The Rising Cost of Prescription Drugs

Similar to overall health spending, spending on prescription drugs continued to rise in 2004 and 2005. Prescription drug spending rose 8.6 percent in 2004 as compared to 2003, and 5.8 percent in 2005 as compared to 2004. The federal government attributed the slower rate of growth experienced in 2005 to lower Medicaid spending for prescription drugs, and the growing use of tiered formularies (described on p. 200 of the book). In addition, there were fewer new drugs introduced to the market in 2005 as compared to other years. As new drugs tend to cost substantially more than older alternatives, this slowdown in the introduction of new drugs exerted a damping effect on the rate of spending for prescription drugs.

These issues are discussed in the federal report describing the highlights of changes in national health spending for 2005, available at


The Controversy Surrounding the Rising Cost of Prescription Drugs and the Role of For-Profit Pharmaceutical Manufacturers

A recent study compared the “availability, use, and prices of biopharmaceuticals in five major European Union (EU) countries, Canada, Australia, Japan, and Mexico, relative to the United States.” The authors found that “per capita spending on biopharmaceuticals was at least twice as high in the United States as in the other countries. This difference reflects primarily greater availability and use of new, relatively high-price molecules and formulations. Prices for identical formulations are not higher on average in the United States.”

This study provides additional evidence that the increased use of newer pharmaceutical products, which typically are substantially more expensive than older alternatives, is a major contributor to the rising cost of pharmaceutical products in the United States and the increasing share of health care expenditures these products account for.

Henry et al. described how Australia deals with the issue of balancing costs and benefits in setting pharmaceutical policy, suggesting that the Australian experience has shown that “decisions about funding new drugs can be based on formal measures of cost-effectiveness.”


Two very informative commentaries were recently published, addressing the issues underlying pharmaceutical policy as it pertains to issues of cost effectiveness:


In addition, the Congressional Budget Office published an extensive study called *Prescription Drug Pricing in the Private Sector* ([www.cbo.gov/ftpdocs/77xx/doc7715/01-03-PrescriptionDrug.pdf](http://www.cbo.gov/ftpdocs/77xx/doc7715/01-03-PrescriptionDrug.pdf)).
The Marketing of New Drugs to Physicians

Two states—Vermont and Minnesota—recently required that doctors publicly disclose any payments they receive from pharmaceutical companies. The results of analyzing these new data have been reported in both news reports and medical journals: “[Between 1997 and 2005 in Minnesota] drug makers paid more than 5,500 doctors, nurses, and other health care workers in the state at least $57 million. Another $40 million went to clinics, research centers, and other organizations. More than 20 percent of the state’s licensed physicians received money. The median payment per consultant was $1,000; more than 100 people received more than $100,000.”


“The Vermont and Minnesota laws requiring disclosure of payments do not provide easy access to payment information for the public and are of limited quality once accessed. However, substantial numbers of payments of $100 or more were made to physicians by pharmaceutical companies.”


In an editorial accompanying the article by Ross et al., Brennan and Mello caution: “To be clear, for-profit industries do not share the same ethical norms to which physicians and other health care professionals must adhere. Their primary commitment is to create shareholder value, not maintain an altruistic commitment to patients. But at some point the leadership of the
pharmaceutical industry and their boards of directors must begin to recognize that growing public and professional mistrust could substantially detract from that value.”


**Direct-to-Consumers Marketing of Pharmaceuticals**

Two important research reports examined the effect of direct-to-consumers (DTC) marketing of pharmaceuticals. Bradford et al. examined the issue of whether DTC ads affected the rate at which physicians prescribed the drugs Vioxx and Celebrex, both COX-2 inhibitor drugs that were widely used for patients with arthritis until serious safety concerns were raised. The authors concluded that “DTC advertising of COX-2 inhibitors appears to have increased the number of prescriptions written for these products.”


In the second study, Kravitz et al. reported their study in which they trained professional actors to provide a history of two specific mental health conditions. They then had these actors visit one of 152 primary care physicians, requesting treatment. On a random basis, the actor/patient either requested a specific brand-name drug, made a general request for a drug without suggesting a specific brand, or made no request for a drug. The authors concluded that “patients’ requests have a profound effect on physician prescribing in major depression and adjustment disorder. Direct-to-consumer advertising may have competing effects on quality,
potentially both averting underuse and promoting overuse” (p. 1995).


In an editorial accompanying the Kravitz article, Matthew Hollon, of the University of Washington School of Medicine, stated: “Direct-to-consumer advertising, by simultaneously advancing consumerism over shared decision making and providing pseudoeducational material to patients, can undermine choices patients and physicians make together and negatively impact the public’s health” (p. 2032).


In response to studies such as these, in November 2006 the Government Accountability Office issued a report, the title of which states its principal conclusion: “Improvements Needed in FDA’s Oversight of Direct-to-Consumer Advertising” (www.gao.gov/highlights/d0754high.pdf).

**Managed Care Plans’ Efforts to Control Pharmaceutical Costs**

The journal *Health Affairs* published a series of informative articles on the steps private insurers and managed care organizations are taking to try and manage the rising costs of pharmaceutical products.


**Making Prescription Drugs More Affordable for Medicare Beneficiaries: The Medicare Modernization Act**

Medicare’s Prescription Drug Plan is described on pp. 202–7 of the book. First approved by Congress in 2003 as part of the Medicare Prescription Drug, Improvement, and Modernization Act, the new Medicare prescription drug benefit was first available to seniors on January 1, 2006. The plan is based on seniors selecting coverage for prescription drugs from any of the approved plans available in their geographic area. As the federal government is prohibited by the original legislation from offering its own plan, all available plans are private, market-based plans.

In the months leading up to January 1, 2006, seniors experienced extensive marketing of the available plans. Some news outlets reported that seniors felt bombarded by plan choices, which resulted in confusion over which one to choose. The Kaiser Family Foundation has cataloged all the plans available in different parts of the country at [www.kff.org/medicare/healthplantracker/](http://www.kff.org/medicare/healthplantracker/). As of April 2007, their data showed states offering long lists of available plans, ranging from a low of 45 in Alaska to a high of 66 in Pennsylvania and West Virginia. Trying to sort through these options has proven difficult for many seniors.
The federal Centers for Medicare and Medicaid Services has established a link on its web site (www.medicare.gov/) to assist seniors in their choice.

During the first few months of 2006, as the program began operation, there were frequent news reports of widespread confusion on the part of seniors trying to access prescription drugs through the new plan they had selected. The confusion and difficulty obtaining needed medications were especially acute for low-income seniors, who had been abruptly switched from getting their drugs under their state’s Medicaid program to getting them from a new private plan to which they had been assigned. At one point, a number of states had to intervene on an urgent basis to assure that these low-income seniors were able to get their medications.


Within several months, most of these problems were worked out, and most seniors who signed up for a plan had little difficulty accessing their medications. The federal government reported that, by June 2006, a total of 32.8 million Medicare beneficiaries (out of a total of 43 million on Medicare, or 77%) had some form of prescription drug coverage. The average monthly premium for a basic plan was found to be $24 (http://hhs.gov/news/press/2006pres/20060614.html).

Of those covered:

- 10.4 million had coverage through one of the new, stand-alone private plans;
- 6.0 million had coverage as part of their participation in a “Medicare Advantage”
managed care plan;

- 6.1 million beneficiaries eligible for both Medicare and Medicaid had been switched from their state-based, Medicaid prescription drug coverage to a Medicare plan;
- 6.9 million received prescription drug coverage through their preexisting retirement benefits, with Medicare now subsidizing that coverage; and
- 3.5 million were receiving coverage as part of government retirement plans.

Researchers at the Kaiser Family Foundation reported that, despite the plethora of plans available in most states, on a national basis ten organizations accounted for 72 percent of beneficiaries enrolled in a private plan. Of these, two organizations—United Health Care / PacifiCare and Humana—accounted for 44 percent of all enrolled beneficiaries. The authors of the report stated (p. w4): “The concentration of Part D enrollment in a few organizations is consistent with historical patterns in the MA [Medicare Advantage] market before Part D. In 2005 almost half of all MA enrollment was concentrated in seven firms: Kaiser, PacifiCare, Humana, UnitedHealthcare, HealthNet, Aetna, and CIGNA, with another 17 percent enrolled in Blue Cross / Blue Shield affiliates.”


As expected when the Medicare prescription drug plan was adopted, a number of seniors faced unexpected difficulty when they reached the “doughnut hole”—the situation of having exhausted the first phase of coverage and being responsible for 100 percent of the cost of prescription drugs, until they reached the catastrophic coverage limits. (See p. 205 of the book for further discussion of coverage levels and the “doughnut hole.”) Berkowitz et al. published a
valuable description of issues surrounding the “doughnut hole”:


**Drug Reimportation from Canada**

As discussed on pp. 207–8 of the book, the Bush administration had adopted a policy of blocking the importation of prescription drugs from Canada. A growing number of people had sought to have their prescriptions, written by doctors in the United States, filled by pharmacies in Canada—either by mail order or by going to Canada themselves to fill the prescriptions. After much controversy, in October 2006 the Bush administration reversed its policy, and now permits small quantities of prescription drugs (defined as a 90-day supply or less) to be shipped or brought from Canada to the United States.

**Drug Safety and the FDA**

In March 2006, the Government Accountability Office issued a report addressing issues of drug safety and administrative oversight in the Food and Drug Administration (FDA). The report found that “FDA lacks clear and effective processes for making decisions about, and providing management oversight of, postmarket safety issues” and provided a series of recommendations to Congress on steps to address this problem ([www.gao.gov/highlights/d06402high.pdf](http://www.gao.gov/highlights/d06402high.pdf)).

In another change intended to increase quality and accountability, in March 2007 the FDA initiated new policies that would prohibit from acting as an expert advisor to the FDA any physician or scientist who receives more than $50,000 from a drug company that makes the
product under consideration, or from a company that offers a competing product to the drug that is under consideration.