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Demonizing Drugmakers The Political Assault on the Pharmaceutical Industry

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Executive Summary

Few sectors of the economy have provided more benefits to consumers than the pharmaceutical industry. Drugmakers have been vilified by patients and politicians alike, however, because of what they see as unreasonably high drug costs.

Yet medicine is not the most important component of the recent rise in health care expenses. Moreover, the primary reason for current increases in total drug costs is that more and more people are using newer medicines—which means that consumer benefits are rising even faster.

Simplistic comparisons between drug costs in the United States and those in other countries have little value. Economic wealth, exchange rates, product liability rules, price controls, and other factors all contribute to the price of drugs.

More important, prices for U.S. pharmaceuticals are not excessive relative to the benefits they offer. Drugs have contributed to the sharp reduction in mortality rates from many diseases, including AIDS (Acquired Immune Deficiency Syndrome). Pharmaceuticals also reduce the cost of alternative treatments. Thus, restricting access to the newest and best drugs can be economically counterproductive.

Unfortunately, the only way to develop new

drugs is to invest heavily in research and development. The \$30 billion spent annually by U.S. drugmakers dwarfs the budget of the National Institutes of Health and investments by foreign drug companies. Profits of U.S. firms tend to be high, but not uniformly so, and they create a “virtuous cycle” that encourages more R&D to create new medicine.

Yet industry critics propose everything from socialized medicine to price controls and limits on patents. Such measures would, however, reduce incentives to create new medicines. It is true that some people, especially poor people in less-developed countries, lack sufficient access to pharmaceuticals. Private charity at home and abroad should make pharmaceuticals more available to people who are most in need, and Washington should include a drug benefit as part of overall Medicare reform. In the meantime, states should help needy seniors through limited pharmaceutical access programs.

Policymakers must avoid taking steps that would, intentionally or not, wreck a world-leading industry and deny people access to life-saving medicines.

Increasingly, policymakers treat the innovative drug industry like a political piñata—whacking it with accusations and threats while expecting it to yield its treasured prizes.

Introduction

Few sectors of the economy have been more successful or provided greater benefits than the pharmaceutical industry. Many Americans owe their health and lives to new products that emerge on a regular basis from that industry. In the coming years genetic research is likely to dramatically expand the benefits of pharmaceutical research and development.

One might fairly expect most people, especially those who are ill, to be grateful. However, demonstrators around the world are targeting the pharmaceutical industry—apparently for daring to sell the AIDS drugs that it created at high cost. The tone for the war on “Big Pharma” was set in the 2000 presidential race, when then-vice president Al Gore campaigned against drugmakers with faux populist rhetoric: “Big tobacco, big oil, the big polluters, the pharmaceutical companies, the HMOs, sometimes you have to be willing to stand up and say no, so families can have a better life.”¹ It was an astonishing comparison that equated companies that make life-saving products with companies that are often accused of harming consumers. Yet in the same speech, the vice president acknowledged “a time of almost unimaginable medical breakthroughs”—produced by the very companies he was attacking.² Although George W. Bush won the election, his administration largely abandoned its defense of drug patents at later meetings of the World Trade Organization. In the fall of 2001, Department of Health and Human Services secretary Tommy Thompson implicitly threatened to override Bayer’s patent for Cipro if the company did not sharply cut the drug’s price during negotiations to purchase a large quantity for protection against the new threat of anthrax bioterrorism.

Legislators have been even more hostile. Rep. Bernard Sanders (I-Vt.) argues that because people can’t afford necessary drugs, “many are suffering and even dying.”³ Instead of lauding drugmakers for prevent-

ing pain and death, he blames them for causing pain and death.

State officials voice similar criticism. West Virginia governor Bob Wise (D) says that pharmaceutical prices are “outrageous” and warns that big, brand-name drug companies are “going to be spreading lies and half-truths” in response to his state government’s efforts to control the prices they charge.⁴

The rhetorical assault has been backed by legislative attacks, which have left the pharmaceutical companies under siege. One lobbyist told the *National Journal* “The industry has gotten a lot of bad press, and it seems that, each day, there’s a new headline. I think it’s going to be increasingly difficult to win battles. Everybody’s looking at the PhRMA [Pharmaceutical Research and Manufacturers of America] companies as villains. They’re really getting nailed.”⁵

On what seems to be a daily basis, both federal and state politicians are putting forward proposals for various forms of price controls, patent invalidations, and advertising restrictions. The hunt is on for more generous drug benefits at lower prices. A potentially unprecedented expansion of the Medicare entitlement in the form of prescription drug benefits has become the top domestic policy issue in Congress. Whether those benefits will be managed in private competitive markets or subjected to centralized price controls remains to be seen. State legislators faced with bloated Medicaid program budgets have latched on to high drug prices as the key culprit. The political appetite for increased Medicare and Medicaid drug benefits shows no sign of abating. Many officeholders hope to feed it with a steady diet of mandatory price ceilings, weakened patent rights, and restrictive drug formularies (lists of covered and preferred drugs). Increasingly, policymakers treat the innovative drug industry like a political piñata—whacking it with accusations and threats while expecting it to yield its treasured prizes.

Others fault drug companies for advertising their wares too directly and aggressively to consumers, claiming that such advertising merely increases purchases of high-priced

“me-too” drugs that offer little therapeutic advantage over cheaper and older ones. Drugmakers are also accused of exploiting legal loopholes to extend their patented drug monopolies well beyond reasonable bounds.

Negative treatment of drugmakers in the media may have hit its peak last May, when ABC News aired an hour-long special report, “Bitter Medicine: Pills, Profit and the Public Health,” which leveled a series of one-sided charges against the pharmaceutical industry. The program stated that there was little evidence that the huge increase in drug spending over the past six years has dramatically improved the health of Americans. Narrator Peter Jennings observed that much of the profit from prescription drug sales comes not from breakthrough drugs but from drugs that are similar to already popular medications. ABC News quoted National Institute of Health Care Management Foundation president Nancy Chockley as finding that “most of the growth was really in drugs that did not show any significant clinical improvement.” Jennings made other accusations about the drug industry, including that its lawyers and lobbyists have created or found so many loopholes in the patent laws that some generic drugs are delayed or never get to market. The program concluded, “The rules by which this hugely profitable industry operates do not always serve customers adequately.”⁶

Even in the aftermath of last fall’s elections, which restored Republican Party control of both houses of Congress and a marginally more favorable Capitol Hill climate for the pharmaceutical industry, the crusade against drug companies continues. The heat is still on brand-name drugmakers to yield more of their profits and the patent rights that protect them so that generic imitators can flood the market with lower-cost versions of today’s drugs and officeholders can dispense them more widely to public health program beneficiaries. Whether the issues ahead are indirect price controls, coerced “discounts,” dilution of patent rights, reimportation of U.S.-manufactured drugs

from lower-priced foreign markets, or old-fashioned political scapegoating, the common focus is to force down prices. Under one guise or another, government would confiscate revenue from firms, in effect seizing their property.

The steady political barrage aimed at “demonizing drugmakers” is having dangerous effects. The most recent annual survey by the polling firm Harris Interactive finds that the public image of pharmaceutical firms has plummeted over the last five years. In 1997, 79 percent of respondents thought that drug companies did a good job of serving their consumers; in 2002, only 59 percent did.⁷ Although brand-name drug manufacturers have not yet sunk to the political pariah status of tobacco companies, oil companies, and HMOs, it increasingly seems that the more good drugmakers do, the more hated they become.

The Problem of Costs

What’s driving the political attacks on the pharmaceutical industry is the rising cost of prescription drugs. In its latest survey on drug pricing, the NIHCM Research and Educational Foundation found total pharmaceutical outlays rising 17.1 percent during 2001—almost twice as much as the annual increase in total medical expenditures (9.6 percent) and much more than overall medical inflation (2.3 percent).⁸ NIHCM expected drug costs to continue rising, at a 13.5 percent rate in 2002, an average 11.7 percent a year between 2003 and 2007, and a somewhat slower average annual rate of 10.3 percent between 2008 and 2011.⁹

With government outlays accounting for more than 45 percent of all health care spending (plus another 10 percent in tax subsidies for private health insurance premiums), soaring drug costs weigh heavily on federal and state government budgets, encouraging legislators to clamp down. For example, Medicaid spending for outpatient drugs increased by an average of 18.1 percent

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Insistence on government intervention risks killing the goose that lays the golden eggs.

per year from 1997 to 2000, compared to 7.7 percent for total Medicaid expenditures.¹⁰ Officeholders would prefer to offer even more generous drug benefits to their citizens, but without asking them to pay most, if not all, of the costs.

Moreover, some of their constituents are accustomed to insurance coverage for most other forms of medical care that, from an insured person's perspective, appears to be largely free, and they therefore complain about rising out-of-pocket costs for prescription drugs. In particular, the traditional Medicare program does not provide outpatient prescription drug benefits, and even other supplemental private insurance coverage for seniors requires significant copayments and cost sharing. For example, only 28 percent of outpatient prescription drug expenditures was paid out of pocket in 1998 across the entire U.S. population, but 50 percent of drug expenditures was paid out of pocket by the average Medicare beneficiary in 1996.¹¹ Moreover, approximately one-third of all Medicare seniors lack any insurance coverage for outpatient prescription drugs. Unless they qualify for subsidized drug discount cards or state-based assistance programs, seniors who don't have drug coverage lack bargaining clout and must pay cash to meet the highest retail prices in the marketplace.

More recently, even workers and families with private insurance coverage for prescription drugs increasingly see themselves at greater financial risk. Pressured by the rising costs of health plan benefits, their employers and health insurers are asking them to share more of the costs of prescription drugs by paying higher copayments when they fill prescriptions for brand name (nongeneric) drugs.

Thus, many patients are more likely to know when pharmaceuticals cost more, even if they otherwise pay little or no attention to higher charges by doctors and hospitals that are covered by comprehensive third-party insurance. This disparate treatment in health care expenditures increases sensitivity to rising drug prices and fuels political demands

for expanded coverage and lower prices.

Even more sensitive to prices are AIDS patients in poor nations. AIDS is a hideous disease, difficult enough to treat in wealthy industrialized countries. It poses an even greater crisis in less-developed nations, where the standard treatment regimen costs many times the local per capita income. Concern for the impoverished has spurred the anti-pharmaceutical campaign to go international.

Alas, drug industry critics have gotten the issue almost entirely wrong, from the statistics they cite to the solutions they promote. Their insistence on crude government intervention to lower drug prices, rather than dynamic market-based innovation to improve our overall health, risks killing the goose that lays the golden eggs.

Torturing Statistics

Despite conventional political assumptions, prescription drugs are not the driving force behind rising health care costs. In fact, hospital care costs were the most important component of rising health care expenses in 2001, accounting for 51 percent of the increase.¹²

Nor are costs rising so fast because drug-makers are hiking prices. It only seems so because, as the old adage goes, if you torture statistics long enough, they will confess to anything. According to the NICHM Research and Educational Foundation, just 37 percent of the rise in retail prescription drug spending in 2001 was attributable to price hikes. More of the drug spending increase was caused by other factors: 39 percent represented an increase in the use of drugs, and the remaining 24 percent a shift to the use of newer, more effective, and thus more expensive pharmaceuticals.¹³ As the foundation observed in its May 2001 report on annual drug expenditures, "Simply put, Americans are demanding, and physicians are prescribing, a higher volume of medicines every year."¹⁴

This is not a new phenomenon. Between 1996 and 1999 a rising number of pharmaceutical consumers accounted for 14 percent of increases in drug spending, and a rising

number of prescriptions per consumer generated 38 percent of the increase. The latter rose most rapidly among people aged 65 and above.¹⁵ Actual price increases, in contrast to higher usage, are likely to be tempered in coming years by the expiration of aging patents. In August 2000, the NIHCM estimated that, between 2000 and 2005, existing brand-name drugs that would account for nearly \$20 billion in cumulative U.S. spending were scheduled to go off patent and face competition from lower-cost generics that would be likely to drive down their prices.¹⁶

Nor do lower prices overseas demonstrate that firms are overcharging U.S. consumers. In recent years, American politicians have organized well-publicized bus trips to Canada to allow constituents to purchase pharmaceuticals at lower prices. "There's no question that prescription drugs cost too much in this nation," claimed Sen. Jim Jeffords (I-Vt.).¹⁷

No question? Simplistic international cost comparisons must be viewed with skepticism. Prices in other nations generally reflect the lower incomes in some countries and the highly politicized nature of most foreign health care systems that rely on price controls and access restrictions. Exchange rate variations also matter, because America's relatively strong dollar makes drugs overseas seem particularly cheap.

Patricia Danzon of the Wharton School notes that drug prices in Mexico, for example, are low compared to those in Europe as well as in the United States, because Mexico has a much lower per-capita income and spends far less on health care and pharmaceuticals (around one-tenth and one-third of U.S. levels, respectively). The Mexican government also regulates drug prices and provides only limited patent protection for pharmaceuticals.¹⁸

What about the much-touted lower drug prices in Canada? They partly reflect slow growth in the Canadian economy and the decline of the Canadian dollar, which has lost nearly a quarter of its value over the past decade. As a result, many goods—not just pre-

scription drugs—are cheaper there than in the United States. Canadians also benefit from less, and less expensive, product liability litigation. Economist Richard Manning estimates that one-third to one-half of the drug price differential between the two countries is due to the higher cost of liability litigation in America.¹⁹ Danzon also points to differences between Canada and the United States in the degree of patent protection and price controls that are applied to pharmaceutical products.²⁰ When Dr. John Graham, director of the Pharmaceutical Policy Research Center at Canada's Fraser Institute, and Tanya Tabler, a student at the Faculty of Pharmacy at the University of Alberta, recently surveyed prices on both sides of the U.S.–Canada border, they found that although drug costs were lower in Canada, the price differences within the two countries meant that "a shopper can save almost as much money by bargain hunting within his own area as by crossing the border."²¹

After adjusting cross-national drug price differences for such factors as the role of generics (which have a relatively larger market share in the United States), volume discounts, and frequency of use, Danzon and Jeong D. Kim found, using 1992 data, "that the average U.S. consumer would have paid 3 percent more in Canada, 27 percent more in Germany, 30 percent less in France, 9 percent less in Italy, 8 percent less in Japan, 44 percent more in Switzerland, 9 percent more in Sweden, and 24 percent less in the UK."²²

New Drug Development Improves Patient Treatment and Well-Being

A narrow emphasis on the cost of prescription drugs is misguided in another way. Prices cannot be debated in isolation. Drugs do not simply represent unnecessary expenses that need to be controlled (although medical professionals are as apt as patients to think in these narrow terms).²³ Even though the steadily increasing demand for drugs drives up their prices and overall cost, that demand reflects the premium that Americans place on improved well-being. That is, more patients

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utilize drugs to meet their medical needs more effectively.

The highest-priced drugs do not represent luxury goods; they address serious and painful conditions. About half (50.6 percent) of the \$22.5 billion increase in retail drug spending in 2001 occurred among just nine categories of medicines—those used to treat depression, high cholesterol, diabetes, arthritis, high blood pressure, pain, allergies, ulcers, and other gastrointestinal ailments.²⁴

Consumers demand pharmaceuticals because they offer enormous benefits. Some 400 new drugs ended up on the market during the 1990s because people desired them, just as they wanted thousands of other new products—computers, software, cell phones, autos, SUVs, and much, much more. As J. D. Kleinke, president of Health Strategies Network, puts it, “medical progress is expensive.”²⁵

For instance, cancer is a scourge that touches many of us in a personal way. Pharmaceutical producers are fighting back. “Cancer Doctors See New Era of Optimism” was the headline for one recent article in the *New York Times*.²⁶ That optimism stems from the fact that drugmakers had more than 400 anti-cancer medicines in the pipeline in 2001.²⁷

Not all of those innovations will work, of course, and even those that do may become available too late for some people. Yet anti-cancer medicines under development embody dramatic hope for the future: 68 address lung cancer, America’s deadliest cancer; 59 combat breast cancer; 55 go after colon cancer; 52 attack prostate cancer; and another 52 target skin cancer, a common risk facing anyone who regularly works or plays outdoors.²⁸ Dr. William Gradisher of Northwestern University reports: “For ten years, what we have all been hoping for is new biological therapies. Now almost every company has several in development. There is a plethora of new drugs.”²⁹ Merck is working on a vaccine for cervical cancer.³⁰ Even thalidomide, the anti-morning sickness drug that caused birth defects, has been enlisted for use in the war on cancer.³¹

So fast are the advances coming that one doctor repeatedly operated on Minnesotan

Todd Hendrickson in order to “keep Mr. Hendrickson alive so he could keep searching for a medical cure.”³² In August 2000, Hendrickson became the first patient to take the drug Gleevec, approved by the Food and Drug Administration three months before, and he remained alive the following year.³³ Gleevec is thought to be just one of a “new generation of cancer fighters,” reports Nicholas Wade in the *New York Times*, that “will be the long-awaited payoff for decades of research into the molecular biology of cancer. Unlike chemotherapy and radiation, blunderbuss weapons that attack healthy as well as cancerous cells and can cause severe side effects, the new agents are designed to kill cancer cells alone. In principle, they should eliminate malignancies more effectively while being far gentler on the patient.”³⁴

Nor are pharmaceutical companies targeting only cancer. Xigris, which combats sepsis, an infection of the bloodstream, was approved in November 2001. “We’re talking about tens of thousands of lives per year potentially saved by this product if used appropriately,” predicts Dr. Jay Siegel of the FDA.³⁵

There are 122 drugs under development for heart diseases and strokes. Congestive heart failure and strokes are each the targets of 18 medicines in development; peripheral vascular disease is the target of 12; adjunctive therapies and hypertension are each the target of 11 prospective drugs.³⁶

Drugmakers are developing nearly 100 new products to fight AIDS and AIDS-related conditions.³⁷ Although hopes for a vaccine have been raised and dashed before, the prospect seems to be improving: “Experts now dare to say they may finally be on a path to a vaccine that will offer at least some protection,” reports Denise Grady in the *New York Times* “They are hedging their bets, cautioning that a finished product is probably still 10 years away. But scientific advances have led to renewed enthusiasm.”³⁸

Another 256 medicines will strike infectious diseases of all sorts, including hepatitis, pneumonia, staph infections, and sexually transmitted diseases like herpes and gonorrhea.³⁹ A number of vaccines, ranging from improved

polio compounds to new treatments to prevent cocaine addiction, Alzheimer's, and traveler's diarrhea, are also in process.⁴⁰ Drugs are being developed to combat more mundane conditions, such as high cholesterol, psoriasis, and obesity.⁴¹ Even something as simple as an antihistamine to ameliorate an allergy for cat hair can dramatically improve the quality of life (and make a marriage possible).⁴² One can look at the benefits another way: 358 medicines under development address more than 30 diseases that disproportionately afflict women.⁴³

Existing compounds are often found to have new uses. For example, pain relievers may help prevent Alzheimer's.⁴⁴ Statins, used to lower cholesterol, appear to reduce the likelihood of strokes as well as heart attacks.⁴⁵

All told, pharmaceutical advances have transformed health care. "Three decades ago medical technology was rather primitive by today's standards," says Dr. E. M. "Mick" Kolassa of the University of Mississippi School of Pharmacy. "Today, physicians have at their disposal medications and technologies that provide for the immediate diagnosis and treatment of most of the disorders that affect modern man."⁴⁶ Charting the human genome is opening up new, even more dramatic vistas, in which drugs are likely to be customized to individuals and potential side effects charted and avoided.⁴⁷ Sean Lance, CEO of the biopharmaceutical firm Chiron, predicts, "We are going to win over HIV, malaria, and tuberculosis because of biotech."⁴⁸

Reduced Mortality

By one estimate, new prescription drugs accounted for nearly half (45 percent) of the variation of the reduction in mortality among different diseases between 1970 and 1991. Longevity has increased seven years since 1960 alone. According to Columbia University Graduate School of Business professor Frank Lichtenberg, "On average, each new drug approved during the period 1970-91 is estimated to have saved 11,200 life-years in 1991 (and presumably continued to do so in subsequent years)."⁴⁹

Pharmaceuticals are an especially important reason why deaths from AIDS in the United States have dropped from 50,610 in 1995 to 15,245 in 2000. When that disease was first identified in the early 1980s, there was no treatment. In 1987, there was just one. Now there are 64 different AIDS drugs available, with more than a hundred more in development. Among the 25 top-selling categories of drugs in the United States, the most expensive are those designed to treat HIV (human immunosuppressive virus) and AIDS.⁵⁰

Seniors are disproportionately heavy consumers of drugs as well as other forms of health care—spending about three times as much as those under 65. As a group, seniors also benefit disproportionately: the relationship between drug expenditures and life expectancy is stronger at age 60 than it is at age 40.⁵¹

Saving Money

Medicines do more than extend lives. They improve the quality of lives—not just the patients' lives but the lives of their family members and other caregivers. Pharmaceutical products provide economic benefits as well by reducing other medical expenditures by, for example, lowering the rate of hospitalizations, surgeries, and other invasive medical treatments. One recent study of the use of anti-AIDS drug cocktails calculated that the drugs actually saved \$2,000 annually by reducing hospitalizations.⁵² More broadly, Lichtenberg used data from the 1996 Medical Expenditure Panel Survey and concluded that replacing 1,000 prescriptions for older drugs with 1,000 prescriptions for newer drugs would increase drug costs by \$18,000 but slash hospital costs by at least \$44,000.⁵³

More generally, Lichtenberg figures that every \$1 increase in pharmaceutical expenditures actually lowers hospital spending by \$3.65. Although use of drugs might increase physician care, leading to a \$1.54 increase in ambulatory care, Lichtenberg reports that because pharmaceutical R&D spending is so small in comparison to total hospital care

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expenditures, “pharmaceutical R&D spending would reduce total health expenditures (including pharmaceutical R&D) if it reduced hospital expenditure by as little as about 2 percent.”⁵⁴

In sum, as health care analyst Kleinke explains:

Added pharmacy costs that offset other medical costs represent the economics of progress. They reflect a profound, permanent movement in our health care system away from medical labor and toward medical technology—a belated catching-up of health care with the rest of the “new economy.” The added costs associated with breakthrough drugs represent a major structural shift from the provision of traditional medical services to the consumption of medical products, a systemic rotation from labor to capital.⁵⁵

Thus, government actions that discourage creation and distribution of drugs will “save” money only at enormous cost. People will die sooner. Their lives will be more painful. And other health care expenditures will rise.

Profits, Prices, and Progress

Related to complaints about the rising costs of newer drugs are complaints about profits in the pharmaceutical industry. Here, too, raw numbers must be treated with caution and not analyzed out of context. For example, the drug industry has been attacked for having average profits of 19 percent. In fact, adjusting for accounting vagaries involving R&D investments (which are written off as current expenses instead of depreciated over time), the actual return is 9 percent.⁵⁶

There are a number of ways to measure drug industry profits, but none of them suggest unwarranted levels. Henry Grabowski and John Vernon of Duke University figured

the industry’s internal rate of return on new drug introductions to be 11.1 percent, compared to a cost of capital of 10.5 percent, for the period from 1980 to 1984 (expressed in 1990 prices).⁵⁷ Dr. Steve Wiggins of Texas A & M University estimated that, because the industry’s capital costs ran 15.1 percent in 1990, its estimated return was between 13.5 and 16 percent.⁵⁸ Lakshmi Shyam-Sunder and Stewart Myers of the MIT Sloan School of Management similarly figured a 15 percent nominal return (10 percent real) as of January 1990.⁵⁹ And even unadjusted pharmaceutical profits have often trailed similar profit figures for other firms, such as Coca-Cola, Microsoft, Nabisco, and the Tribune Company.⁶⁰

No Guarantees in the Risk-Reward Calculus

Although most drugmakers do well, some do not. For example, Merck and Schering-Plough recently faced slower than expected sales and profits. A year later, the latter’s earnings had improved but Merck was still struggling. Bristol-Myers Squibb and Eli Lilly also suffered significant earnings drops. Bayer found it difficult to sell its drug subsidiary.⁶¹

Moreover, Duke University economists Henry Grabowski and John Vernon compare pharmaceutical company returns to those of venture capital firms that spread money to a large number of projects, most of which fail.⁶² In a nutshell, higher rewards provide the incentive to take on higher risks.

In any case, higher-than-expected profits are a result of higher-than-average R&D investments; these profits in turn will finance future R&D. Dr. Maven Myers termed this the “virtuous cycle.”⁶³ Disrupting this cycle by cutting profits means less R&D. There simply is no free lunch: lowering profits will lower R&D. F. M. Scherer of Harvard University explains:

Combined with evidence that profit rates of return on pharmaceutical industry R&D investments tend to exceed risk-adjusted capital costs by

only modest amounts, the pattern suggests that pharmaceutical industry R&D is best described by a virtuous opportunities rent-seeking model. That is, as profit opportunities expand, firms compete to exploit them by increasing R&D investments, and perhaps also promotional costs, until the increase in costs dissipates most, if not all, supranormal profit returns.⁶⁴

Many people appear to believe that pharmaceuticals fall from the sky rather like manna from heaven. In their view, employees of the evil drug companies got up before anyone else and grabbed the manna, and then sold it at outrageous prices.

If only it worked that way.

American pharmaceutical makers spent more than \$26 billion in 2000 and some \$30 billion in 2001 to find medical needles in haystacks. The National Institutes of Health (NIH) also plays an important role, a fact emphasized by some industry critics.⁶⁵ But more than half (54 percent) of government R&D expenditures for health care primarily fund basic research, and they represent only about a small fraction of drug R&D.⁶⁶ Even Public Citizen admits, “NIH officials claim [tracking pharmaceutical research spending is] a tough task because so much NIH work is basic research into diseases that is converted years later—often through several other related discoveries that build on one another—into a marketed drug.”⁶⁷

Indeed, private companies are responsible for moving products through testing and development before they can reach the market. Firms are generally credited with the discovery and development of about 90 percent of new medicines, while the NIH played a role in the remainder.⁶⁸ Explains Henry Grabowski of Duke: “Government-supported research gets you to the 20-yard line. Biotech companies get you to the 50-yard line and [the big pharmaceutical companies] take you the rest of the way to the goal line. By and large, government labs don’t do any drug development. The real originator of 90

percent of prescription drugs is private industry. It has never been demonstrated that government labs can take the initiative all the way.”⁶⁹

The Rising Cost of Risky Investments in Drug R&D

R&D spending by U.S. pharmaceutical firms, as a percentage of sales, has grown from 11.4 percent in 1970 to an estimated 17.7 percent in 2001.⁷⁰ Private-sector financing of drug industry R&D averages more than four times as much (as a percentage of sales) as average R&D spending for all U.S. industries.⁷¹ If adjusted for the prolonged time period that it takes for drugs to be fully approved for sale, the R&D share of drug industry spending represents almost one-third of total costs.

The industry estimates that drugs cost an average of \$500 million to develop. Most independent analyses run far higher, and they report a steadily increasing price tag for successful development of a new drug. Three studies in the 1980s figured the average drug cost to run between \$108 million and \$231 million; one estimate in the 1970s ran \$120 million.⁷² In 1993 the congressional Office of Technology Assessment figured the cost at \$194 million (after tax) and \$359 million (before tax), in 1990 dollars.⁷³ More recent estimates by Lehman Brothers and the Boston Consulting Group are \$608 million (after tax) and \$880 million (before tax).⁷⁴ A new study from the Tufts Center for the Study of Drug Development matches the latter estimate, calculating that “between the time research begins to develop a new prescription medicine until it receives approval from the FDA to market the drug in the United States, a drug company typically spends \$802 million over the course of 10 to 15 years.”⁷⁵ Real R&D costs per drug prior to FDA approval have increased two-and-a-half times over the past decade or so.⁷⁶

Public Citizen recently contested the above estimates of the cost of new drug development, pegging it at \$110 million.⁷⁷ But, according to Ernst and Young:

Higher-than-expected profits are a result of higher-than-average R&D investments. There simply is no free lunch.

A drug company typically spends \$802 million over the course of 10 to 15 years for each new prescription medicine.

In several key aspects, the Public Citizen approach deviates from standard methodologies adopted by previous research and the financial and accounting communities. On many issues, the report presents selective evidence and ignores strong evidence to the contrary. These shortcomings understate the report's estimated costs of pharmaceutical R&D.⁷⁸

Even such substantial investments by the drug firms do not guarantee results. Of every 5,000 to 10,000 substances reviewed, only about 250 make it to the animal-testing stage. Around 5 of them go on to human clinical trials. Only one, on average, makes it into the market. Even at that point, only 3 of 10 new drugs actually make money. Indeed, Duke's Grabowski figures that only 10 percent of drugs generate a return on investment.⁷⁹ Those few must pay for everything—research, administration, regulatory delays, and failures.⁸⁰ Thus, the small marginal cost of making an extra pill is irrelevant, because no drugs would be developed at all and no companies would survive if that cost alone determined the price.

The traditional incentive used to attract capital for running the arduous, costly, and risky enterprise of drug development has been the granting of exclusive patent rights by the federal government. Patents provide monopoly rights to sell and license innovative drug products for a limited number of years. Winners in the race to innovate count on the potentially high profits protected by patents to cover their sunk costs of R&D and to replenish their capital for future rounds of drug discovery efforts.⁸¹ Patents play a disproportionately important role in the drug industry. The share of inventions introduced because of patent protection is eight times higher in pharmaceuticals than in a set of 11 other industries.⁸²

Of course, some critics contend that the market really doesn't work because exclusive patent rights last too long, limit competition, and lead to excessive economic concentra-

tion. In fact, the pharmaceutical industry is remarkably open and competitive, comprising 650 companies, none of which holds more than 11 percent of the worldwide market.⁸³ The top 10 firms account for no more than 60 percent of sales.⁸⁴ Competition does indeed lag in certain diagnostic areas, where a few drugs tend to dominate the market. In the top 30 drug categories, the leading drug averages 33.5 percent of the market, and the top four drugs account for 68.1 percent.⁸⁵

No Rest for the Successful

Not even the best company can rest on its laurels. Pharmaceutical firms holding exclusive patent rights remain subject to generic competition when their patents expire, and they also face the more immediate threat of therapeutic competition from other brand-name manufacturers.

Actual price increases, in contrast to higher usage, are likely to be tempered in coming years by the aging of patents. For example, *Business Week* estimated in December 2001 that drugs that were then worth \$35 billion per year in U.S. sales could fall off patent and face price competition from generics by 2005.⁸⁶ For example, Eli Lilly has profited greatly from its anti-depression drug Prozac. With the patent for Prozac expiring, however, Michael Arndt of *Business Week* reported in July 2001 that "Lilly will no longer be protected from cheaper generics. Within weeks, the company could see two-thirds of its global market for Prozac—and much of its profit—vanish."⁸⁷ After Eli Lilly's earnings for the first quarter of 2002 fell 22 percent, the company responded by ramping up R&D, greatly improving its future prospects. It even created a subsidiary, InnoCentive, to award grants to scientists.⁸⁸

Generics can provide vigorous competition against brand-name drugs that have expired patents. After the 1984 Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act dispensed with duplicative safety and efficacy testing requirements for generics firms, the role of generics exploded. Generic drugs now make up more than 47

percent of the prescriptions filled for pharmaceutical products.⁸⁹ Increased generic competition reduced the returns on brand-name drugs by an estimated 12 percent.⁹⁰

Generic drug producers do little original research, because they are designed to imitate brand-name drugs and be offered for sale at lower prices. Ironically, it is the brand-name drug industry that has come under criticism recently for producing “me-too” drugs.⁹¹ A May 2002 study by the NIHCM Research and Educational Foundation found that only 15 percent of new drug approvals from 1989 to 2000 were for “highly innovative drugs”—medicines with new active ingredients that provide significant clinical improvement. It noted that in the last half of the 1990s the number of incrementally modified drugs approved by the FDA grew at a faster pace than drugs based on new molecular entities. It then criticized new “standard-rated” incrementally modified drugs—those approved in 1995 or later but providing no significant clinical improvements over existing products—for accounting for 36 percent of the increased retail spending on prescription drugs from 1995 to 2000.⁹²

That sort of criticism misunderstands and minimizes the valuable role of “between-patent” competition. A recent National Bureau of Economic Research study by Frank Lichtenberg and Tomas Philipson points out that a patent protects an innovator only from other competitors seeking to produce the same product, but it does not protect him or her from other competitors producing better products under new patents.⁹³ In the case of drug innovators, such between-patent competition (called “creative destruction”) occurs early instead of late in the life of a patent. It is at least as effective, and perhaps twice as effective, as generic competition (“uncreative destruction”) in cutting consumer prices. In fact, only a minority of drugs—perhaps as few as 10 percent—ever faces any generic competitors at all.⁹⁴ Perhaps more important, stimulating therapeutic competition within various dis-

ease categories produces newer medications that are likely to be more effective in reducing mortality, morbidity, and, ultimately, total medical expenditures.

Even me-too products increase competition and thereby lower prices. Some me-too drugs result when a company proceeds on a parallel research track but comes in second or third. Moreover, me-too pharmaceuticals often yield important advances.⁹⁵ For instance, the antidepressant Zoloft helps many people who weren’t aided by earlier products.⁹⁶ Lichtenberg found only weak support for the view that new “priority review” drugs (drugs assessed as representing advances over available therapy) reduce mortality more than new “standard review” drugs (drugs appearing to have health effects similar to those of already marketed drugs).⁹⁷ Indeed, Raymond Woosley and Sally Usdin Yasuda of Georgetown University report that 72 percent of the drugs approved from 1981 to 1988 and classified by the FDA as offering little therapeutic value compared to existing products turned out to be a front-line therapy for the disease they treated. For example, the FDA classified Prozac as providing only a marginal improvement over existing anti-depressive medications.⁹⁸

“New and improved” versions of existing drugs may have different safety and efficacy profiles from other drugs in the same therapeutic class, which enables physicians to match drugs with the needs of different patients so that more people can be treated with a particular type of therapy than would be the case if only one drug were available. Other incrementally modified drugs can enhance patients’ choice and convenience and make it easier for patients to comply with prescribed drug regimens.⁹⁹

Quite simply, newer medications tend to be more effective in reducing mortality, morbidity, and ultimately total medical expenditures.¹⁰⁰ If anything, drugmakers are being singled out for criticism because the system has worked too well, encouraging development of a host of newer, better, and more expensive medicines.

Most countries regulate drug prices. . . . Massive waiting lists, care denied, disincentives for R&D, and limited access to new technologies and treatments are standard.

**Reimportation
policies for drug
sales would
effectively apply
foreign price
controls on the
American market.**

Political Solutions That Cause More Problems

Alas, since new, better, and more expensive medicines are considered to be a problem, American politicians have come up with a host of counterproductive “solutions.” The most common is price controls, though other favorites include stripping away patent protection, limiting advertising, and expanding taxpayer-financed subsidies.

Price Controls

Price controls can be direct or indirect. Some proposals would link U.S. prices to foreign levels; others would limit the costs of drugs purchased as part of federal or state programs. Some creative state legislators would bring the non-poor under Medicaid, which imposes price controls on pharmaceuticals.

Most countries other than the United States regulate the prices of drugs, whether directly through price controls, indirectly through limits on reimbursements under social insurance programs, or indirectly through profit controls imposed on drug companies.¹⁰¹ Any form of price restriction tends to be inherently arbitrary and generate a host of unintended consequences. Whatever the official criteria of the price control regime, warns John Calfee of the American Enterprise Institute, “decisions would be dominated by political forces, including managed care organizations, domestic versus foreign manufacturers, patient groups, insurance firms, employee benefit managers, labor unions, and other advocacy groups.”¹⁰²

The general case against price controls is clear.¹⁰³ Their experience running back to ancient times is extremely poor.¹⁰⁴ They inflate demand, depress supply, create shortages, shift activity to unregulated sectors, and encourage wasteful avoidance and evasion activity.¹⁰⁵ They also inevitably drift toward more complicated controls, entrench vested interests, take on a life of their own, and become extremely difficult to dismantle.¹⁰⁶

Price controls have the same impact on

health care. Massive waiting lists, care delayed and denied, disincentives for research and development, and limited access to new technologies and treatments are standard.¹⁰⁷

Problems are rife even in the best of single-payer health systems, such as the one in Canada, that rely on price controls.¹⁰⁸ They include long lines; minimal access to diagnostic technologies; patients fleeing abroad, particularly to America, to jump local queues; provinces contracting out treatment to U.S. hospitals; pressure to sharply boost spending; and even proposals to move closer to the American system.¹⁰⁹ Indeed, when the province of Ontario closed its hospitals around Christmas 1993 because it was out of money, Theodore Freedman, president of Toronto’s Mount Sinai, which was shuttered for two weeks, put it bluntly: “This is not about health care. This is about the deficit.”¹¹⁰ A government commission now wants to increase the national government’s subsidies by 50 percent.¹¹¹

Price controls have also sharply reduced access to needed drugs in Canada.¹¹² Of 400 drugs considered for reimbursement by the Canadian province of Ontario between 1994 and 1998, only 24 were approved. Provinces waited months or years before adding newer medicines to their formularies.¹¹³ Unfortunately, explains Dr. McArthur, in the province of British Columbia more than a quarter of all doctors report that they have had to admit patients to the emergency room or the hospital because of government-mandated substitutions of prescription drugs to older and less expensive medicine; 6 of 10 have seen their patients’ condition worsen or symptoms accelerate due to mandated substitution of drugs.¹¹⁴

Europe’s experience with price controls on pharmaceuticals is similar. Europeans also have far less access to prescription drugs, particularly newer, more effective products.¹¹⁵ The research group Europe Economics has found that patients often wait years for access to even life-saving new medicines.¹¹⁶ Incredibly, the more useful the product and the more people to be helped, the smaller likelihood

that European governments will quickly approve it. Countries “facing tight budget constraints will be more resistant to a given price demanded by a company the higher they expect the demand for the product to be,” according to Europe Economics.¹¹⁷ (More recently, the pharmaceutical industry has begun to take a more aggressive stance in fighting use and price controls in Europe.)¹¹⁸

The group Public Citizen claims that European firms “still maintain robust R&D activities, despite the price controls in the European market.”¹¹⁹ Yet a 1992 study found that countries with the lowest prices (due to price controls) yielded the least productive drug research.¹²⁰ U.S. R&D expenditures now outstrip those in Europe, and American firms produce more new medicines.¹²¹ Over the last decade company investment has doubled in Europe. Over the same period it quintupled in the United States.¹²²

American firms appear to be increasing their edge, something that has not gone unnoticed in Europe. Reports David Pilling of the *Financial Times*:

Companies that until recently were considered glowing examples of European competitiveness are slipping behind their US competitors. By 2002, according to forecasts, only three of the world’s 25 top-selling drugs will be made by Europeans. US companies will account for no fewer than 20. Only a decade ago, half of all top-selling drugs were European.¹²³

Reimportation—“Importing” Foreign Price Controls

Yet socialist Rep. Bernard Sanders (I-Vt.) complains that “in Vermont and all over the United States, alone among industrialized nations, the drug companies can charge any price they want for their product—no matter what the consequence.”¹²⁴ Many legislators at the federal and state level would change that. For example, Rep. Tom Allen (D-Maine) would limit U.S. prices paid by Medicare ben-

eficiaries to the average foreign price of drugs sold in Canada, France, Germany, Italy, Japan, and the United Kingdom.¹²⁵ Some state legislators have suggested limiting state prices to those charged in other countries, particularly in Canada.

In 2000, Congress passed legislation that would have allowed reimportation from foreign markets of drugs originally produced in the United States.¹²⁶ Although President Clinton signed the Medicine Equity and Safety Act into law on October 28, 2000, HHS Secretary Donna Shalala blocked implementation of its reimportation provision the following December because she could not certify (as required by the legislation) that reimported drugs would be safe and that the legislation would result in significantly lower prices.¹²⁷ Supporters of reimportation returned to the issue during the 107th Congress, focusing on reimportation from Canada or other highly industrialized countries that would raise fewer concerns over counterfeit or poor-quality imports.¹²⁸ In July 2001, HHS Secretary Thompson reaffirmed the Shalala decision, and congressional efforts to enact revised versions of reimportation authority fell short.

Reimportation policies for drug sales would effectively apply foreign price controls on the American market. As Sen. Byron Dorgan (D-N.D.) explains, “It is not my intention to have the American people go to another country for their drugs. It is my intention to force the pharmaceutical industry to reprice their drugs here in the United States.”¹²⁹ Representative Sanders is even more explicit in saying, “it is likely that the day after reimportation passes, the pharmaceutical industry will lower their prices in the United States to the same level that they sell their products worldwide.”¹³⁰

As noted earlier, accurate comparisons of drug costs in different countries are difficult and rare, because drug price data reflect other nations’ relative wealth levels, their fluctuating currency values, the degree to which their health care systems are politicized and their drug prices regulated, their

Unless someone pays for the development of drugs, no one will develop them.

Pharmaceutical price controls in other industrialized countries result in reduced access to new medicines, unnecessary pain, and premature death.

relative mix of generic versus brand-name drugs, and the consumption patterns of their citizens. The extent to which prices are lower abroad reflects one critical fact: "The United States is the last free market for pharmaceuticals; other developed nations control drug prices, as in Japan, Canada, and France, or drug company profits, as in England. So Americans typically pay higher prices for new medications than people anywhere else in the developed world."¹³¹

On the surface, this situation seems unfair, if not arbitrary, to many Americans. As Bill McArthur, a physician formerly with the Fraser Institute admits: "In effect, [Canada] must steal U.S. research and development to maintain itself."¹³² Even so, residents of other nations, like Canada, find their access to pharmaceuticals, especially new, more effective products, to be highly restricted.¹³³

But attempting to flatten prices is not the answer. A uniform international price would be impossible to maintain. Exchange rate vagaries would quickly create radical price divergences in many cases. Trying to maintain uniformity would not only be administratively difficult; it would be economically suicidal, since no business can ignore the economic conditions of the market within which it is selling.

Moreover, U.S. citizens are not paying higher prices to subsidize foreign consumers. Pharmaceutical companies are profit-maximizing businesses that base their prices on local supply and demand. As long as they can cover the marginal cost of selling an additional pill overseas, they will do so. But they will not keep selling at a loss in another country no matter how abundant their primary market (in the United States) remains. They are under no long-term obligation to sell their drug products to anyone. And if drugmakers could charge more in the United States, they would do so, irrespective of foreign opportunities.

Because the Canadian market is only about 6 percent of that of the United States, drugmakers would be more likely to charge

higher prices in Canada, cap the number of pills sold there,¹³⁴ or even exit its market than reduce their prices to any great degree in the United States.¹³⁵ With other foreign markets even less remunerative than that of Canada, pricing restrictions tied to sales overseas would most likely cause companies to sacrifice those markets or at least cut back on sales there in order to protect their primary source of profit, the U.S. market, which accounts for about 40 percent of global sales. Such a policy would help no one: overseas customers would pay more for less quantity and lower quality, U.S. manufacturers would lose sales and revenue, and Americans would bear an even greater relative burden of reduced spending on global R&D.¹³⁶

To the extent that such legislative initiatives lowered prices, they would cut companies' incentive to invest in new drug development, limiting production of and access to new, life-saving compounds. If Washington joined other countries in confiscating the wealth of drugmakers, companies would have little choice but to continue providing their existing wares for less. Firms would not, however, have the same incentive to make new medicines: unless someone pays for the development of drugs, no one will develop them.¹³⁷

Europe has managed as well as it has because it, like Canada, can free ride to some degree off of the United States. Even so, pharmaceutical price controls in other industrialized countries result in reduced access to new medicines, unnecessary pain, and premature death.¹³⁸ There are no less-regulated foreign markets for innovative drugs off of which Americans can free ride, a situation that makes proposals for new restrictions particularly dangerous.

Any form of price control reduces the incentive to invest. For example, public attacks on drugmakers accompanied the Clinton administration's 1993 proposal to allow HHS bureaucrats to set prices of new breakthrough drugs. The real annual rate of increase in industry R&D spending fell from 9 percent that year to about one-third as much, just over 3 percent in 1994, and 4 per-

cent in 1995 (reflecting the slight lag in implementing R&D investment decisions) before returning to double-digit percentage annual levels for the rest of the decade as the political threat to pharmaceutical industry profit margins receded.¹³⁹ In 2001 U.S. industry R&D rose 17 percent, compared to just 2 percent for American companies in much more heavily regulated Europe.

John Vernon of the University of Pennsylvania's Wharton School finds that the larger the proportion of a firm's pharmaceutical sales that are subject to price regulation, the smaller its R&D expenditures will be as a proportion of its sales. Price controls and other equivalent regulations clearly reduce the expected return on investment. Vernon estimates that if U.S. policy mandated price regulation that was identical to the "average" degree of price regulation present in other pharmaceutical markets outside the United States, it would lead to an approximate 46.5 percent reduction in drug industry R&D investment intensity and correspondingly high costs in terms of foregone medical innovation.¹⁴⁰

Mandatory Discounts

Within the past decade, a more limited version of price controls has crept into the U.S. health care system in the form of mandatory "best price" discounts for several federal health care programs. Medicare's coverage of prescription drugs is generally limited to those administered to hospital patients, but Medicaid uses extensive price controls through the "mandatory" discounts that it imposes on drug reimbursements. Those discounts then are leveraged into similar price controls for other federal government health programs.

The Omnibus Budget Reconciliation Act of 1990 (OBRA) required drug manufacturers to give state Medicaid programs price discounts that (following several initial phase-in years) amounted to the greater of (1) 15.1 percent off the average manufacturer price charged to wholesalers, or (2) the best price given to any private customer.¹⁴¹ Two years later, the Veterans Health Care Act of 1992

(PL 102-185) increased the bargaining power of the Department of Veterans Affairs and other federal agencies (the Department of Defense, the Public Health Service, and the Indian Health Service) that administer health programs. It required drug manufacturers to make their innovator drug products¹⁴² available on the Federal Supply Schedule (FSS) when those products are eligible for Medicaid reimbursement. The legislation required drug manufacturers to sell their products to the four federal agencies at a discount that amounted to the greater of (1) 24 percent off their nonfederal average manufacturer price, known as the federal ceiling price—or (2) the lowest price given to a comparable nonfederal purchaser.¹⁴³ The actual pricing calculations required under the law to determine the final FSS price are more complex than this simplified description, but in most cases the FSS price is the federal ceiling price.¹⁴⁴

By tying participation in the FSS to Medicaid reimbursement eligibility, the Veterans Health Act provided the Department of Veterans Affairs, as the largest single FSS purchaser, greater leverage in negotiating FSS prices. However, drug manufacturers soon responded by limiting most of their discounts for private buyers to no more than the minimum Medicaid-mandated discount of 15.1 percent. The General Accounting Office found that between 1991 and 1993 the median discount for private buyers declined from 24 percent to 14 percent for HMOs and from 28 percent to 15 percent for group purchasing organizations.¹⁴⁵ The Congressional Budget Office similarly found that the weighted average "best price" discount in a sample of brand-name drugs declined from 37 percent in 1991 to 19 percent in 1994.¹⁴⁶ Although these best price discounts probably saved the federal government and state governments some money in their respective financial shares of drug reimbursement costs, they caused drugmakers to raise their prices for private sector payers. In short, OBRA shifted costs instead of reducing them.

Drug manufacturers generally put up with

The larger the proportion of a firm's pharmaceutical sales that are subject to price regulation, the smaller its R&D expenditures will be as a proportion of sales.

Several states have moved to impose price controls that could jeopardize incentives for drug development and reduce access to high quality health care for Medicaid beneficiaries.

the mandated FSS price discounts because FSS sales account for a relatively small share (less than 2 percent) of their total sales. Also, manufacturers did not want to forfeit sales revenue from the much larger Medicaid market (more than 10 percent of total sales), although, as noted above, they had to adjust other prices to accommodate Medicaid discounts. Washington's demands might have been arbitrary, but they did not dominate the market. However, proposals to extend the FSS discounts to Medicare drug purchases (accounting for more than 40 percent of outpatient pharmaceutical sales) would increase revenue losses for drugmakers and make them much more reluctant to participate in the FSS. OBRA's experience suggests that drugmakers would become more hesitant to grant large discounts to any purchaser, since that would mean extending the price break to a much greater share of the market.¹⁴⁷

State-Based Price Controls

In recent years, many states have been hard pressed to keep their budgets under control. Tax revenues have declined as the economy worsened, but expenditures have continued to rise. The state share of Medicaid program expenditures, and prescription drug spending in particular, is one of the fastest growing components of state budgets. Not surprisingly, many state legislators, seeking a quick fix, have targeted for special attention the highly visible prices that their Medicaid programs pay for prescription drugs. If price cuts are achieved through negotiations based on the bulk purchasing power of state agencies (or even voluntary compacts of several states) and limited to regular participants in state-funded programs, the process resembles normal bargaining by organized purchasers that occurs elsewhere in the marketplace. However, most of the state-based Medicaid discounts are mandatory and, unlike market-driven rebates, they are not negotiated on the basis of the demonstrated ability of a particular state Medicaid program to move market share from one manufacturer's drugs to those of a competitor.¹⁴⁸

Moreover, several states have moved well

beyond that to attempt to impose far-reaching price controls that could jeopardize incentives for innovative drug development and reduce access to high quality health care for their Medicaid beneficiaries. In search of much deeper price concessions, they are threatening to restrict access to Medicaid reimbursement through tight formularies and by unilaterally imposing price cuts on rebates. For example, Florida and Louisiana have passed legislation requiring price rebates before drugs can be placed on their Medicaid formularies.¹⁴⁹ A number of states require prior authorization before doctors can prescribe certain expensive drugs for Medicaid patients. Florida experimented with another form of political extortion by allowing firms to provide other health services in order to avoid drug price controls or exclusion from the state Medicaid drug list. Florida negotiated a separate deal with Pfizer that allowed all of that company's medicines on the Medicaid formulary in exchange for financial contributions to a "disease management" program that is supposed to cut costs, and additional donations of pharmaceutical products to 30 community health centers¹⁵⁰

Maine and Vermont have adopted the most extreme restrictions, passing blatant price control systems—in the form of commissions assigned to set "fair" prices for their Medicaid programs—and then expanding the Medicaid-designated discount to non-Medicaid recipients.¹⁵¹ Such measures encourage people, especially seniors, with current private drug coverage to rely instead on seemingly more generous public benefits. Moreover, the restrictive Medicaid formularies used to extract price concessions necessarily channel patients to older, less effective medications.¹⁵²

For example, in May 2000 the governor of Maine signed into law the Act to Establish Fairer Pricing for Prescription Drugs. The legislation authorized the state to negotiate rebates for some of the 325,000 uninsured state residents (regardless of their income) who are not eligible for Medicaid. The rebates were to be at least equal to those applicable to the state's Medicaid program. If

drug manufacturers did not agree to negotiate rebate agreements with state officials, their drug products would be subject to prior authorization requirements before they could be eligible for any other reimbursements under Maine's Medicaid program.¹⁵³ The state was also given authority to impose more explicit limits on drug prices if negotiations with drug manufacturers did not produce prices comparable to the lowest prices paid in Maine.¹⁵⁴

However, PhRMA challenged the constitutionality of the "Maine Rx Program" before it could be implemented. PhRMA claimed that the act violated the U.S. Constitution's dormant Commerce Clause and was preempted by the federal Medicaid statute under the Supremacy Clause. Although a federal district court in Maine struck down the program as unconstitutional on both grounds, the U.S. Court of Appeals for the First Circuit reversed the decision. It found that (1) there was no evidence that the administrative burden imposed by prior authorization would likely harm Maine's Medicaid recipients, (2) the program regulated only in-state activities, and (3) its local benefits outweighed any incidental burden on interstate commerce. The case was appealed to the U.S. Supreme Court. The High Court heard oral arguments on January 22, and a decision is expected by late June.¹⁵⁵ While at least nine states besides Maine have adopted laws recently that either restrict access to higher-priced drugs in their Medicaid programs or mandate larger discounts for reimbursable drugs, even more states are holding off passage of legislation similar to Maine's until the Supreme Court decides the legal issues.¹⁵⁶

Vermont also ran into legal challenges to its efforts to impose additional price rebates for drug purchases by elderly and low-income residents who were not eligible for Medicaid. The D.C. Circuit Court of Appeals ruled on April 10, 2001, that, because no Medicaid funds were expended under this Medicaid demonstration project (the Pharmacy Discount Program or PDP) and

thus no Medicaid savings were produced, HHS officials lacked authority to approve Vermont's plan to require drug manufacturers to rebate a portion of the price of drugs purchased directly by PDP participants.¹⁵⁷

On June 1, 2001, Maine launched a prescription drug program similar to that of Vermont, called Healthy Maine Prescriptions. It too faced legal challenges in the federal court system. Healthy Maine Prescriptions differed from the aforementioned Maine RX Program. It operated as an experimental state Medicaid program expansion under a federal waiver that extended Medicaid's prescription drug price ceilings to other Maine customers who earned too much to qualify for Medicaid but still had annual incomes no greater than three times the federal poverty level. About half of the 225,000 eligible beneficiaries in Maine participated in Healthy Maine Prescriptions. Unlike the original version of Vermont's PDP, this second Maine program included a voluntary contribution from the state equal to about 2 percent of the program's drug costs. PhRMA filed a lawsuit in federal court that challenged the authority of Secretary Thompson to approve the demonstration project. Although Federal District Court judge Ricardo Urbina ruled in February 2002 that the state contribution was sufficient to justify the experimental program,¹⁵⁸ the U.S. Court of Appeals for the District of Columbia struck down the program on December 24, 2002.¹⁵⁹ It ruled that the program violated Medicaid law and was an inappropriate expansion of the Medicaid program, even as a demonstration project. The three-judge panel of the appeals court determined that Maine's voluntary financial contribution never received formal federal approval and the state still could abandon or reduce its payments at any time (even if the court upheld the program). With no guarantee of state money to contribute to the cost of the program and no federal money either, the court ruled that it was illegal for drug companies to bear almost the entire cost of the Healthy Maine Prescriptions program.¹⁶⁰

Another price control strategy is reference

The U.S. Court of Appeals for the District of Columbia ruled that Healthy Maine Prescriptions violated Medicaid law.

States can play a constructive role in making prescription drugs affordable for lower-income seniors without extending the reach of take-it-or-leave-it price controls.

pricing, which groups drugs by therapeutic purpose and limits reimbursement (usually for Medicaid) to the cheapest product. Under a Michigan law approved in November 2001, a committee decides the “best-in class” drugs in 40 categories. A drug may be included on the preferred drug list only if its manufacturer agrees to pay steep rebates to the state that go beyond those already required by the Medicaid program. Preferred drugs then get special treatment by both the state Medicaid program and a state-funded program for the elderly. Other higher-priced drugs that are not on the list will face greater hurdles for reimbursement. A patient’s doctor wanting to prescribe those drugs must obtain prior authorization from state pharmacy technicians before they will be eligible for state reimbursements.¹⁶¹

Unfortunately, not all drugs are alike. As E. M. Kolassa notes, “The prices charged for new medicines, although higher than those charged for older medicines, are low when compared with their improved value.”¹⁶² Arbitrarily moving Medicaid patients away from new drugs will have an impact on some beneficiaries’ health; it may also affect non-Medicaid recipients, since doctors, out of habit, if nothing else, tend to prescribe the same drugs for all patients.¹⁶³

To the extent that state efforts take hold and artificially reduce prices, they will have the same effect as any other politically mandated price control. Although one small state would have only a limited impact on the national marketplace, a “mandatory rebate” coalition of several large states might create a system approximating national price controls. Diane Rowland, executive director of the Kaiser Commission on Medicaid and the Uninsured, observes, “Alone, they can be picked off, but if they stand together, they can win.”¹⁶⁴ They can win, that is, if winning is defined as plucking the pharmaceutical goose, even if doing so eventually kills it.

States can play a constructive role in making prescription drugs affordable for lower-income seniors without extending the reach of take-it-or-leave-it price controls. Quite simply,

states should aid those most in need. The best vehicle for such assistance is a senior pharmaceutical assistance program that uses subsidies, discounts, or both, usually targeted at the indigent elderly. The oldest such initiatives at the state level go back to 1975. Today, 34 states have plans, though their eligibilities and benefits differ.¹⁶⁵ Such programs should be strictly limited to those in need: In 2001, just over 8 percent of Medicare beneficiaries spent \$2,000 or more annually out-of-pocket on pharmaceuticals.¹⁶⁶ The average senior spends more than twice as much on entertainment than on medicine.¹⁶⁷

Other state-based initiatives might include tax credits for drug purchases, buyers’ clubs, and purchasing cooperatives. Education is also a good tool: a half dozen states engage in “counter-detailing” efforts that encourage, but do not require, doctors who prescribe more expensive drugs to consider alternatives.¹⁶⁸

Stripping Away Patent Protection

Another fundamental assault on the pharmaceutical industry comes from those who would strip patent protection from drugs that generate the most social benefits. Some would erode patent rights to accelerate the market entry of lower-priced generic drug alternatives, others would do so to reduce the price of medicines that could counteract bioterrorism, and still others would do so to combat AIDS and other serious diseases in less-developed countries.

Hatch-Waxman Revisited

Patents give their owners the right to exclude others from making, using, or selling an invention for a fixed period of time. Drug manufacturers are in a unique position in that they cannot sell their patented products until they have successfully completed clinical trials and received FDA approval. The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) attempted to offset the special regulato-

ry burdens imposed on drugmakers by restoring the effective patent life of their approved drug products. It extended the duration of market exclusivity for brand-name prescription drugs for specified periods of time.¹⁶⁹ At the same time, Hatch-Waxman created an expedited approval process for generic drugs that eliminated duplicative tests for safety and efficacy. The legislation was a compromise that aimed to balance the goals of maintaining incentives to invest in developing innovative drugs and encouraging generic competition to reduce the prices of older ones.

Under the early years of the new regime, both brand-name drugmakers and their generic competitors prospered. By the early 1990s, the average effective patent life was restored to nearly 12 years, after it had dipped as low as 9.5 years in the period before Hatch-Waxman.¹⁷⁰ The generic drug industry's market penetration rose from 18 percent of all prescriptions to more than 40 percent.¹⁷¹ Additional reforms of the regulatory process for new drug approvals (the Prescription Drug Users Fee Act of 1992 and the Food and Drug Administration Modernization Act of 1997) combined to reduce the average drug development time by another two years.¹⁷²

However, the rising costs of prescription drug bills in recent years have triggered various complaints about brand-name companies exploiting legal loopholes to extend the patent life of their higher-priced drugs and delay competition from makers of cheaper generic drugs. On July 31, 2002, the Senate approved the Greater Access to Affordable Pharmaceuticals Act of 2002 (S. 812) to limit patent-holding drug firms to a single automatic 30-month stay, which would delay approval of a generic drug application whenever a brand-name drugmaker sued its generic competitor for alleged patent infringement.¹⁷³ The 30-month stay is meant to approximate the average time needed to resolve such patent disputes, but the Senate provision aimed at curbing the practice of "late-listing" additional patents after a gener-

ic drug application is filed in order to generate and "stack" multiple 30-month stays. The legislation would have also allowed generic drugmakers to legally challenge "frivolous" patents, and it restricted agreements between brand-name manufacturers and potential generic competitors that would delay the latter's entry into the market.

Just one day before the approval of S. 812, the Federal Trade Commission issued a study entitled "Generic Drug Entry Prior to Patent Expiration." The study highlighted two provisions under Hatch-Waxman that are "susceptible to strategies" that may sometimes prevent the availability of more generic drugs. The FTC recommended that, in the case of patent infringement disputes, the FDA should permit only one automatic 30-month stay per drug product per new generic drug application. Brand-name drugmakers claiming infringement of their later-listed patents could seek a preliminary injunction in court, but without benefit of the automatic stay. The FTC also recommended that legislation should require brand-name drug companies and first generic applicants with 180-day market exclusivity rights to provide copies of patent infringement settlement agreements to the FTC and the Justice Department so that they could be monitored to prevent any "parking" of generic exclusivity.¹⁷⁴

Although the House never voted on the generic drug provisions, President Bush announced on October 21, 2002, that the FDA would propose a new rule that would allow brand-name drugmakers only a single 30-month stay to resolve alleged patent infringements.¹⁷⁵ Unlike the Senate bill, the Bush administration proposal did not authorize generic drugmakers to sue brand-name companies for filing "frivolous" patents meant solely to prevent competition. Nor did it set specific time limits for patent infringement lawsuits by brand-name drugmakers against generic competitors.¹⁷⁶

Political skirmishing over patent protection may have closed a few legal loopholes, but evidence of the alleged patent abuses was relatively rare in any case. Interest groups on

Under the early years of Hatch-Waxman the generic drug industry's market penetration rose from 18 percent of all prescriptions to more than 40 percent.

The out-of-pocket visibility of expensive new drugs makes drug-makers “a likely and easy target.”

both sides of the debate were maneuvering and repositioning in search of marginal gains through indirect means. Brand-name drug-makers in some cases were pushing the limits of Hatch-Waxman to offset more recent declines in the effective patent lives of their products due to longer clinical trial periods required by the FDA.¹⁷⁷

Managed care insurers were hoping to highlight high prescription drug prices as the scapegoat for soaring health insurance premiums, according to analyst J. D. Kleinke, who observed that “pharmacy cost increases are something of a public relations convenience for the nation’s health insurers.”¹⁷⁸ Kleinke pointed out that insurance premiums have been increasing far out of proportion to increases in total medical costs in recent years, as part of the so-called health underwriting cycle, following the harsh pricing wars of the mid-1990s. Even though prescription drugs account for too small a share of medical spending to be the primary cause of significant increases in insurance premiums, the out-of-pocket visibility of expensive new drugs makes drugmakers “a likely and easy target.”¹⁷⁹ Ironically, the 1990s brand of managed care relied on disease management theories that deliberately liberalized the use of pharmaceuticals. It assumed that low drug copayments, as well as aggressive and earlier medical treatment, would reduce the long-run costs of chronic diseases. But, as Kleinke notes, many expensive breakthrough drug therapies do not pay off quickly enough for health insurers who face short-term financial targets and rapid turnover among the population of their health plan enrollees.¹⁸⁰ He faults insurers for adopting strategies that are based on visible, short-term cost savings and failing to address the larger issue of health care quality. They relied on price-driven tiering of drug coverages and copayments instead of developing better incentives to constrain drug spending based on long-term clinical and economic value.¹⁸¹ Of course, the fundamental problem at the heart of the conflict is the lack of direct and accountable relationships between insurers and most health care consumers. If more employees relied less on comprehensive third-party group insurance

that was selected, administered, and seemingly “paid” either by their employers or by government program administrators, they could purchase their own insurance and be the ultimate decisionmakers regarding how much and what kind of drug coverage they received.

The federal government’s efforts to find a political balance between encouraging competition and allowing competition become more complex when its patent enforcement role collides with its financial stake as a major purchaser of prescription drugs. The temptation is to renege on its previously promised patent protection in order to arbitrarily drive down the prices it pays. Nevertheless, the only legitimate course of action is to consistently protect the regime of limited monopoly rights (patents) that it created. Federal officials should not get caught up in the fine-tuning, legal wrangling, and game playing over the terms and conditions of patents for innovative drugs.¹⁸² Policymakers should instead more consistently guarantee a set of fixed but limited terms for drug patents and thereby encourage the continued availability of investment capital needed for productive drug development.¹⁸³

Fighting the Wrong War against Bioterror

Consider the federal government’s recent approach to the drug industry’s role in the war against terrorism. In the aftermath of the September 11 terrorist attacks, analysts warned about anthrax, botulism, equine encephalitis, hemorrhagic fevers (such as Ebola), plague, ricin, smallpox, and tularemia.¹⁸⁴ The federal government began devoting resources to creating vaccines and treatments. The obvious policy step should have been to turn loose the drug industry as well.

“You have a huge science-based industry that is not aimed properly,” says Martin Rosenberg, a retired scientist with GlaxoSmithKline: “The government simply must put the right carrot in front of the companies.”¹⁸⁵

That carrot should be patents, which allow firms to profit from their research. The prospect of a reasonable return is necessary given the enormous expense required—as much

as \$50 billion over the next 5 to 10 years, according to one estimate, to provide “substantial protection against most threats.”¹⁸⁶

Of course, uncertainty about future demand for more esoteric treatments and vaccines might discourage companies from spending heavily to develop such new products. Vaccines directed at bioterrorism have not generated much enthusiasm among venture capitalists.¹⁸⁷ In cases where normal market incentives seem inadequate to develop pharmaceuticals that have substantial value, government could provide an incentive for private production—not only purchasing a stockpile but, if necessary, subsidizing the creation of production facilities. In the case of vaccines that might protect citizens against bioterror threats like smallpox, Washington should foster the products’ general availability rather than lock them away in a government stockpile. Individuals could then decide in a noncrisis atmosphere whether or not to get vaccinated in advance, balancing the risks and benefits. That said, one must be wary of the serious difficulties that are likely to arise from government–industry partnerships in the development, in contrast to supply and distribution, of drugs.¹⁸⁸

In his State of the Union Address on January 28, President Bush announced that a new initiative called Project BioShield would guarantee up to \$6 billion in permanent funding over the next 10 years to develop and make available drugs and vaccines to protect against biological and chemical weapons. The proposal would begin to address the need for stable procurement incentives to encourage innovative private sector development of medical countermeasures against a host of current and next-generation bioterror threats. It also would provide greater flexibility to the FDA to accelerate the availability of promising countermeasures and authorize their use in an emergency.¹⁸⁹

Unfortunately, the federal government’s clumsy response to a series of anthrax-related bioterror attacks in the fall of 2001 and its heavy-handed treatment of the makers of Cipro may have already undercut the incen-

tive for future private undertakings. Cipro, used to treat inhaled anthrax, is Bayer A.G.’s largest-selling product, generating revenue of \$1.6 billion a year. Cipro exists because of private R&D. Priced at between \$5 and \$7 a pill, the five-day regimen, followed by use of other, cheaper antibiotics, would cost between \$50 and \$70, hardly an excessive price for a life-saving product. Yet shortly after the first wave of anthrax threats surfaced, the Canadian government rushed to strip Bayer of its patent and approved production of a generic substitute. Similar threats soon emanated from Congress, and HHS Secretary Thompson later denied that he had planned to strip Bayer of its patent, but that was the common perception based on his testimony before Congress, a perception that added to the public pressure that caused Bayer to sharply cut its price for Uncle Sam.¹⁹⁰

Business Week reporters John Carey and Amy Barrett noted:

Thompson highlighted the fact that Cipro costs about 10 times as much as equally effective drugs, he emboldened Brazil and other countries to break patents to lower drug costs, and he set a worrisome precedent for future government meddling in the cost of medicines. If a free-market Republican Administration can force Bayer to cut its price, how will the government be able to resist stepping in when the soaring cost of a future Medicare drug benefit threatens to break the bank?¹⁹¹

Such highly visible efforts to weaken patent rights for short-term gains undermine the incentive to create additional treatments and develop drugs to combat other potentially lethal diseases. This is particularly curious behavior when the U.S. government is otherwise working with private drugmakers to develop new and improved anthrax vaccines, when pharmaceutical companies are ransacking their shelves for compounds that might be

In the case of vaccines that might protect citizens against bioterror threats, Washington should foster their general availability rather than lock them away in a stockpile.

Efforts to weaken patent rights for short-term gains undermine the incentive to create additional treatments and develop drugs to combat other potentially lethal diseases.

effective against new diseases, and when researchers are attempting to develop new means to detect and treat anthrax, smallpox, and other potential bioterrorist weapons.¹⁹²

Nancy Bradish Myers, an analyst with Lehman Brothers, warned: "If the federal government is going to threaten to break valuable patent rights at the first sign of a crisis, it will likely serve as a significant deterrent to other drug companies who would like to do the 'right thing' and use their R&D capabilities to help the government fight bioterrorism."¹⁹³ A better alternative is for the government to negotiate a discount, just like any other bulk buyer (and perhaps include certain legal liability protections), in building reasonable public stockpiles.

Although one can imagine a unique public health emergency requiring extreme action, that was not the case with Cipro, which was not even the only treatment for anthrax. Doxycycline and penicillin are also useful in treating anthrax, and the FDA now encourages the many makers of both to publicize their usefulness in treating inhalation anthrax.¹⁹⁴ The reason they were not initially considered for treatment of inhalation anthrax in the fall of 2001 was because of FDA rules. Although those older drugs are safe and approved to treat that particular form of anthrax-caused illness, they could not be officially marketed as such without official FDA approval, a seemingly senseless expense just a few years ago when the likely benefits appeared to be so small (the last anthrax case occurred in 1978).¹⁹⁵ FDA rules have also posed a barrier to the production and licensing of smallpox vaccine. Changes that have occurred in process and technology of smallpox vaccine development since regular vaccinations ended three decades ago require that new batches of vaccine be classified as a "new drug" and that they meet significantly higher regulatory standards.¹⁹⁶

Trading Away Drug Patent Rights

Washington's apparent willingness to abandon property rights emboldened other nations to weaken patent protections at the November 2001 World Trade Organization meeting in Doha, Qatar.¹⁹⁷ In that situation,

the justification was a different kind of public health emergency—AIDS.

The impact of AIDS in the United States is horrid; its impact in Africa is catastrophic. AIDS is now the leading cause of death on that continent. Erica Barks-Ruggles of the Brookings Institution reports that

21.8 million people have died from HIV/AIDS since the beginning of the epidemic. Four-fifths of those deaths have occurred in sub-Saharan Africa—over 2.4 million in the first eleven months of 2000 alone, an average of one death every eight seconds. More than 70 percent of all people living with the disease, or 25.3 million HIV-positive individuals, live in Africa. Over 10 percent of the population is infected in sixteen African nations.¹⁹⁸

Obviously, such nations need help. The *New York Times* has editorialized that "Americans today can surely understand the need to give poor countries every possible weapon to fight back."¹⁹⁹ Few would disagree with that sentiment. The critical question is who should do so, and how should they do it?

Observes commentator Andrew Sullivan: "The reason we have a treatment for HIV is not the angelic brilliance of anyone per se but the free-market system that rewards serious research with serious money."²⁰⁰ Yet some self-styled activists treat the AIDS epidemic as the fault of the very parties that seek to cure it. They would strip the companies that produce AIDS drugs of some or all patent protection, through such means as compulsory licensing and parallel importation.²⁰¹ Some countries have exploited those practices to boost their own generic drug industries. For example, India stopped respecting drug patents in the 1970s, although it has promised to again accept intellectual property rights starting in 2005 as the price of joining the World Trade Organization. Brazil has authorized the copying of Viracept, an AIDS medicine produced by Roche. Explained

Health Minister Jose Serra, “We are in favor of patents, but not the abuse of patents.”²⁰²

At its November 2001 ministerial conference in Doha, the World Trade Organization declared legal clarifications of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) treaty that would allow poor countries to declare “national emergencies” and produce generic substitutes of brand medicines.²⁰³ In practice, those states apparently can abrogate patents at will, since the Doha declaration gives nations “the freedom to determine the grounds upon which such licenses are granted.”²⁰⁴ Although the precise impact of the Doha declaration remains subject to ongoing trade negotiations, it appears to encourage developing nations to expand their use of compulsory licenses to produce patented medicines (with minimal royalties) and to allow “parallel imports” of patented drugs from developing nations’ markets where original prices are set lower.²⁰⁵ The pharmaceutical industry put on a brave front, contending that nothing had really changed, but Sanford C. Bernstein & Co. analyst Richard Evans observes that drugmakers now “can write off the developing countries as a long-term source of profits.”²⁰⁶

A more recent round of international trade negotiations, launched in late 2002 and resumed in February 2003, threatens to further loosen the range of exemptions from drug patent protection for virtually any “public health problem.”²⁰⁷ James Love, director of the Consumer Project on Technology, has exulted: “This goes beyond AIDS, malaria and tuberculosis. Any health care item could be included. We want to use this in the United States, in Germany and in Switzerland.”²⁰⁸ Indeed, many developing nations are demanding the right to override existing patents and reduce existing barriers to parallel imports of pharmaceuticals on a wide-scale basis.²⁰⁹

Such an agreement would discourage pharmaceutical patent holders from selling their many other products (those used to treat other diseases and health conditions) at much lower prices in developing nations where demand (i.e., ability to pay) is weak.

Drugmakers would fear that low-priced sales in those markets could be reexported to more lucrative Western markets and undercut prices there. (In fact, \$20 million worth of HIV drugs first sold at a deep discount in Africa were recently stolen and resold in Europe for higher profits.)²¹⁰ Faced with the prospect of undercutting their key streams of revenue, pharmaceutical firms would be most likely to cut their losses and either reduce sales or raise prices in the very markets that most need some of their products.²¹¹ If legal restrictions on the arbitrage of parallel imports across national borders continue to weaken, charging different prices in different markets (“price discrimination” to maximize total revenue) will be difficult to maintain, says University of Michigan law professor Rebecca Eisenberg.²¹²

Last December’s international trade negotiations in Geneva broke down when the United States blocked a draft agreement that would allow pharmaceutical companies in developing nations much greater freedom to export their lower-priced generic versions of patented drugs to other poor countries. U.S. trade negotiators insisted that patent exceptions should apply only to drugs that treat a restricted list of infectious diseases—such as HIV/AIDS, malaria, and tuberculosis—in poor countries. On December 20, 2002, U.S. Trade Representative Robert Zoellick announced a temporary moratorium on U.S. enforcement of drug patents for exports to poor nations to combat diseases posing national health crises.²¹³

The justifications given for invalidating patents are always presented as high-minded. For instance, Julia Neuberger of the King’s Fund, an independent charitable foundation in London, recently announced: “In Africa, commercial interests must not be permitted to restrict access to vital medicines for HIV and AIDS.”²¹⁴ The group Oxfam has charged that patents “are deepening the public-health crisis by increasing the cost of medicines.”²¹⁵

Doctors Without Borders has led a coalition that opposes international trade rules that might discourage the importation of

The Doha declaration appears to encourage compulsory licenses and “parallel imports” of patented drugs.

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less expensive drugs. “We’re basically talking about a system that could help save millions,” said Ellen ‘t Hoen, program director for the private, nonprofit organization.²¹⁶

But without patents the newer drugs would not exist because there would be little incentive to produce them. Observes Jean Lanjouw of Yale University: “Private firms currently do very little research on products for the developing world. There is little doubt that the lack of patent protection in major developing country markets has contributed to this disinterest.”²¹⁷

Yet even Lanjouw would use U.S. patent procedures to force pharmaceutical firms whose patents relate to a global disease to sacrifice patent protection overseas in order to preserve it at home. As she explains: “Those patentees would effectively be required to choose to make use of their patent protection either in rich countries or in poor countries, but not in both.”²¹⁸

If required to do so, Western drug companies would likely choose to preserve their patent protection in the developed world rather than the developing world, particularly for products whose primary market was concentrated in wealthy states (e.g., AIDS and cancer drugs). Such a policy, however, like other more radical measures, would arbitrarily strip companies of their intellectual property rights. Unless reimportation of drugs from developing nations back in to wealthy countries was effectively restricted, patent rights in those industrialized states would soon be impaired as well. Moreover, such a policy would ignore any incentive for the most advanced pharmaceutical firms to tailor their drugs to meet any unique needs in the Third World, such as different strains of infectious diseases. For example, while HIV-1C dominates sub-Saharan Africa, HIV-1E is moving through Southeast Asia, and HIV-1 is most prominent in Western markets.²¹⁹ In fact, Dr. Roger Bate, director of the International Policy Network in London, argues that the sustained attack on patents for AIDS drugs has begun to discourage their development even in the industrialized nations.²²⁰

The Lanjouw proposal also ignores the fact that many drug companies already provide some of their patented products for free and offer deep discounts on others in poorer nations—sometimes up to 90 and even 100 percent for AIDS compounds. Yet making pharmaceuticals available by suspending patent rights would still leave those drugs extremely expensive for poor people in poor nations. Copies of AIDS compounds may cost roughly \$1,500 to \$2,000 per year for versions currently available in Brazil and India, while the cheapest AIDS cocktail from the Indian company Cipla runs \$350 annually. Thus, the annual cost of the treatment regimen can still exceed the per capita GDP of poor nations.

Some observers would not tamper with international patent law but believe that it is up to the pharmaceutical industry to save mankind. Dr. Donald Berwick, president of the Institute for Healthcare, called upon drugmakers to selflessly donate their AIDS medicines.²²¹ It is, of course, easy to give away other people’s money. Yet drug companies have already recognized the economic limits of what they can charge customers in the poorest nations by heavily discounting prices there. Bristol-Myers charges \$54 in Africa for Zerit, compared with \$3,589 in the West.²²² Glaxo first heavily discounted and then licensed generics firms to produce its AIDS medicine in South Africa. Pfizer donated, through private clinics, the new and very expensive drug Diflucan that is used to treat fungal infections of the brain. Even this has not stilled the criticism.²²³ On January 24, 2003, Pharmacia announced at the World Economic Forum that it would work with the International Dispensary Association Foundation in Amsterdam to launch a not-for-profit pilot program that would award non-exclusive licenses to generic drug companies that agreed to manufacture and supply cheap copies of Pharmacia’s AIDS drug delavirdine in the world’s poorest countries.²²⁴

Private drug companies have been more responsive than many governments. In a recent well-publicized court battle in South Africa, the final settlement was less about

providing AIDS drugs than about ensuring due process for exceptions to international rules on international intellectual property embodied in the World Trade Organization.²²⁵ Consequently, South Africa's health minister, Manto Tshabalala-Msimang, was forced to acknowledge that the country still had "no plans" to disseminate AIDS drugs to the general public.²²⁶ South Africa has compounded the problem by imposing a \$14 value-added tax on medicines, including AIDS medicines.²²⁷ Lawyers later went to court to try to force that government to distribute AIDS drugs for newborns.²²⁸

Fighting AIDS in Africa involves much more than the cost of patented products. In fact, Amir Attaran and Lee Gillespie of Harvard found that because patents already were absent in many poor countries, there are no legal barriers to production and acquisition of products patented in richer ones. Instead, "a variety of de facto barriers are more responsible for impeding access to antiretroviral treatment, including but not limited to the poverty of African countries, the high cost of antiretroviral treatment, national regulatory requirements for medicines, tariffs and sales taxes, and, above all, a lack of sufficient international financial aid to fund antiretroviral treatment."²²⁹

Even after buying drugs at a 90 percent discount, the country of Mali says that it can treat only 600 of 130,000 patients. Moreover, many low-income developing countries lack the medical infrastructure necessary to ensure that patients follow what are complex and harsh AIDS treatment programs.²³⁰ According to Robert Goldberg, "Pharmaceutical-firm donation programs currently have just four countries participating because of a lack of health-care infrastructure—including trained medical staff—and interest."²³¹ Per capita health spending in some African states runs barely \$10 a year. Cultural attitudes and practices are also important. Indeed, limited resources might be better devoted to prevention.²³² Observes Dr. Saumya Das: "One of the biggest lessons I've learned is that fighting bio-medical battles in third-world coun-

tries is a complex enterprise. There's more to it than throwing a bunch of resources their way."²³³ Richard Tren, director of Africa Fighting Malaria in Johannesburg, South Africa, is even more blunt: "It's easier to blame and shame corporations than corrupt governments."²³⁴

University of Chicago law professor Alan Sykes suggests several policy alternatives. Governments of developing nations could increase their own public funding of medical therapies at current prices, with assistance from more developed nations. The concept of "national emergency" could be construed more narrowly (but still tied to "reasonable commercial terms"), with arm's-length price negotiations required before nations resorted to any compulsory licensing.²³⁵

"Napsterizing" Brand-Name Drugs?

Three researchers at the National Bureau of Economic Research recently framed the drug patent protection issue in more stark, but convincing terms. James Hughes of Bates College, Michael Moore of the University of Virginia, and Edward Snyder of the University of Chicago asked whether an extreme policy experiment of "Napsterizing" pharmaceuticals—which would eliminate all patent rights on existing and future brand-name prescription drugs without compensation to the patent holders—would improve or reduce consumer welfare. The obvious trade-off would be between (1) substantial gains to existing consumers by accelerating entry of generics and increasing access to the current stock of pharmaceuticals and (2) the harm to future consumers by reducing the flow of new pharmaceuticals to market to address currently untreated illnesses or improve on existing drug treatment. Hughes, Moore, and Snyder found that for every dollar in consumer benefit realized from providing greater access to a lower-priced current stock of drugs, future consumers would be harmed three dollars in present value terms due to reduced future innovation.²³⁶ They also imply that current policy offers sub-optimal patent protection, because actual and poten-

Fighting AIDS in Africa involves much more than the cost of patented products.

Expanded drug coverage, even if limited and well designed, needs to be developed in the context of overall structural reform of Medicare, rather than grafted onto today's antiquated program.

tial consumers of currently available prescription drugs are more likely to have a greater voice than "unidentified potential consumers of prescription drugs not yet on the market."²³⁷

The Looming Shadow of Medicare Prescription Drug Benefits

Since its inception in 1965, the traditional Medicare program has never covered outpatient prescription drugs (with the small exception of certain drugs that cannot be self-administered and are related to a physician's services, or are provided in conjunction with covered durable medical equipment).²³⁸ Today, various forms of supplemental private insurance coverage for outpatient drug needs are becoming more expensive and declining in scope and scale. More than one-third of Medicare recipients lack any insurance coverage at all for most drugs. When they purchase drugs, they pay the highest retail prices for them. Seniors tend to consume a disproportionate share of the nation's prescription drug supply, primarily because they are more likely to suffer from multiple chronic conditions that respond best to modern drug therapy. Perhaps most important of all, seniors as a whole represent the most likely voters. Hence, adding prescription drug benefits to Medicare's health care coverage has become a powerful issue for current officeholders and their political challengers.

Nevertheless, addressing the issue of Medicare prescription drug benefits directly is not a task for the faint-hearted: Two earlier attempts to add a pharmaceutical benefit to Medicare, the 1988 Catastrophic Coverage Act and President Clinton's Health Security Act of 1994, quickly failed. For the past three years, Congress has again come up short in trying to devise a workable Medicare drug plan. This year, it will resume consideration of the issue in the context of a Bush administration proposal to spend up to \$400 billion over the next 10 years for prescription drug

benefits in a "modernized" Medicare program.²³⁹

Creating a voluntary stand-alone drug coverage plan as the latest layer on an unreformed Medicare program is no answer. More generously subsidized insurance coverage of drug purchases, particularly for routine early-dollar expenses, will stimulate demand for seemingly "cheaper" drugs and overuse of benefits. "People with health insurance fill more prescriptions and take more medicines," observes the NIHCM Research and Educational Foundation.²⁴⁰ They also use more medications when faced with lower copayments.²⁴¹ That surge in demand is sure to be followed by runaway budget costs that collide with underfunded, irresponsible political promises. The next round of maneuvers aimed at dodging this conflict soon would include drug coverage rollbacks, tighter drug formularies, and rigid price controls—all threatening to chill future innovative medical research and to snuff out the next round of development of life-saving drugs.

Expanded drug coverage, even if limited and well designed, needs to be developed in the context of overall structural reform of Medicare, rather than grafted onto today's antiquated program. The aging of America's population alone has created frightful financial pressures on Medicare. As Comptroller General David Walker told the House Budget Committee in July 2001, "Medicare as currently structured is fiscally unsustainable."²⁴² Walker warned:

Although the short-term outlook of Medicare's Hospital Insurance trust fund improved somewhat in the last year, the long-term projections are much worse due to a change in expectations about future health care costs. . . the long-term outlook for Medicare's financial future—both Hospital Insurance (HI) and Supplementary Medical Insurance (SMI)—is considerably worse than previously estimated. The Congressional Budget Office (CBO) also increased its long-term esti-

mates of Medicare spending. The slowdown in Medicare spending growth that we have seen in recent years appears to have come to an end. In the first 8 months of fiscal year 2001, Medicare spending was 7.5 percent higher than the previous year. The fiscal discipline imposed through the Balanced Budget Act of 1997 (BBA) continues to be challenged, while interest in modernizing the Medicare benefits package to include prescription drug coverage has increased. Taken together, these developments mean higher, not lower, health care cost growth. They reinforce the need to begin taking steps to address the challenges of meaningful Medicare reform.²⁴³

Medicare's Hospital Insurance (Part A) trust fund will resume spending more than it collects in taxes in 2013, and it faces a long-term actuarial deficit of 2.4 percent of taxable payroll. The Supplementary Medical Insurance (Part B) side of Medicare will continue to grow faster than both Part A and the overall economy. It will double its share of GDP within 33 years—without adding any new drug benefits.²⁴⁴

Real Reform, Real Choices

Medicare reform should go beyond simply avoiding the dangers of placing an open-ended drug benefit inside the traditional Medicare program. Yet most Republican-sponsored Medicare drug benefit proposals of recent years have been content to stop at that point and fall well short of a fundamental restructuring of Medicare. They have mostly relied on simply drilling another deep but narrow silo of separately financed drug benefits in the form of a heavily subsidized Medicare Part D program and then scrambled desperately to entice private sector entities to manage it.

Ideally, long-term Medicare reform would transform the program so that it offered seniors a choice among competing plans that

included pharmaceutical benefits. It would encourage private insurers to assemble packages of integrated, linked benefits that produced the greatest value for both beneficiaries and taxpayers by coordinating efficient tradeoffs between drugs, surgery, hospitalization, and outpatient care options. Beneficiaries then could choose the plan options that were best tailored to meet their respective needs and preferences.

The Medicare+Choice (M+C) program, launched in 1997, provides a limited amount of private health plan choice. However, its rates of participation—by both insurers and beneficiaries—have dropped precipitously in recent years. Roughly 12 percent of Medicare participants are enrolled in M+C plans. They generally receive more generous levels of drug coverage, but those benefits are increasingly jeopardized by flawed Medicare payment formulas.²⁴⁵

Congress must begin with a clean slate and proceed to eliminate the uncertainties and excesses of its complex regulatory requirements, time limits, and payment methodologies for the faltering M+C program. A sustainable framework for Medicare modernization requires moving from an antiquated defined benefit structure (which covers a specific set of health services) to a defined contribution model, under which seniors could choose among competing packages of health benefits with taxpayers' costs capped at preset levels.²⁴⁶ It is crucial that the traditional Medicare fee-for-service coverage program be required to improve by competing for market share on a level playing field. Many Medicare reformers emphasize the enhanced benefits and higher quality care—including prescription drug benefits—that new private plan options might make available to beneficiaries, but they tend to underplay, if not neglect, the key ingredients needed to make those improvements affordable. One necessary element includes a payment system in which private plans bid to provide required benefits, beneficiaries capture the savings from choosing less-costly options, and the government's share of

A sustainable framework for Medicare modernization requires moving from an antiquated defined benefit structure to a defined contribution model.

Defined contribution payments must be determined by competitive market prices.

Medicare funding reflects the enrollment-weighted average costs of the mandatory benefits provided in all plans (including traditional Medicare). Seniors seeking additional supplemental benefits would pay higher premiums that reflect their marginal costs. Medicare beneficiaries who accepted greater individual responsibility would be rewarded with broader health coverage choices and possible cash rebates.

Defined contribution payments must be determined by competitive market prices rather than remain linked to the politically driven and bureaucratically administered price controls of the traditional Medicare program. Competitive bidding mechanisms and reasonable ground rules for periodic open enrollment choices could help end the current program's maze of distorted prices and poor information.

In July 2001 the Bush administration first outlined The President's Framework to Strengthen Medicare, which loosely tracked the elements of the above approach but avoided spelling out many legislative details. It also emphasized its recommendations for enhanced benefits while saying much less about the steps that would be required for containing future Medicare cost growth.

The Bush plan included a voluntary drug discount plan for Medicare seniors, through a consortium of private companies, but its administrative implementation was delayed by court challenges.²⁴⁷ Disagreement was sharp not only over how great the discount would likely be but also whether drugmakers or pharmacists would bear most of the discount.²⁴⁸ Drugstores went to court to block the initiative. After several rounds of legal battle, a federal judge ruled on January 29, 2003, that the Bush administration had no legal authority to create a Medicare-sponsored discount drug card program.²⁴⁹

The rest of the July 2001 framework emphasized that a range of new, competing Medicare plan options all must offer subsidized prescription drug benefits and that Medicare should provide true stop-loss protection from high expenses.²⁵⁰ On March 3,

2003, President Bush proposed an updated and somewhat more detailed Framework to Modernize and Improve Medicare. It outlined three different categories of benefits options: Enhanced Medicare, Traditional Medicare, and Medicare Advantage.

Enhanced Medicare would be designed to offer better, more attractive benefits than those provided by Traditional Medicare, such as a subsidized prescription drug benefit, preventive care benefits, and protection against high drug expenses. Beginning in January 1, 2006, seniors participating in Enhanced Medicare would receive a choice of preferred provider organization plans similar to those offered through the Federal Employees Health Benefit Plan. Enhanced Medicare plans would feature a single deductible for all medical services, as opposed to the separate Part A and Part B deductibles in Traditional Medicare. Enhanced Medicare plans would be administered by a new agency under the Department of Health and Human Services.

The president promised to preserve the option of the Traditional Medicare benefit structure for seniors who were satisfied with their current coverage. However, his proposed framework would protect beneficiaries remaining in the traditional program against high out-of-pocket prescription drug expenses and offer a drug discount card to them.

Medicare Advantage would provide the option of managed care plans similar to those currently available through the Medicare+Choice program. Participants who selected more efficient, lower-cost plans could qualify for rebates on their premiums. Some Advantage plans might choose to offer benefits packages without drugs for those participants who were satisfied with other drug coverage that they already have.

The Bush framework would provide further assistance to low-income seniors. If they enrolled in Enhanced Medicare, they would receive prescription drug coverage without paying additional premiums, and they would receive additional subsidies to help pay their cost-sharing for prescription drugs. By 2004, all low-income seniors would not only have access to

discounted prices through a Medicare-endorsed drug discount card; they would also receive as much as an additional \$600 per year to subsidize their prescription drug purchases or other forms of prescription drug coverage (such as coverage offered under plans in the current Medicare+Choice program).²⁵¹

Unfortunately, this proposed framework still left many key details either unclear or undecided. The Bush administration said little about what would be included in a “basic federal standard” for benefits through Enhanced Medicare. It apparently decided to defer to Congress regarding such fundamental items as required levels of cost-sharing by participating seniors, the threshold at which insurance protection against high drug expenses would kick in, and the manner in which competitive bidding by private health plans would proceed under Enhanced Medicare. The Bush framework also declines to offer any significant cost-saving reforms for Traditional Medicare. Although it promises insurance protection against high drug expenses at no additional cost to beneficiaries, the level at which this protection would commence remains unstated.

Administration officials have conceded that the proposed Bush framework will cost taxpayers more money than the current law version of Medicare. They already have budgeted up to \$400 billion in new spending over the next 10 years to pay for the Bush Medicare modernization proposal. The Bush framework falls short of the FEHBP model of cost containment that it hopes to mimic, because it avoids making a clear commitment to cap taxpayers’ share of premiums charged by private plans participating in Enhanced Medicare or to provide the same level of subsidy to a beneficiary regardless of which program (Traditional Medicare, Medicare Advantage, Enhanced Medicare) he or she may choose. Instead, it appears most likely to do little more than offer higher subsidies to private plans promising more generous benefits under Enhanced Medicare, in the hope that this eventually will induce more seniors to participate in them instead of the Traditional Medicare option.

A more far-reaching, but much longer-term Medicare reform proposal idea would redirect a portion of younger workers’ Medicare tax payments into Personal Retirement Insurance for Medical Expenses—tax-advantaged savings vehicles that could be used to prefund insurance and health care expenses during retirement.²⁵² However, an initial round of the intermediate reform measures to restore competitive private health plan options for seniors, as suggested above, would first be needed to realign the current Medicare structure before it could be transformed into a more fully privatized system of health care choices for seniors. Transitional finance issues may slow the evolution toward this ultimate objective, but a full return to individual responsibility and private-sector health care offers the only long-term hope for surmounting the perennial chronic financial crises and bureaucratic morasses of Medicare as we know it.

If Congress cannot resist the urge to add drug benefits without tackling fundamental Medicare reform, it should at least do less harm by emphasizing higher deductibles and catastrophic loss protection for prescription drug coverage, targeted assistance to lower income seniors, and reformed coverage options for individual Medigap insurance purchasers.²⁵³ Under no circumstances should the door be opened to universal subsidies to seniors for routine, manageable drug expenses.

The average out-of-pocket drug expenditure for all Medicare enrollees in 2001 was about \$650.²⁵⁴ The best way to target a more limited Medicare prescription drug benefit would be to deal effectively first with the relatively small slice of Medicare beneficiaries (less than 10 percent) that faces more than \$2,000 a year in out-of-pocket drug expenses. Implementing a catastrophic prescription drug benefit and adding supplemental assistance to lower-income Medicare beneficiaries just beyond the eligibility limits for Medicaid drug coverage assistance would provide some breathing room for decisionmakers to get a better fix on future program costs, while targeting necessary relief to those seniors most in need.

Administration officials have conceded that the proposed Bush framework will cost taxpayers more money than the current law version of Medicare.

The suppression of ads might aid some market leaders in the industry, but it would not benefit consumers.

This approach would also head off far greater threats to the future quality of life for younger workers and their families. Medicare's growing claims on their future earnings already limit their ability to purchase their own health insurance, educate their children, and save for retirement. Strip mining today's on-the-shelf inventory of drugs through political price controls will undermine incentives to provide the capital and skilled manpower to develop future rounds of blockbuster drugs in the decades ahead.

Direct-to-Consumer Advertising: Don't Tell, Don't Sell?

Some industry critics want to control costs by restricting industry spending, especially on marketing. A particular target is direct-to-consumer (DTC) advertising. Some health care benefits managers complain that DTC ads cause excessive use of prescription drugs or that they steer consumers toward more expensive brand-name drugs.²⁵⁵ During congressional consideration of a proposed new Medicare benefit for prescription drugs, some legislators (including House Ways and Means Committee chairman Bill Thomas, R-Cal.) toyed with proposals to limit corporate tax deductions for prescription drug advertising expenses, on the theory that DTC ads would unnecessarily increase federal drug spending.²⁵⁶

Pharmaceutical marketing accounted for \$13.8 billion in 1999. Yet more than half of that—\$7.2 billion in that year—was for free samples of drugs, which serve as a discount when doctors pass them out to patients.²⁵⁷ Most of the rest went for professional advertising and promotion.

Advertising promotes price competition and lowers prices.²⁵⁸ Indeed, professionals—doctors, opticians, and lawyers—have long used advertising restrictions to squelch competition and maintain fees. Comparative advertising can be especially important. Michael Neff, who managed drug purchases for California's public health care system, asks: "Do we want to see more head-to-head testing?" His answer is "You bet! Yes, sir!"²⁵⁹

Disseminating information about new pharmaceuticals is an important mechanism for letting patients and doctors know what is available. One estimate is that more than 1,700 articles are published every year in each of 325 professional journals on the 25 leading medications.²⁶⁰ Marketing helps professionals keep afloat in this information flood. Moreover, what company in America makes a product and tells no one about it? Imagine General Motors developing a new car and keeping it secret.

The suppression of ads might aid some market leaders in the industry, but it would not benefit consumers.²⁶¹ Existing FDA restrictions, which prevent companies from promoting formally unapproved but informally recognized alternative uses of drugs—which have been found to be safe—clearly hurt patients. Writes Alexander Tabarrok of the Independent Institute, "There have been numerous instances in which the FDA has reduced the speed at which beneficial new drugs, and beneficial new uses of old drugs, have been widely adopted."²⁶²

Paul Rubin of Emory University figures that the FDA's ban on aspirin producers advertising the benefits of aspirin in combating heart disease alone may have been killing tens of thousands of people a year.²⁶³ Moreover, the FDA impedes the treatment of cancer by preventing companies from distributing articles relating how cancer drugs have demonstrated their effectiveness in combating other forms of cancer.²⁶⁴ Ellen Stovall, executive director of the National Coalition for Cancer Survivorship, complained to a House subcommittee:

The excessive zeal of the FDA in this arena is exerting a chilling effect on the sharing of information within the medical community on whom our treatment and our very lives depend. FDA's policy stifles education by denying individuals with cancer access to valuable information about medically appropriate indications from the pharmaceutical spon-

sors who are often the best sources of up-to-date information.²⁶⁵

The amount of mass media advertising directly aimed at patients remains relatively low—\$2.8 billion in 2001, not much more than 2 percent of pharmaceutical sales. But it has increased dramatically, up from just \$55 million in 1991.²⁶⁶ Such advertising undoubtedly helps increase demand, which in turn has raised drug expenditures—treated by some bill payers as a negative in and of itself.²⁶⁷ Yet people use medicines because the benefits exceed the costs. And increased demand makes products available that would otherwise be unprofitable. Thus, advertising does not compete with R&D; rather, the two are complementary. Marketing hikes revenues and investment returns, making more money available for and increasing the incentive for R&D. Even as drugmakers advertise, they devote a larger share of sales to R&D than does the medical industry generally, or computer makers and software developers, or automakers.

Another criticism of direct-to-consumer marketing is that ads are irrelevant or misleading, causing patients to demand products that are not good for them.²⁶⁸ As in any industry, ads vary in quality. But doctors remain a gatekeeper, often prescribing other brands, generics, older products, or nothing. Apparently some physicians begrudge their patients an explanation. Dr. Sandra Adamson Fryhofer of Emory University denounced drug ads because, “Not only do we have to take time to explain to these patients the nature of the medical problem they have, and whether it needs to be treated with drugs, but we also have to discuss whether the drug they have seen promoted is their best option.”²⁶⁹ It’s a curious objection. Doctors might occasionally find the duty to say no to be unpleasant, but their role, after all, is to serve patients, and they should be prepared to explain why a particular advertised drug is not appropriate. Indeed, Dr. Richard Dolinar, an endocrinologist from Phoenix, says, “If advertising sometimes results in patients asking for a drug that is inappropriate, I will say so.”²⁷⁰

Empowering Patients

In fact, advertising can play an important role in informing and empowering patients, which may be one reason why the American Medical Association has suggested that the government ban ads. Expanded knowledge is particularly important in what has traditionally been a physician-led process: patients can ask better questions and make better judgments if they know some of the options available. Patients’ desire for greater knowledge is obvious from a greater reliance on the Internet for health information.²⁷¹

More information means better health. One impact seems to be to make patients more likely to follow prescription schedules.²⁷² Doctors, too, are likely to make better use of pharmaceuticals. Observes John Calfee, “The documented gaps between research findings and physician practices are notoriously difficult to close.”²⁷³

Drug information is particularly useful in reaching people who have not been diagnosed despite having treatable conditions, such as diabetes, hyperlipidemia (high cholesterol), and hypertension.²⁷⁴ A 1999 survey conducted by *Prevention* magazine estimated that consumer ads had caused some 25 million people to talk for the first time with their doctors about particular health problems.²⁷⁵ “I think more patients are coming in for treatment just to see if a drug they have seen advertised might help them with a problem,” observes Dr. Dolinar.²⁷⁶

Saving Lives

As the *Journal of the American Medical Association* acknowledges:

Nearly everyone agrees that it was important to advise high-risk consumers about a new vaccine for pneumococcal pneumonia. Many of those consumers are generally in good health and not visiting a physician on a regular basis. Promotion to physicians alone would not have brought the vaccine to the health high-risk consumer.²⁷⁷

A survey of men with prostate cancer found that the majority desired more infor-

Drug information is particularly useful in reaching people who have not been diagnosed despite having treatable conditions.

The benefits of DTC ads appear substantial while deception and harms from inappropriate prescribing appear to be minimal.

mation. “The results of our survey clearly indicate the need for more comprehensive and actionable information about current treatment options for prostate cancer,” explains Dr. Jay Gillenwater, president of the American Foundation for Urologic Disease.²⁷⁸

Jamie Reno, a San Diegan suffering from non-Hodgkin’s lymphoma, describes how better communication of drug information saves lives:

I found out about the [experimental drug] Bexxar trial myself. I didn’t rely on my doctors, and neither should you. Unfortunately, when you learn you have a life-threatening disease, you’re often too sick and/or scared to do much research. So you take your doctor’s word. That’s what I did. Big mistake. My first oncologist, at a renowned cancer hospital, never shared one bit of information about the lymphoma research I’ve since learned is going on.²⁷⁹

Although drug industry critics like Arnold Relman and Marcia Angell of the Harvard Medical School commend the fact that “DTC ads are not permitted in other advanced countries less in the thrall of the pharmaceutical industry,” patient advocates in Canada’s nationalized system complain about the lack of information available to them.²⁸⁰ And the European Commission has proposed allowing direct advertising to consumers.²⁸¹ Nationalized health care systems can survive only so long as people are not aware of the full extent of medical products and services to which government is denying them access. American health care would not be improved by keeping patients ignorant and quiescent.

John Calfee concludes that the benefits of DTC ads appear substantial while deception and harms from inappropriate prescribing appear to be minimal. The drug advertising provides valuable information to consumers on risks and side effects, as well as about potential

treatments and dosages. Calfee acknowledges that DTC ads may indirectly increase drug utilization, but that reflects the fact that better-informed health care organizations, physicians, and patients will find many of the advertised drugs to be extremely valuable. To the extent that unwise spending choices are made, they are due more to excessive levels of third-party insurance coverage that insulate consumers from the full cost-benefit tradeoffs of their drug consumption decisions.²⁸²

Real Solutions for Improved Drug Access and Affordability

The fact that the typical “solutions” to reduce pharmaceutical prices would make Americans worse off does not mean that nothing should be done in response to concerns over access and cost. Some people of limited means have trouble getting the drugs that they need. A wealthy and compassionate society should respond.

The principle that should govern any action, private or public, is “first do no harm.” Government should not interfere with a pharmaceutical market that works as well as it does only because it remains relatively free. Instead, remedies should be narrowly targeted to meet genuine needs.

Fix the FDA: Fully, Fundamentally, and Finally

The current political spotlight on prescription drug prices has drawn attention away from a more important issue—regulatory barriers to the availability of the best medicine. The most “unaffordable and unavailable” drugs are those that carry no price tag, because the FDA keeps them off the market. The starting point for improving access to the drugs of today and tomorrow should be reducing government barriers that inflate their development costs and thus their eventual market prices.²⁸³ But some historical background is needed before we move on to a discussion of current reform measures.

Today the FDA must certify prescription medicines for both safety and efficacy. The latter requirement was passed after the thalidomide scare in 1962. In the absence of that unnecessary mandate, drug companies still would have no incentive to sell ineffective products, doctors would have no incentive to prescribe them, and patients would have no incentive to buy them. Although regulatory efficacy requirements may not have significantly improved the overall quality of prescription drugs, they have certainly lengthened the time necessary to win approval of them and limited their availability in the marketplace. The 1962 amendments to the Food, Drugs, and Cosmetic Act effectively shifted “primary decision-making authority in pharmaceuticals from market mechanisms to a centralized regulatory authority.”²⁸⁴

By 1967 the average review time for a drug application had more than tripled from its pre-1962-amendments level.²⁸⁵ Congress’s bias toward regulation exacerbated the agency’s natural bureaucratic tendency to be risk averse: To approve a drug that is either ineffective or harmful would hurt one’s career far more than holding up approval of efficacious, helpful products.²⁸⁶

The delays were obviously costly: Total development costs per successful drug more than doubled between 1963–1975 and 1970–1982.²⁸⁷ By the 1980s, new drugs were routinely receiving faster approval in Europe than in America.²⁸⁸ Henry Grabowski calculated in 1995 that reducing FDA review time by one year alone would cut annual industry costs by \$361 million.²⁸⁹

By the early 1990s, total approval and development times ran 100 percent and 75 percent, respectively, higher in America than in other industrialized states.²⁹⁰ Of 150 new drugs and vaccines approved by the FDA between 1990 and 1994, 61 percent were available first overseas. On a head-to-head basis America increasingly lagged behind other industrialized states.²⁹¹

Such delays are deadly as well as costly. For instance, families with a member suffering

from Alzheimer’s disease were frustrated by the agency’s refusal to authorize, despite strong evidence of its efficacy, the use of the drug THA, which is available in other nations.²⁹² Delays in bringing propranolol, a beta-blocker for use in treating angina and hypertension, to the U.S. market may have cost 100,000 lives. Nearly as many may have perished from the lack of availability of the anti-bacterial medicine Depra. Thousands have also died waiting for misoprostol, a drug for gastric ulcer, and streptokinase and TPA, for heart conditions.²⁹³ Equally costly was the delay in bringing anti-AIDS drugs, such as AZT, to the market.²⁹⁴ Estimates of lives lost because of the FDA’s regulatory overcaution defy precise measurement, but, by the mid-1990s, Robert Goldberg offered this chilling calculation:

By a conservative estimate, FDA delays in allowing U.S. marketing of drugs used safely and effectively elsewhere around the world have cost the lives of at least 200,000 Americans over the past 30 years. That figure does not include deaths that might have been prevented by the use of drugs such as 5 Prozac, which is associated with the decline in suicides of individuals suffering from depression.²⁹⁵

Enormous pressure from AIDS activists and Vice President Dan Quayle’s Competitiveness Council eventually caused the FDA to speed up trials of potentially life-extending drugs.²⁹⁶ The Prescription Drug User Fee Act of 1992 allowed drugmakers to pay for new FDA employees to review drugs. The 1997 Food and Drug Administration Modernization Act led to creation of a fast-track approval process for “priority review drugs.” Drug applications thought to represent a significant therapeutic advance were to be assessed more quickly.²⁹⁷ In the 1990s, average drug approval times in the United States fell sharply.²⁹⁸

Some critics argue that the FDA reforms have gone too far, with an increasing number of drugs allegedly being pulled from the market. “While many of these early changes were neces-

The most “unaffordable and unavailable” drugs are those that carry no price tag, because the FDA keeps them off the market.

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sary, subsequent laws, passed in 1992 and again in 1997, have taken deregulation too far and left the FDA beholden to the very industry it is supposed to regulate and the public vulnerable to unsafe drugs,” says Jennifer Washburn of the New America Foundation.²⁹⁹

In fact, recalls have not risen despite quicker approvals in recent years.³⁰⁰ Moreover, fewer mistakes may also mean fewer life-saving developments: the FDA can avoid mistakes only by an overly cautious policy that screens out many likely winners. Overall, the danger of allowing the sale of a few ineffective medicines pales compared with the benefit of allowing patients speedier access to additional effective ones.

Even the harm caused by the occasional Rezulin, a diabetes drug recently withdrawn from the market for causing liver damage and perhaps as many as 60 deaths, must be balanced against the lives saved by speeding to market scores of drugs, the vast majority of which are safe.³⁰¹ The 47 drugs approved between 1972 and 1992 in Europe but not America, and later recalled, were responsible for an estimated 145 deaths. Although tragic, those victims were few compared to the number of victims of FDA-induced delays in the approval of a score of different drugs. Even pharmaceuticals like practolol, for use against high blood pressure, which proved to have serious side effects, may nevertheless have been cost-effective, with the potential of saving 10,000 to 20,000 lives a year.³⁰²

Dale Gieringer of Stanford University has estimated that some 5,200 people died and another 18,100 people were seriously harmed worldwide by drug accidents, including thalidomide, between 1950 and 1980. Over that same period, he calculated that FDA regulation might have prevented 1,000 deaths and 5,000 injuries in America. Gieringer concluded that the worst-case scenario for a regime of looser regulation would amount to a couple of thousand deaths and another 8,000 casualties, compared to his calculation that as many as 120,000 lives were lost and many more injuries incurred per decade due to drug delays caused by tighter FDA regulation.³⁰³

“The drive to expedite drug approvals has undermined a review system that was once the world’s gold standard,” complains Washburn.³⁰⁴ What patients need, however, is not a “gold standard,” but a system that weighs speed as well as safety, since delay is itself unsafe. One must constantly balance any possible side effects of a drug against its benefits.³⁰⁵

Overall regulatory reform thus far has been real, but it remains inadequate. In May 2000 the FDA okayed the leukemia drug Gleevec after just two and a half months, a record time.³⁰⁶ Nevertheless, a recent poll found that huge majorities of doctors (including 77 percent of oncologists) believed that the agency was still too slow in approving new products, and that strong majorities believed that Americans were dying as a result.³⁰⁷ The changes “do not constitute basic reforms,” explain Joanna Siegel and Marc Roberts of Harvard. “They target AIDS and other life-threatening illnesses, rather than address the standards for drug approval generally. . . . They represent departures targeted only to exceptional circumstances.”³⁰⁸ The overall system remains overly bureaucratic, costly, and time-consuming.

Problems are particularly acute in the area of responding to bioterrorism. Testing on humans to prove the effectiveness of experimental drugs against toxic substances or organisms is not possible—or thought to be ethical—yet it remained an agency requirement even after the anthrax attacks in the fall of 2001. Since 1999, the FDA had considered changing that rule, but the proposal was “just wallowing in the agency,” complained Dr. Frank Young, a former FDA commissioner, in November 2001.³⁰⁹ It was not until May 30, 2002, that the FDA finally amended its regulations so that certain human drugs and biologics intended to reduce or prevent serious or life-threatening conditions could be approved for marketing on the basis of evidence of effectiveness in appropriate animal studies when human efficacy studies were not ethical or feasible.³¹⁰

Although the agency disclaims responsibility, median drug approval time rose from

11.6 months in 1999 to 15.6 months in 2000.³¹¹ In particular, clinical trials now take longer, in part in response to government demands.³¹² Complains E. M. Kolassa:

Many claim that the FDA is now approving new drugs much more quickly than in previous years—but that statement is misleading. Although the FDA has shortened the period between the submission of the New Drug Application (NDA) and final marketing approval, the time between the submission of the research plan (IND) and the NDA, a period also substantially under the control of the FDA, has increased by an amount greater than the approval time has shortened. The net result is that the total time for the approval of new drugs has increased by roughly 5 months while the FDA, and critics of the pharmaceutical industry, claim the opposite.³¹³

There is good reason, then, to treat the FDA, as Michael Tanner of the Cato Institute suggests, as “one of the most destructive of all federal government agencies,” a bureaucracy that “is clearly an unnecessary burden to the American health care system.”³¹⁴ At the very least FDA decisionmaking should be decentralized and streamlined further.³¹⁵

FDA Reform Strategies

But additional reforms should be broader and more permanent. A number of strategies could further speed drugs to market. Even limited procedural reform would help: the European Commission has set as a goal reducing European approval time from about 18 months to 9–12 months, below the FDA average. The organization’s “decision will help patients all around Europe to get new and better medicines than is the case today,” explains Erkki Litkanen, European commissioner for enterprise.³¹⁶ More fundamentally, FDA regulatory approval could be limited to safety, with effectiveness left up to the marketplace, which is where it belongs.

Even better, the FDA could operate as a certifying agency, providing a special stamp of approval (or withholding one) for a drug’s effectiveness rather than posing legal barriers to its entry into competitive markets. Then patients, doctors, and hospitals could consider approval by the FDA and European and Japanese pharmaceutical regulators. Private organizations also could test drugs and publicize their findings, just as the independent safety certifications and standards-writing organization Underwriters Laboratories reviews most electrical equipment.

The Progress and Freedom Foundation proposes allowing private entities to become FDA-licensed “Drug Certifying Bodies” and “Device Certification Bodies” to oversee pharmaceutical and product development, though the underlying legal standards of efficacy and safety and FDA enforcement would remain unchanged.³¹⁷ Congress could choose to accept approval by selected foreign nations: For instance, Peter Barton Hutt of the law firm Covington and Burling suggests giving the FDA three months to review the administrative record of the European Medicines Evaluation Agency, after which it would have to specify evidence that a drug was unsafe or ineffective, or else the drug could be sold.³¹⁸ Or certification could be left even more directly to other private bodies competing in a free market.³¹⁹ Unapproved drugs could be marketed as such, with doctors, pharmacists, hospitals, and insurers all operating as gate-keepers to advise patients. The potential for product liability lawsuits and medical malpractice claims also would remain a potent constraint on pharmaceutical practice.³²⁰

To Reduce Prices, Reduce Costs

There are other means, too, to help reduce pharmaceutical prices. For instance, the FDA could lower costs by moving more drugs to over-the-counter sale status. In 1972 the agency loosened its approval process, allowing more than 600 drugs to become available without prescriptions. The FDA recently considered shifting the allergy drugs Allegra,

FDA regulatory approval could be limited to safety, with effectiveness left up to the marketplace, which is where it belongs.

The first line of defense for those who cannot afford needed drugs should be private charity.

Claritin, and Zyrtec to over-the-counter status. In late November, it finally approved OTC sales of Claritin. It may take the same stance toward antibiotics, contraceptives, and treatments for other chronic conditions, such as high blood pressure, high cholesterol, and osteoporosis.³²¹ The Consumer Healthcare Products Association estimates that consumers could save nearly \$13 billion annually (although insurance plans rarely cover the cost). Moreover, people could buy those medicines without visiting a doctor to get a prescription.

Internet pharmacies, where consumers typically consult an online physician, might also help promote competition and reduce costs. The Clinton administration proposed cracking down on such enterprises, but existing laws adequately cover fraud. Current sites tend to focus on precisely the drugs most appropriately turned into over-the-counter products, the so-called lifestyle drugs like the anti-impotence treatment Viagra and the anti-baldness drug Propecia.³²²

Nor does government alone bear responsibility for making the system more cost-conscious. Splitting pills in half (because many drugs cost about the same per pill, regardless of the dosage) is a common practice that has the potential of saving drug consumers hundreds of millions of dollars annually.³²³ Asking doctors to consider costs and prescribe alternatives would also significantly reduce the pharmaceutical bill for many Americans.³²⁴ Doctors and patients also should develop strategies to reduce wasted (unused) medicines, estimated to cost \$1 billion a year.³²⁵

A Role for Charitable Assistance

The first line of defense for those who cannot afford needed drugs should be private charity. The pharmaceutical companies already do their part. Forty-nine firms have their own programs for the uninsured and indigent, which gave away 2.8 million prescriptions in 1998.³²⁶ PhRMA maintains a directory of drugmaker programs, as well as RxHope.com, an Internet service to match

patients to federal, state, and private charitable drug assistance programs. Medicare maintains a website that lists private and public sources of assistance.³²⁷ At least two private companies, Harsonhill and the Medicine Program, provide eligibility and application information on all of the private programs.³²⁸ In September 2001, GlaxoSmithKline created a national discount program for low-income elderly without insurance coverage for pharmaceuticals.³²⁹

Private charity also can help at the international level. Rather than expecting drug-makers alone to bear the burden of caring for AIDS patients and those who suffer from malaria or any of a number of other deadly or debilitating diseases, residents of Western nations should generally contribute to ensure both access and adequate follow-through treatment. For instance, an international coalition, the Academic Alliance for AIDS Care and Prevention in Africa, plans to establish a state-of-the-art AIDS clinic at Makerere University in Uganda in 2002. A number of international aid programs, through the United Nations and World Bank, have been proposed.³³⁰ However, there is more than enough history of failure with foreign aid to be cautious: Governments that cannot provide health care on their own probably cannot use foreign money effectively to provide it.³³¹

Assistance through private organizations would be better. Charitable groups such as Doctors Without Borders that have shamelessly attacked pharmaceutical firms while doing little themselves to increase access of those suffering from AIDS to drug treatments should step forward. (The organization rejected an opportunity to purchase a combination of U.S. drugs for \$350 annually per patient to treat African AIDS sufferers.)³³² Even Western investors in poor countries can play a role: the London-based mining concern Anglo American PLC plans to provide AIDS drugs to employees and their families.³³³

In April 2001 UN Secretary General Kofi Annan made a pitch for help to representatives of 1,800 American foundations. Such

organizations should purchase pharmaceuticals (a consortium of aid groups could negotiate deeply discounted prices with drugmakers) as well as help develop the practical infrastructure necessary to administer drugs (transmitting knowledge and administering treatment regimens).³³⁴ Research, too, can be promoted through private philanthropy: Microsoft's Bill Gates pledged \$100 million in June 2001 to a global fund to combat AIDS and also helped fund research on malaria (donating nearly \$125 million in 1999 and 2000 for the latter).³³⁵ Oracle's Larry Ellison is promoting biotechnology and underwriting research for vaccines for the Third World.³³⁶ There is a moral responsibility to help, but it is a responsibility that should be shared by everyone.

Conclusion

Americans understandably are concerned about rising pharmaceutical costs. Those concerns may be even greater overseas: last year the French government announced that it planned to "continue and strengthen" its push for lower prices on some medicines in an attempt to save between \$500 million and \$600 million a year.³³⁷ But costs are not everything.

People continue to use drugs, even while complaining about the cost, because of their great benefits. And those benefits come only because profit-minded private firms are able to raise capital for R&D investments in the risky and uncertain business of pharmaceutical production. Marcia Angell and Arnold Relman of the Harvard Medical School argue that drugs are necessary for people's health and even their survival, yet "the drug companies often behave as though their only responsibility is to their shareholders."³³⁸ Of course, such an argument could be made for any health care provider, as well as farmers and even producers of other necessities, such as clothes and houses.

Yet without pharmaceutical industry shareholders, there would be no companies

and no R&D. Pharmaceutical firms are particularly important because they are entrepreneurial. Although profits are the driving economic force, that doesn't mean that the people who staff pharmaceutical companies don't also desire to do good: John Crowley left Bristol-Myers Squibb Co. to found a start-up biotechnology concern to search for the cure for Pompe disease, a rare metabolic killer that afflicted two of his children.³³⁹ But it is the potential for profit that allows entrepreneurs like John Crowley to raise capital, and to spend more than any government, no matter how public-spirited, devotes to the search for new drugs.

"Other countries don't allow prescription drug companies to gouge their consumers," argued Rep. Tom Allen (D-Maine) in supporting a proposal to allow reimportation of American drugs sold abroad.³⁴⁰ "Gouging," however, may be in the eye of the beholder. In the short term, price controls would leave drugmakers with little choice but to continue selling their products; patients would therefore receive more for less. But over the long term companies would cut R&D budgets, focus on more certain, me-too medicines, and expand spending in areas likely to offer a better return, such as advertising and marketing. The tradeoff is inescapable. Industry critics act as though Americans can have everything they have now, and have it cheaper. But cutting consumer spending on drugs means cutting access to new medicines. As long as Americans value better health, longer lives, and improved quality of life, their spending on medicine, and pharmaceuticals, will, and should, increase.

Some industry critics aren't worried about the risk of lost drugs. "It could very well be that some research can wither without significant consequence, says Public Citizen."³⁴¹ Perhaps. But that is easy to say only if one is healthy and expects to remain so—forever. Unfortunately, there's nothing about the operation of the political process to give much hope that government controls will yield a rational, reasoned, and non-harmful reduction in pharmaceutical R&D.

Today, high costs pose a serious, but manageable, problem. Intrusive regulation and price con-

As long as Americans value better health, longer lives, and improved quality of life, their spending on medicine, and pharmaceuticals, will, and should, increase.

trols would pose a far more serious, and far less manageable, problem tomorrow. New drugs are saving countless lives today. New federal and state controls, in contrast, would be hazardous to Americans' health. Government policymakers must avoid taking steps that would, intentionally or not, wreck a world-leading industry and deny people access to life-saving medicines.

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58. Steven Wiggins, "Rates of Return, Innovation, and Drug Price Controls," Enterprise Research Center; see also Gretchen Krueger, Texas A & M University press release, May 17, 1993.

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62. Bailey, "Goddam the Pusher Man," p. 48.
63. Maven J. Myers, "The Interrelationship between Pharmaceutical R&D and Profit," *Journal of Research in Pharmaceutical Economics* 4, no. 2 (1992).
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74. *Parexel's Pharmaceutical R&D Statistical Sourcebook 2000*, ed. Mark Mathieu (Waltham, Mass.: 2000), p. 65; Tollman, et al., pp. 3, 5.
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115. See, for example, "Access to New Medications Delayed in Europe," National Center for Policy Analysis, Idea House, www.ncpa.org/pi/health/pd100300e.html; "In Europe, Access to New Medications Takes Time," Galen Institute, September 28, 2000, www.galen.org/news092800.html. Kerry Capell of *Business Week* finds that Europe's cash-strapped national healthcare systems "rely on cheaper, older, and often less expensive drugs. Access to new and potentially lifesaving medicines is delayed, and frequently restricted." Another side effect of European price controls is that relatively lower drug prices there provide little incentive for generic manufacturers to enter the market. "The upshot is that governments end up paying higher prices than needed for older, branded medicines," he notes. See Kerry Capell, "Commentary: Europe Pays a High Price for Cheap Drugs," *Business Week Online*, February 17, 2003, www.businessweek.com/print/magazine/content/03_07/b3820139_mz034.htm?gb.

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118. See, for example, Vanessa Fuhrmans and Scott Hensley, “Price Controls in Europe Draw Drug Makers’ Criticism,” *Wall Street Journal*, December 13, 2001, p. B4.
119. “Rx R&D Myths,” p. 20.
120. Lacy Glenn Thomas, “Price Regulation, Industry Structure and Innovation,” *Pharmaco-Economics*, 1, suppl. 1, pp. 9–12.
121. At the start of the 1990s, Europe accounted for nearly 50 percent more in R&D spending than the U.S., but at the end of the decade the U.S. spent 25 percent more on research investment than did European countries. As a result, the number of U.S.-sourced new medicines increased by roughly 50 percent between three early years of the 1990s (1991–93) and the final three years (1997–99), while the number of new medicines produced from European firms declined. Kolassa, pp. 16–17.
122. Alan Cowell, “Europe Moves to Speed Up Approval of New Drugs,” *New York Times*, July 19, 2001, p. W1.
123. David Pilling, “Winning the Drugs War,” *Financial Times*, April 13, 1999, p. 15; see also Orzechowski and Walker, pp. 12–16.
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125. The Prescription Drug Fairness for Seniors Act (H.R. 1400) was introduced in the 107th Congress on April 6, 2001.
126. Reimportation is aimed at overriding U.S. drug companies’ distribution networks and preempting their restrictions on resale of pharmaceutical products. The U.S. drug distribution system generally allows only U.S. manufacturers to reimport their own drugs back into the country. The new legislation was designed to overcome several existing legal barriers to drug reimportation imposed by the Food, Drug, and Cosmetic Act (manufacturing and labeling rules for approved New Drug Application products) and the Prescription Drug Marketing Act of 1987 (essentially prohibiting most reimportation unless required for emergency medical care). See Eisenberg, p. 131.
127. See, for example, Robert Pear, “In a Turnaround, White House Kills Drug-Import Plan,” *New York Times*, December 27, 2000.
128. The most common argument used against reimportation is safety—the risk of receiving adulterated products. Americans routinely bring lower-priced medications in from Mexico, though there is great variety in the quality of medications produced there. See, for example, Sarah Lunday, “When Purchasing Medicine in Mexico, Buyer Beware,” *New York Times*, April 17, 2001, p. D5. But that concern becomes less compelling when dealing with an industrialized state such as Canada. See also Jonathan Klick, “Drug Reimportation’s No-Win Solution,” *Regulation* 25, no. 1 (2002): 6. Indeed, drug industry arguments that, for short-term tactical reasons, salute the FDA role in keeping “unsafe” drugs out of the U.S. are puzzling and counterproductive in the long run. In effect, they disparage the quality and safety of their own products and undercut the longstanding critique of deadly overcaution in FDA drug approvals. See “Sure, Cheap Canadian Drugs,” *Wall Street Journal*, July 23, 2002, p. A14.
129. Quoted in David Broder, “The Fight against Cheaper Drugs,” *San Diego Union-Tribune*, September 24, 2000, p. G-2.
130. Sanders.
131. Sheryl Gay Stolberg and Jeff Gerth, “In a Drug’s Journey to Market, Discovery Is Just the First of Many Steps,” *New York Times*, July 23, 2000, p. 13.
132. Quoted in Tom Bray, “Prescription Drug Donnybrook,” *Washington Times*, August 1, 2000, p. C15.
133. McArthur, “Prescription Drug Costs.”
134. In European markets, some drug companies recently have begun to restrict supplies of their products to meet local demand only, as a way to limit parallel imports from European countries where prices are lower to those that allow higher prices. Vanessa Fuhrmans and Scott Hensley, “Drug Makers Try to Curtail Cheap Imports,” *Wall Street Journal*, April 11, 2002, p. B1.
135. For example, in letters sent to Canadian wholesalers and retailers on January 3, GlaxoSmithKline warned that the drugmaker would stop supplying any companies that failed to provide assurances that they would cease cross-border sales (primarily to U.S. customers). Although Glaxo subsequently backed off its January 21 deadline for implementing this new policy, it continues to explore methods to stop supplying Canadian wholesalers with U.S.-made drugs that they export back to American consumers. For example, on January 21, Glaxo asked Canadian wholesalers and retail pharmacies to “self-certify” that they are not exporting Glaxo drugs outside of Canada or else risk having their supplies cut

off. By the end of January, United Pharmacists, Ltd., a Canadian drug wholesaler, had stopped selling Glaxo products to pharmacists who sell medicine to U.S. patients over the Internet. "Canadian Wholesaler Defers to GlaxoSmithKline Threat," *Wall Street Journal Online*, January 29, 2003, www.online.wsj.com/article_print/0,,SB104385770373012464,00.html; Joel Bagole, "Glaxo Tries New Tack on Cheap Canadian Drugs," *Wall Street Journal*, January 22, 2002, p. D2; "Drug Maker Drops Canada Cut Off Deadline," Associated Press, January 22, 2003, www.nytimes.com/aponline/business/AP-GlaxoSmithKline-Canada.html; "GlaxoSmithKline May Stop Sales to Canada," Associated Press, January 11, 2003, www.nytimes.com/aponline/health/AP-Glaxo-Canada.html. On February 12, 2003, the FDA issued a warning to third-party suppliers that they may be violating civil and even criminal law by making it possible for Americans to buy drugs from Canada. The warning presumably was aimed at roughly 30 Canadian pharmacy services that appear to offer sales to U.S. citizens over the Internet. Thomas M. Burton, "The FDA Begins Cracking Down on Cheaper Drugs from Canada," *Wall Street Journal*, March 12, 2003, p. A1.

136. Calfee points out that if Congress enacted another version of parallel import legislation in the future, it also would create serious political risks: "Congress would have placed its stamp of approval on the principle that controlled prices in foreign nations should trump market-driven domestic prices. . . . An attempt to impose European-style price controls is the logical endpoint of current attempts to link U.S. and Canadian prices." John Calfee, "Why Drugs from Canada Won't Cut Prices," *Consumers' Research*, November 2002, p. 12.

137. Bandow, "The Faux Pharmaceutical Crisis," pp. 2-3.

138. For recent evidence of reduced access to newer brand-name drugs in Canada and other European countries when their governments have overreached in demanding steep discounts, see "Sure, Cheap Canadian Drugs," *Wall Street Journal*.

139. Calfee, 2000, pp. 45-47; see also Robert Goldberg, "Ten Myths About the Market for Prescription Drugs," National Center for Policy Analysis Policy Report no. 230, October 1999, pp. 24-28; "Examining the Relationship between Market-Based Pricing and Bio-Pharmaceutical Innovation," pp. 17, 18.

140. John A. Vernon, "Estimating the Impact of Price Regulation on Investment in Pharmaceutical R&D: A Study of the World's Leading Drug Firms," *Regulation* 25, no. 4 (2002).

141. Patricia M. Danzon, *Price Comparisons for Pharmaceuticals* (Washington, D.C.: AEI Press, 1999), p. 17. OBRA (Public Law 101-508) replaced the closed formularies used by many state Medicaid programs with a rebate system that allowed more "open" formularies. As long as drug manufacturers rebated a portion of their drugs' prices back to the states and to the federal government, all of those drug products would be covered under the Medicaid program. See NIHCM Research and Educational Foundation, "A Primer: Generic Drugs, Patents and the Pharmaceutical Marketplace," June 2002, p. 25.

142. "Innovator" (brand-name) drugs are those approved by the FDA after extensive clinical testing under a new drug application. Federal ceiling prices do not apply to generic drug products. See NIHCM Research and Educational Foundation, "A Primer," p. 16.

143. The final price under this formula may be slightly higher, however, due to adjustments for excess drug price inflation.

144. NIHCM REsearch and Educational Foundation, "A Primer," pp. 16, 17.

145. United States General Accounting Office, "Medicaid: Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals," GAO/HEHS-94-194FS, Washington, D.C., 1994.

146. Congressional Budget Office, "How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry," January 1996.

147. Danzon, 2000, p. 60. Danzon also points out that the pharmaceutical market is currently bifurcated into price-inelastic retail and price-elastic managed care/group purchasing segments. Today a company can offer a discount in the latter without raising prices in the former. Effectively merging the markets by requiring the same discount would force producers to base pricing on the weighted average of the combined market, thereby raising prices to managed care/group purchasing entities. Indeed, "This effect is likely to be large, because of the relatively large size of the price-inelastic retail sector." Danzon, *Price Comparisons for Pharmaceuticals*, pp. 42, 45; see also Anna E. Cook, "Strategies for Containing Drug Costs: Implications for a Medicare Benefit," *Health Care Financing Review* 20, no. 3 (Spring 1999): 35.

148. Cook, 1999, pp. 33, 34.

149. Florida even insisted on additional rebates that averaged 6 percent more than the federally mandated discounts its Medicaid program was already receiving. As of July 2001 its very restrictive Medicaid

formulary required doctors wishing to treat Medicaid patients with nonformulary drugs to first receive preauthorization from pharmacists working for the state government. Drug companies essentially had to provide special rebates if they wanted full access to Florida's Medicaid program and a predictable stream of reimbursements. See Russell Gold, Scott Hensley, and Joni James, "Drug Intervention: Pfizer Ducks Pressure on Prices by Helping State Save on Medicaid," *Wall Street Journal*, July 9, 2001, p. A1; Russell Gold, Scott Hensley, and Andrew Caffrey, "Industry Headache: States Square Off against Drug Firms in Crusade on Prices," *Wall Street Journal*, December 7, 2001, p. A1.

150. For more detailed descriptions of the political process behind this arrangement, see Robert Pear, "U.S. Backs Florida Plan to Cut Drug Costs," *New York Times*, September 19, 2001, p. A14; Gold, Hensley, and James, p. A1.

151. Maine approved both strategies; Vermont enacted only the latter. See, for example, Victoria Griffith and Adrian Michaels, "Vermont Bus Trips Increase the Drugs Price Pressure," *Financial Times*, July 9, 2001, p. 4; James Frogue, "Vermont's Plan to Control Drug Prices for Seniors: A Bad Prescription," Heritage Foundation Executive Memorandum no. 737, April 12, 2001.

152. Robert Goldberg, "Medicaid Waivers: Wrong Cure for High Drug Prices," National Center for Policy Analysis Brief Analysis no. 351, March 13, 2001, pp. 1-2.

153. Because drug products of manufacturers that failed to reach rebate agreements with Maine would be subject to prior authorization hurdles, doctors for thousands of state Medicaid patients would be much less likely to prescribe them. Those doctors still interested in doing so first would have to specifically request permission from the state. Drug manufacturers wishing to retain revenue from Medicaid reimbursements in the state therefore faced strong incentives to participate in the Maine Rx Program as well.

154. Bart Jansen, "Judges See Fatal Flaw in Maine Drug Plan," *Portland Press Herald*, December 6, 2002, www.216.239.57.100/search?q=cache:XHhruM1PjpMC:www.pressherald.com/news/state/021206health.shtml+Judges+See+Fatal+Flaw+in+Maine+Drug+Plan&hl=en&ie=UTF-8.

155. *Pharmaceutical Research and Manufacturers of America v. Kevin Concannon, et al.*, U.S. No. 01-188, certiorari granted June 28, 2002.

156. Robert S. Greenberger and Andrew Caffrey, "Justices to Review Maine's Controls on Drug Costs," *Wall Street Journal*, July 1, 2002, p. B5.

157. *Pharmaceutical Research and Manufacturers of America v. Thompson, et al.*, 251 F.3d 219 (D.C. Cir. 2001). On June 13, 2002, Vermont modified its pharmacy discount plan, now known as "Healthy Vermonters," to implement it as a Medicaid waiver project with the state paying 2 percent of the cost of drugs dispensed to enrolled individuals. However, it still relies on a preferred drug list and supplemental rebates. See Jansen.

158. *Pharmaceutical Research and Manufacturers of America v. Thompson and Concannon*, 191 F. Supp. 2d 48 (D.D.C. 2002).

159. *Pharmaceutical Research and Manufacturers of America v. Thomson, et al.*, 313 F.3d 600 (D.C. Cir. 2002).

160. Robert Pear, "Law Requiring Lower Drug Prices Is Struck Down," *New York Times*, December 25, 2002, p. A1; "Prescription Plan in Maine Rejected by Federal Court," *Wall Street Journal*, December 26, 2002, p. D6.

161. PhRMA and several patient advocacy organizations filed a lawsuit in federal district court that seeks to invalidate the Michigan program because it excludes Medicaid drugs based solely on price, harms Medicaid beneficiaries, and violates the Medicaid statute. They claim that federal law requires all drugs to be approved for Medicaid beneficiaries unless there is a clinical reason for their exclusion from a state's drug formulary. The lawsuit also asks the court to prohibit HHS Secretary Thompson from approving as many as 13 other states' programs that share some or all of the features of the Michigan plan. *Pharmaceutical Research and Manufacturers of America v. Thompson and Scully*, D.D.C. No. 02-1306, filed June 28, 2002. However, drug companies and mental health advocates also filed a different lawsuit in state court in Michigan, claiming that the state program is unconstitutional and endangers patients' lives. Although a lower state court initially halted the program with a temporary injunction, the Michigan Court of Appeals on December 13, 2002, permanently lifted the injunction. It ruled that, absent evidence of any specifically applicable legislative limitation on the state Department of Community Health's authority to establish and administer health care programs, the agency had the power to implement the challenged policies. "Michigan Plan to Cut Drug Costs Is Upheld," *Associated Press*, December 16, 2002, www.nytimes.com/online/health/AP-Medicaid-Prescriptions.html. On March 28, U.S. District Judge John D. Bates similarly ruled, in the federal court case (*Pharmaceutical Research and Manufacturers of America v. Thompson and Scully*), that Michigan could continue its plan to require doctors to use a

list of discounted drugs when treating low-income patients who receive state aid. "Judge Backs State's Use of Discount Drug Program," *Washington Post*, March 29, 2003. p. A5.

162. Kolassa, p. 10; see also Frank R. Lichtenberg and Suchin Virabhak, "Pharmaceutical Embodied Technical Progress, Longevity, and Quality of Life: Drugs as 'Equipment for Your Health'," National Bureau of Economic Research Working Paper no. 9351, November 2002 (noting that people consuming newer drugs had better post-treatment health and experienced fewer activity, social, and physical limitations).

163. Gold, Hensley, and Caffrey, p. A13.

164. *Ibid.*, p. A1. In fact, nine states and the District of Columbia are organizing a joint nonprofit operation to manage their prescription drug plans and ensure that state programs gain the full benefit of any price discounts negotiated with drugmakers. Milt Freudenheim, "States Organizing a Nonprofit Group to Cut Drug Costs," *New York Times*, January 14, 2003, p. A1.

165. As of January 2003, 34 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to the low-income elderly or persons with disabilities who do not qualify for Medicaid. Twenty-seven state programs are in operation, and seven others have been authorized. Twenty-six states provide for a direct subsidy, and eight offer a discount only for eligible or enrolled seniors. National Conference of State Legislatures, "State Pharmaceutical Assistance Programs," www.ncsl.org/programs/health/drugaid.htm. See also U.S. General Accounting Office, "State Pharmacy Programs: Assistance Designed to Target Coverage and Stretch Budgets," GAO/HEHS-00-162, Washington, September 2000.

166. In 2001, approximately three out of four seniors spent less than \$2,000 annually on prescription drugs (counting both expenses covered by insurance and expenses paid out-of-pocket). Dana P. Goldman, Geoffrey F. Joyce, and Jesse D. Malkin, "The Costs of a Medicare Prescription Drug Benefit," *Topics in Economic Analysis and Policy* 2, no. 1, www.bepress.com/bejeap/topics/vol2/iss1/art3.

167. Bailey, "Goddam the Pusher Man," p. 46.

168. Russell Gold, "States Battling High Drug Costs Appeal to Doctors," *Wall Street Journal*, August 22, 2001, p. B1.

169. During the period of market exclusivity, other drug manufacturers are prohibited from relying on the drug patent holder's clinical data to

gain FDA approval of their competing products. NIHCM Research and Educational Foundation, "A Primer," pp. 4, 5.

170. *Ibid.*, p. 5.

171. Congressional Budget Office, 1998, p. 27.

172. *Ibid.*, pp. 6, 7; Tufts Center for the Study of Drug Development, "Clinical Development Times for New Drugs Drop 18%, Reversing 12-Yr. Trend," Tufts CSDD Impact Report 1 (July 1999): 1-3, <http://csdd.tufts.edu/InfoServices/ImpactReportPDFs/impactReportJuly1999.pdf>. On the other hand, a 1998 Congressional Budget Office study estimated that the combined effects of Hatch-Waxman and state drug product substitution laws, along with more active promotion of generic drug substitution by insurers and government health programs, lowered the average returns from marketing a new drug by roughly 12 percent. In 1994, for example, retail purchasers saved an estimated \$8 billion to \$10 billion by substituting generic for brand-name drugs. See Congressional Budget Office, 1998, pp. 31, 45-47.

173. Under existing law, an automatic stay may be triggered when a generic drugmaker seeks to sell its own product before expiration of the patent of a similar brand-name drug. When the generic competitor claims that the challenged patent either is invalid or is not infringed, the patent holder may claim the automatic stay while the dispute is resolved. Filing of the lawsuit stays FDA approval of the abbreviated new drug application until the earliest of: (1) the date the patents expire, (2) a determination of noninfringement or patent validity by a court in the patent litigation, or (3) the end of the 30-month automatic stay period. In any event, the automatic stay cannot operate any longer than the remaining term under the challenged patent.

174. "Generic Drug Entry Prior to Patent Expiration: An FTC Study," Federal Trade Commission, July 2002.

175. The Bush proposal would, however, allow a single 30-month stay per patent. That was interpreted as continuing to allow multiple patent extensions, in the sense that a brand-name manufacturer could seek separate extensions on any patent that it held on a medication that was challenged by a generic competitor. The Senate bill would have allowed such 30-month stays only on those patents that had been filed at the time the brand-name drug was originally approved. The Bush administration's plan would also prohibit drug companies from filing new patents based on different packaging, different added ingredients, or "different forms" of patented drugs. Its new regulations would require drugmakers to provide more

detailed information when they file patents and certify that information. See Amy Goldstein, "Bush Plans New Rules on Generic Medicine," *Washington Post*, October 21, 2002, p. A1.

176. "Lawmakers, Groups Respond to Bush Administration Proposal to Speed Market Entry of Generic Drugs," *Kaiser Daily Health Report*, October 22, 2002, www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=14151.

177. See Scott Gottlieb, "Patent Mistakes," *Wall Street Journal*, October 23, 2002, p. A18.

178. Kleinke, 2001, pp. 48-49.

179. Kleinke, 2000, pp. 80, 81.

180. *Ibid.*, p. 83.

181. Kleinke, 2001, p. 50.

182. Indeed, even as generic drugs were being touted as one of the best means to hold down medical costs, the average price of a generic prescription drug was rising almost twice as rapidly as the average price of all brand-name drugs. Ronald Pollack, executive director of Families U.S.A., a national consumers' organization, complained that the economic benefit provided by generic drugs "often turns out to be considerably less than it could be." Milt Freudenheim, "As Patents on Popular Drugs End, Costs for Generics Show a Surge," *New York Times*, December 27, 2002, p. A1.

183. See, for example, Gottlieb.

184. August Gribbin, "Lethal Pathogens Handy in Nations Harboring Terrorists," *Washington Times*, October 21, 2001, p. A4; Melody Petersen and Andrew Pollock, "Big Push to Accelerate Vaccine Effort," *New York Times*, September 28, 2001, p. C8.

185. Quoted in Amy Barrett, "How to Get Pharma's Big Guns Aimed at Microbes," *Business Week*, November 5, 2001, p. 40.

186. Scott Hensley and Ron Winslow, "Drug Companies Contemplate New Role as 'Biodefense Contractors,'" *Wall Street Journal*, November 12, 2001, p. B1

187. Terence Chea, "Vaccines Are Hot Topic, but Not Hot Investment," *Washington Post*, December 13, 2001, p. E1.

188. John E. Calfee, "Pharmaceutical Patents and Public Safety: Profit Incentives Help Fight Terror," *Consumers' Research*, November 2001.

189. Office of the Press Secretary, "President Details Project Bioshield," News Release, The White House, February 3, 2003, www.whitehouse.gov/news/releases/2003/02/20030203.html. The

initial version of Project Bioshield's incentives may risk being limited to guaranteed purchases of mature countermeasures, as opposed to ensuring sufficient rewards for successful development of high-risk projects. For an example of stronger incentives that include improved patent protection, outcome-based procurement guarantees, and favorable tax treatment, see Title II of the Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002, S. 3148, introduced in the Senate on October 17, 2002, by Sen. Joseph Lieberman (D-Conn.) and Sen. Orrin Hatch (R-Utah).

190. See, for example, Jill Carroll and Ron Winslow, "Bayer Agrees to Slash Price for Cipro Drug," *Wall Street Journal*, October 25, 2001, p. A3.

191. Carey and Barrett.

192. See also Laura Johannes and Laurie McGinley, "Search for Better Anthrax Vaccine Increases," *Wall Street Journal*, October 19, 2001, p. A9; Ronald Bailey, "The Best Biodefense," Reason Online, November 7, 2001, www.reason.com; "Drug May Be on Shelf for Curing Smallpox," *Washington Times*, November 21, 2001, p. A6; Justin Gillis, "Scientists Race for Vaccines," *Washington Post*, November 7, 2001, p. E1.

193. Carroll and Winslow.

194. Reed Abelson and Andrew Pollack, "Other Drugs to Combat Anthrax Are in Ample Supply If Needed, Health Official Says," *New York Times*, October 23, 2001, p. B8.

195. See, for example, Holman W. Jenkins Jr., "Of Germs and Geopolitics," *Wall Street Journal*, October 24, 2001, p. A23.

196. "A Wartime FDA," *Wall Street Journal*, November 15, 2001, p. A26.

197. Geoff Winestock and Helene Cooper, "Activists Outmaneuver Drug Makers at WTO," *Wall Street Journal*, November 14, 2001, p. A13.

198. Erica Barks-Ruggles, "Meeting the Global Challenge of HIV/AIDS," Brookings Institution Policy Brief No. 75, April 2001, p. 1. See also Erica Barks-Ruggles, et al., "The Economic Impact of HIV/AIDS in Southern Africa," Brookings Institution Conference Report No. 9, September 2001; Tom Carter, "Doctors Losing War on AIDS," *Washington Times*, May 13, 2001, p. A1.

199. "The Urgency of Cheaper Drugs," *New York Times*, October 31, 2001, p. A18.

200. Andrew Sullivan, "Profit of Doom," *New Republic*, March 26, 2001, p. 6.

201. Such steps are allowed under the World Trade Organization, and especially the WTO's

Trade-Related Aspects of Intellectual Property Rights (TRIPS) treaty.

202. Quoted in Miriam Jordan, "Brazil to Break Roche Patent on AIDS Drug," *Wall Street Journal*, August 23, 2001, p. A1.

203. Prior to the 1994 TRIPS agreement, which was part of the Uruguay Round agreement that established the WTO, national intellectual property laws (including intellectual property protection for pharmaceuticals) were largely unregulated within the GATT system of international trade rules. TRIPS required that patents be made available for all "inventions, whether products or processes," including pharmaceutical products. However, the compliance deadlines were extended for many developing nations to as late as 2005. See Alan O. Sykes, "TRIPS, Pharmaceuticals, Developing Countries, and the Doha 'Solution,'" University of Chicago, John M. Olin Law & Economics Working Paper no. 140 (2d Series), January 2002, pp. 5-6, 22, www.law.uchicago.edu/Lawecon/index.html. However, the original TRIPS agreement also did not fully resolve contentious issues of reimportation and compulsory licensing, practices that can erode patent protection for pharmaceuticals.

204. Celia Dugger, "A Catch-22 on Drugs for the World's Poor," *New York Times*, November 16, 2001, p. W1.

205. Sykes, p. 2.

206. Quoted in Louis Uchitelle, "U.S. Companies Largely Back Trade Decisions," *New York Times*, November 15, 2001, p. C3. See also Gardiner Harris and Rachel Zimmerman, "Drug Makers Say WTO Setback Will Not Have Significant Impact," *Wall Street Journal*, November 15, 2001, p. B5; Winestock and Cooper, p. A2.

207. See "Trading Drugs," *Washington Times*, November 26, 2002, p. A18.

208. Uchitelle.

209. See Elizabeth Becker, "Trade Talks Fail to Agree on Drugs for Poor Nations," *New York Times*, December 21, 2002, p. B3. For example, Egypt claimed that erectile dysfunction constituted a health emergency warranting production of a Viagra knockoff drug. See Robert Goldberg, "U.S. Betrayed by WTO Patent Policy," *Columbia Daily Tribune*, November 26, 2002, www.archive.columbiatribune.com/2002/nov/20021126com m007.asp.

210. Goldberg, 2002.

211. See Sykes, p. 20; Roger Bate, "Protecting Patents: Property Rights Save AIDS Patients," *Wall Street Journal Europe*, December 1, 2000, p. 8.

212. Eisenberg, p. 129.

213. Office of the United States Trade Representative, "U.S. Announces Interim Plan to Help Poor Countries Fight HIV/AIDS and Other Health Crises in Absence of WTO Consensus," Press Release, December 20, 2002, www.ustr.gov/releases/2002/12/02-119.pdf. See also Tom Hamburger, "U.S. Flip on Patents Shows Drug Makers' Growing Clout," *Wall Street Journal*, February 6, 2002, p. A4.

214. Julia Neuberger, "A Plan for the World—Health," *New Statesman*, October 22, 2001, www.newstatesman.com.

215. Quoted in Harvey Bale, "Patents and Public Health: A Good or Bad Mix?" *Washington Times*, April 19, 2001, p. A17.

216. Quoted in Becker.

217. Jean O. Lanjouw, "A Patent Policy Proposal for Global Diseases," June 11, 2001, p. 23, www.208.243.20.130/dybdocroot/views/papers/lanjouw/20010611.pdf.

218. Jean O. Lanjouw, "A Patent Policy Proposal for Global Diseases," Brookings Institution Policy Brief no. 84, June 2001, p. 3.

219. Padraig O'Malley, "AIDS Drugs: The Bottom Line or Bottoming Out?" *The World Paper*, May-June 2001, p. 3.

220. Roger Bate, "When Activists Win," December 5, 2002, Tech Central Station, www.techcentralstation.be/2051/wrapper.jsp?PID=2051-100&CID=2051-120502M; see also "The AIDS Initiative," *Wall Street Journal*, February 7, 2003, p. A10.

221. Donald Berwick, "We All Have AIDS," *Washington Post*, June 26, 2001, p. A17.

222. Romesh Ratnesar, "Taking It to the Streets," *Time*, April 23, 2001, p. 47.

223. Rachel Zimmerman, "Glaxo Licenses AIDS Drug to Generics Firm," *Wall Street Journal*, October 8, 2001, p. A16; Dyan Machan, "Doing Badly by Doing Good," *Forbes*, October 29, 2001, pp. 92-94.

224. Pharmacia, "Pharmacia to Launch Pilot Program for Expanding Access to Needed Medicines in World's Poorest Countries," News Release, January 24, 2003, www.pharmacia.com/newsroom/script_press.asp?id=376. To facilitate this alternative to compulsory licensing, approved copies of the anti-retroviral drug would be different in shape, color, packaging, and name from versions sold in richer Western nations to prevent smugglers from bringing the cheap version back

- into developed countries. See Paul Geitner, "Pharmacia Tries New Approach on AIDS," Associated Press, January 24, 2003, www.kansas city.com/mld/kansascity/business/5023376.htm.
225. The litigation initiated by international pharmaceutical companies was settled in a face-saving gesture for both parties. Drugmakers decided that if they continued it, they had more to lose in unfavorable publicity than they could gain in stronger patent enforcement.
226. Quoted in "South Africa's Failure on AIDS," *New York Times*, June 21, 2001, p. A24
227. See Jon Jeter, "Political Resistance in S. Africa Blocks Wide Use of HIV Drugs," *Washington Post*, October 1, 2001, p. A18; Rachel Swarns, "Despite Legal Victory, South Africa Hesitates on AIDS Drugs," *New York Times*, April 21, 2001, p. A4; Jon Jeter, "Global Issues Dog S. Africa on AIDS," *Washington Post*, April 20, 2001, p. A1.
228. The South African government even refused to distribute nevirapine, which is available for free from its manufacturer and can reduce HIV transmission from mother to newborn during labor.
229. Amir Attaran and Lee Gillespie, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" *Journal of the American Medical Association* 286, no. 15 (October 17, 2001): 1886.
230. See Sullivan; David Finkel, "Few Drugs for the Needy," *Washington Post*, November 1, 2000, p. A1.
231. Robert Goldberg, "Fight AIDS with Reason, Not Rhetoric," *Wall Street Journal*, April 23, 2001, p. A22.
232. Michael Specter, "India's Plague," *New Yorker*, December 17, 2001, pp. 74-85
233. Saumya Das, "Epidemic Proportions," *American Prospect*, July 30, 2001, p. 25.
234. Richard Tren, "Economic Growth Key to Tackling AIDS," *European Voice*, December 2, 2002, www.cnehealth.org/pubs/12022002_aids_tren.htm.
235. Sykes, pp. 23, 24.
236. James W. Hughes, Michael J. Moore, and Edward A. Snyder, "'Napsterizing' Pharmaceuticals: Access, Innovation, and Consumer Welfare," National Bureau of Economic Research Working Paper no. 9229, October 2002, pp. 1-3, 38-39.
237. *Ibid.*, pp. 3-4.
238. See, for example, U.S. General Accounting Office, "Medicare Payments for Covered Outpatient Drugs Exceed Providers' Costs," GAO-01-1118, Washington, September 2001, p. 1.
239. Executive Office of the President of the United States, *Budget of the United States Government: Fiscal Year 2004* (Washington: U.S. Government Printing Office, February 3, 2003), pp. 123-24.
240. NIHCM Research and Educational Foundation, "Prescription Drug Expenditures 2001," p. 5.
241. Dykes, p. 5. See also Jack Meyer, Emily Waldman, and Zachary Dyckman, "The Impact of Cost-Sharing on Pharmaceutical Utilization of Senior Medicare Enrollees," *New Directions for Policy*, Washington, April 2000, pp. 1-2.
242. David M. Walker, "New Spending Estimates Underscore Need for Reform," Testimony before the Committee on the Budget, House of Representatives, General Accounting Office, GAO-01-1010T, July 25, 2001, p. 3.
243. The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, "2003 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," Washington, March 17, 2003, p. 2. In 2002, Medicare actuaries conservatively projected that the discounted net excess of cash spending over cash income during the next 75-year period would be \$5.1 trillion (even after including the two Medicare trust funds' balances and future interest income, as well as general revenue transfers to Part B). The "Financial Report of the United States Government," using accrual accounting, estimated that the net present value of negative cashflow (funds needed to cover projected shortfalls) was \$4.7 trillion for Part A and an additional \$8.1 trillion for Part B. Tom Miller, "Public Health Care," in *Cato Handbook for Congress: 108th Congress*, (Washington: Cato Institute, 2003), pp. 272-74.
244. Walker, p. 1.
245. Essentially, Congress overshot the mark in clamping down on payments to M+C plans in the 1997 Balanced Budget Act. It compounded this error by also trying to "compress" country-level payment rates to adjust for regional differences. The complex formula for redistributing funds ended up underpaying counties where demand for M+C options was greatest and overpaying other counties where M+C interest remained low or nonexistent. As a result, the program has been plagued by withdrawals and service reductions by participating private health plans. See Tom Miller, "Competitive Alternatives to Medicare," in *Privatization 2002*, ed.

Geoffrey F. Segal (Los Angeles: Reason Public Policy Institute, 2002), pp. 7–9; Robert Pear, “H.M.O.’s Plan to Drop Medicare, Calling Fees Too Low,” *New York Times*, September 22, 2001, p. A8; and Susan Okie, “More HMOs Quite Medicare Plan,” *Washington Post*, September 22, 2001, p. A25.

246. Miller, 2003, p. 276. See also Doug Bandow and Michael Tanner, “The Wrong and Right Ways to Reform Medicare,” Cato Institute Policy Analysis no. 230, June 8, 1995; Doug Bandow, “Medicare Reform: The Choice Option,” Citizens for a Sound Economy Issues and Answers, June 1, 1995. In 1999, Rep. Bill Thomas (R-Calif.) and Sen. John Breaux (D-La.) led a majority of members of the Commission on Medicare Reform in advancing use of Medicare funds to underwrite private choice by beneficiaries among competing plans. Senators Breaux and Bill Frist (R-Tenn.) subsequently introduced legislation, S.1895, in the 107th Congress that built upon most of the Medicare commission’s principles.

247. Robert Pear, “Administration Revising Its Drug Discount Proposal,” *New York Times*, November 2, 2001, p. A20; Jane Bryant Quinn, “Discounts on Your Rx Drugs,” *Newsweek*, August 6, 2001, p. 25; Robert Pear, “Bush and Health Care Companies Promise Medicare Drug Discounts,” *New York Times*, July 13, 2001, p. A1; Amy Goldstein, “Bush Has Pharmacy Discount Card Plan,” *Washington Post*, July 11, 2001, p. A1; Robert Pear, “Bush Drug Plan Calls for Using Discount Cards,” *New York Times*, July 11, 2001, p. A1.

248. In fact, there are already numerous private drug discount programs. See Francesca Lunzer Kritz, “What’s In Your Wallet?” *Washington Post*, November 20, 2001, p. F1; Milt Freudenheim, “Novartis Plans Drug Discount for Elderly,” *New York Times*, November 8, 2001, p. C4; Ceci Connolly, “A New Kennedy Campaign on Drug Costs,” *Washington Post*, September 25, 2001, p. A18; Francesca Lunzer Kritz, “Why Wait? Try Out the President’s Drug Plan Now,” *Washington Post*, July 24, 2001, p. 6.

249. Neely Tucker, “Judge Rejects Bush’s Drug Discount Plan,” *Washington Post*, January 30, 2003, p. A7.

250. Miller, 2002, p. 8. See also Amy Goldstein, “Bush Urges a Reshaping of Medicare,” *Washington Post*, July 13, 2001, p. A1; “Bush Medicare Plan,” OnPolitics, July 12, 2001, www.washingtonpost.com.

251. The \$600 subsidy would apply to all low-income seniors until January 1, 2006. It would continue beyond that date for those low-income seniors who continue to participate in

Traditional Medicare. Other low-income seniors apparently would receive other types of subsidized drug coverage under either Enhanced Medicare or Medicare Advantage.

252. Andrew Rettenmaier and Thomas Saving, “Saving Medicare,” National Center for Policy Analysis Policy Report no. 222, January 1999.

253. Of all the various forms of supplemental insurance available to Medicare beneficiaries, individually purchased “Medigap” policies provide the least comprehensive coverage of prescription drugs. All Medigap policies sold since July 1992 must conform to one of 10 standard policies. Only three of those Medigap policy types cover prescription drugs. The coverage is limited, yet it remains subject to high and increasing premiums. Medicare beneficiaries anticipating higher drug costs are more likely to enroll in one of those three standardized plans and to purchase more drugs once enrolled. Because of this adverse selection, many private insurance carriers do not offer those plans. The most effective reform of the Medigap market would trade some first-dollar coverage in most of the other standard Medigap policies in return for adding better catastrophic and prescription drug coverage to them. See Medicare Payment Advisory Commission, “Report to the Congress: Selected Medicare Issues,” Washington, June 2000, pp. 11–12, 27–28.

254. Goldman, Joyce, and Malkin.

255. John E. Calfee, “Public Policy Issues in Direct-to-Consumer Advertising of Prescription Drugs,” AEI-Brookings Joint Center for Regulatory Studies Related Publication 02-7, May 2002, p. 6. J. D. Kleinke observes that widespread DTC advertising is most likely for drugs whose net benefits develop slowly and do not “pay off” immediately for those insurers who would otherwise resist covering them. Kleinke, 2001, p. 54. Ernst Berndt also notes that DTC ads primarily involve drug products that deal with conditions that are not life threatening but have widespread incidence and are likely to be undertreated. Berndt, p. 112.

256. Last year, Rep. Thomas and other House Republicans briefly considered placing limits on direct-to-consumer drug advertising, believing that such advertising contributed to sharp increases in consumer spending on prescription drugs. One option under review would have charged higher copayments on drugs to be covered by Medicare that were advertised directly to consumers. See Markian Hawryluk, “GOP May Tap Private Sector for Medicare Drug Benefits,” *amednews.com*, May 6, 2002, www.ama-assn.

- org/sci-pubs/amnews/pick_02/gvsb0506.htm; Robert Pear, "Medicare Proposal Promotes Generic Drugs," *New York Times*, March 6, 2002, p. A17; Ira Teinowitz, "House Measure Rules Out DTC Ban," *AdAge.com*, May 1, 2002, www.adage.com/news.cms?newsId=34611. In addition, Sen. Debbie Stabenow (D-Mich.) introduced S. 2486, which would limit a pharmaceutical company's tax deductions for advertising, promoting, or marketing of prescription drugs to no more than the company's research and development expenditures in any taxable year. See "Senate Democrats Push Bill to Limit Tax Deductibility of Drug Advertising," *BNA's Health Care Policy Report*, May 13, 2002, p. 674. Another bill (H.R. 2352) by Rep. Pete Stark (D-Calif.) would deny tax deductions for consumer advertising that presents only the benefits of a drug without accurately describing the risks. Pear, "Medicare Proposal Promotes Generic Drugs."
257. "Prescription Drugs and Mass Media Advertising," NIHCM Research and Educational Foundation Research Brief, September 2000, p. 1.
258. Paul Rubin, "Regulatory Relief or Power Grab: Should Congress Expand FDA's Enforcement Authority?" Heritage Foundation Backgrounder no. 900, June 11, 1992, p. 11. See also Richard Manning and Alison Keith, "The Economics of Direct-to-Consumer Advertising of Prescription Drugs," *Economic Realities in Health Care Policy 2*, no. 1 (2001): 7.
259. Quoted in Michael Schrage, "Drug Makers Jump into Comparison Marketing," *Los Angeles Times*, June 10, 1993, p. D11.
260. Kolassa, p. 22; E. M. Kolassa, "Maximising Patient Choice," *The Economist*, September 8, 2001, p. 10.
261. For a detailed discussion of the likely effect of competition promoted by advertising in the pharmaceutical industry, see Merrill Matthews, "Who's Afraid of Pharmaceutical Advertising? A Response to a Changing Health Care System," Institute for Policy Innovation Policy Report 155, May 2001, pp. 8-13.
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302. Grabowski and Vernon, 1983, pp. 44–46.
303. Dale Gieringer, "The Safety and Efficacy of New Drug Approval," *Cato Journal* 5, no. 1 (Spring–Summer 1985): 189–96.
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314. Tanner, pp. 182–83.
315. Sam Kazman, "Saying Yes to Drugs," *Journal of Regulation and Social Costs*, June 1992, pp. 35–36.
316. Cowell.
317. Lenard et al., pp. 18–24.

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320. See, for example, Louis Lasagna, "The Chilling Effect of Product Liability on New Drug Development," in *The Liability Maze*, ed. Peter W. Huber and Robert E. Litan (Washington: Brookings Institution, 1991), pp. 334-59.
321. See, for example, Jacob Sullum, "Paying through the Nose," *Washington Times*, May 23, 2001, p. A19; Ceci Connolly, "Panel: Reclassify Allergy Pills," *Washington Post*, May 12, 2001, p. A1; Milt Freudenheim, "Panel Says 3 Allergy Drugs Should Be Sold Over the Counter," *New York Times*, May 12, 2001, p. B1; Mark Thompson, "No Doctor Required," *Time*, July 17, 2000, p. 38; Sarah Lueck, "FDA Examines More Switches of Drugs to Be Nonprescription," *Wall Street Journal*, June 29, 2000, p. B26; Sheryl Gay Stolberg, "U.S. May Ease Sales of Drugs Over Counter," *New York Times*, June 28, 2000, p. A1. The pharmaceutical firms involved, facing a loss in revenue—particularly because over-the-counter substances are not covered by health insurance, responded with paternalistic arguments about forcing patients to rely on self diagnosis. See, for example, "3 Allergy Drugs Ruled Safe without Prescription," *Washington Times*, May 12, 2001, p. A1; Melody Petersen, "A Push to Sell Top Allergy Drugs over the Counter," *New York Times*, May 11, 2001, p. A1; Ceci Connolly, "Allergy Pills Spark Dispute," *Washington Post*, May 10, 2001, p. A1. Yet these same companies laud their new emphasis on advertising directed at patients. Although at least one health policy analyst complained that OTC sales vitiate patents (see Robert Goldberg, "Pill-Splitters vs. Gene Hunters," *Washington Times*, May 22, 2001, p. A16), the patents in fact remain intact. The prices of the drugs fall because their parent companies must now compete in a broader market where the costs to consumers are not moderated by insurance.
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323. Tara Parker-Pope, "An Easy Remedy: Cut Your Drug Bills in Half by Cutting Pills in Half," *Wall Street Journal*, July 27, 2001, p. B1
324. Tara Parker-Pope, "Doctors Often Hold the Key to Paying Less for Prescriptions," *Wall Street Journal*, September 7, 2001, p. B3
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326. See generally Fred Brock, "Around the Prescription-Drug Hurdle," *New York Times*, October 7, 2001, p. BU3.
327. See www.medicare.gov/Prescription/Home.asp.
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329. Melody Petersen and Milt Freudenheim, "Drug Giant to Introduce Discount Plan for the Elderly," *New York Times*, October 3, 2001, p. C1.
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340. Quoted in, "Budget," *National Journal's CongressDaily*, July 11, 2001, www.nationaljournal.com/pubs/congressdaily.
341. "Rx R&D Myths," p. 21.

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