. Their stance on the last front, however, is more complex and equivocal. Sellers in many other industries enjoy various natural defenses against arbitrage. For example, the sellers of highly perishable goods (ice-cream cones, daffodils) and custom-made goods (wedding dresses, portraits) need not worry that arbitrageurs will buy them at low cost from low-margin consumers and resell them to higher-margin consumers. Sellers of services (landscaping, automotive repair) likewise are largely immune to arbitrage. Finally, the sellers of goods that are heavy or bulky and thus expensive to transport can vary their prices considerably without attracting arbitrageurs. The manufacturers of most drugs have none of these natural defenses. With few exceptions,<sup>30</sup> their products have long shelf lives, are standardized (at least with respect to chemical composition), and are small and light and thus easily transported. Finally, their markets are large and lucrative and thus highly attractive to arbitrageurs.<sup>31</sup>

Despite these disadvantages, pharmaceutical firms have managed to erect (or can avail themselves of) several artificial barriers to unauthorized redistributions of their

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<sup>28</sup> See Maskus, "Parallel Imports in Pharmaceuticals."

<sup>29</sup> See [http://frugalliving.about.com/od/frugalseniors/a/Senior\\_Discount.htm](http://frugalliving.about.com/od/frugalseniors/a/Senior_Discount.htm).

<sup>30</sup> One such exception would be vaccines that must be kept cold until the time they are injected. That requirement increases transportation costs and thus raises the barriers to arbitrage somewhat. See Prashant Yadav, "Differential Pricing for Pharmaceuticals," (2010), <http://www.dfid.gov.uk/Documents/publications1/prd/diff-pricing-pharma.pdf>, p. 30.

<sup>31</sup> See Maskus, "Parallel Imports in Pharmaceuticals."

products. None is perfect, but in combination they are sufficient to prevent or curb many forms of arbitrage – and thus to preserve extensive opportunities for differential pricing.

The first of the barriers involves patent law and thus affects the (large and important) subset of drug manufacturers whose products are protected by patents. As we saw in Chapter 2, patent laws typically grant patentees, among other things, the right to prevent others from “selling” or “importing” embodiments of their inventions.<sup>32</sup> However, all jurisdictions temper this seemingly absolute ban with some intertwined exceptions. Those exceptions are commonly known collectively as the “first-sale” doctrine or the “exhaustion” doctrine. In brief, they give purchasers of patented products (or of products that can only be used to practice patented processes) permission to use those products in various ways that otherwise would constitute patent infringement. For example, as one might expect, purchasers of the products are allowed to “use” them as they wish. In most instances, they may rent or resell them to other persons within the country in which they were originally sold. And sometimes they are permitted to export or import the products.

The ambit of this constellation of privileges is highly contested. In the United States, it has fluctuated over time. For most of the twentieth century, it was broadly construed. Authorized sales of patented products generated sharp limitations on the patentees’ ability to control both domestic sales and imports.<sup>33</sup> For a brief period at the end of the century, the scope of the privileges was much diminished by a series of decisions by the lower federal courts.<sup>34</sup> Recently, the Supreme Court has reinstated expansive versions of both the “first-sale” and “exhaustion” privileges. In the *Lexmark* case in 2017, the Court ruled that sale of a patented product exhausts the patentee’s right to enforce restrictions on the use, resale, or importation of that article, even if the patentee make such purported restrictions explicit as part of the original sale.<sup>35</sup>

The positions taken by lawmakers in other countries with respect to the scope of these doctrines vary considerably. For our purposes, the most important issue is whether a patentee may prevent the importation of patented products that the patentee (or its licensee) has sold abroad. (The way this question is most commonly put is: May a patentee prevent “parallel importation”?) As we have seen, the TRIPS Agreement expressly leaves this issue to the discretion of each nation. Somewhat surprisingly, not all countries have yet made clear how they will exercise that discretion. Most of the countries that have done so have selected one of three options. The first is commonly known as “national exhaustion.” This position is the most favorable to patentees, permitting them to prevent

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<sup>32</sup> The pertinent provision of U.S. patent law is typical: “Except as otherwise provided in this title, whoever without authority makes, uses, 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.” 35 U.S.C. 271(a).

<sup>33</sup> See, e.g., *United States v. Univis Lens*, 316 U.S. 241 (1942); *Curtiss Aeroplane & Motor Corp. v. United Aircraft Engineering Corp.*, 266 F. 71, 79-80 (CA2 1920) (exhaustion applies to sales of goods overseas unless patentee forbids reimportation when products are first sold).

<sup>34</sup> See *Mallinkrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 706 (CAFC 1992); *R. Braun Med., Inc. v. Abbott Labs*, 124 F.3d 1419, 1426 (CAFC 1997); *Jazz Photo Corp. v. International Trade Commission*, 264 F.3d 1094 (CAFC 2002); *Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368 (CAFC 2005).

<sup>35</sup> See *Impression Prods., Inc. v. Lexmark Int’l, Inc.*, 137 S. Ct. 1523 (2017).

importation of their products even when the patentees have authorized their sales abroad. At the opposite extreme is “international exhaustion,” which denies to patentees the authority to prevent parallel importation – i.e., to block importation of products sold under their authority anywhere in the world. This is the rule that the U.S. Supreme Court recently adopted. In between these poles lies so-called “regional exhaustion,” which prevents patentees from blocking importation of patented products that have been sold with the patentee’s authority in other countries within a designated region.

Each of these three major positions may be qualified in various ways. For example, some jurisdictions (such as Japan) that adhere to the principle of international exhaustion permit patentees to override that principle by marking their goods with prohibitions on parallel importation; others (such as the United States) refuse to do so. (The former position is sometimes described as “default international exhaustion”; the latter as “per se international exhaustion.”<sup>36</sup>) Similarly, there are several varieties of regional exhaustion. For example, the EU requires all member countries to permit parallel importation from other EU countries<sup>37</sup> (unless a manufacturer has been forced by a compulsory license to offer goods at a particular price in a particular country<sup>38</sup>), but permits each member country to decide for itself whether to permit parallel importation from non-EU countries. Most have decided not to do so, but the United Kingdom, when it was a member of the EU, seems to have been an exception.

The impact of this complex and shifting regime on arbitrage should be apparent. Pharmaceutical firms have greatest freedom to charge high prices for their patented drugs in countries that adhere to national exhaustion, because both customs officials and courts will help them prevent importation of drugs from other countries where the firms are selling them at lower prices. Sets of countries – such as the EU or the Organisation Africaine de la Propriété Intellectuelle in west-central Africa – that adhere to the principle of regional exhaustion make it harder for the firms to engage in price discrimination, because they cannot block importation from other countries in the set. Finally, firms enjoy the least freedom to charge high prices in countries that adhere to international exhaustion.

The second artificial barrier concerns parallel importation of *drugs* – whether they are patented or not. The United States is the premier example of a jurisdiction that restricts imports of pharmaceutical products more severely than imports of other products. Two statutes do the work: The Food, Drug, and Cosmetic Act forbids the importation of drugs not bearing certifications that they were made in specified manufacturing facilities and sold with approved labels.<sup>39</sup> The effect is to empower pharmaceutical companies to block sales in the United States of drugs manufactured elsewhere. The Prescription Drug Marketing Act of 1987 goes even further, forbidding re-importation even of drugs originally manufactured in the United States, unless required for emergency medical

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<sup>36</sup> See Vincent Chiappetta, "Patent Exhaustion: What's It Good For?," *Santa Clara Law Review* 51 (2011).

<sup>37</sup> [Discuss the derogation periods for poor countries or countries originally lacking patent protection – Spain and Portugal before 1995; Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovak Republic, Slovenia after 2004].

<sup>38</sup> See Maskus, "Parallel Imports in Pharmaceuticals," 5.

<sup>39</sup> 21 U.S.C. 355(a) (2004).

care.<sup>40</sup> Periodically during the past 25 years, either Congress or the President has sought to suspend these rules, usually to enable importation of drugs from Canada, but thus far none of these initiatives has come to fruition.<sup>41</sup>

A third barrier to arbitrage consists of a miscellaneous collection of rules that regulate the distribution of drugs. As we saw in Chapter 2, most countries seek to protect their residents against unsafe or ineffective drugs by restricting the circumstances in which they are sold. The most important of those restrictions is the prescription-based system by which many medicines are distributed. In most countries, it is unlawful for patients to obtain certain drugs without attestation by a doctor that the patients need them. This has the effect of sharply limiting one potential source of drugs for arbitrageurs. Other countries only permit licensed distributors to sell pharmaceutical products. Still other countries either fix the profit margins of pharmacies or require pharmacies to share with the government any cost savings they obtain through the use of imported drugs – and thus reduce their incentive to obtain cheaper drugs through parallel importation.<sup>42</sup> None of these regulations forbid arbitrage outright, but they impede it.

Finally, pharmaceutical firms have developed a variety of distribution and marketing systems that raise the costs and thus reduce the incidence of parallel importation of their products. For example, firms sometimes intentionally restrict the supply of drugs they deliver to low-margin countries<sup>43</sup> – although their use of this tactic, at least overtly, is limited by the hazard that, at least in some jurisdictions, it may be deemed anticompetitive.<sup>44</sup> Next, the firms sometimes offer the same drug in different markets at different dosages or in different shapes, capitalizing on the fact that patients accustomed to taking a drug in one format are often reluctant to switch to another format. Finally, they

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<sup>40</sup> Pub. L. No. 100-293, 102 Stat. 95 (1987). The pertinent provision is codified as 21 U.S.C. 381(d)(1) (2004).

<sup>41</sup> In 2000, the U.S. Congress seemed to carve a major exception out of this rule, permitting parallel importation from Canada and Mexico, provided that doing so would pose “no additional risk to the public’s health and safety.” However, the Clinton administration concluded that the exception would pose unwarranted safety risks and did not permit the law to go into effect. See “In a turnaround, White House Kills Drug-Import Plan,” *New York Times* (December 27, 2000) at 1. The Bush Administration subsequently took the same position. See Robert Pear, “Plan to Import Drugs from Canada Passes in Senate, but Bush Declines to Carry it Out,” *New York Times* (July 18, 2002), <http://www.nytimes.com/2002/07/18/us/plan-import-drugs-canada-passes-senate-but-bush-declines-carry-it.html?pagewanted=all&src=pm>. President Trump several times pressed the members of his administration to facilitate importation of drugs from Canada, but never prevailed. See Rachel Sachs, Trump Administration, In Shift, Announces Plan To Permit Drug Reimportation,” *Health Affairs*, July 31, 2019, <https://www.healthaffairs.org/doi/10.1377/hblog20190731.727552/full/>.

<sup>42</sup> See Maskus, “Parallel Imports in Pharmaceuticals,” 5.

<sup>43</sup> See Kerrin M. Vautier, Economic Considerations on Parallel Imports, in *Parallel Imports in Asia* (Christopher Heath ed., 2004); Matthias Ganslandt & Keith Maskus, “Parallel Imports and the Pricing of Pharmaceutical Products: Evidence from the European Union,” *Journal of Health Economics* (2005).

<sup>44</sup> Within the EU, the relevant legal hazards are Articles 81 and 82 of the Treaty of Rome. In October of 2005, the European Association of Euro-Pharmaceutical Companies asked the European Union antitrust authorities to investigate Pfizer for using contracts in Spain that reward wholesalers for keeping products within the Spanish market. Source: “European Pharma Lobby Group Complains To EU About Pfizer,” *Dow Jones Newswire*, Oct. 17, 2005. [Recheck.]

sometimes market the same drug in different countries using different brand names or packaging – forcing arbitrageurs to bear the costs of relabeling or repackaging the drugs if they wish to move them from one country to another.<sup>45</sup>

To summarize, three of the four conditions necessary for price discrimination (market power, variations in marginal valuations among potential customers, and the capacity to differentiate among those customers) are present to an unusually high degree in the pharmaceutical industry. The fourth condition (curbs on arbitrage) is less clear cut, but an overlapping set of barriers – some legal; others nonlegal – interfere substantially with unauthorized resales of drugs and thus protect the ability of manufacturers to engage in differential pricing.

Against this backdrop, one would expect price discrimination in drugs to be rampant. Because the impediments to arbitrage across national boundaries are particularly strong, and because the markets for drugs in different jurisdictions often differ sharply, one would expect to find especially large price differentials across countries. More specifically, because drug prices in the United States are subject to few regulations, and because the U.S. has the strongest shields against parallel importation, one would expect drug prices to be highest of all in the U.S.

Several reports by or to the United States Congress are consistent with these predictions. For example, in the early 1990s, two reports by the General Accounting Office concluded that drug prices were substantially higher in the United States than in Canada or the United Kingdom.<sup>46</sup> Similarly, a 2002 Report prepared for the House of Representatives found that the retail prices for five brand-name drugs in one Congressional District were substantially higher than the retail prices for the same drugs in Canada, France, Germany, Italy, Japan, and the United Kingdom.<sup>47</sup> A 2003 Report came to the same conclusions.<sup>48</sup>

These findings, however, have not held up well to scrutiny by scholars. In a series of articles, Patricia Danzon and several co-authors have offered compelling criticisms of the methodologies underlying the government reports.<sup>49</sup> Other scholars concur. Price

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<sup>45</sup> See Margaret K. Kyle, "Strategic Responses to Parallel Trade," in *Petrie-Flom Drugs Conference* (2009), 5. The power of these strategies to impede arbitrage, particularly in developed countries, is enhanced by the fact that many patients are reluctant to obtain drugs from sources not specified by their doctors, particularly if the appearance or packaging of the versions available from other sources differs from that of the version with which they are familiar. See Kremer, \_\_\_\_.

<sup>46</sup> See U.S. GEN. ACCOUNTING OFFICE, *PRESCRIPTION DRUGS: COMPANIES TYPICALLY CHARGE MORE IN THE UNITED STATES THAN IN CANADA* (1992) (comparing U.S. and Canadian manufacturer's factory prices for 121 brand-name drugs; concluding that, on average, prices in the U.S. are 32% higher); U.S. GEN. ACCOUNTING OFFICE, *PRESCRIPTION DRUGS: COMPANIES TYPICALLY CHARGE MORE IN THE UNITED STATES THAN IN THE UNITED KINGDOM* (1994) (comparing U.S. and U.K. manufacturer's factory prices for 77 brand-name drugs; concluding that, on average, prices in the U.S. are 60% higher).

<sup>47</sup> See Kyle, "Strategic Responses to Parallel Trade."

<sup>48</sup> See Minority Staff Special Investigations Division, "Prescription Drugs Are More Expensive in Rep. Waxman's Congressional District in California Than in Canada, Europe, and Japan," ed. U.S. House of Representatives Committee on Governmental Reform (2002).

<sup>49</sup> See Patricia Danzon and Lei-Wei Chao, "Cross-National Price Differences for Pharmaceuticals: How Large, and Why?," *Journal of Health Economics* 19 (2000): 192.; Patricia Danzon, ed. *Price Comparisons*

differentials among countries do exist, and residents of the United States often pay the most, but those disparities are substantially less than was once thought.<sup>50</sup>

The most surprising – and, for our purposes, troubling – aspect of this emerging scholarly consensus is that price differentials, when they do exist, do not closely track differences in countries' wealth. For the reasons outlined above, we would expect to find the highest prices in the richest countries and the lowest prices in the poorest countries. Sadly, we don't. A survey of the empirical literature by Prashant Yadav concludes broadly:

“If pharmaceutical companies were engaging in differential pricing based on income elasticity and if per capita income (GDP) is a good index of demand elasticity, we should find a high positive correlation when comparing pharmaceutical prices across countries with differences in per capita income. However, multiple studies have found this fit to be poor and in fact in many instances concluded that observed prices may be inversely correlated with the per capita income, implying poor countries pay higher prices.”<sup>51</sup>

There are two major exceptions to this pattern. First, since 2001, a growing number of pharmaceutical firms have adopted tiered pricing systems for many of the first and second-generation ARVs that have proven so crucial in controlling HIV and AIDS infections. Second, the prices of most vaccines are now strongly correlated with countries' per-capita incomes. However, both of these encouraging developments are best understood either as responses to the threat of generic competition or as manifestations of philanthropy. Specifically, they result from a combination of strong public pressure, a belated recognition by pharmaceutical manufacturers of the public-relations hazards of appearing insensitive to the AIDS epidemic, and shrewd funding and distribution strategies by government agencies and private donors.<sup>52</sup>

Outside of these zones, examples of differential pricing based on countries' per-capita incomes are distressingly rare. Even in the context of AIDS drugs, the practices of the major manufacturers prior to the recent initiative were troubling. For example, indicated on the map below are the prices found by Richard Hornbeck for a one-year course

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*for Pharmaceuticals: A Review of U.S. And Cross-National Studies* (1999); Patricia Danzon and Michael F. Furukawa, "Prices and Availability of Biopharmaceuticals: An International Comparison," *Health Affairs* 25, no. 5 (2006); Patricia Danzon and Jeong D. Kim, "International Price Comparisons for Pharmaceuticals: Measurement and Policy Issues," *Pharmacoeconomics* 14, no. Suppl. 1 (1998).

<sup>50</sup> See John R. Graham and Beverly A. Robson, "Prescription Drug Prices in Canada and the United States: A Comparative Survey," *Public Policy Sources* 42 (2000); Judith L. Wagner and Elizabeth McCarthy, "International Differences in Drug Prices," *Annual Review of Public Health* 25, no. 35 (2004).

<sup>51</sup> Yadav, "Differential Pricing for Pharmaceuticals". 20-22.

<sup>52</sup> See Jeffery Atik & Hans Henrik Lidgard, "Embracing Price Discrimination: TRIPS and the Suppression of Parallel Trade in Pharmaceuticals," *UNIVERSITY OF PENNSYLVANIA JOURNAL OF INTERNATIONAL ECONOMIC LAW* 1043 (2006); Peter J. Hammer, *Differential Pricing of Essential AIDS Drugs: Markets, Politics, and Public Health*, *JOURNAL OF INTERNATIONAL ECONOMIC LAW* 883, n. 31 (2002). [recheck]

of the important AIDS cocktail, 3TC/AZT/EFV, in May of 2002 in selected Latin American countries.<sup>53</sup>

Figure 2



These differentials surely support the claim that international price discrimination exists, but are impossible to reconcile with the hypothesis that prices are lowest in the poorest countries. (Per-capita income in Argentina is roughly 50% higher than in Colombia, but the cost of the drug in Argentina was roughly one third of the cost in Colombia. Per-capita income in Haiti is roughly one tenth that of Argentina, but the drug costs more in Haiti. And so forth.)

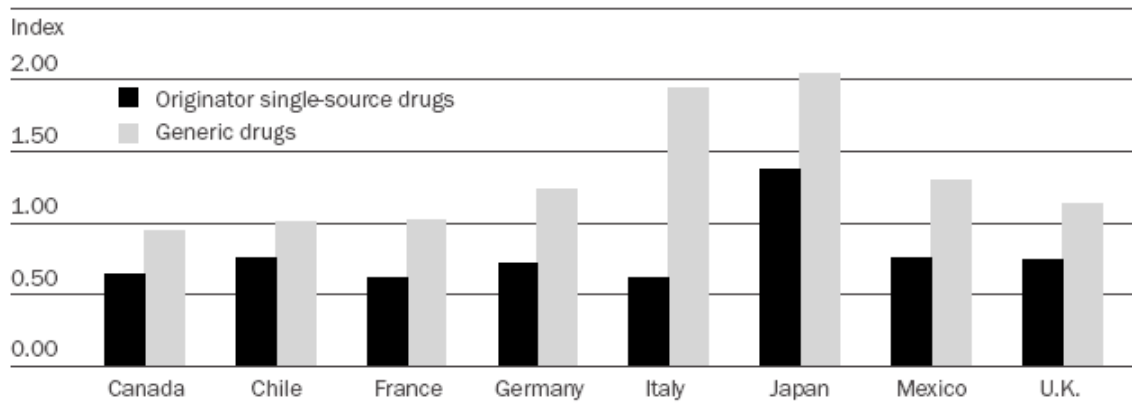
Rebecca Hellerstein's study of the prices in different countries of a wide variety of ARVs is even more grim. Her principal finding is that, in 2000, when ARVs were still protected by patents, there was very little correlation between drug prices and per-capita income. Indeed, "prices [were] routinely as high or higher in poor countries such as

<sup>53</sup> See Richard A. Hornbeck, "Price Discrimination and the Smuggling of Aids Drugs," *Topics in Economic Analysis and Policy* 5, no. 1 (2005): 11.

Uganda or Tanzania as in wealthy countries such as the US or EU.”<sup>54</sup> Michael Scherer and Jayashree Watal came to a similar conclusion. They examined wholesale prices for 15 ARVs during 1995 to 1999 in 18 poor or middle-income countries. They found “only a faint indication of a systematic income-correlated pattern. ... [P]rices in our sample of nations were approximately equal on average to presumed US transaction prices. However, in 89 out of the 465 cases, they were higher than the US list price parity value of 1.0, sometimes very substantially.”<sup>55</sup>

Once one looks outside the category of AIDS drugs, the correlation between per-capita income and price attenuates further. For example, a comprehensive study by Patricia Danzon and Michael Furukawa of the relative prices of drugs (both patented and generic) in eight countries revealed the following comparisons:<sup>56</sup>

**Price Indexes: On-Patent Brand-Name Drugs (Originator, Single-Source) Versus Generic Drugs, Manufacturer Prices In Eight Countries Relative To U.S. Prices, Adjusted For U.S. Discounts, 1999**



SOURCE: Authors' calculations based on data from the IMS Health Midas data set, 1999.

NOTE: United States equals 1.00.

Among the striking aspects of this chart are; the high prices of patented drugs in Chile and Mexico compared to those in the European countries; and the remarkably high prices in Japan.<sup>57</sup>

<sup>54</sup> See Rebecca Hellerstein, "Do Drug Prices Vary across Rich and Poor Countries?," *Social Science Research Council Publication* (2003): 29. See also "Reference Prices, Cross-Border Information Flows, and Market Segmentation: The Case of Antiretrovirals," *Federal Reserve Bank of New York* (2010), <http://www.newyorkfed.org/research/economists/hellerstein/hellerstein.pdf>.(reporting similar results for ARV pricing in 2000).

<sup>55</sup> See F.M. Scherer and Jayashree Watal, "Post-Trips Options for Access to Patented Medicines in Developing Countries," *Journal of International Economic Law* 5, no. 4 (2002): 913.

<sup>56</sup> See Patricia Danzon and Michael Furukawa, "Prices and Availability of Pharmaceuticals: Evidence from Nine Countries," *Health Affairs* (2003), <http://content.healthaffairs.org/cgi/content/full/hlthaff.w3.521v1/DC1>.

<sup>57</sup> A later study by the same authors came to similar conclusions. See Danzon and Furukawa, "Prices and Availability of Biopharmaceuticals: An International Comparison."



In a survey of the prices (as of 1998) of a wide variety of prescription drugs, Keith Maskus found similar anomalies. For example, 100-mg tablets of Sandimmune (a drug that inhibits transplant rejection) were 17% more expensive in Mexico than in the United States. Cipro (a powerful antibiotic) cost more in Brazil than in the United States. And Effexor (used to treat depression and anxiety disorders) cost more in Mexico, Brazil, the Czech Republic, and Korea than in the United States. To be sure, Maskus' study provides some support for the prediction that pharmaceutical firms, given the opportunity, will charge more for their products in rich countries than in poor countries. Specifically, he found significantly positive correlations between the prices for many drugs and per-capita GNP measured at purchasing-power-parity rates. But the correlation is less strong than he – or we – would have predicted.<sup>58</sup>

In short, the available data concerning differential pricing on the international level suggests that firms do indeed tune their prices to match different conditions in different countries. But the resultant pricing pattern is not exactly what we would have predicted – or hoped for.

What about pricing practices *within* a country? Because every nation currently adheres to the principle of patent “exhaustion” within its own borders, we would expect price differentials to be smaller at the domestic levels. But the impediments to arbitrage even inside a given country are significant enough that we should find at least some discrimination. And indeed we do.

The United States provides perhaps the best illustration. The system by which drugs are distributed and paid for in the U.S. is extraordinarily complex. A recent paper by Ernst Berndt and Joseph Newhouse provides the best available account of how it works. The following chart, distilled from their paper, summarizes the principal channels through which medicines and money flow.<sup>59</sup>

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<sup>58</sup> Maskus summarizes his findings as follows:

Looking at the computations, 17 of the 20 individual-drug correlations are significantly positive, ranging from 0.18 (Cozaar) to 0.90 (Imitrex). Two of the PPP correlations approach unity (Pulmocort and Imitrex), suggesting for those drugs that the brand owner practices something like Ramsey pricing. Six more have correlations of at least 0.5, which might be considered to support the underlying pricing model. However, nine drugs have correlation coefficients that range between 0 and 0.5, and three are negative. Neoral and Imovane both display significantly negative correlations between income levels and prices. As noted in the penultimate column, the correlation between average prices and per-capita GNP is clearly positive but well below unity.

These results provide some support for the idea that prices for identical, brandname drugs, are inversely related to per-capita income levels. However, there are numerous exceptions to this rule and several correlation coefficients are well below unity. Thus, the result is hardly conclusive; it seems that other factors go into national pricing decisions by the multinational pharmaceutical companies.

Maskus, "Parallel Imports in Pharmaceuticals," 29-30 and Table 1.

<sup>59</sup> See Berndt and Newhouse, "Pricing and Reimbursement in U.S. Pharmaceutical Markets."



occupants of the yellow lozenge in the center of the chart) pay “slightly higher but still relatively low prices.” Third-party payers (insurers and employers – shown on the left of the chart) pay somewhat higher prices, “depending in large part on their ability to implement tiered formularies.” Finally, pharmacies (also shown in the center lozenge) pay the most.<sup>60</sup>

Once again, these differences confirm the potential for and profitability of price discrimination in the pharmaceutical industry. But several aspects of this pattern are surprising. First, the price differentials are relatively modest. Second, the mechanism is crude – simple third-degree discrimination. Third and most important, the differentiation occurs among categories of intermediaries, not among individual patients. For the reason sketched at the outset of this section, it is at the patient level that one finds the greatest variation in reservation prices – and thus the greatest opportunities for lucrative differential pricing. But so far, the firms have not sought to exploit those opportunities.

To summarize, it is clear that pharmaceutical firms do indeed engage in a fair amount of price discrimination, both at the international level and domestically. But the magnitude of the price differentials is significantly less than economic theory would have led us to expect. Even more importantly, the pattern of discriminatory prices diverges in many respects from what economic theory would have predicted. Why?

Until the pharmaceutical firms are willing to explain publicly their marketing strategies,<sup>61</sup> we cannot be certain. But a combination of six factors probably account for the divergence. First, as we saw in Chapter 2, some countries limit that prices that can be charged for some drugs. The result, of course, is that prices are lower for those drugs in those countries than the amount the manufacturers would select if they were free to pick the profit-maximizing prices for those markets.<sup>62</sup> Older molecules and “global products” (i.e., drugs that are sold throughout the world) are especially likely to be subject to such regulations.<sup>63</sup> This factor goes far toward explaining why some prices are lower than we might expect in European countries and in Japan, but does nothing to explain the surprisingly high prices in developing countries.

A related factor that has more insidious effects is that some of the developed countries that set ceilings on drug prices tie those ceilings to reference indices of prices in other markets.<sup>64</sup> If the markets used in those indices include developing countries, then the result would indeed be to exert upward pressure on the prices in developing countries. Dropping the price it charges in India, for example, could cost a manufacturer significant

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<sup>60</sup> See *ibid.*, 32.

<sup>61</sup> See Donald G. McNeil, Jr. "Patent Holders Fight Proposal on Generic AIDS Drugs for Poor," *The New York Times*, May 18, 2000.

<sup>62</sup> See Margaret K. Kyle, "Pharmaceutical Price Controls and Entry Strategies," *Review of Economics and Statistics* 89, no. 1 (2007); "Strategic Responses to Parallel Trade," 4.

<sup>63</sup> See Danzon and Chao, "Cross-National Price Differences," 162.

<sup>64</sup> See Maskus, "Parallel Imports in Pharmaceuticals," 9-10.; Kyle, "Strategic Responses to Parallel Trade," 4.; Danzon, Patricia M. (1997), *Pharmaceutical Price Regulation: National Policies versus Global Interests*, Washington DC: The American Enterprise Institute.

revenue in France or Italy. Even if a particular developing country is not currently included in any of the indices, a manufacturer may be loathe to adopt a very low price in that jurisdiction for fear that, in the future, regulators in Europe or Japan might decide to include it.

The third factor pertains, not to the effect of government regulation, but to the structure of national markets. As we have seen, the principle of “national exhaustion” shared by all countries inhibits price discrimination within a country. Assume, to simplify a bit, that a firm has no choice but to offer a given drug to all residents of the country at the same price. Other things being equal, the price the firm selects will be tied to per-capita income or wealth; the poorer the country, the lower then price. But other things are often not equal. The markets for drugs in different countries vary on many dimensions. Two of those dimensions are especially relevant here. First, most residents of most developing countries do not enjoy any insurance protection – either for health care in general or for drugs in particular. Thus, unlike most residents of the United States, they are obliged to pay for pharmaceutical products out of their own pockets. Second, many developing countries are characterized by extreme inequality of wealth and income.<sup>65</sup> The effect of these two factors, in combination is that, in those countries, the demand for drugs is divided between two semi-autonomous segments: a very small group of wealthy consumers who are able to pay substantial amounts and are relatively insensitive to fluctuations in price, and a much larger group of poor consumers who are able to pay little and are highly sensitive to fluctuations in price. Such markets are said to have demand curves that are sharply “convex to the origin.” The profit-maximizing price in such markets may be high.<sup>66</sup> By pricing a drug at a level that only the elite can afford, the manufacturer may be able to make more money than by choosing a level that will make the drug accessible to the bulk of the population.<sup>67</sup>

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<sup>65</sup> A metric commonly used to measure of inequality of income or wealth is the Gini coefficient. A coefficient of 0 denotes perfect equality; a coefficient of 100 denotes perfect inequality (i.e., where one person earns all the income or owns all the wealth). With respect to income inequality, Canada, Western Europe, the Scandinavian countries, and Australia have coefficients under 35. The coefficient of the United States is currently around 45. Most of the countries in Central America, South America, and sub-Saharan Africa for which we have data have coefficients over 50; some have coefficients over 60. See [http://en.wikipedia.org/wiki/List\\_of\\_countries\\_by\\_income\\_equality](http://en.wikipedia.org/wiki/List_of_countries_by_income_equality). For a detailed examination of the impact of inequality in one country, see Calvin McDonald, Christian Schiller, and Kenichi Ueda, "Income Distribution, Informal Safety Nets, and Social Expenditures in Uganda," *International Monetary Fund Working Paper WP/99/163* (1999), <http://www.imf.org/external/pubs/ft/wp/1999/wp99163.pdf>.

<sup>66</sup> See Jerome Dumoulin, "Global Pricing Strategies for Innovative Essential Drugs," *International Journal of Biotechnology* 3, no. 3/4 (2001); Sean Flynn, Aidan Hollis, and Mike Palmedo, "An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries," *Journal of Law, Medicine & Ethics* (2009); Amy Kapczynski, "Innovation Policy for a New Era," *ibid.*: 267; Maskus, "Parallel Imports in Pharmaceuticals," 33-34; Scherer and Watal, "Post-Trips Options."

<sup>67</sup> See WHO, *Investing in Health for Economic Development – Report of the Commission on Macroeconomics and Health* (2001) (“Commission Report”) (noting the following three reasons why “pharmaceutical companies are often reluctant to cut their prices in the low-income countries”: 1) fear of having high-income markets undermined; 2) *higher profits from “a few high-priced sales to a narrow segment of rich customers as opposed to broad-based sales at close-to-production cost”* and 3) little economic incentive to provide drugs at cost in low-income countries).

The fourth factor is that drug prices in a country are influenced by forces other than the marketing strategies of the manufacturers. In the United States, as we have seen, a wide variety of intermediaries distribute drugs to patients. Competition among them curbs markups – at least to some degree. But in some developing countries, there is only one distributor, either because the market is too small to support more or because the government confers a monopoly on a particular firm. In such situations, the distributor commonly charges high markups.<sup>68</sup> The adverse impact on consumers can be severe. For example, a survey of drug prices in developing countries found enormous disparities: “Wholesale mark-ups ranged from 2% in Pakistan to a combined mark-up by importers, distributors, and wholesalers of 380% in El Salvador. Retail mark-ups ranged from 10% in Mongolia to 552% in El Salvador.”<sup>69</sup>

A fifth factor that operates to limit intra-country price discrimination, particularly in the developed world, is concern for the privacy of information contained in medical records. Such concerns are especially strong in the EU, but are also significant in the United States. Sometimes they find expression in legal rules, forbidding unauthorized uses of data. Even when they are not embodied in legal prohibitions, those concerns likely discourage pharmaceutical firms from seeking or using the data that would enable them to engage in fine-tuned first-degree discrimination.

The final factor may well be the most important. For the reasons surveyed in the previous section, many people consider price discrimination immoral. This reaction goes much further than opposition to the use of private information. Even when the criteria that sellers employ to differentiate among customers are entirely public, many consumers and observers denounce differential pricing as a form of “gouging.” This sentiment underlies vocal cries in the United States for suspension of the prohibitions on parallel importation of pharmaceutical products. Politicians (in both parties) are responsive to those cries – in part because they frequently issue from the politically powerful block of senior citizens.<sup>70</sup> Pharmaceutical firms, keenly aware both of public sentiment on this score and of the hazard that lawmakers will alter the system of rules that protect their most lucrative market, are understandably squeamish about increasing the degree to which they engage in discriminatory pricing. Lowering their prices in developing countries would gain them little (or nothing) and could cost them a great deal.

### C. Reform

Assume for the moment that our only objective is to help alleviate the health crisis in the developing world. How should we modify the laws and institutions that currently govern the practice of price discrimination by pharmaceutical firms?

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<sup>68</sup> See Maskus, "Parallel Imports in Pharmaceuticals," 34; Yadav, "Differential Pricing for Pharmaceuticals". 19, 36-38.

<sup>69</sup> See A. Cameron et al., "Medicine Prices, Availability, and Affordability in 36 Developing and Middle-Income Countries: A Secondary Analysis," *The Lancet* 373 (2009): 246.

<sup>70</sup> See, for example, Patricia Barry, "Dems, GOP Support New Bill to Allow Lower-Cost Drugs from Canada," *AARP Bulletin* (2011), <http://www.aarp.org/health/drugs-supplements/info-03-2011/lowercost-drugs-from-canada.html>; RxRights.org, "AARP Endorses Drug Reimportation Bill," March 30, 2011, <http://www.rxrights.org/your-thoughts/aarp-endorses-drug-reimportation-bill>.

Most of the activists and scholars who have addressed that question fall into one of two camps. The first group argues that the various legal rules that regulate the ability of the firms to treat each country as a distinct market should be modified so as to encourage parallel importation and thus reduce international price differentials. This recommendation is usually justified on the ground that it will enable public-health officials in developing countries to obtain crucial drugs at the lowest possible prices.<sup>71</sup>

The second group argues that we should do the opposite. Instead of discouraging price discrimination among countries, we should foster it. This recommendation is usually justified on the ground that it will prompt pharmaceutical firms to set very low prices for their products in low-income countries, confident that those products will not be exported to middle or high-income countries, where the firms are charging and earning more.<sup>72</sup>

When set against the backdrop of the theory and practice reviewed in the preceding two sections, neither of these proposals seems promising. Adoption of the first might well have some short-term benefits for developing countries. But soon, the firms' inability to charge different prices in different countries would almost certainly cause them either to raise prices in all developing countries – or (even worse) to withdraw their drugs from developing countries altogether. The net effect would be to exacerbate, rather than alleviate, what we have been calling the “access problem.”

Adoption of the second position, however, would amplify the distortions we see under the current legal regime. By further reducing the pressure that the pharmaceutical firms experience from parallel importation, it would strengthen their capacity to treat each national market as distinct. As a result, we would likely find additional examples of the anomalies described in Section B, above. The most troubling of those anomalies, of course,

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<sup>71</sup> See Samuel L. Ernst, "The Pharmaceutical Industry's Corrupt Price Discrimination System: A Single Solution?," *University of Pacific Law Review* 51 (2020).; F.M. Abbott, "First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation," *Journal of International Economic Law* 1, no. 4 (1998); Suerie Moon et al., "A Win-Win Solution?: A Critical Analysis of Tiered Pricing to Improve Access to Medicines in Developing Countries," *Globalization and Health* 7 (2011): 10; Carlos Correa, *Trade Related Aspects of Intellectual Property Rights* (Oxford: Oxford University Press, 2007), 80 ("The right to parallel import under an international principle of exhaustion has been regarded by many developing countries as a key component of a patent system sensitive to public health needs."); James Love and Tim Hubbard, "The Big Idea: Prizes to Stimulate R&D for New Medicines," *Chicago-Kent Law Review* 82 (2007): 1548-50; James Love, "Policies That Ensure Access to Medicine, and Promote Innovation, with Special Attention to Issues Concerning the Impact of Parallel Trade on the Competitive Sector, and a Trade Framework to Support Global R&D on New Health Care Inventions.," <http://www.cptech.org/ip/health/econ/jamie-hosbjor.html>; Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (Oxford: Oxford University Press, 2011), 46.

<sup>72</sup> See Patricia Danzon and A. Towse, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents* (Washington, D.C.: American Enterprise Institute -- Brookings Joint Center for Regulatory Studies, 2003).; Roger Bate and Kathryn Boateng, "Drug Pricing and Its Discontents: At Home and Abroad," *American Enterprise Institute for Public Policy Research* 9 (2007), [http://www.aei.org/files/2007/08/09/20070808\\_22039HPO09Bate\\_g.pdf](http://www.aei.org/files/2007/08/09/20070808_22039HPO09Bate_g.pdf).; Frank Muller-Langer, *Creating R&D Incentives for Medicines for Neglected Diseases* (Wiesbaden, Germany: GWV Fachverlage, 2009), 197. (and sources cited therein).

is that the prices set by the firms in many developing countries would remain high – indeed, might well be higher than the prices in developed countries.

A third approach seems more promising than either of these options. Instead of either curbing international price discrimination or unleashing it, we should adjust several legal rules in ways that would both (a) strengthen pharmaceutical firms' ability and incentive to engage in differential pricing and (b) regulate their exercise of that enhanced power so that it redounds to the benefit of developing countries.

To advance the first half of this prescription, we would first have to amend the rules governing the exhaustion of patent rights – at least insofar as they pertain to pharmaceutical products. An especially aggressive approach would be to persuade every country in the world to adopt the principle of national exhaustion. The effect, of course, would be to harden the boundaries between national markets and increase the ability of pharmaceutical firms to set different prices in each. But we would not need to go that far. To facilitate international price discrimination, we would need only to block parallel importation “upward” (i.e., from poorer countries to richer countries), not downward (i.e., from richer countries to poorer countries) or “horizontally” (i.e., between similarly situated countries). Thus, the poorest countries could continue to adhere to the doctrine of international exhaustion, and groups of countries with similar economic profiles – such as OAPI in Western Africa – could continue to apply the principle of regional exhaustion.

To be most efficacious, these principles would be enforced both by countries from which drugs might be exported and by countries to which they might be imported. So, for example, not only would the United States continue to block parallel imports from Ghana, but Ghana would work with the pharmaceutical firms to help detect and block exports to the United States. This might seem obvious, but, when overlaid on the recommendations set forth in the preceding paragraph, it would entail a significant departure from the current regime. At present, every country applies the same rules to exports of patented products that it does to imports. Countries that permit goods subject to local patents to be imported also allow them to be exported, while countries that prohibit imports also prohibit exports.<sup>73</sup> Our proposal would sometimes result in delinking these rules. As suggested above, the poorest countries could permit drug imports, but would prohibit drug exports (more specifically, exports to richer countries) – and then make a serious effort to enforce that prohibition.

These reforms would significantly increase the power of pharmaceutical firms to engage in price discrimination, but as we have seen, it is far from guaranteed that they would exercise that power to reduce prices in poor countries. It is crucial that we induce them to do so. The first step toward achieving that result would be to remove the perverse incentive created by the price-control regimes in some developed countries. All countries must renounce any use of drug prices in developing countries when calculating the indices they employ in capping their own drug prices.<sup>74</sup> This would free pharmaceutical firms to lower prices sharply in the poorest countries without fear that, as a result, they will be

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<sup>73</sup> See Maskus, "Parallel Imports in Pharmaceuticals," 3.

<sup>74</sup> See *ibid.*, 42-43.

obliged to lower prices in their more lucrative markets. A reform of this sort need not cost developed countries anything; they can easily adjust other terms in their indices to keep their price levels in their own jurisdictions steady. (A more ambitious response to this problem would be to abandon reference pricing altogether in favor of pricing based upon pharmaco-economic assessments – i.e., evaluations of the health benefits of each drug.<sup>75</sup> For reasons explored in the next two chapters, such a change would have several advantages, but it unnecessary to catalyze differential pricing.)

This change would help, but by itself would not suffice to keep drug prices in poor countries down. Success would also require addressing the problem created by the highly convex demand curves in many developing countries – i.e., the fact that, ironically, the profit-maximizing price in those countries is often high. To address this problem, developing countries would need in some way to regulate the behavior of the firms. But exactly how is not immediately obvious.

The most straightforward approach would be the adoption of price controls. As we have seen, although many developed countries already have such controls, very few developing countries do so. (The principal exception is Brazil.) Nothing in the TRIPS Agreement or the Free Trade Agreements by which a growing number of developing countries are bound prevents them from adopting such controls.<sup>76</sup> If developing countries instituted such controls, they could use them to force drug prices down to levels well below those prevailing in Europe or the United States.

Unfortunately, this approach would have two disadvantages. First, it would reduce the revenue that pharmaceutical firms could earn in developing countries. The point of price regulation is of course to compel the firms to charge less than the amount that would maximize their profits. Such regulation would thus cost the firms revenue. If the drugs to which the regulations were applied were aimed at global diseases, we should perhaps not be terribly worried about this outcome. However, if the drugs at issue were aimed at one of the neglected diseases, the result would be to worsen, at least modestly, the “incentive problem.” In other words, the firms would in the future have less reason to invest money in projects aimed at those diseases, because they would earn less. The second disadvantage is that price regulation might cause the firms to withdraw the drugs subject to these regulations from poor countries. In part, this is because their revenues might decline to the point where maintaining a presence in those markets would not be worth it.<sup>77</sup> A more serious worry – from the standpoint of the firms – is that the adoption of vigorous price regulation would both create and publicize huge gaps between the prices the firms are charging in the United States and the prices they are charging in poor countries – and would thereby intensify calls either to permit parallel importation of drugs into the United States or for the adoption of price regulation in the United States. This, of course, is the firms’ nightmare. (A possible response: but won’t the firms be able to explain away those disparities on the ground that they are involuntary – i.e., that the firms are being *forced* to

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<sup>75</sup> See Yadav, "Differential Pricing for Pharmaceuticals". 53-54.

<sup>76</sup> [\*Recheck all the FTAs.]

<sup>77</sup> [\*How has Brazil avoided this hazard? In brief, the Brazilian market is so big that the firms are reluctant to abandon it. Insert examples from the AIDS drugs fight.]



keep prices down in developing countries? The fact that senior citizens in the United States have brushed aside that argument when it has been offered to justify the difference between drug prices in Canada and in the United States strongly suggests that the answer is no.) The net result: Price regulation in developing countries – unless supplemented by other adjustments of the legal regime – could backfire.

A second option would be the imposition of compulsory licenses in developing countries.<sup>78</sup> Pharmaceutical firms could be compelled to permit generic firms to manufacture and distribute patented drugs for a modest licensing fee. Competition among the generics would then push down the prices of those drugs – to levels approaching the marginal costs of producing them. We will examine this strategy in detail in Chapter 7. For the time being, it's sufficient to note that the feasibility of this approach depends upon insulating developing countries from the threats of retaliation that have thus far discouraged them from taking this tack.<sup>79</sup>

A third option: We could encourage pharmaceutical firms (or their distributors) to engage in price discrimination *within* each developing country – in other words, to charge wealthy residents more than poor residents.<sup>80</sup> At first, this proposal may seem both radical and impracticable. As we saw in Section B, in no country do the firms currently discriminate significantly among patients on the basis of their ability and willingness to pay for drugs. The primary reason is that every country currently adheres to the principle that patent rights are exhausted by the first authorized distribution of a patented product within the country. This principle – which can be thought of as the least common denominator among exhaustion regimes – reduces the ability of the pharmaceutical firms to prevent arbitrage within their borders.

But, as we saw in Section A, pharmaceutical firms are unusual in the minimal degree to which they differentiate among consumers when setting their prices. The sellers of many other products and services that are shielded by intellectual property rights currently engage in much more aggressive forms of domestic price discrimination. Moreover, some of the products and services subject to such discrimination – such as gasoline or higher education – are far from luxuries but rather are essential to economic and social mobility. Intra-national differential pricing of drugs thus should not be unthinkable.

The legal tools that would make such a practice feasible are also close at hand. Lawmakers in the United States have already deployed various doctrines that assist firms in other fields to engage in differential pricing. For example, the federal courts recently adopted a narrow interpretation of the first-sale doctrine in copyright law when applied to licenses of computer software. The result has been to enable software firms to charge

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<sup>78</sup> For proposals to use compulsory licenses in this context, see Flynn, Hollis, and Palmedo, "Essential Medicine Patents," 9-10; Kevin Outterson, "Pharmaceutical Arbitrage: Balancing Access and Innovation in Prescription Drug Markets," *Yale Journal of Health Policy, Law & Ethics* 59, no. 193 (2005).

<sup>79</sup> See James Love, "Terrorism, Pfizer Style," Huffington Post, April 1, 2006, [http://www.huffingtonpost.com/james-love/terrorism-pfizer-style\\_b\\_18290.html](http://www.huffingtonpost.com/james-love/terrorism-pfizer-style_b_18290.html).

<sup>80</sup> See Yadav, "Differential Pricing for Pharmaceuticals".

some sets of customers (e.g., students) much less than it charges others, without fear that the former will resell the programs to the latter.<sup>81</sup> Similarly, until recently the federal courts permitted the sellers of medical devices to override the first-sale doctrine in patent law by stamping their products with the phrase, “single-use only.”<sup>82</sup> By suppressing the market in used versions of these devices, this rule sharply increased the ability of the sellers to engage in differential pricing. So, analogously, lawmakers (either courts or legislatures) in developing countries could easily declare that restrictions upon the resale of pharmaceutical products (e.g., resale prohibitions stamped on the outside of the boxes containing the products) are enforceable. If law-enforcement authorities were willing to enforce that rule against noncompliant drug distributors, drug arbitrage would be sharply curtailed.

The strategies discussed in the preceding paragraph have the merit of representing relatively modest adjustments in the existing legal regime. But legislatures in developing countries could achieve the same effect more directly: they could simply declare that, henceforth, any resale of a pharmaceutical product not authorized by the original seller shall be unlawful. In other words, at least with respect to drugs, they could abandon the first-sale doctrine. This change might seem eye-opening, but it would be well within their power. No provision of the TRIPS Agreement (or of the Free Trade Agreements to which some developing countries are subject) forbids it.

A less aggressive option would be to impose a restriction on resales of drugs similar to the “droit de suite” recognized in many European countries – namely, a right, on the part of the creator of a work of fine art to collect a fee whenever that work is resold.<sup>83</sup> Analogously, drug resellers could be required by developing countries to pay a fee to the manufacturer. If the fee were higher than the difference between the prices that the firms, left to their own devices, would charge high-margin and low-margin consumers, then such a regime would be the functional equivalent of a ban on unauthorized resales. If the fee were lower than that difference, then some arbitrage would occur, but the firms would collect from the arbitrageurs money that partially compensate them for the diverted trade. The net effect would be to approximate, albeit with some increase in transaction costs, the kind of differential pricing that would result from a complete ban.<sup>84</sup>

Through one or another of these mechanisms, developing countries could sharply curtail intra-national arbitrage in pharmaceutical products. But that alone would not be enough to guarantee robust price discrimination within developing countries. It would also be crucial that the firms be able to employ some criterion that would effectively

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<sup>81</sup> See *Vernor v. Autodesk*, 2010 U.S. App. Lexis 18957 (9<sup>th</sup> Cir. 2010).

<sup>82</sup> See *Mallinkrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 706 (CAFC 1992); *R. Braun Med., Inc. v. Abbott Labs*, 124 F.3d 1419, 1426 (CAFC 1997). These rulings have now been displaced by the Supreme Court’s decision in *Lexmark*, discussed above.

<sup>83</sup> See Sam Ricketson, “Moral Rights and the Droit De Suite: International Conditions and Australian Obligations,” *Entertainment Law Review* 1 (1990).

<sup>84</sup> Legal scholars would say that the two regimes are equivalent, except that the former protects the seller’s entitlement with a “property rule,” while the latter protects the seller’s entitlement with a “liability rule.” See Guido Calabresi and A. Douglas Melamed, “Property Rules, Liability Rules, and Inalienability: One View of the Cathedral,” *Harvard Law Review* 85 (1972).

differentiate between high-margin and low-margin customers. What might that criterion be? Several approaches are imaginable. Here are two that would be easy to implement:

In many developing countries, rich residents and poor residents use relatively autonomous health-care systems. The rich rely on private doctors and hospitals; the poor use public-health services. In Namibia, for example, “[i]t is estimated that public health care facilities serve 85% of the Namibian population and is mostly accessed by lower income groups. The private for-profit healthcare system mostly serves the remaining 15% of the population, consisting of middle and high income groups.”<sup>85</sup> The situations in South Africa and Bolivia are similar.<sup>86</sup> As Prashant Yadav suggests, in such jurisdictions, the pharmaceutical firms could assign very different prices to the drugs they make available through these two channels.<sup>87</sup> Because this would be a form of second-degree price discrimination, the barriers between the two sub-markets would not be watertight. If the difference between the prices of drugs in the private and public health-care sectors were large enough, the more wealthy patrons of the former would begin to frequent the latter, thus corroding the scheme to some degree. However, in most developing countries, the commitment of the better-off residents to private health care is strong enough to withstand a substantial price differential.

A more precise approach would capitalize upon the systems of Community Health Workers (CHWs) that many developing countries have already deployed or are in the process of deploying.<sup>88</sup> To understand this option requires a bit of background: In most developing countries, poor residents of rural areas have limited awareness of or access to professional health-care services -- clinics, physicians, and nurses. Our long-term ambition should of course be to increase sharply the number of clinics and physicians in rural areas, or to improve public transportation systems so that the rural poor can easily and cheaply get to the existing clinics, but neither of these goals is likely to be achieved in the near future. Instead, a growing number of countries are employing networks of CHWs to address the basic health needs of the rural poor. CHWs (also sometimes known as “frontline health workers”) are laypersons trained in basic disease-prevention and diagnostic techniques. Their background and responsibilities vary somewhat by country, but in the typical system, their primary role is to visit regularly all of the households in a particular zone, providing the residents four services. First, they offer instruction and assistance on a wide variety of topics: birth control, pre-natal care, breast feeding and other dimensions of infant care, nutrition, the use of insecticide-treated bednets, techniques for

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<sup>85</sup> See WHO and Ministry of Health and Social Services Republic of Namibia, *Namibia Country Cooperation Strategy, 2010-2015* (Country Office in Namibia: World Health Organization, 2010), 4.

<sup>86</sup> On South Africa, see Neil Soderlund, Gillian Schierhout, and Alex van dan Heever, *Private Health Care in South Africa: Technical Report to Chapter 13 of the South African Review 1998* (Durban, South Africa: Health Systems Trust, 1998). On Bolivia, see <http://www.pacificprime.com/countries/bolivia/>

<sup>87</sup> See Yadav, "Differential Pricing for Pharmaceuticals". 41-47.

<sup>88</sup> For a comprehensive survey of CHW systems, and a powerful argument for their expansion, see Prabhjot Singh, *One Million Community Health Workers* (New York: The Earth Institute, Columbia University, 2011). One of the settings in which the CHW model has been developed and refined is the Millennium Villages Project. See <http://millenniumvillages.org/>. Our own knowledge of the CHW system in general and the Millennium Villages Project in particular derives in large part from Herrick Fisher, formerly a coordinator of the project in Ruhira, Uganda. See <http://millenniumvillages.org/the-villages/ruhira-uganda/>.

preventing or managing diarrhea, the use of ARVs to prevent transmissions of HIV from mothers to newborns, and so forth. Second, they gather information concerning the health of each person in each household and record that information using standard templates on mobile telephones. That data is then aggregated to track the incidence of diseases and to guide the development of appropriate public-health initiatives. Third, the CHWs provide on-the-spot treatments to persons suffering from common, easily diagnosed illnesses. Not long ago, this would have been impossible or unsafe. Recently, however, short-course therapeutics for many maternal and childhood diseases have been developed that can be administered safely by appropriately trained laypersons. These include “single-dose albendazole for helminthes, low osmolarity oral rehydration therapy and zinc for diarrhea, artemisinin-based combination therapy for malaria, antibiotics for pneumonia and newborn sepsis, nevirapine for HIV, and depo-provera for family planning.”<sup>89</sup> Some of these treatments require drugs. In those instances, the CHWs deliver the drugs directly to the patients and provide instructions concerning their use.<sup>90</sup> Fourth, when CHWs encounter persons suffering from uncommon or complex diseases, they refer such persons to suitable public-health facilities, private clinics, or hospitals and provide advice about how to get there.

This system has proven remarkably effective in many settings. Several formal reviews have concluded that it leads to dramatic reductions in both mortality and morbidity.<sup>91</sup> Systems of this sort are already in place and working well in several countries. They include the Community Health Agents in Brazil (currently providing basic care to over 120 million people);<sup>92</sup> the Village Health Workers, Maternal Child Health Workers, and the Female Community Health Volunteers in Nepal (currently serving the entire rural population),<sup>93</sup> the Community Health Workers working with Partners in Health in Haiti;<sup>94</sup> the Millennium Villages Community-Based Management for Health system in Uganda;<sup>95</sup> large-scale systems in Nigeria, Ethiopia, and Kenya; and smaller systems in most African countries.

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<sup>89</sup> See *ibid.*, 17.

<sup>90</sup> See *ibid.*, 38.

<sup>91</sup> See, for example, ZA Bhutta et al., "What Works? Interventions for Maternal and Child Undernutrition and Survival," *Lancet* 371, no. 9610 (2008); Zohra S Lassi, Batool A Haider, and Zulfiquar Bhutta, "Community-Based Intervention Packages for Reducing Maternal and Neonatal Morbidity and Mortality and Improving Neonatal Outcomes," *The Cochrane Library*; Henry Perry et al., "How Effective Is Community-Based Primary Health Care in Improving the Health of Children?," *American Public Health Association*, <http://www.future.org/sites/future.org/files/FinalCBPHCReporttoERP-7July2009.pdf>; Singh, *One Million Community Health Workers*, 12.

<sup>92</sup> See James Macinko et al., "Going to Scale with Community-Based Primary Care: An Analysis of the Family Health Program and Infant Mortality in Brazil, 1999-2004," *Social Science Medicine* 65, no. 10 (2007); Singh, *One Million Community Health Workers*, 22.

<sup>93</sup> See Claire Glenton et al., "The Female Community Health Volunteer Programme in Nepal: Decisionmakers' Perceptions of Volunteerism, Payment and Other Incentives," *Social Science & Medicine* 70, no. 12 (2010); Singh, *One Million Community Health Workers*, 42.

<sup>94</sup> See <http://www.pih.org/pages/community-health-workers/>.

<sup>95</sup> See Herrick Fisher, Community Health Workers and Millennium Villages, Community Based Management for Health, Presentation to the Ugandan Ministry of Health, April 2, 2009.

Not only is the system efficacious, it is also remarkably efficient. Extrapolating from the costs of existing systems, Prabhjot Singh and his co-authors estimate that deployment and maintenance of CHW systems serving the entire rural population in sub-Saharan Africa would cost approximately \$6.56 per person served per year.<sup>96</sup> Somewhat surprisingly, the largest component of that cost (\$3.59) would be devoted, not to the workers' salaries or to overhead, but rather to "supplies" – the most expensive of which are drugs.<sup>97</sup>

The funds used to run CHW systems come from a variety of sources: the United Nations; private donors; the governments of developing countries; and so forth. Unfortunately, those funds currently are far less than would be required to serve the entire rural populations in most developing countries. The number of persons the system could reach would thus increase if we could devise a way of reducing the costs per person. An obvious way of doing so would be to reduce the costs of the drugs.

The way in which this model could be integrated into a system of intra-national price discrimination should by now be obvious. In each developing country, pharmaceutical firms would provide drugs at very low cost to the local CHW system serving the rural poor. Those drugs would then be delivered in small quantities by individual health workers to individual patients. The risk that the drugs would "leak" out of this distribution channel would be low. The managers of the CHW system would have a strong incentive to prevent diversion (because it would put at risk their supply of inexpensive drugs). And the patients who benefit from the system would have little incentive or ability to resell them to more wealthy patients. As a result, the firms' more lucrative markets would not be undercut.

Reliance upon the CHW system would have another crucial advantage. One of the major drawbacks of making medicines readily available to the poor residents of developing countries is that, all too often, the recipients fail to complete the courses of treatment. Once they feel better, they cease taking the drugs. The result is to permit a few of the pathogens to remain in their bodies. Moreover, the survivors tend to be the most drug-resistant bugs. If the survivors later multiply or are transmitted to other persons, the overall result is to accelerate the emergence of drug-resistant strains of the disease in question – and thereby to reduce the efficacy of the drug from which the patients benefitted. That's bad for everyone, including the company that is selling the drug. The CHWs, by monitoring their patients' conduct and insisting that they complete the prescribed course, could sharply reduce this problem.<sup>98</sup>

The two criteria that we have examined – the separation between public and private health-care systems, and the CHW system that provides drugs (as well as many other services) to the rural poor in many developing countries – by no means exhaust the set of criteria that might be employed to implement a regime of intra-national price discrimination. Other differentiating mechanisms could be developed in the future,

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<sup>96</sup> See Singh, *One Million Community Health Workers*, 52.

<sup>97</sup> See *ibid.*, 58.

<sup>98</sup> I am grateful to Prabhjot Singh for this insight.

particularly as the health ministries in developing countries gather additional information concerning their residents. Indeed, awareness of the potentially large benefits of this strategy might prompt the ministries to accelerate the process by which they gather and process that data.

What if the firms, empowered in these various ways to engage in domestic price discrimination in developing countries, nevertheless refused? In that case, compulsion might be necessary. But the compulsion would take a quite different form from the variants we have considered thus far. Instead of requiring the firms to make drugs available at a low price to all of its residents, the country would require the firms to make drugs available at a low price only to its poor residents; the firms would be free to maintain their profitable marketing strategy for the small slice of well-off residents. Outright compulsion would probably prove unnecessary. A credible threat of either selective price regulation or a selective compulsory license would probably be enough to nudge the firms into adopting their own differential pricing systems.

Adoption of this combination of reforms would have several advantages. It would ensure that the poorest residents were provided access to the drugs they needed, but would at the same time increase rather than decrease the revenues of the pharmaceutical firms. That effect, in turn, would reduce the risk that the firms would respond to this reform by seeking to withdraw from developing countries and would mitigate (at least to a modest degree) rather than exacerbate the “incentive problem.”

There remains one worry, however. Wouldn't the firms fear and resist this reform for the reason discussed above – namely, that it would intensify anger among Americans over the fact that (on average) they pay the highest drug prices in the world and thus would increase the risk that the US would adopt some form of price control? Perhaps, but on this crucial axis, the combination of adjustments we have just reviewed would be less troublesome for the firms than would be the adoption by developing countries of blanket price controls or compulsory licenses.

To see why, recall that popular reactions to differential pricing systems depend heavily on how those systems are “framed.” One aspect of “framing,” in turn, is how the systems are justified. An example of successful framing is the first-degree price discrimination practiced by most US colleges and universities. Large tuition discounts awarded to some students are explained as necessary to ensure that all persons, regardless of their financial means, have access to higher education.<sup>99</sup> This explanation is widely

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<sup>99</sup> See for example, Harvard College, Office of Admissions, [http://www.admissions.college.harvard.edu/financial\\_aid/index.html](http://www.admissions.college.harvard.edu/financial_aid/index.html) (“Our goal in admissions and financial aid is clear: We want to bring the best people to Harvard, regardless of their ability to pay — and we do. About 70 percent of our students receive some form of aid, with over 60 percent receiving need-based scholarships.”); Yale University Office of Admissions, <http://admissions.yale.edu/financial-aid-prospective-students> (“We believe that a Yale education should not be limited to only those who can afford the full cost of attendance. By committing to an admissions policy that does not consider a student’s ability to pay, and by meeting the full financial need of all admitted students (with no loans required), we ensure that Yale is accessible to the most talented students from around the world, regardless of their family’s income.”); Swarthmore College Financial Aid, <http://www.swarthmore.edu/financialaid.xml> (“In order to make a Swarthmore education available to qualified students, we expect to award in excess of \$29 million for

accepted by Americans, even by the students who do not benefit from the discounts. Although agitation against high tuitions is common,<sup>100</sup> agitation against financial aid is rare.

Differential pricing of drugs within developing countries could be justified, readily, on the same basis. If challenged by Americans concerning the unfairness of this scheme, the pharmaceutical firms could plausibly respond: We are not treating developing countries more favorably than the United States. Rather, we are giving a break to poor *individuals* in those countries. In other words, we are adjusting our prices to ensure that all *persons*, regardless of their means, have access to life-saving drugs.

To be sure, activists in the United States might respond: If that is indeed what you are doing, then you should at least provide the same discounts to poor Americans. The pharmaceutical firms might address this objection in one of two ways. First, they could point out that only a tiny percentage of Americans are so poor that they would qualify for the discounted prices in developing countries using whatever criterion is in force there. The second alternative is more radical: they could institute an analogous differential pricing system in the United States. The potential advantages of that reform would be huge: the firms would earn larger profits, and more people in the United States would have access to medicines. But this option, attractive as it is, would take us far afield.<sup>101</sup> Our focus in this book is on the health crisis in the developing world, not inequality in access to health in the developed world. We therefore put it to one side.

There remains one more piece to this puzzle. If the distributors of drugs in developing countries extracted high profit margins, the benefits of the scheme we have outlined would be dissipated. Developing countries should alter their laws to prevent that from occurring. This might be achieved in any of various ways. Those countries that require distributors to be licensed should make certain that they issue such licenses to several unaffiliated distributors and then apply their competition laws to ensure they do not collude. Those countries that are too small to support more than one distributor domestically could authorize distributors from other developing countries to do business within their borders. Alternatively, as Keith Maskus suggests, they could enter into regional exhaustion arrangements with nearby countries with similar economies; the

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scholarships for the coming year. About 54 percent of our student body receives scholarship assistance through Swarthmore on the basis of demonstrated financial need, and a total of 70 percent of our students will share more than \$36 million in scholarships, loans, and work opportunities during the 2011-2012 academic year. (Although our aid awards are loan-free, some families borrow to pay their shares.) Although we believe that the primary responsibility for financing education lies with students and their parents or guardians, we stand ready to help fill in the gap when family resources do not meet our costs. Swarthmore's strong financial aid program demonstrates our commitment that all capable students have access to the College.”)

<sup>100</sup> See, for example, Larry Gordon and Patrick McGreevy, "Student Protests Disrupt Meeting of Uc Regents," *Los Angeles Times*, November 28, 2011; Alice Speri and Anna M. Phillips, "Cuny Students Protesting Tuition Increase Clash with Police," *New York Times*, November 21, 2011.

<sup>101</sup> It would also require a modification of the recommendation we made on page \_\_\_\_, above – namely, that parallel importation should be blocked only when it flows “upward.” The implementation of intra-national price discrimination systems in rich countries would require that “downward” and “lateral” parallel importation also be blocked.

“threat of [parallel importation] within such regions would discipline country-specific monopoly pricing.”<sup>102</sup> Last but not least, the Ministry of Health might assume the role of drug distributor. This option would be especially attractive in countries that achieve effective domestic price discrimination by charging lower prices to the persons who use the public-health system.

To summarize, we propose the following combination of adjustments in the laws and institutions that affect differential pricing of drugs:

- 1) Modification of each nation’s rules governing parallel importation so as to prevent unauthorized movements of drugs “upward” – i.e., from poor countries to rich countries.
- 2) A commitment by developed countries not to consider drug prices in developing countries when administering their systems for regulating drug prices in their own jurisdictions.
- 3) The adoption (and enforcement) by developing countries of prohibitions (or restrictions) on unauthorized domestic resales of pharmaceutical products.
- 4) The identification or development of a mechanism for intra-national price discrimination. (At present, the most promising of those mechanisms would be to supply drugs at low prices to the growing networks of community health workers.)
- 5) If necessary, the adoption by developing countries of regulations compelling pharmaceutical firms to make use of those mechanisms.
- 6) Regulations within developing countries that prevent drug distributors from reaping excessive profits.

Although this combination of reforms is designed to help resolve the crisis in the developing world, adoption of it would also likely improve social welfare in general. Recall, from Section A, that the merits, from a social welfare standpoint, of a price discrimination scheme cannot be determined in the abstract. Rather, each particular scheme must be assessed by asking a series of context-specific questions: Would it result in an increase in the number of people who have access to the product at issue? Would it create incentives for socially beneficial innovations in the future? Would it result in a redistribution of wealth from rich to poor? Are the submarkets that would benefit from adoption of the scheme characterized by positive externalities? Would it alleviate inefficiencies in the marketing system it would displace? Would it be consistent with popular attitudes concerning the morality of pricing systems?

The pricing system that would result from the set of reforms we have advocated here would generate positive or neutral answers to every one of these questions. It would get drugs to more people in developing countries without reducing the number of people who obtain those drugs in the developed world. It would increase incentives for the

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<sup>102</sup> Maskus, "Parallel Imports in Pharmaceuticals," 43. One of us has proposed that the countries of Central America could all benefit by entering into regional collaboration agreements for a variety of purposes. See William W. Fisher and Martha Field, *Legal Reform in Central America: Dispute Resolution and Property Systems* (Cambridge, MA: Kennedy School of Government, 2001). A regional exhaustion system for drugs would be one such purpose.



discovery and testing of vaccines and medicines that address the diseases rampant in the developing world. Although the scheme would not cause a transfer of wealth from rich countries to poor countries, it would create a situation within developing countries in which rich residents paid more for drugs than poor residents – and would thereby reduce (albeit to a small degree) the sharp inequalities of wealth within those countries. For reasons we explored in Chapter 3, increasing the availability of vaccines and medicines to the poor residents of the developing world would generate strong positive externalities. The system would avoid the deadweight loss associated with the currently high drug prices in many developing countries – caused in part by the firms’ rational responses to highly convex demand curves. And, for the reasons just outlined, the system could be justified to the general public in ways that would show it to be consistent with popular conceptions of justice.

Indeed, we can go further. Not only would this system result in an overall increase in social welfare, it would leave every country – and every significant group within every country – either better off or no worse off. Many lives in the developing world would be saved – or rendered less miserable. Rich residents of developing countries would pay no more than they currently do for existing drugs – and would benefit from the increased research and development devoted by pharmaceutical firms to neglected diseases (which threaten them as well as their poor neighbors). The residents of developed countries would pay no more for drugs than they currently do. And the shareholders of the pharmaceutical firms would benefit from the firms’ increased profits. To use the economists’ terminology, the state of affairs created by adoption of this plan would be “pareto superior” to the current state of affairs. This is not true of many of the packages of reforms we will consider in subsequent chapters – and, indeed, is rare among legal reforms of any sort.

Despite these advantages, implementation of this slate of reforms would not be easy. It would require many legal changes in many countries. Moreover, those changes would have to be coordinated; piecemeal or partial reform could make things worse, not better. In particular, modifying the rules of exhaustion so as to make international price discrimination easier, without simultaneously adjusting several other rules to ensure that the resultant price differences benefitted the poor residents of poor countries, would likely kill more people than it would save.

Another problem: although, as explained above, all countries and groups would benefit from adoption of this slate, explaining why a particular country should adopt a particular reform would sometimes be difficult. For example, why should Chile, which has a per-capita GDP of \$15,400, agree to abandon its current system of international exhaustion – and, in particular, to block parallel importation from Bolivia, which has a GDP of \$4,800? The answer to that question is that, in the absence of such an agreement, the pharmaceutical firms, fearing corrosion of their Chilean market, will not drop the prices of their products in Bolivia below the prices in Chile. So a refusal by Chile to modify its rules would not benefit Chileans but would hurt Bolivians. But two features of that answer are worrisome: it’s counterintuitive; and it asks Chileans to modify their own legal system, not to help themselves, but to help their Bolivian neighbors.

The difficulty of persuading so many countries simultaneously to alter their laws suggests that we might try to implement the slate of reforms in one fell swoop through some kind of multilateral treaty. For example, we might modify Article VI of the TRIPS Agreement to require all member countries of the World Trade Organization to modify their exhaustion rules along the lines sketched above. That option, though appealing in its comprehensiveness, is hazardous – for the reason highlighted two paragraphs back. If it were not married to mandatory reforms on several other fronts, it could do more harm than good. However, we should not dismiss this option out of hand. In subsequent chapters, we will take up other possible adjustments of the TRIPS Agreement that, if paired with a change in Article VI, might have large aggregate benefits.

Finally, it bears emphasis that the slate of reforms we have identified is not a panacea. As we have indicated, it would go far toward alleviating the “access problem.” However, its impact on incentives to develop new drugs, though favorable, is likely to be modest. In the next two chapters, we consider some very different reforms whose capacity to address the “incentive problem” would be much greater.

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