

MARKET WATCH

Competition: An Antidote To The High Price Of Prescription Drugs

Under this proposal, government-owned patents would produce drugs that cost 60 percent less than those of private firms.

by Peter Stein and Ernst Valery

ABSTRACT: Patent protection and factors unique to prescription drugs weaken the forces keeping prices near costs for other products. A growing public consensus that affordable drugs should be available to all is likely to increase the upward pressure on prices. To restore competition to all parts of the pharmaceutical industry, we propose a new institute at the National Institutes of Health that would compete with the private sector for pharmaceutical intellectual property by establishing competition for research and development contracts open to public and private institutions; retain the resulting patents; and grant cost-free, nonexclusive licenses to all qualified producers.

THE PHARMACEUTICAL industry, comprising only 1 percent of U.S. gross domestic product (GDP) and 7 percent of total U.S. health care costs, receives more than proportionate attention from the media, advocacy groups, and the political debate. The industry is accused of unreasonable prices, discrimination against U.S. consumers in favor of those abroad, and insensitivity to a mix of public health problems ranging from the AIDS epidemic to bioterrorism. Worldwide, the industry is subjected to and threatened with unusually stringent regulation.

The high level of criticism and regulation is attributable to a mix of factors unique to the pharmaceutical industry. (1) It is largely structured as a parallel set of imperfectly competing markets. (2) Costs are not universally shared. Those with serious medical problems incur a disproportionate share of total spending, and what is a small part of national GDP becomes a

large part of family budgets. (3) Physicians, bearing no share of the cost, play a major role in determining individual purchasing decisions. (4) Fixed copayments shield individual users from sensitivity to or knowledge of costs. (5) Opportunities for third-party payers, who bear two-thirds of prescription drug costs, to exercise price discrimination are limited by ethical, political, and liability concerns.¹ (6) Access to prescription drugs is increasingly treated as a necessary component of quality of life in the United States.

In the pharmaceutical marketplace, producers shielded from price competition sell to consumers who often do not personally pay the bill. The inherent price instability of such a marketplace has led to the mix of regulation and subsidies found throughout the world.

■ **The drug industry: monopolistic or highly competitive?** Superficially, the pharmaceutical industry does not resemble a clas-

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sic monopoly. The largest firm accounts for only 20 percent of U.S. sales. Firms energetically compete to discover new products. While patents nominally shield firms from competition for twenty years, the average protection period is reduced to eleven years by the mandated certification process.² Furthermore, the successful developer of a breakthrough product must anticipate competition from “me-too” drugs during the patent period, and generic duplications afterward.

This description, however, ignores the unique structure of the industry. Each firm has a research and development (R&D) section and a manufacturing and marketing (M&M) section. The M&M section is subdivided into product divisions, each of which has a lifetime, determined by patent law and technological progress, that is much shorter than that of the firm. Most products have exclusive access to a customer base whose purchasing decisions are relatively price-insensitive.

Sometimes different drugs with similar goals compete for the same customers. But for insured customers, price is seldom a determining purchasing factor. Advertising campaigns boast of efficacy, convenience, and reduced side effects, but are silent regarding price. Even when identical generic drugs become available, manufacturers successfully compete without substantial price reductions.³ Thus, the M&M sections can be modeled as parallel noncompeting (more accurately, not engaging in price competition) divisions. Each has effective exclusive control of a defined segment of the pharmaceutical demand, albeit for a limited time. The firm and industry division makeup changes as older drug sales decline and new drugs emerge. But at any moment, the marketplace resembles many independent, highly inelastic markets, largely unaffected by competitors' pricing decisions.

In contrast, firms' R&D sections operate in a highly competitive environment. Patent law provides for only one winner in each race for a patentable new drug. Entrants face high entry fees, low probabilities of success, and long delays between entry and the initial flow of revenue. Despite these obstacles, current market

leaders cannot prevent well-financed new firms from entering and winning races.

Given these different operating environments, the industry cannot be classified as either competitive or noncompetitive. The more important question is how the rewards of the industry's entrepreneurial activities are divided between producers and consumers.

In principle, a competitive marketplace provides consumers with a steady flow of new products at a price close to the cost of production. However, pharmaceutical R&D competition does not do this. New products create their own demand, even in a noncompetitive environment. R&D competition determines the slice sizes of a pie whose increasing size is driven by the advance of science. Furthermore, R&D competition will not determine prices of a division that lacks competitors or finds its sales insensitive to competitors' prices. Thus, drug firms enjoy a greater share of the total surplus their products generate than do producers in other industries, and society suffers the deadweight loss attributable to reduced competition in its M&M sector.

The magnitude of the deadweight loss and allocative inefficiency are in dispute. Presumably, the allocative inefficiency attributable to reduced price competition should be reflected in higher profit margins and consumer prices than those in comparable but competitive industries. For example, Uwe Reinhardt argues that the drug industry's profit margin is elevated (18 percent), while the degree of risk is no greater than that of typical Standard and Poor's 500 firms.⁴ However, others argue that profit margins in the drug industry are no higher than those in comparable industries.⁵

Robert Guell and Marvin Fischbaum estimated the industry's allocative inefficiencies by comparing drug prices for matched pairs of drugs in the United States and Europe. Since no manufacturer can consistently sell below M&M costs, the lower price of the pair provides an upper limit to the M&M cost in a competitive marketplace. They found an allocative inefficiency in the U.S. market of \$5 billion for total sales of \$8 billion, or about 60 percent of sales.⁶ If these results are represen-

tative of the entire industry, introducing competition into the M&M sector should lower consumer prices by roughly 60 percent.

■ **The problem and current solutions.**

Because of patent law, the pharmaceutical marketplace can be characterized as a parallel set of markets lacking price competition, each with its own highly inelastic demand curve. The growing public consensus that prescription drugs should be universally available will increase the price instability inherent in such a market. Ultimately, producers' price increases will be tempered only by the fear of government intervention and regulation.

Several mechanisms to ensure access to pharmaceuticals at a fair price while maintaining a steady flow of new and improved products have been considered. Approaches fall into four broad categories: regulation, subsidizing consumers, increasing demand-curve elasticity, and limiting patent protection.

Although naturally monopolistic sectors of the economy such as transportation, communication, and utilities have been regulated in the past, the efficacy of regulation has been questioned recently. The United States has increasingly opted to replace regulation with competition using ingeniously restructured marketplaces. Regarding consumer subsidies, although subsidies benefit those receiving them, new sources of income increase rather than decrease the upward pressure on prices in an industry with an inelastic demand.

Raising the elasticity of the demand curve with increased copayments or formularies may decrease third-party payers' costs but will be experienced as higher costs and less access by consumers. Attempts to control prices by allowing the importation of drugs is akin to the hope that the Canadian tail can wag the U.S. dog, since firms themselves set both foreign and domestic prices. Regarding patent protection, faced with a reduced patent-protection period, firms may increase prices to maintain a product's lifetime revenue. More threatening to the public interest is the danger that firms will not pursue R&D for certain drugs because the patent-protection period is too short to make that pursuit profitable.

Bringing Drug Patents Into The Public Sector

The industry structure that binds R&D and M&M divisions together in the same firms is the root cause of excessive drug prices. We propose separating the two functions by enabling the government to seek drug patents and allowing all pharmaceutical firms to market the resulting products freely, thereby "genericizing" a large part of the industry at a new molecular entity's (NME's) birth. Before analyzing this proposal, we briefly describe two other ways to accomplish the same goal.

■ **Ban drug patents.** In 1946 Congress made devices relating to fissionable material production ineligible for patents. Today, for different reasons, Congress could decide to deny drug patents. Such legislation would surely lead to drastic reductions in pharmaceutical R&D. To maintain the flow of new products, the government would have to fund the R&D that the private sector is no longer performing. Intellectual property generated would reside in the public domain, accessible to any potential producer, and all new products could be generically marketed.

A number of serious objections could be raised to such an approach. (1) Publicly funded R&D may be less efficient than corporate R&D, resulting in fewer new products. (2) The government must spend more than \$100 billion to equal the planned private U.S. pharmaceutical R&D over the next five years. (3) Because of the lengthy R&D process and the large private R&D establishments, the transition to a publicly funded regime will be difficult to manage. (4) The World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement bars the United States from denying drug patents.⁷ (5) Integrating the United States into the global pharmaceutical marketplace would be difficult if it pursued this policy. These concerns and the risks inherent in a sudden disruption of the industry make it unlikely that banning patents could receive serious consideration.

■ **Buy drug patents.** Instead, the federal government could purchase drug patents from corporations at a mutually satisfactory price

and license them without cost to all producers, thereby lowering drug prices and reducing the deadweight loss that the absence of competition generates.⁸ While competition between producers would benefit consumers by promoting increased M&M efficiencies, freely negotiating patent holders would have little incentive to accept prices lower than the present value of their patents' future earnings.⁹ Thus, buying patents would not lower the current patent rent, set solely by patent owners, but would simply shift it from consumers and insurers to the government.

A Proposed Public/Private Competition For Patents

We propose "genericizing" a part or all of the pharmaceutical industry by enabling the government to acquire patents and license them freely to all qualified producers. Pharmaceutical intellectual property can be brought into the public domain in three ways. Two of these (denying and purchasing) have been discussed above. The federal government also could enter the competition for drug patents on an equal footing with firms.

■ **The proposal.** To pursue the latter course, the federal government would seek patents by funding R&D in government facilities, universities, hospitals, and research institutions. The government would seek approval from the Food and Drug Administration (FDA) for resulting patents. Once approval was obtained, the government would grant royalty-free, nonexclusive manufacturing/marketing licenses for domestic sales to all qualified producers. In foreign markets, the government could license patents at commercial fees or, as an incentive, allow grant recipients to seek foreign patents in exchange for a share of the revenues.

Public patent competition has major advantages over denying or purchasing patents. In addition to the patent development cost, a patent purchaser must expect to pay the patent's entire anticipated profit. A public/private competition completely avoids objections 3, 4, and 5, delineated in the previous section, to denying patents. However, objections 1 and 2 ap-

ply equally to the public/private competition and must be addressed.

Since the federal government has never sought pharmaceutical patents, its efficiency in doing so remains untested. However, it has successfully sponsored considerable scientific research: for example, the invention of the atomic bomb in 1942, the enormous growth of physical and biological scientific research since World War II, and the concept and early development of the Internet.

The relative efficiencies of public and private pharmaceutical R&D are difficult to evaluate, because direct head-to-head competition is rare. Detractors of public research often point to the competition to sequence the human genome. Although Celoron won the race, the public researchers were not far behind, and the competition is credited with spurring both efforts. However, general principles derived from a single example are often wrong.

The widely asserted beliefs that potential financial gain sharpens inventors' wits and the best scientists will sell their talents to the highest bidder are hard to test. However, private-sector competition has not prevented universities from attracting many of the best minds in the lucrative and commercially relevant fields of information science, economics, life sciences, and nanotechnology. Public and nonprofit institutions play host to a wealth of innovative biological talent, whose collective work forms the foundation on which the pharmaceutical industry rests. For example, of the eighty-six Nobel Laureates in Medicine recognized in the past thirty years, eighty were from public and nonprofit institutions, and only six were from corporate laboratories.

A trial in a limited sector would provide a test of the proposal's feasibility. The entry of the government into the patent competition would hardly be welcomed by existing firms but would not disturb the prevailing industrial framework. The relative efficiencies of the publicly and privately funded programs would be given by the relative ratio of patents to funding. A demonstration that publicly funded pharmaceutical R&D can successfully compete and reduce drug prices would pro-

vide considerable support for a broad extension of the concept.

■ **The cost of competing.** To establish the maximum program cost, we assume a program scope coincident with the total U.S. pharmaceutical R&D, with one important difference. The implicit goal of public R&D is the greatest community quality-of-life improvement given the appropriated funding, as opposed to maximum financial reward. Because the goals of private and public efforts differ, the ratio of R&D spending to quality-of-life improvement may be less for a public than a private program. The factors entering into our estimate are enumerated below.

(1) Total U.S. pharmaceutical R&D spending is not a matter of public record. Pharmaceutical Research and Manufacturers of America (PhRMA) reported R&D expenditures of 17 percent of sales, or \$19.9 billion, in 2000.¹⁰ Analyzing financial reports of several large drug firms, Reinhardt found average R&D spending of 12.9 percent of sales, which translates into \$15.1 billion.¹¹

(2) Since the structure of the industry's M&M sector is determined by who holds what patents, R&D aimed at increasing patent life or granting entry into markets dominated by competitors' patents brings financial reward without increasing public welfare. Thus, such R&D would not be in a government-funded portfolio.

However, PhRMA reports that in 2000, "21.5% [of pharmaceutical R&D] is devoted to significant improvements in, and/or modifications of, existing products."¹² Such R&D probably refers to changes in dosages or delivery systems, or both, in products with expiring patents to impede generic competition or maintain brand loyalty to compete with them.

Also, after an NME is successfully marketed, competing firms often investigate patentable related entities likely to have similar therapeutic effects. These "me-too" products allow entry into a previously barred marketplace. According to studies conducted in the 1980s and 1990s, "me-too" drug products account for 53–84 percent of drug sales.¹³

Various researchers have studied the frac-

tion of new patents classifiable as "me-too" drugs. In the 1990–1999 decade, the FDA classified NME reviews as either "priority" or "standard" and gave 57 percent of NMEs a standard review. A standard review is given when the NME "appears to have therapeutic qualities similar to those of one or more already marketed drugs."¹⁴ In the 1980–1989 decade, the FDA classified 41 of 258 NMEs as 1A (Important Therapeutic Gain), 80 as 1B (Modest Therapeutic Gain), and 137 as 1C (Little or No Therapeutic Gain).¹⁵ Assuming that all of 1C and part of 1B are "me-too" drugs, 53–84 percent of drugs patented from 1980–1999 are "me-too." A study of NMEs reviewed by the Italian Ministry of Health from 1984 to 1992 concluded that 66 percent were "me-too" drugs.¹⁶ A study by a task force of the Minnesota Medical Association concluded that "me-too" drugs account for 75 percent of sales.¹⁷ While these estimates vary and may use different criteria, no "me-too" estimate is lower than 53 percent, and one is 84 percent.

(3) Industry supporters argue that the R&D sections of pharmaceutical firms vigorously compete with each other. Thus, there must be major duplication of R&D effort.

While the winner of any NME race reaps the patent's entire producer benefit, the public's marginal benefit ascribable to the winner's entry into the race is only the value of the NME for the period between the winner's and runner-up's discovery times. The expenses of the winners' and losers' parallel R&D efforts are borne by the consumer community, since each firm funds its total R&D expenses out of the revenues of its winners. Thus, many equally efficient firms can succeed financially if each produces sufficient winners to finance its total R&D expense, even though a social cost/benefit analysis would not find all of their parallel R&D efforts to be an efficient use of resources.

Some level of duplication in a publicly funded program will be beneficial. Duplication establishes competition, and the desire to win any race—scientific, financial, or athletic—spurs all competitors. Moreover, parallel lines of research reduce the risk of overall failure. But the goals of a publicly funded pro-

gram (the success of any effort) and of a firm (that firm's success) differ, and the two would make different decisions about funding a parallel effort when several others are currently being pursued.

Neither the ideal level of R&D duplication nor data on the current level in the drug industry are known. Assuming that every "me-too" patent is the result of a "losing" R&D effort parallel to a breakthrough drug, an analysis of the ratio of "me-too" to breakthrough patents indicates that on average the industry supports at least three and possibly more than seven parallel lines of R&D.¹⁸ It is unlikely that the directors of a program with public-interest goals would choose to fund such a high level of duplication.

(4) It is not clear that a public program geared toward the pressing health needs of Americans would fund all of the current pharmaceutical industry R&D—for example, new therapies for maladies thought to be adequately addressed and cosmetic drugs.

By combining values for the above factors, we estimate a range for the cost of a federal program duplicating the industry's R&D effort: Assuming PhRMA's \$19.9 billion estimate for total industry R&D, deducting PhRMA's 21.5 percent for modifications, deducting the lowest estimate of 53 percent for "me-too" R&D, deducting 15 percent for R&D to reduce duplication but taking no deduction for R&D inappropriate for a public program, we obtain an annual expenditure of \$6.3 billion for the federally funded program.¹⁹ Assuming Reinhardt's estimate of \$15.5 billion for industry R&D and the 84 percent estimate for "me-too" R&D, the estimated cost of a federally funded program drops to about \$1.6 billion.

Thus, if a federally funded R&D program is as efficient as that of the drug industry, spending roughly \$6.3 billion or less per year will produce breakthrough drugs at roughly the current industry rate, and the resulting patents would be roughly equally divided between the private and public sectors.

■ **Role of the private sector.** The federal program would not in any way prevent private firms from seeking pharmaceutical patents in

any area. The government program's goals would be a matter of public record. Private firms could choose to compete, pursue areas that are not being addressed, or attack publicly or privately held patents with "me-too" R&D. Furthermore, firms could submit R&D proposals to the public program on the same terms as public and not-for-profit institutions. To the extent that industry claims that returns on its R&D investment are not excessive are correct, the R&D sector of the industry could continue to be profitable carrying out R&D for a competitive publicly funded program. The M&M divisions would, of course, compete by manufacturing and marketing the publicly licensed drugs.

To ensure fairness and a level playing field for those who carry out pharmaceutical R&D inside and outside of the publicly funded program, sturdy barriers must be erected between the patent-seeking federal agency and both the patent office and the FDA.

■ **Implementation.** Implementation of a public/private competition for drug patents would require an administrative structure, a source of funding, and a change in the legislation regarding patents resulting from federally funded research.

The National Institutes of Health (NIH) is the natural home for the program. Full funding of \$6 billion would require roughly a 25 percent increase in the NIH's R&D budget and the creation of a new institute to fund R&D for discovering, patenting, and seeking approval of new drug products. The institute would be governed by a board, comprising physicians, life science and pharmacology researchers, and representatives of the public, that would establish the institute's priorities by balancing public needs with pharmaceutical research capabilities. The institute would presumably be divided into sections with defined areas of responsibility. Each section's grant-awarding process would rely on the advice of peer-review panels composed of recognized leaders in each section's area of responsibility. Such panels have proved effective in insulating scientific decision making from political considerations.

The cost of a full-scale program could be financed by a combination of new prescription drug taxes, licensing revenues for foreign sales, and general revenues of the federal government. Since 2.9 billion prescriptions were written in the United States in 2000, a tax of approximately two dollars per prescription would by itself finance the full-scale program.²⁰ Because the U.S. government would finance the program, international beneficiaries should pay a fair share via licensing fees.

The Bayh-Dole Act defines patent policy regarding federally funded nonprofit and small-business R&D.²¹ It allows those entities to retain title to resultant patents so long as they negotiate licensing to fully utilize the patents. Since the goal of our proposed program is non-exclusive, royalty-free licensing of pharmaceutical patents, full-scale implementation would require amending the Bayh-Dole Act.

Given the long delay between the award of the first grant and the first drug sale, considerable patience would be required before the public enjoys the full benefit of the regime. Benchmarks and metrics would need to be designed carefully to evaluate the program's success and give the pharmaceutical industry time to adapt to the changing marketplace.

■ **Benefits to consumers.** In the current marketplace, pharmaceutical firms set prices to cover R&D, manufacturing, and marketing expenses in addition to the rent charged for their patents. Prices of the same products competitively marketed under cost-free licenses would eliminate all R&D and rent charges and decrease marketing expenses.

Lower prices. Guell and Fischbaum's analysis of identical drugs marketed in different countries shows a 60 percent differential between the two prices. In each case, the lower price can be taken as an upper limit for the drug's production-plus-distribution cost. In competition between equally efficient public and private R&D efforts, the public sector would win half of the races, and these drugs' prices should be 60 percent lower than they would have been if the private sector had owned the patents. The resulting savings would be roughly \$30 billion on \$100 billion sales, or about five

times the R&D cost of \$6.3 billion calculated earlier. The benefit could conceivably double if the private sector opted out of competing R&D and concentrated instead on production.

Implementation of our proposal would cause a major restructuring of the pharmaceutical industry. Given the magnitude of the change and the lack of applicable precedent, the cost and benefit estimates given are rough at best and should be taken only as indicators of the potential savings.

DTC ads and "me-too" R&D. A successful program might also greatly reduce direct-to-consumer advertising and "me-too" R&D, activities many believe do not augment and may even reduce societal welfare. Since all manufacturers may market drugs protected by publicly owned patents, no producer would be likely to fund advertising campaigns that benefit its competitors as much as itself. While the marketing programs employed by drug firms are probably inappropriate for a federal program, some effective way must be found to educate health care professionals about the uses and benefits of its products. Perhaps the educational need generated by publicly funded R&D will induce the NIH or FDA to issue unbiased evaluations of all new drug products.

"Me-too" competition between private firms can be expected to continue. However, if the price differentials between private and publicly licensed drugs with similar therapeutic efficacy are as great as we predict, insurers may refuse to reimburse the difference and diminish enthusiasm for "me-too" R&D to compete with publicly licensed drugs. Conceivably, the implicit threat of public "me-too" R&D to enable publicly licensed competition with privately held breakthrough patents would restrain the growth of nonpublic drug prices.

■ **Comparison with other proposed solutions.** The public/private patent competition has several advantages over other proposed ways to deal with high drug prices. Increasing copays restrains prices but denies drugs to price-sensitive consumers. Consumer subsidies do not restrain prices, but rather transfer them from individual consumers to

taxpayers. Since importing Canadian and European drugs and using the bargaining power of Medicare do not inhibit important drivers of drug prices such as excessive marketing costs and marginally useful R&D, some term them ineffective. On the other hand, both are simultaneously criticized as restraining R&D critical to the advance of public welfare.

The proposal presented here will increase the level of R&D in areas that bring the greatest social benefit, lower production costs by competition, and provide an alternate line of pharmaceutical products unencumbered by excessive marketing costs and marginal R&D.

■ **Testing the concept.** The natural division of the pharmaceutical industry into distinct product lines facilitates testing the efficiency, practicality, and costs/benefits of the concept without amending the Bayh-Dole Act. Given authority and funding, the NIH could establish a single section of the proposed NIH pharmaceutical R&D institute. This section would target a particular research thrust and award grants to qualified institutions for the whole range of R&D, from initial research to a useful new drug. Such grants would be awarded with the understanding that the federal government would retain patent rights and grant royalty-free licenses. Since current law gives the federal government march-in rights to distribute royalty-free, nonexclusive licenses for inventions made with federal assistance when necessary to meet requirements for public use, a limited test would not require amending the Bayh-Dole legislation.

NOTES

- Centers for Medicare and Medicaid Services, "National Health Care Expenditures and Selected Economic Indicators, Levels, and Average Annual Percent Change: Selected Years 1980–2012," February 2003, cms.hhs.gov/statistics/nhe/projections-2002/tl.asp (15 April 2004).
- H. Grabowski and J. Vernon, "Longer Patents for Increased Generic Competition in the U.S.," *PharmacoEconomics* 10, Supp. 2 (1996): 110–123.
- F. Scherer, "Pricing, Profits, and Technological Progress in the Pharmaceutical Industry," *Journal of Economic Perspectives* 7, no. 3 (1993): 97–113.
- U.E. Reinhardt, "Pharmaceutical Prices and the Market: The Economics of Prescription Drug Pricing" (Presentation at the National Press Club, Washington, D.C., March 2001).
- See, for example, Scherer, "Pricing, Profits, and Technological Progress"; and Ernst and Young, "Pharmaceutical Industry R&D Costs" (Washington: Pharmaceutical Research and Manufacturers of America, 2001).
- R. Guell and M. Fischbaum, "Towards Allocative Efficiency in the Prescription Drug Industry," *Milbank Quarterly* 73, no. 2 (1995): 213–229; and R. Guell and M. Fischbaum, "Estimating Allocative Inefficiency in the Prescription Drug Industry," *Applied Economic Letters* 4, no. 7 (1997): 419–423.
- R. Glennester and M. Kremer, "A Better Way to Spur Medical Research and Development," *Regulation* 23, no. 2 (2001): 34–39.
- R. Guell, "Haggling for a Patent: What a Government Would Have to Pay for Prescription Drug Patents," *Health Economics* 6, no. 2 (1997): 179–185.
- PhRMA, *2001 Industry Profile* (Washington: PhRMA, 2001).
- Reinhardt, "Pharmaceutical Prices."
- PhRMA, *2001 Industry Profile*.
- M. Goozner, "The Price Isn't Right," *American Prospect*, 11 September 2000, www.prospect.org/print/V11/20/goozner-m.html (16 April 2004); D. Drake and M. Uhlman, *Making Medicine, Making Money* (Kansas City: Andrews and McMeel, 1993); S. Garattini, "Are Me-Too Drugs Justified?" *Journal of Nephrology* 10, no. 6 (1997): 20–23; and J. Peters, "Hard to Swallow: The High Cost of Direct-to-Consumer Advertising," *Minnesota Medicine* 84, no. 1 (2001): 10–15.
- Goozner, "The Price Isn't Right"; Drake and Uhlman, *Making Medicine*; and Garattini, "Are Me-Too Drugs Justified?"
- Goozner, "The Price Isn't Right."
- D. Drake and M. Uhlman, *Making Medicine, Making Money* (Kansas City: Andrews and McMeel, 1993).
- Garattini, "Are Me-Too Drugs Justified?"
- Peters, "Hard to Swallow."
- Goozner, "The Price Isn't Right"; Drake and Uhlman, *Making Medicine*; and Garattini, "Are Me-Too Drugs Justified?"
- $\$19.9B \times (1 - 0.215) \times (1 - 0.53) \times (1 - 0.15) = \$6.3B$
- S.M. Foote and L. Etheredge, "Increasing Use of New Prescription Drugs: A Case Study," *Health Affairs* 19, no. 4 (2000): 165–170.
- Patent and Trademark Act Amendment of 1980*, P.L. 96-517.