

ELECTION 2004

Prescription-Drug Prices

Richard G. Frank, Ph.D.

In 2002, the United States spent \$162.4 billion on prescription drugs. Government has traditionally played a smaller role in purchasing prescription drugs than in paying for health care services overall,¹ accounting for 22 percent of prescription-drug spending as compared with 44 percent of all spending on personal health. The Medicare Modernization Act adds a prescription-drug benefit to the Medicare program, thereby reshaping the government's role as a payer for prescription drugs: the federal government's share of the country's prescription-drug spending can be expected to increase to between 30 and 40 percent during the first two years. The prices that the government pays for prescription drugs will be critically important. They will affect the cost of the new drug benefit, the financial stability of the Medicare program, and the incentives for prescription-drug manufacturers to develop new pharmaceutical agents.

The Medicare Modernization Act calls for prescription-drug plans to compete to enroll individual Medicare beneficiaries. Regulations regarding formulary structure, payment arrangements, and other policy features are beginning to emerge from the Centers for Medicare and Medicaid Services. The law's provisions requiring that prescription-drug plans bear risk may create incentives for them to bargain aggressively for lower prices. The law denies government a direct role in setting prices. This stipulation means that prescription drugs will be unique among health care services within the Medicare program, in which the government sets physicians' fees, hospital rates, and nursing home reimbursements.

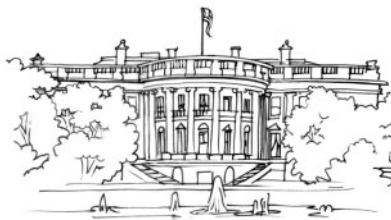
A key feature of the pharmaceutical industry is that drugs can be manufactured at a variable cost of pennies per pill, but drug companies incur high

fixed research-and-development costs to bring new drugs to market. If manufacturers were paid prices that reflected their variable costs, as other industries are, the average cost of a drug would not be covered, and the companies would lose money. The implication is that with lower prices, drug-company profits will diminish and research-and-development efforts may be reduced, resulting in a diminished flow of new drugs. There is therefore a constant tension between drug policies that control today's prices and those that promote tomorrow's innovative products. The positions of the presidential candidates, as they have been articulated in the campaign through September, reflect that tension.

The candidates differ sharply on two issues affecting drug prices: the importation of prescription drugs from other nations and the role of government in negotiating prices for Medicare. These viewpoints represent basic differences in the outlooks of President George W. Bush and Senator John F. Kerry that extend beyond prescription drugs.

Prices for brand-name prescription drugs are 35 to 55 percent lower in other industrialized countries than in the United States.² The central reason for these price differentials is that Canada and most European countries (13 of the 15 countries in Western Europe) directly regulate the prices of prescription drugs. High U.S. prices are said to be necessary to cover the costs of research and development for new and better drugs, given the price levels in Europe and Canada. Americans are increasingly asking why they should subsidize the development of new drugs that are also used by Canadians and Europeans.

The Bush administration has resisted attempts



by U.S. consumers to purchase drugs from other nations. Administration officials cite concerns about health and safety as justification for this reluctance to permit importation. Mark McClellan, the former commissioner of the Food and Drug Administration (FDA), observed that “there is no evidence that unapproved imported drugs are becoming safer or more reliable” and noted that “we are concerned with any measures that increase the flow of these unapproved drugs.”³

Senator Kerry believes that U.S. consumers would benefit from the importation of prescription drugs. He recognizes the safety issues associated with importation and proposes that the FDA work with the states to develop safe importation processes.

Assuming that an acceptable method of regulating the safety of imports can be established, permitting importation from Canada and Europe would drive international drug prices toward a single price per product. This is the case because it would enable countries that currently pay high prices to purchase drugs from countries where prices are lower. Because European and Canadian distributors would have opportunities to sell prescription drugs at higher prices to buyers in other countries such as the United States, a substantial international compression of prices would result. Given the size of the U.S. market, even modest reductions in prices would imply a major savings.

The Congressional Budget Office staff forecast that allowing importation would have only a minimal effect on U.S. prices. They think that prescription-drug manufacturers would be able to control the volume of drugs sold to individual countries where prices are low, so that they received only approximately as much as they needed for their domestic use. This would limit the opportunities for those countries to resell drugs to countries where prices were higher. However, under European regulation of the resale of prescription drugs, fines are imposed on firms that attempt to control the volume of goods sold to individual countries. Similar provisions prohibiting the restriction of supply are part of proposed U.S. legislation allowing the importation of prescription drugs. Measures taken by prescription-drug manufacturers to counter importation could also result in a political backlash. Therefore, allowing drug importation may have a greater effect on U.S. drug prices than the Congressional Budget Office anticipates.

With regard to the second key difference between

the candidates' approaches, the Medicare Modernization Act explicitly prohibits the government from directly negotiating prices for prescription drugs for Medicare. The prospect of the federal government's incurring large new expenses for drug coverage is troubling to many, especially in light of the growing federal budget deficit.

President Bush has consistently advanced policies that keep government out of any direct role in setting prices for prescription drugs. His approach appears to be grounded in three lines of reasoning. The first is a conviction that the “best health care system is that health care system generated in private markets.”⁴ The second is a desire to “make sure there are incentives for the private sector to develop new and inexpensive drugs.”⁵ And the third is the evidence suggesting that private pharmacy-benefit managers can obtain most of the savings that would be available through direct government negotiation (and thus spend about 25 percent less than unmanaged payers currently do). The Congressional Budget Office has also suggested that direct negotiations would have a “negligible effect on federal spending.” But direct government negotiation may realize savings on brand-name drugs that have little competition — cases in which prescription-drug plans would be unable to negotiate lower prices by taking advantage of competition among similar products for positions on drug formularies.

Senator Kerry favors an active role for government in the purchasing of prescription drugs. He notes that Medicaid and the Department of Veterans Affairs (VA) both obtain substantial price discounts for prescription drugs through regulation and direct government negotiation. For Medicaid, the government requires a minimal level of rebates or the “best price” offered in the private sector, whichever is lower. The VA obtains prices through direct government negotiation with the industry. Kerry notes that Medicaid obtains savings of 20 percent and the VA negotiates discounts of 40 percent from the prices charged to cash payers. Kerry appears to be confident that such discounted prices could also be available to the Medicare program.

Paying VA prices for the drugs used by Medicare beneficiaries would benefit the federal budget. Of course, lower prices would also affect the revenues of pharmaceutical companies. For drugs that are unique, prescription-drug plans will have little ability to negotiate prices. Thus, higher prices would most likely be paid for the most innovative products.

Yet it would not be politically acceptable simply to let the industry name its price. Thus, at a minimum, some direct price negotiation by the government is likely to occur regardless of which candidate is elected.

At first blush, Kerry's positions appear to be more "consumer friendly" than Bush's. Kerry supports policies that create stronger downward pressure on prescription-drug prices than Bush's policies do. This more aggressive stance toward controlling today's drug prices must be considered in light of the effect of lower prices on the flow of new drugs that will be available to the next generation of consumers. Bush supports policies that protect the existing drug-price structures in the name of ensuring adequate economic incentives to innovate.

The United States is entering uncharted waters in both of these key areas — the importation of prescription drugs and the role of the government in controlling their cost. A voter's choice between the candidates might well be guided by philosophy and a sense of whether profits in the pharmaceutical industry are high enough so that reductions in drug prices would not substantially impede the development of future drugs.

Importation would have some predictable consequences: U.S. prices would decrease, the world would move toward a single price for a given drug, and Canada and Europe would probably make larger contributions toward the cost of research and development. The magnitude of the financial gain in the United States, however, is uncertain; my guess is that there would be modest price reductions for consumers in the United States and substantial price increases for Europeans and Canadians.

From the Department of Health Care Policy, Harvard Medical School, Boston.

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The Tobacco Buyout and the FDA

Steven A. Schroeder, M.D.

An unlikely alliance between tobacco growers and tobacco-control advocates will be tested this fall, as a congressional conference committee attempts to reconcile separate versions of tobacco legislation that the House and the Senate have attached to the Foreign Sales Corporation Act. On June 17, 2004, the House voted to abolish a long-standing quota system (whereby a defined number of farmers are permitted to grow tobacco in quantities set by the government each year) and to pay \$9.6 billion from the federal treasury to tobacco farmers to ease the transition. In addition, the House bill would eliminate all existing restrictions on tobacco growing, thereby moving tobacco farming to a free-market system. On July 15, the Senate passed a related bill, but it differs from the House version in a number of significant ways (see Table). The Senate version designates more money — \$13 billion — for relief for

tobacco farmers, with the money to come from tobacco manufacturers, through government assessments. It places some restrictions on future tobacco farming and, in an important step, authorizes the Food and Drug Administration (FDA) to regulate the tobacco industry — the contents of tobacco products, as well as companies' marketing strategies and release of information — in the future.

Tobacco farming in the United States is governed through a complicated system of quotas that were established during the Depression. The federal government imposes rules concerning who may grow tobacco and how much they may grow, setting yearly quotas on the basis of tobacco-product manufacturers' estimates of expected purchases. Government also sets a minimal price for the growers that is well above the price of tobacco grown elsewhere in the world. Many tobacco farmers,