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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

Macromarketing refers to the study of market systems, the impact and consequence of marketing systems on society, and the impact and consequences of society on marketing systems (Hunt 1977). This paper analyzes the marketing system involving the development, marketing, and regulation of prescription drugs in the U.S. The analysis will highlight the dynamics of this macromarketing system (Nason 2006), focusing on the microactions of the microactors that create macrostructures (Lusch 2006). The prescription drug macromarketing system is a large and complex system operating to serve the needs of its host society while providing a return to its investors. The three primary sets of actors are drug companies, consumers, and government (Wilkie 2001; Wilkie and Moore 2006).

Since the actions of drug companies have consequences far beyond the boundaries of individual firms, it is important to identify the positive and negative consequences of this macromarketing system (Mittelstaedt, Kilbourne, and Mittelstaedt 2006). The general purpose of this article, then, is to comprehend, explain, and describe the effects this macromarketing system is having on U.S. society (Wilkie and Moore 2006). While this system provides positive benefits to society, there are several significant problems which are described. Vaile, Grether, and Cox (1952) point out that marketing systems create a marketplace dynamism to foster continual innovation to enhance the society's standard of living over time. The following analysis describes a system that is out of balance in that the prescription drug macromarketing system is underperforming. The marketplace dynamics in the prescription drug macromarketing system actually restrict competition and fail to provide incentives for innovation.

Peterson (2006) recommends that future work in macromarketing take on a developmental approach in which authors offer solutions to problems they identify. Therefore, this article goes beyond simply identifying an unbalanced macromarketing system. This article offers a set of reforms or corrections to the macromarketing system that propose to reduce the negative outcomes and increase the positive outcomes of the system. Nason (2006) argues that a limiting force of making past macromarketing research more meaningful is that it lacks an independence from the managerial-focused marketing discipline. This article does not take a managerial advocacy perspective. This article's recommendations for improving the macromarketing system attempt to take into account the fairness to marketplace actors (Laczniak and Murphy 2006). However, the overall objective of recommendations is to adjust the macromarketing system in order to provide the greatest benefits to society given the legal, political, and social value systems which provide the context for this system (Layton and Grossbart 2006).

The analysis of the prescription drug macromarketing system begins with a brief description of the prescription drug industry. This helps to provide a context from which subsequent discussions of microactors can be better understood in their roles as participants of this system. Then costs and benefits of the system to society are discussed, which will conclude in arguing that this particular system could be serving society much better, especially considering the societal investment in the system, and that reforms are needed. Finally, a series of proposed reforms are offered that will attempt to rebalance this system.

Dynamics of the Prescription Drug Macromarketing System

The following discussion will describe the activities of the primary microactors of the prescription drug macromarketing system (Lusch 2006; Wilke 2001).

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). The following is a quote from a Pfizer publication about Pfizer's assistance program:

> Medicare beneficiaries with incomes that fall below 200 percent of the Federal Poverty Level will be eligible to purchase up to a 30-day supply of most Pfizer medicines for just $15—a significant discount that is funded by Pfizer. For participants falling below 135 percent of the Federal Poverty Level, the U.S. government is providing a $600 credit toward the purchase of medicines at a discounted rate. Once the $600 is depleted, eligible U Share Card members will have the benefit of the $15 flat fee for most Pfizer medicines (Pfizer 2004, p. 28).

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, Worzel, and McKinnon 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).

Pharmaceutical brand drug advertisements have increased from rarity when Baby Boomers were young adults to ubiquity for the young adults of Generation Y (Kopp and Sheffer 1997). 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).

As discussed previously, 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).

Government

The U.S. Department of Health and Human Services (HHS) and its various sub-agencies are the federal organizations primarily involved in working with the prescription drug industry. The Food and Drug Administration (FDA) is the HHS agency primarily responsible for ensuring the safety of prescription drugs. The National Institutes of Health (NIH) and the National Cancer Institute (NCI) are also heavily involved in funding research and working with pharmaceutical companies. The FDA is led by political appointees. The FDA depends on recommendations from a variety of panels from the scientific and medical communities.

The FDA has a lengthy and expensive process to obtain approval to market a prescription drug. According to the FDA's web site (www.fda.org), it typically takes over eight years to obtain approval. The cost of obtaining approval for a drug, chiefly because of the human clinical drug trials, can exceed over $100 million (Haley 2002).

State governments exercise the authority to license physicians. States have medical licensing boards which are staffed by state medical association members. State medical associations are members of the American Medical Association (AMA) which publishes the *Journal of the American Medical Association (JAMA)*. The AMA accepts funding from pharmaceutical companies. Pharmaceutical companies sponsor many AMA events. The AMA and various government agency panels (usually staffed by leading medical researchers) recommend treatment regimens for various medical conditions.

Academic medical researchers are typically funded by the NIH, NCI, or other governmental agencies, as well as by pharmaceutical companies. Researchers publish in a variety of medical journals; among the most prestigious are *JAMA*, the *New England Journal of Medicine*, and *The Lancet*. Many medical journals accept advertising from the pharmaceutical industry. A typical drug company advertisement is called an advertorial, which is a lengthy description of a company's drug trial in a format that appears like an article. Spiller and Wymer (2001, 2002) reported, in their study of physicians' sources of prescribing information, that advertorials next to physician desk references and drug company sales representatives were the most important sources of information influencing physicians' prescription decisions.

Consumers

U.S. consumers are taking more prescription drugs now than they did a generation ago. Consumers are also paying much more for their prescriptions than they used to as a result of higher levels of consumption of prescription drugs and as a result of escalating prices. For example, in 2006, drug prices increased four times the general inflation rate (Freudenheim 2006). Drugs for cancer treatments have risen dramatically. For example, in 2006 the cost of a two week supply of nitrogen mustard (developed more than 60 years ago) increased from $78 to $548. Most new cancer drugs are priced at $25,000 to $50,000 annually. According to Pfizer chairman, Henry McKinnell, these increases are not driven by research spending or production costs, but rather they are driven by the industry's profit goals (Berenson 2006).

Consumers often learn about prescription drugs from industry advertising, which is nearly ubiquitous in the America media (Sheehan 2003). Consumers also use the Internet to access information about advertised drug brands. Although, consumers need a physician's prescription in order to obtain prescription drugs, physicians often comply with patients' requests for branded prescription drugs consumers have seen advertised (Mintzes 2002).

Competition and Markets

Nason (2006) writes that corporations support less rather than more competitive markets. He argues that business strategy naturally seeks to destroy competitive markets to win profitable advantage. Corporate influence on regulatory processes and guidelines works against competitiveness in the macromarketing system that balances private and societal interests (Dixon 1984, Layton and Grossbart 2006). The prescription drug industry is among the most profitable industries. For example, in 2002 profits registered by the top 10 drug companies were equal to more than half of the $69.6 billion in profits netted by the *entire* list of Fortune 500 companies (Public Citizen 2003). In 2003, the pharmaceutical industry fell to the third most profitable, behind mining and crude oil production and commercial banks (Angell 2004). The following discussion will present various factors that have led to the imbalance of the pharmaceutical macromarketing system.

The Competitive Rules

Nason (2006) writes that one manner in which business can control competitive markets to obtain advantage is to influence the competitive rules. In the pharmaceutical macromarketing system, the FDA oversees drug safety by requiring industry to conduct clinical trials then report the results to the FDA, who then uses the submitted reports to make decisions. Congress passed a law in 1992 that allows the FDA to collect user fees from drug companies. The fees are approximately $300,000 for each new drug application, accounting for half the FDA's budget for drug evaluation and 12 percent of the agency's overall budget (Willman 2000). This resultant dependence on corporate funding has created a culture at the FDA in which employees feel pressure to speed up drug approvals and to avoid negative actions against drug applications (Adams 2002; Andell and Relman 2001; Deyo 2004; Grassley 2006).

Since drug companies are in control of the research process, they control the study design, procedures and methods, and sample. This provides an opportunity to influence the process. The challenge for drug companies is to prove that their drug is more effective than a placebo (nothing), and that it does not unduly harm patients (Angell 2004). The manufacturer of the drug Paxil conducted nine clinical studies on the treatment of adolescents for depression. Eight of the nine studies showed that Paxil was no more effective than a placebo and, in fact, increased frequency of suicidal thoughts and attempts. The company published the one study showing that the drug was more effective than a placebo and did not publish the other eight studies (Abramson 2004). Since medical journals often publish drug company sponsored research, drug companies use these publications in their approval strategies. The majority of drug trials involving human subjects are funded by drug companies (Fraser 2006). Drug companies delay or prevent the publication of data that show their drugs are ineffective (Abramson 2004; Willman 2003).

Even studies conducted by academic researchers are often tainted by financial ties between researcher and the affected drug company. When financial ties exist between researchers and industry, the studies' results are 3.6 times more likely to be pro-industry (Abramson 2004). Hence, medical journals which guide prescribing physicians publish articles showing drug efficacy while failing to show drug deficiencies. Private drug companies fund 75 percent of the studies published in the *New England Journal of* Medicine, the *Journal of the American Medical Association*, and *The Lancet* (Santini 2006). In 80 percent of published studies funded by the drug company testing its own drug, the results are positive, while only 30 percent of published studies funded by a drug company testing a competitor's drug come out positive (Fraser 2006). Drug companies have an unprecedented ability to control what physicians know and do not know about a drug (Angell 2000; Brownlee 2004; Willman 2003).

Since drug companies are in control of the clinical studies, they have the opportunity to end trials early if results do not look promising. For example, if results are not going well, drug companies can end the trial early before the sample reaches statistical significance, and not report the study's findings. The FDA also relies upon drug companies to report negative reactions to their drugs (post marketing surveillance). Drug companies have an opportunity, then, to under-report negative reactions to their drugs, having the effect of making drugs appear to be more safe and effective (Abramson 2004; Angell 2004).

The FDA relies on expert advisory panels to advise it on decisions regarding drug approval and related matters. The FDA usually accepts and implements panel recommendations. The majority of these experts who are hired by the FDA to advise it have financial relationships with the drug companies that are affected by their decisions (Abramson 2004, Angell 2004). Even though federal law prohibits the FDA from using experts with financial conflicts of interest, the FDA is allowed to waive this restriction if it feels the expert is essential (Zwillich 2006). According to a *USA Today* study, the FDA waived the restrictions more than 800 times between January 1, 1998 and June 30, 2000. The study also found that in 92 percent of advisory committee meetings, at least one member had a financial conflict of interest. At 55 percent of these meetings, half or more of the FDA advisors had conflicts of interest. At 57 meetings during the period in which the topics involved broader process issues, 92 percent of members had conflicts of interests. At 102 meetings dealing with the fate of a specific drug, 33 percent of the experts had a financial conflict of interest. The FDA will not disclose the details of conflicts of interest other than to report that such a conflict exists. Types of conflicts typically include stock ownership, consulting fees, research grants, spousal employment, and payment for speeches and travel (Cauchon 2000, Deyo 2004).

As an example, Vioxx, a drug opposed by FDA scientists and later withdrawn from the market because it caused numerous heart attack deaths, was approved based on the recommendation of a panel. The panel included 32 members, 10 of whom had conflicts of interests with the drug manufacturer. Nine of the 10 members with conflicts voted to approve Vioxx. Had the 10 members with conflicts not been involved, the remaining members would have voted 14 to eight not to approve the drug (Harris and Berenson 2005).

Conflicts of interest occur in top appointed positions also. For example, former FDA commissioner Lester Crawford resigned after only two months after it was discovered that he hid ownership of stock in food and drug companies the FDA regulates (Kaufman 2006). Another former commissioner, Arthur Hull, resigned after it was discovered that he was taking unauthorized rides aboard a General Foods jet. General Foods owns NutraSweet, which Hull helped to get approved over the objections of FDA scientists (Murray 2002).

Another way in which drug companies influence the competitive rules of the macromarketing system is by creating a revolving door of employment opportunities between the drug companies, their public relations firms, and government. Almost two-thirds of FDA employees work for the pharmaceutical industry after retiring from government service (Haley 2002). Drug companies are also successful in obtaining government positions for industry lobbyists and attorneys (Lenzer 2004; Mulkern 2004).

Restrict Entry of Competitors

Nason (2006) argues that a macromarketing analysis should examine how the system restricts entry of competitors. The prescription drug macromarketing system does this in two ways. First, processes have been constructed in such a way that vast sums of money are required to obtain approval for a new drug and years pass before a new drug enters the market. These two structural dimensions of the macromarketing system place a barrier to entry on start-up companies that want to compete.

Second, the interconnections between drug companies, physicians, hospitals, government regulators, research scientists, lobbying groups, government officials, medical associations, and medical journals have evolved into a giant feedback loop, reinforcing the system's hierarchy and orthodoxy. This reinforcing feedback loop creates a culture that rewards conformance and punishes non-conformance (Griffin 1996; Mihaly 1996).

Elaborating on cultural barriers to entry further, it should be noted that conventional medicine, or allopathic medicine, relies heavily on invasive treatments such as surgery, radiation, chemotherapy, and synthetic drugs. Alternative medicines, such as naturopathic medicine, rely instead on non-invasive treatments like nutritional supplements, manual therapy, hydrotherapy, herbalism, acupuncture, counseling, environmental medicine, aromatherapy, whole foods, cell salts, nontoxic chemicals, and so on (Block 2003). Alternative medicine approaches medicine as restoring the body to health, allowing the body to repair itself. Alternative medicine sees a role for traditional medicine (such as in mending broken bones or surgery to repair physical trauma), but prefers not to use toxic drugs, radiation, chemotherapy, or other treatments that harm the body (Pelletier and Weil 2002). The U.S. prescription drug macromarketing system has a long history of attacking innovations in medicine that were alternatives to conventional medicine, threatened the sales of prescription drugs, or countered the conventional medical practices that were common practices (DeMeo 1993). The FDA has a history of attacking alternative medicine innovations that offered promise of effectively treating major diseases like cancer for a small fraction of the expense of less effective conventional methods (Ausubel 2000; Epstein 1998; Moss 1996).

Collusion

Nason (2006) suggests that the industry component of a macromarketing system has incentives to reduce competition and that one means to achieve this is through collusion, sharing markets, or price fixing. In a 1998 settlement, 16 pharmaceutical manufacturers agreed to pay more than $700 million to settle accusations that they conspired to overcharge independent and chain-store pharmacies while giving discounts or rebates to some managed-care and hospital groups (*New York Times* 1998). In 2002, 18 drug companies were sued for colluding to inflate the cost of cancer drugs (Kaiser Family Foundation 2002). Pfizer has been convicted of scheming with food additive producers to allocate customers and territories in order to avoid competition and inflate prices (U.S. Department of Justice 1999). Over twenty-one states have filed legal actions accusing drug companies of conspiring to inflate drug prices to state Medicaid programs (*NewsTarget* 2006).

Obtaining Government Protection

Nason (2006) argues that businesses, in attempting to influence competitive markets, may obtain government protection for this purpose. Drug companies have been successful using this strategy. Layton and Grossbart (2006) recommend that macromarketing research examine whether or not public policy initiatives impact the workings of a competitive marketing system. In the prescription drug macromarketing system, both these factors work to reduce industry competition. Ann-Marie Lynch, a lobbyist for the drug industry trade association Pharmaceutical Research and Manufacturers of America, was appointed by the Bush administration in 2001 to the Department of Health and Human Services as deputy assistant secretary in the office of

policy. Her work was instrumental in banning the government from using Medicare's buying power to negotiate for lower drug prices in the new Medicare prescription drug coverage (Mulkern 2004). The Bush administration's rationale for banning Medicare from negotiating prices with drug companies was that doing so was a government intrusion into the private marketplace. Another government agency, the Veteran's Administration, was negotiating drug prices prior to the Bush Administration and in doing so, pays 48 percent less for drugs on many frequently used drugs (Pear 2006). After the Democrats replaced the Republications as the majority party in both houses of Congress in November 2006, the Democrats have been trying to pass a law that would require Medicare to negotiate for lower drug prices. President Bush was strongly opposed and threatened to veto this law, which has been blocked in the Senate by Republicans. The Bush Administration issued a written statement which said it believes negotiating for lower drug prices would represent government interference, impeding competition, limiting access to lifesaving drugs, reducing consumer convenience, and, ultimately, raising drug prices (Pear 2007a). A recent congressional investigative report found that the Bush Administration's Medicare drug program has been responsible for an $8 billion surge in profits for the 10 largest drug companies in the first six months of the program (Waxman 2006). A study by the Health Reform Program reported that the Bush plan will increase drug company profits by $139 billion over eight years (Sager and Socolar 2004).

The U.S. grants drug companies patents in order to provide the industry with an incentive to undertake financial risk and investment in developing innovative drugs to cure diseases and save lives. Companies are rewarded with a 20 year monopoly on a patented drug. In return, society hopes to get innovative, life saving drugs. This system of patent protection has been modified over the years from its original intent. As a result of political support and industry legal strategies, most patents are elongated years beyond the original patent period, sometimes doubling the original duration of 20 years (Rubin and Rubin 2003). Furthermore, many patented drugs are not innovative, offer little benefit over alternative drugs, and much of the financial risk of truly innovative drugs is undertaken by taxpayers (Angell 2004).

Drug companies have many tactics for extending their patents. For example, new uses for the drug are recommended. A pill made be hardened so it will digest slower, allowing for a reduced number of times the pill will have to be taken during the day. Welbutrin was made into a twice a day version (Welbutrin SR) and later into a once a day version (Welbutrin XL). A drug can be reformulated into a metabolite, which is the chemical compound the drug becomes after being converted by the body's own chemistry. Due to a recent act of Congress (The Uruguay Rounds Agreements Act, Public Law 103-465), drug companies can prolong their patents three years by waiting until the last year of their patents before testing their drug on children. Drug companies typically delay the generic release of the drug by tying up the generic drug company with law suits. One recent trend is for drug companies to offer payments to generic drug companies for not releasing the drug in a generic form for a specific period of time. This can be done legally by using this strategy as a means to settle law suits, which has cost American consumers many millions of dollars (Boast 2001; Rubin and Rubin 2007).

Prescription Drug Macromarketing System Reforms

Peterson (2006) recommends that future work in macromarketing take on a developmental approach in which authors offer solutions to problems they identify. Therefore, rather than further expounding upon problems of the prescription drug macromarketing system, a set of reforms are offered to improve the system. 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 suggested reforms 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. Two additional reforms are offered.

First, 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).

Implementation Issues

Resistance from the pharmaceutical industry is to be expected. This resistance will probably produce intensive political lobbying to influence politicians and intensive issue advertising to influence consumers. Industry activity can result in delaying reforms as it has in the past. However, given that the Americans can no longer afford its $2 trillion per year health care system, and given that Americans are increasingly aware of the failures of the system, popular support for reforms is likely. For example, the industry was able to delay health care reforms during the Clinton Administration in the early 1990s until it again became a central issue in the 2008 presidential election (Measley 2008). A recent national survey reported that 82 percent of Americans support reforms and that 80 percent of Americans believe price gap for prescription drugs sold to Americans and the rest of the world is unacceptably high (Consumer Reports 2008).

In regards to the recommended reforms to improve drug safety, removing conflicts of interests of government scientists and individuals serving on advisory panels was emphasized. It should be noted that the mission of the FDA is to ensure drug safety for consumers (www.fda.gov/opacom/morechoices/mission.html). There are numerous examples where conflicts of interests have resulted in decisions which have harmed public health. For example, aspirin has been found to beat Warfarin in preventing strokes and has far fewer side effects (Maugh 2005). Vioxx, which killed a number of people, was an aspirin substitute and was approved by panel members with ties to the drug's manufacturer (Associated Press 2005). A Union of Concerned Scientists (2006) survey of FDA scientists indicates that scientists are unhappy with the pro-industry emphasis of the Bush administration and want to return to an unbiased emphasis on public safety.

While the need to remove conflicts of interest is apparent, implementing this reform has met resistance. There are two arguments made in opposition to the suggested reforms. First, that the prevalence of scientists with industry financial ties is so great that sufficient numbers of experts without conflicts of interests cannot be found. Second, that the most qualified scientists should be used regardless of whether or not they have financial conflicts of interest with the regulated industry. Angell (2000, 2001, 2004) has argued that (1) there are numerous government scientists without conflicts of interests who are qualified to determine the safety and effectiveness of a drug based on clinical data, and (2) the culture which has allowed conflicts of interests to exist can be changed to one in which it is no longer acceptable. Industry will resist a reduction of its influence over the regulation process. The Center for Science in the Public Interest has recommended a compromise position in which a limited amount of a conflict of interest is permitted (2007). It recommends that scientists serving on FDA panels not have more than $50,000 in payments from a drug company during the period of one year prior to serving on the panel. This recommendation could serve as an intermediate step, which is more politically achievable in the short term, toward achieving the ultimate goal of completely independent scientists evaluating proposed drugs.

It is recognized that the needed reforms in total may be too ambitious to implement in the near term. Many industry interests will be perceived as threatened and, hence, industry opposition will result. While industry has been successful in creating a pro-industry political culture, consumer discontent with an inefficient system that society cannot financially sustain will force recalcitrant politicians to search for compromises that will lower consumer discontent while minimizing industry restrictions. While industry efforts may delay reform, they are unlikely to prevent reforms in the long term. It is also possible that populist politicians will use consumer demand for reform as a power base, making reform more politically acceptable. Whichever path future change takes, that is, one of small incremental steps toward substantive reform or a more rapid reformation driven from a populist demand, it is likely that change will occur in this macromarketing system. The current system is sufficiently imbalanced and under-serving society to the point to which improvements are demanded.

The U.S. system of government has become a two party system (Democrats and Republicans) which can discourage reform. A unified minority (41%) of Republicans can block the passage of laws in the U.S. Senate. The politically conservative Republican leadership supports a private, profit-seeking health care system and is opposed to greater government regulation (Pear 2007b). Conservatives view increased regulation as a step toward a single-payer government-ran health care system (Pear 2007b). While progressive Democrats want such a system, similar to most industrialized nations, moderate Democrats are programmatic and accept a mixed system that will reduce total costs and reduce the number of poor citizens lacking access to health care (Krugman 2009). Progressives are unlikely to get a single payer system in the short term because of industry power and conservative resistance. Conservatives are unlikely to maintain the status quo given the increasing cost of the health care system, the rising U.S. national depth, the growing proportion of uninsured individuals, and the declining popularity of the post-Bush Republican Party. It is likely, then, that more government intervention in the health care system and greater efforts to control the escalating prices of prescription drugs will occur. However, the privatization of the U.S. health care system will be curtailed, but preserved.

Recent practical efforts to control spiraling drug costs like those of Great Britain are likely to be followed. The U.K. government agency, the National Institute for Health and Clinical Excellence (NICE), is undertaking efforts to place a societal value on the benefits of prescription drugs. For example, NICE recently placed a value of $22,750 (15,000 pounds) to save six months of a citizen's life. A new drug, called Sutent, delays cancer progression for six months and costs $54,000. Under the NICE formula, the British health system would only pay $22,750. Therefore, Sutent would not receive NICE approval. Drug companies are quietly reducing their prices to obtain NICE approval, especially since other countries are following NICE's example. It is likely that more countries will arrive at acceptable prices of drugs based on their value to society (Harris 2008). This may very well appeal to U.S. policy makers who are finding the custom of unregulated drug pricing unsustainable.

Discussion and Conclusion

The market does not necessarily harmonize private and societal interests (Dixon 1984). This may be due to marketing influences on regulatory processes (Layton and Grossbart 2006). Nason (2006) points out that it is important to understand the forces that shape

macromarketing systems. Nason emphasizes that on the producer side of marketing systems, “business strategy naturally seeks to destroy competitive markets” (p. 221). This article has examined several dimensions of the prescription drug macromarketing system and found that the system has been unbalanced by producer forces.

This article examined some of the competitive-reducing strategies of drug companies. This examination included several of those suggested by Nason (2006). 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.

Layton and Grossbart (2006) argue that marketers naturally seek to use their resources to influence competition to their advantage and to create disadvantage for their competitors. These efforts serve private interests but not societal interests (Harris and Carman 1983). This has been referred to as external perversions of the political and economic control systems (Arndt 1981). In macromarketing systems having large corporations with vast resources and a regulatory system creating extensive links between industry and government, such external perversions of control systems resulting from anti-competitive activities over time are a risk (Cornwell and Drennan 2004; Dixon and Polyakov 1997). Periodic reforms of these systems may be required to rebalance the system to restore private and societal harmony.

Peterson (2006) recommends future macromarketing research offer solutions to the problems that are identified. 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 was 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. It is hoped that this article will stimulate further debate and discussion of this and similar macromarketing systems.

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