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A Macromarketing Analysis of Prescription Drugs in the U.S.

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ABSTRACT
The U.S. prescription drug macromarketing system is examined. Over time, this system has become unbalanced. The system has evolved into one in which market competition has been restricted. This market system now has substantial entry barriers, producer collusion, and extensive linkages between producers and government resulting in government protection of producers. Suggested reforms are offered which aim to bring into greater harmony the interests of both producers and society, while acknowledging the importance of prescription drugs to society and maintaining producer incentives to invest in research and development of innovative new drugs.

ARTICLE

Dynamics of the Prescription Drug Macromarketing System

Drug Companies

Prescription drug sales in the U.S. were about $274.9 billion in 2006, an increase of about nine percent over 2005 (Longwell 2007). Sales in the U.S. rose to $286.5 billion in 2007 (Goldstein 2008). Prescription drug price increases average about 12 percent a year (down from a high of 18 percent in 1999) (Angell 2004). Drug companies spend about 30 percent of sales on marketing prescription drugs (Rotz, Worzel, and McKinnon 2005), and about 14 percent of sales on research and development (Mahan 2005; Mayer 2005).

Drugs are sold to consumers through retail pharmacies (online and brick and mortar), hospitals (nonprofit, corporate, and government), and benefit management companies. U.S. citizens pay for prescription drugs directly through paying the full cost themselves at the retail level, or indirectly through shared insurance premiums, insurance copayments, taxes (from which government spends money for prescription drugs through various programs), and higher consumer prices (from which employers pay for insurance premiums for employees).

In addition to obtaining revenues from sales, drug companies also obtain government subsidies through government funding of research and development. A variety of government agencies, primarily agencies of the U.S. Department of Health and Human

Services (for example, National Institute of Health, National Cancer Institute), provide research grants to scientists working in universities and nonprofit agencies. Pharmaceutical companies eventually profit from producing and marketing drugs resulting from these government grants (Abramson 2004, Angell 2004).

In the U.S., drug prices are not regulated by government. Some customer groups have sufficient market power to negotiate reduced prices. These include large insurance companies and benefit management companies. The government is a large purchaser of prescription drugs through its various programs. However, while the Veterans Administration negotiates lower prices, the Social Security Administration is prevented by law from negotiating with drug companies for reduced prices (a provision contained in the new Medicare prescription coverage). Large hospitals also negotiate with drug companies for lower prices on some drugs.

Prescription drug pricing policies have been criticized for being unfair to the poor (Anand 2007; Reuters 2007). To refute these criticisms, drug companies established hardship programs for poor people. For the poor to qualify for these programs a consumer must meet eligibility criteria. They must not have public or private prescription drug coverage. They must make too much money to qualify for public assistance (for example, Medicaid). Consumers must have household incomes at such a level that paying for medicine at retail prices would pose a hardship (determined by the drug company) (see freemedicinefoundation.com). In 2004, Pfizer, the largest (in terms of sales) drug company, distributed $345 million worth of prescription drugs in assistant programs (freemedicinefoundation.com) from sales of $52,516 million (Mayer 2005), representing 0.66 percent of sales. The cost of assistance programs to drug companies is offset by government tax credits (freemedicinefoundation.com).

Drug Industry Marketing

Pharmaceutical marketing activities are ubiquitous in the United States. Three primary targets for pharmaceutical marketing tactics are: (1) consumers, (2) physicians, and (3) government (Rotz et al. 2005). Drug companies market directly to U.S. consumers using various direct-to-consumer advertising (DTCA) tactics using a push strategy. They market indirectly to consumers using a pull strategy by marketing directly to prescribing physicians (Spiller and Wymer 2001; 2002).

Companies began to advertise directly to consumers in 1985 when the U.S. Food and Drug Administration (FDA) lifted the ban on DTCA (Alperstein and Peyrot 1993). In more recent times, over 80 percent of consumers report seeing prescription drug ads (Dickinson 2002). Drug industry spending on DCTA increased from $55 million in 1991 (Macias and Lewis 2003) to $266 million in 1994 to $2.6 billion in 2002 (Donohue and Berndt 2004). DCTA spending climbed to $3 billion in 2004 (Barlett et al. 2004), then again to $4.2 billion in 2005 (Kaiser Family Foundation 2006), and was predicted to reach a record $5 billion in 2006 (Thomaselli 2006).

Drug companies' pull strategy targets physicians who write prescriptions (Angell 2004, Greider 2003). There is approximately one drug salesperson (detailer) for every 4.5 office-based doctors (Rotz et al. 2005). In 2003, drug companies spent $4.7 billion detailing to the 490,000 office-based doctors in the U.S. (Abramson 2004). The pharmaceutical industry invests substantial sums of money targeting physicians, developing the marketing relationship when future physicians are medical students.

Marketing activities include free meals, gifts, samples, consulting agreements, sponsorship of continuing medical education, payments for including patients in drug trials, advertisements in medical journals and so on (Abramson 2004; Angell 2004; Ross, Lurie, and Wolfe 2000). Drug companies purchase physician prescribing data from retail chain drug stores to determine the effectiveness of their various marketing activities such as DCTA campaigns, sales representatives' visits, and physician attendance at industry supported medical conferences (Kalantri 2004).

The goal of the drug industry's government relations activities are aimed at keeping its marketing activities free of regulation. The drug industry spent $262 million on political influence in the 1999-2000 election cycles: $177 million on lobbying, $65 million on issue ads and $20 million on campaign contributions. The pharmaceutical industry has more lobbyists than any other industry–625 (more than one for each member of Congress). More than half the lobbyists are former members of Congress or individuals who worked in Congress or related government positions (Public Citizen 2005).

Prescription Drug Macromarketing System Reforms

Vaile, Grether, and Cox (1952) point out that marketing systems perform two key tasks for their societies. They deliver a standard of living for citizens and they create a marketplace dynamism to encourage continual innovation (Wilkie and Moore 2006). The reforms suggested below are aimed at rebalancing the prescription drug macromarketing system in order to better accomplish these two key tasks.

Reward Innovation

The existing patent system should be restructured to its original purpose. Only real innovations should be given the 20 year patent monopoly, and this should not be allowed to be extended. Real innovations refer to newly discovered molecular entities that treat a health condition more effectively than currently available treatments. This means that the clinical trials should be designed to determine if the new drug is more effective than the most widely used treatments available rather than simply determining if the new drug is better than nothing (a placebo). Imitations of existing drugs should not receive patent protections. Imitative drugs should be subject to a competitive market.

In about half of the new drug discoveries, the discovery and development of the drug (usually the result of a program of basic research) is accomplished by taxpayer-funded scientists (Angell 2004; Young and Surrusco 2001). Typically these discoveries are given to a drug company that takes the drug through clinical trials free or for a modest royalty (Goozner 2005). In these instances in which taxpayer-funded research assumed a great deal of risk and investment in the basic research, then handed the discovery off to a drug company to take the drug through clinical trails and FDA applications, the reward for the innovation should be shared between society and industry. In these cases, the patent should be 10 years instead of 20 years. Again, no patent extensions should be allowed.

Improve Safety

Null, Dean, Feldman, Rasio, and Smith (2004) conducted a meta-analysis of prior research on U.S. death rates attributable to the health care system. They found that in 2003, 106,000 deaths resulted from adverse drug reactions. They found that over a 10 year period, 1.06 million U.S. deaths resulted from adverse drug reactions. To improve drug safety, the following changes are suggested:

(1) Conflicts of interest must be removed from this system. Individuals with conflicts of interests should not serve on panels or committees which make recommendations regarding the approval or labeling of a drug (McCook 2006). Safeguards should be put into place to avoid conflicts of interest of government employees (Union of Concerned Scientists 2006). Government employees should have employment contracts which restrict working for the regulated industry or industry affiliate for a specified period of time after employees discontinue government service.

(2) Drug companies should not be paying the FDA fees to accelerate drug reviews (Grassley 2006). This practice creates a conflict of interest for the agency, it de-emphasizes safety, and it reduces competition by placing a financial barrier of entry for small companies (Fraser 2006). It creates an organizational culture in which FDA scientists feel pressure to approve drugs quickly and feel pressure to produce favorable outcomes for a new drug (Union of Concerned Scientists 2006).

(3) The current system of post-marketing surveillance for prescription drugs grossly under-reports adverse drug reactions. Physicians often do not take the time to report adverse drug reactions to drug companies, which have a conflict of interest in reporting adverse reactions to the FDA. The FDA admits its post-marketing safety system is inadequate (Crosse 2007). A mandatory system requiring health care providers to report adverse drug reactions directly to the FDA is crucial in monitoring drug safety (Grassley 2006).

(4) There must be greater transparency in drug company clinical trials. Experiments on animals and humans testing drug efficacy and safety should be approved by the FDA or some other agency. Trials should not be discontinued prematurely unless the drug appears to be unsafe. All data from all trials should be disclosed to the FDA.

(5) Since the long term safety of new drugs is unknown, newly approved drugs deserve special attention. The safety standards for a new drug for which safe and effective treatments are already available or when the drug is for a non-life threatening condition should be raised (Deyo 2004; Lasser et al. 2002). Black box warnings should be placed on packaging and labels for these drugs, indicating that they are new drugs for which long term safety has not yet been determined. Also, direct-to-consumer advertising should not be allowed for newly approved drugs for an introductory probationary period until long term safety issues are more clearly understood.

Drug Prices

Former U.S. Comptroller General, David Walker, spoke across the U.S. in an effort to alert citizens that an economic crisis is in store for the country (Walker 2007). According to Walker, the cost of U.S. healthcare and future entitlement obligations, such as Medicare with its prescription drug coverage, will bankrupt the nation. Federal forecasters predict that U.S. health-care spending will double by 2016 to $4.1 trillion per year. Prescription drug prices represent just one part of healthcare system costs, but also represent the fastest growing component, increasing at annual double digit rates while hospital and physician expenses increase at single digit rates (Kaiser Family

Foundation 2006). U.S. prescription drug spending is expected to reach $497.5 billion by 2016 (*HealthDay* 2007).

Surveys of U.S. adults find that the percentage of Americans who believe drug prices are unreasonably high is increasing (HarrisInteractive 2004). U.S. policy makers are facing unpleasant choices and drug prices will become a more pressing problem over time (Anand 2007). Some balance must be reached between controlling spiraling drug prices and providing incentives to industry. Some reforms discussed in other sections will increase competition. For example, Medicare should be allowed to negotiate for lower drug prices. Current law prevents this. However, other federal agencies negotiate for lower drug prices and Medicare should not be prevented from using its quantity buying power to negotiate for lower prices. As mentioned previously, the U.S. Congress is attempting to pass legislation to require Medicare to negotiate for lower drug prices. While this would benefit taxpayers in general and Medicare in particular, the inequities in drug prices for individuals produces a social justice macromarketing issue identified by Layton and Crossbart (2006). One way to address this is for the U.S. to adopt the practices of Canada, England, France, Germany, or Japan which have different approaches that result in reduced pricing inequities for individuals (U.S. House of Representatives 2001).

Conclusion

This article argues that within the prescription drug macromarketing system, drug companies are restricting market competition by influencing the competitive rules, engaging in collusion, restricting the entry of competitors, and obtaining government protection. The effect of this imbalance has been to increase profits by increasing prices with reduced competition and enhanced government protection. It appears, then, that the prescription drug macromarketing system is not harmonizing private and societal interests, but has been overly influenced by producers. In this article, suggested reforms were offered to help rebalance the prescription drug macromarketing system. While these reforms may not please individuals at either end of the ideological spectrum, the goal is to rebalance the current system, not replace it. With the overall objective of enhancing competition, primarily by reducing government protection of producers, specific sets of reforms were suggested to reward future innovation, improve public safety, enhance the ability of the poor to afford prescription drugs, and stimulate competition outside of the confines of the medical establishment.

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