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PRESCRIPTION DRUGS: SALES, PROFITS, AND RESEARCH

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The 2004 presidential campaign centers on several foreign and domestic issues, including the cost and availability of prescription drugs. At times, however, it is difficult for concerned citizens and voters to sort out the rhetoric from the facts. The following report focuses on the facts regarding pharmaceutical sales, profits, and research.

Sales and Profits

Worldwide pharmaceutical sales amounted to \$430 billion in 2002. This estimate includes 90 percent of all prescription drugs and certain OTC (over-the-counter) products in more than 70 countries. North American sales made up 51 percent of the worldwide total, and with Japan and the European Union accounted for 85 percent of all sales worldwide. In the United States, about one half of all sales in 2002 were for patented prescription drugs, with the other half split nearly evenly between generics and OTC drugs. With sales of \$8.6 billion in 2002, Lipitor which is used to treat high cholesterol is the number one selling drug in the world. In the U.S. pharmaceutical market approximately 45 drugs in 2001 generated annual sales of over \$1 billion each [Business Communications, pp. 1-2; IMS, pp. 1-3].

The cost and price of drugs are issues because together they determine the amount of the manufacturer's gain which is necessary (lower limit) and the amount justified (upper limit). The most recently reported profit margin for all 16 major pharmaceutical companies in the world, including the four with largest market capitalizations (GlaxoSmithKline, Johnson & Johnson, Merck, and Pfizer) was 15.5 percent. Profit margins ranged from a low of 3.3 percent (Bayer) to a high of 34.4 percent (Wyeth). For all 16 companies, growth in earnings per share for the last five years averaged 15.1 percent. Even so, for the 12-month period ending in October 2003, these major pharmaceutical manufacturers were underperforming the S&P 500 firms in terms of share price by 15 percent [Charles Schwab].

The market by itself cannot resolve the issue of drugs which are priced high enough to retrieve the cost of research and development but are unaffordable for those persons who need those drugs. The problem becomes more ethically complicated when the drugs in question are life-saving. Differential pricing to take account of need and affordability introduces the problems of arbitrage: the reselling of drugs earmarked for poor countries

where they have been priced to make them more affordable in rich countries where the higher prices for the same drugs provide opportunities for profiteering. To sustain such price differentials it is necessary for rich countries to forego importing the lower-price drugs from poor countries or for payers and drug companies to adopt such practices as negotiated contracts with confidential rebates [Danzon and Towse, p. 201].

Research

An estimated \$32 billion was spent in 2002 on research and development by pharmaceutical companies worldwide. Of that total, \$26.4 billion was spent in the United States. For PhRMA (Pharmaceutical Research and Manufacturers of America) members, research and development expenditures represent 18.2 percent of domestic sales. In nominal dollars, spending today on research and development worldwide is more than 25 times greater than the \$1.3 billion spent in 1977 [PhRMA 2003a, p. 10].

The U.S. National Institutes of Health in fiscal year 2001 allocated approximately \$16.2 billion to support basic (extramural) research at universities, medical centers, hospitals, and research institutions, and about \$2.0 billion for the NIH's own (intramural) research labs. This funding is intended to support the NIH's mission to

sponsor and conduct medical research and research training that expands fundamental knowledge about the nature and behavior of living systems; improves and develops new strategies for the diagnosis, treatment, and prevention of disease; reduces the burdens of disease and disability; and assures a continuing cadre of outstanding scientists for future advances [NIH, p. 3].

In fiscal year 2004 NIH has been budgeted \$22.2 billion for extramural research and \$2.7 billion for intramural research. Support for research needed in the war on terrorism was the first priority for program increases [U.S. Health and Human Services, p. 31].

In 2002, PhRMA reported that in the United States 402 medicines were under development to treat cancer, 123 remedies were being developed for heart disease and stroke, 83 drugs and vaccines were in the development stage to address HIV/AIDS, and 176 medicines were under development for neurological diseases. Reflecting the greater complexity of target diseases, it takes 10-15 years to bring a new drug from concept to market [PhRMA 2003a, pp. x, 16-17].

Just 5 in every 10,000 molecules discovered become a new drug, and only 3 of 10 new brand name drugs earn enough to recover their research and development costs [Business Communications, p. 1]. Tufts Center for the Study of Drug Development estimated in 2003 that the fully capitalized cost for developing a new prescription drug averages \$897 million [Tufts, p. 1]. This very high cost reflects the low probability -- 1 out of 250 -- that a given compound which survives pre-clinical testing is approved by the Food and Drug Administration for sale to the public [NIH, p. 8].

Does the cost of research and development justify the price of new prescription drugs? PhRMA says that it does, and denies that government funds play a major role in research and development.

In a 2001 Report to Congress, NIH specifically refuted the misconception that the government pays for most of the research on top-selling prescription drugs [PhRMA 2003a, p. 11].

Families USA argued that drug prices can be reduced without suppressing research and development because: (1) the financial future of any pharmaceutical firm depends on its development of new, successful products and therefore it cannot cut back on research and development; and (2) retail prices reflect large outlays on advertising, marketing, and administration which can and should be cut back [Families USA, p. 10]. Another critic claimed that the income tax credits awarded to U.S. drug companies are used to increase dividends and not to reduce prices [New York, p. 1].

A World Bank discussion paper states that the low return on research and development expenditures is a barrier to the development of medicines needed to fight diseases in developing countries. Between 1975 and 1997 only 13 new products were approved specifically for tropical diseases [Govindaraj, p. 13]. Local production is a solution only if the cost of building local production capacity is not excessive, product quality is assured, and pricing is competitive with products from existing foreign generic manufacturers [Kaplan, p. 2].

NIH calls attention to the special problems in sorting out the linkage between government expenditures on basic research and new drug development.

Analysis of the 47 therapeutic drugs that have reached annual sales in the U.S. of \$500 million, and determination of which of these had intellectual property that ties back to federal funding, was particularly difficult ... due to the fact that [federal] regulations do not require that investigators provide such information to the funding agency, and ... tracking down the “pedigree” of these drugs has to be done manually on a case-by-case basis.

...it is not possible to cross-reference NIH grants and contracts that funded inventions with any patents or licenses embodied in the final product. Nor is it possible to identify other federal and/or non-federal sources of funds that contributed to an inventive technology [NIH, p. 9].

Implications

Nobel laureate (in economics) Gary Becker recently scolded the FDA for driving up drug prices by holding unreasonably to a standard of efficacy. Becker recommends using only the safety standard which the FDA applied prior to 1962 [Becker, p. 16]. He would have physicians prescribe drugs for which there is no proof that they do any good, only the

assurance that they do no harm. Becker's recommendation in effect renders patients into subjects fit for prescription medication by trial-and-error and physicians into targets for malpractice lawsuits. His suggestion could delay the utilization of the most effective therapy and in the extreme could contribute to morbidity and mortality.

Financial gain is essential if private companies are to engage in pharmaceutical research and development. If reasonable gain leads to drug prices which are unaffordable, those who can afford the drugs must help make them more affordable through price-discrimination schemes or governments must subsidize either the manufacturer or user. If it becomes necessary for governments to assume the research and development role, it would be better to support several research labs rather than one on grounds that the scientific method depends on verifiability from independent sources.

References

Becker, Gary. "Get the FDA Out of the Way, and Drug Prices Will Drop," *Business Week*, September 16, 2002.

Business Communications Company. "The \$400 Billion Worldwide Drug Industry Continues to Evolve," <<http://www.bccresearch.com/editors/RC-181N.html>> (October 2003).

Danzon, Patricia and Adrian Towse. "Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents," *International Journal of Health Care Finance and Economics*, Volume 3, 2003, pp. 183-205.

Families USA. "Off the Charts: Pay, Profits and Spending by Drug Companies," July 2001, <<http://www.familiesusa.org/site/DocServer/drugceos.pdf?docID=767>> (October 2003).

Govindarag, Ramesh, Michael Reich, and Jillian Cohen. "World Bank Pharmaceuticals," HNP discussion paper, September 2000.

IMS. "2002 World Pharma Sales Growth: Slower, but Still Healthy," <http://www.imsglobal.com/insight/news_story/0302/news_story_030228.htm> (October 2003).

Kaplan, Warren. "Local Production of Pharmaceuticals and Vaccines," <http://www1.worldbank.org/hnp/hsd/pharma_GD_discussionpapers.asp> (October 2003).

National Institutes of Health. "A Plan to Ensure Taxpayers' Interests are Protected," July 2001, <<http://www.nih.gov/news/070101wyden.htm>> (October 2003).

New York State Wide Senior Action Council. “Don’t Be Fooled by the Pharmaceutical Industry’s Propaganda about Research and Development,” c1998, <<http://www.nysenior.org/Issues/Prescriptions/research.html>> (October 2003).

PhRMA 2003a. “Pharmaceutical Industry Profile 2003,” Washington, D.C.: 2003.

Schwab & Company, Charles. “Major Drugs Fundamentals,” and “Sector and Industry Profile,” reports generated from company website, October 27, 2003.

Tufts Center for the Study of Drug Development. “Tufts Raises Estimate of Cost of Drug Development,” May 2003, <<http://lists.essential.org/pipermail/iphealth/2003May/004723.htm>> (October 2003).

U.S. Department of Health and Human Services. “FY2004 Budget in Brief,” <<http://hhs.gov/budget/04budget/fy2004bib.pdf>> (October 2003).

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