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The Rising Utilization and Costs of Prescription Drugs

According to Forbes Magazine, U.S. expenditures on pharmaceuticals have increased from $82 billion in 1992 to $192 billion in 2002. This is a trend that shows no signs of abating; a 2003 *Health Affairs* study estimates that prescription drug insurance costs for purchasers will increase by an average 11.1 percent annually from 2002 through 2012. Throughout the 1990's, more prescriptions were written, prices for individual drugs increased, and prescribing patterns favored newer, more expensive drugs.

Pharmacists filled 3.1 billion prescriptions in 2003 – 60 percent more than 10 years ago, according to the Food and Drug Administration (FDA), which regulates prescription drugs. Additionally, each year roughly 15 percent of the 200 largest selling pharmaceuticals are new drugs, often more expensive than the alternatives they replace.

Drug companies say that the development of new drugs is essential because it can help save lives, cure diseases, reduce hospital utilization, and diminish severity of some illnesses, while improving the quality of life and the outcomes for many patients.

Drug manufacturers have further stated that higher prices for new drugs are essential to continue funding research and development (R&D) into next-generation drugs. They add that because many foreign governments set prices/limit profits, only the U.S. market can provide the capital necessary for research. And they say that drug prices in other countries are often artificially lower than U.S. prices because of lower standards of living.

Marketing and Advertising Practices - Critics of the industry say that pharmaceutical firms' revenues are often not fully reinvested in R&D, but are shifted to marketing current drugs. According to Families USA, a consumer advocacy group, eight of the nine largest firms spend twice as much on advertising as they do on R&D. Two marketing practices, in particular, have sparked considerable debate.

Direct-to-Consumer (DTC) advertising - Since 1997, when the FDA loosened restrictions on DTC marketing, $3 billion a year has been spent on advertisements encouraging consumers to ask their doctors for specific medications. Pharmaceutical companies say DTC advertising promotes price competition and helps reduce consumer prices by informing providers and consumers about new treatments. They add that DTC rarely competes with R&D for resources. In fact, they state that marketing increases sales and return on investments, which increases the opportunity for more R&D.

Conversely, critics view DTC marketing as increasing the number of "unnecessary" or elective prescriptions. Furthermore, since the late 1990's, the number of FDA actions ordering misleading ads to be pulled has dropped 75 percent, potentially causing consumers to misconstrue a drug's benefits (Public Citizen).

Critics Marcia Angell and Arnold Relman, former editors in chief of the New England Journal of Medicine, note that variants of drugs already on the market are relatively easy to develop but require massive promotion campaigns to attract consumers to a particular brand and persuade physicians to prescribe one instead of another.

Direct marketing to physicians - In 2001, drug manufacturers spent more than $16 billion on direct marketing to physicians, a 74 percent increase from 1997 (GAO.) This type of marketing is useful when serving to inform doctors about new treatment options and helping innovative drugs gain acceptance and use. However, critics say these marketing efforts include not only free drug samples and advertising materials, but also trips and financial payments rewarding prescribing behaviors.

Impact of Pharmacy Benefit Managers (PBMs) - PBMs are companies contracted to manage prescription drug benefits. Typically, they can benefit purchasers through lower costs resulting from bulk purchasing. PBMs also negotiate manufacturer rebates. In 2000, the U.S. Department of Health and Human Services (HHS) estimated that PBMs received direct rebates from manufacturers ranging from 2 to 35 percent of retail prices on brand name drugs.

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HHS said most PBMs passed on about 70 to 90 percent of these direct rebates to insurers/self-insured employers.

However, since negotiations between PBMs and pharmaceutical companies are typically confidential, media reports say PBM's may sometimes "steer" doctors and health plans towards particular product lines, including higher-priced medications (NY Times, 12/11/03) or repackage pills into smaller, costlier doses (Pittsburgh Post-Gazette, 2/19/04). Benefits consultants say purchasers are not always informed in advance of these actions. Some drug companies also are purchasing PBMs to increase the company's market share.

Patent System and Generic Drug Distribution - According to the pharmaceutical industry, profits received during the life of patents are used to cover the sunk costs of R&D, replenishing company capital for future rounds of drug discoveries. Reducing patent rights to produce short-run consumer savings would therefore reduce incentives to invest in R&D for new drugs, since sunk costs incurred during R&D may not be recouped over a shorter patent period. Critics argue that lengthy patent protection effectively bars less expensive generic substitutes, leading to higher overall drug prices. Pending lawsuits also allege collusion between brand name manufacturers and generic producers to delay the introduction of generic alternatives.

Changes Proposed to Improve the System - There are several proposals being considered to contain prescription drug costs:

Changes in FDA practices - Both industry and its critics agree the FDA approval process needs improvement. Some suggestions include: 1) implementing efficacy trials for new drugs against current treatments, rather than only against placebos to determine whether a new drug is a true improvement; 2) reducing the time the FDA takes to approve new drugs for market; 3) accelerating the speed at which drugs are moved to "over-the-counter" status; and 4) funding the FDA new drug evaluations with sources other than drug company users' fees, freeing the agency from financial dependence on the industry it regulates.

Drug Studies - The American Medical Association recently called on the government to establish a *public* registry for *all* drug study results, including research funded by pharmaceutical companies that reflects poorly on their products. Supporters argue this might improve quality outcomes; detractors say it could lead to misinterpretation, particularly if it lacks specifics.

Co-pays - Researchers are just beginning to examine the impacts of basing prescription co-pays on a drug's potential to help patients. An "impact-based" co-pay might improve patient health enough to offer long-term cost reduction.

Re-importation - since other countries negotiate sharp discounts from manufacturers, re-importing American-manufactured drugs from other countries could dramatically lower retail prices of many drugs. The greatest concern with this solution is compromising consumer safety. Furthermore, countries allowing drug exports might quickly face constraints on drug availability since the pharmaceutical industry could restrict their supply.

Patent Limits – Proponents of reducing the patent period argue that a shorter patent life would allow for quicker arrival of generic alternatives in the marketplace, providing a cost savings to the public.

What Purchasers Can Do - Over the past decade, purchasers have used various methods to restrain costs. In combination, these methods have had some success in reducing the aggregate rate of increase, but the trend towards higher prices continues. However, purchasers may be able to reduce prescription drug benefit costs by using one or more of these suggestions:

(1) Introducing and annually updating formularies to include the most clinically effective and cost-efficient drug options;
(2) Inducing employees to choose generic alternatives through lower co-payments;
(3) Forming business coalitions to utilize group purchasing to lower plan costs;
(4) Using PBMs, or negotiating directly with the drug company, to secure manufacturer discounts on commonly used drugs;
(5) Increasing employees' cost-sharing responsibilities through higher co-pays and limits on reimbursements;
(6) Carving out prescription insurance from health insurance and requiring employees to enroll in each part separately (allowing greater competition for each component of the employee insurance benefit);
(7) Making employees aware of the full value of their prescription drug coverage by publicizing not just the co-pay, but also the price of the drug and the share picked up by the employer; and,
(8) Offering mail-order or larger-quantity prescriptions (e.g., 90-day supplies vs. 30-day) to reduce both the overall costs and the employee co-pay expenses.

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