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CHAPTER EIGHT

THE RISE AND HEGEMONY OF THE WESTERN PHARMACEUTICAL INDUSTRY

Richard Harvey Brown
Timothy Recuber

The pharmaceutical industry has, since its emergence in the 1940s, shifted the focus of medicine manufacturing from the mixture of natural animal and vegetable ingredients to the research and development of specific active chemical ingredients which can be patented and monopolized. As the industry's influence and authority have grown, so too have its ability to control public perceptions of drugs and medicine. That ability has been aligned against and tested by a variety of public health scandals and government regulatory efforts over the years. Nevertheless, the industry has shown a remarkable aptitude for shifting its strategies and altering its rhetoric to survive such challenges and maintain its position and profits.

The importance of patents in the pharmaceutical industry has led to an unusual degree of market concentration and monopoly formation in an industry relatively free from price elasticity and competition. While high research and development costs explain part of the high price of medical drugs, almost as much is spent on advertising those drugs as on developing them. Furthermore, research and development are often done to alter or combine existing drugs rather than create new treatments for incurable diseases. In fact, if appearing unprofitable, research into new drugs will often be abandoned. The profit motive drives the decisions of pharmaceutical companies at least as much as any humanitarian concerns, making lifesaving medicines often unavailable or unaffordable for many across the globe.

As such, the need would seem clear for strict international regulation of what has become a global industry. But today, countries still have widely varied standards of regulation and control of pharmaceuticals. International regulatory agencies have largely

been ineffective at controlling both the licit and illicit pharmaceutical trades, and yet there is a good deal of evidence that attests to the monopolistic and oligopolistic power of pharmaceutical corporations to control prices, market shares, and patents worldwide. The pharmaceutical industry has also been heavily involved in crafting international regulatory efforts aimed at illegal or heavily restricted drugs such as opium, heroin, and cocaine. Though often ineffective, the international regulation of illegal, recreational drugs still reinforces the monopoly of those who deal in legal, medically-approved drugs.

This chapter charts the history of the Western pharmaceutical industry from its inception through its current status as a global powerhouse. It examines the patent protection and pricing schemes of research and development firms as well as some of the major struggles between those firms and the US government, generic drug manufacturers, and Third World countries. This chapter also describes the ways in which the drug industry has used its political and economic influence to tailor international regulation for the better part of a century, and the ways in which it advertises and promotes its products in the United States. Finally, the chapter reports on a variety of unscrupulous practices of Western drug companies in the third world--evidence of the power of these transnational companies to evade legal and ethical boundaries to greater profits. The pharmaceutical industry not only monopolizes the licit trade in mind- and mood-altering substances but also employs a hegemonic control over the regulation of that trade as well as the popular perception of drugs in general.

History

The practice of pharmacy has its origins in the human application of herbs to relieve pain or dress wounds. Early on, herbalists began blending different combinations of herbs, sometimes adding chemicals, including mercury and sublimed sulfur. By the twelfth century the beginnings of an international trade in medicinal pharmaceuticals emerged when Crusaders and seafaring merchants introduced Arabian and South American drugs and spices to British herbalists, who incorporated these ingredients in their medicinal concoctions. During this time there was little differentiation between the functions of grocers and apothecaries as they imported the same spices and other types of ingredients. However, the increasing influx of new drugs and the more extensive use of chemicals in the manufacturing and blending of medicines began to require specialized skills. The London Guild of grocers and apothecaries determined that it was no longer feasible for these occupations to be combined, and in 1617 the Society of Apothecaries was instituted (Reekie 1979:3). During this time, drugs and drug-like preparations played only a small part in a more comprehensive program aimed at restoring the patient to a balanced psychosocial state (Drews 1999: 3).

Modern medicine did not emerge until the late nineteenth century with the development of the field of chemotherapy. Coal tar, an industrial byproduct of the carbonization of hard coal, was found to contain substances that could be used as dyes in the textile industry. These became even more important when it was discovered that particular dyes bonded to particular types of tissue (Drews 1999: 23-24, 63-64). The pioneer of chemotherapy, Paul Ehrlich (1854-1915), built upon the work of Robert Koch,

who observed that aniline dyes had the capacity to kill bacteria. Ehrlich surmised that if these dyes could attach themselves to bacteria and parasitic organisms without harming the tissues or cells of the entire body then it would be possible to produce a drug that had the ability to seek out its own target. Ehrlich focused his research on the discovery of just such a "Magic Bullet" drug, and eventually created the first effective chemotherapy, a cure for Syphillis called Salvarsan (Reekie 1979: 4-5; Drews 1999: 66). Many successful European pharmaceutical companies such as Bayer, Hoechst, and Ciba started as chemical dye factories and branched out into medicine at this time because of the newfound importance of aniline dyes (Drews 1999: 24).

Around 1935 the "therapeutic revolution" was initiated with Dr. Gerhard Domagk's discovery of the anti-microbial qualities of a red dye called Prontosil. A few years later the active property of the dye, sulfanilamide, was established in France. Sulfanilamide, rather than the dye itself, was found to possess therapeutic qualities (Reekie 1979:5). This discovery ushered in a new class of drugs, and the era of antibacterial chemotherapy was born (Drews 1999: 68).

Until the late 1940s the manufacturing of medicine was characterized by wholesale chemists and druggists who primarily produced and sold medicines that were derived from natural animal and vegetable ingredients. The typical raw materials that these chemists and druggists used in their tinctures and tablets included bitter aloes, belladonna, cascara, digitalis, ergot and fennel. However, as the scientific community concentrated its efforts on the research and development of specific active chemical ingredients, these active ingredients were soon prescribed more often than the traditional

drugs themselves (Reekie 1979:1; Drews 1999: 24). Many pharmaceutical firms can trace their origins back to the efforts of some apothecaries at the time to standardize and industrialize their production in order to meet the demands presented by these new prescriptions (Drews 1999: 25).

In the U.S., the pharmaceutical industry really only began with the advent of penicillin (Harrison 2004: 41). When the drug was discovered in 1928, and even when its therapeutic effects were demonstrated in 1941, no patents were issued. The U.S. Department of Agriculture took the lead in producing the drug and also licensed it liberally to a number of firms. By 1944 the United States was home to 19 penicillin producers (Harrison 2004: 44). The U.S. had been spurred by the pressures of the first and second World Wars to become less dependent on Europe for its medicines, and the great need for antibiotics during WWII led to a focus on research and development at the U.S. firms that finally matched their European counterparts (Drews 1999: 28-29). After penicillin, the pace of drug development quickened. For example, in 1943 Waksman discovered the drug Streptomycin, which was effective at combating tuberculosis. The first comprehensively used antibiotic, chloramphenicol, was introduced in 1949 and in 1953 Tetracycline became the first antibiotic to be manufactured after its chemical formula had already been established (Reekie 1979:5).

The therapeutic revolution was firmly entrenched by the 1950s, and both pharmaceutical outputs and profits soared. A wide array of drugs such as corticosteroids, antihistamines, antidepressants, and diuretics became available to help treat and alleviate numerous ailments. Reekie's examination of the growth of the pharmaceutical industry in

Britain reveals just how rapid its rise was, particularly after the National Health Service (NHS) was instituted in that country in 1948. Pharmaceutical output in Britain rose from a pre-war amount of 21 million pounds to 894 million pounds in 1976. Other countries witnessed similarly dramatic increases as well. Profits for pharmaceutical firms in the United States increased from $150 million before World War II to $12.2 billion in 1976 (Reekie 1979: 7). By 2002, the top ten American pharmaceutical companies were reporting $35.9 billion in profits (Public Citizen 2003). The total production profits of pharmaceutical firms located in the Western world reached $43 billion by 1975 (Reekie 1979: 7) and today the world market for pharmaceuticals has been estimated at between 330 and 360 billion dollars (IMS Health 2000; Gassman et al 2004: 5). The United States and Japan are the top two markets in the world, accounting for 55 percent of global pharmaceutical sales, followed by France and Germany (IMS Health 2000). Today drug companies are some of the most profitable firms in the world, and those profits often translate into wide-ranging political-economic power and influence.

Monopolies and Economics

The pharmaceutical industry has been marked by an unusual degree of market concentration and monopoly formation. It has also been multinational in character since World War Two, attempting to extend its market across the globe while reducing its costs by establishing subsidiaries in developing countries (Bruun 1975:157). Furthermore, this industry has been one of the most popular in terms of investments, primarily because drugs have ranked between first and second in profitability among all industries since 1955. In 2001 and 2002, the pharmaceutical industry was the most profitable of all

industries represented in the Fortune 500 list of the top 500 American firms. Profits by the top ten pharmaceutical companies in 2002 were equal to greater than half of profits by the rest of the top 500 companies. These top ten pharmaceutical firms reported a profit of 17 cents on every dollar of revenue, compared with a Fortune 500 average of 3.1 cents per dollar (Public Citizen 2002a: 1-2).

How does the pharmaceutical industry managed to procure profits that are well above those of other manufacturing industries? Before answering that question, it is important to note that there are really two different kinds of pharmaceutical companies with two different business plans. Research and development (R&D) firms spend large amounts of time and money developing innovative new drugs. Their profits come from patenting those new drugs and monopolizing their production and sale until the time that those patents expire (in the U.S., twenty years). Generic drug companies, however, make their money producing copies of drugs for which patents have expired. They do not spend money developing new drugs and are thereby able to sell their generic equivalents at greatly reduced prices (Greider 2003: 27; Robinson 2001: 184-185).

It is clear then that patents and patent protection are of vital importance to the giant R&D firms that make up what Robinson (2001) calls "Big Pharma." And these firms have some very legitimate concerns regarding their patents. The estimated costs of researching and developing a new drug today range from $100 million to $800 million (Leavitt 2003: 38-39; Public Citizen 2002b). Furthermore, drugs are typically patented at the beginning of the R&D process, meaning that by the time a new drug reaches the marketplace its patent life may be closer to ten than twenty years. Add to this the ease

with which most drugs can be copied (see Harrison 2004: 27-28; Leavitt 2003: 71-72), as well the prospect of lackadaisical patent enforcement in international markets, and it is easy to see why these companies worry about their large research and development investments.

And yet the industry remains incredibly profitable, for several reasons. First and foremost, R&D pharmaceutical companies have been able to attach extremely high prices to their patented drugs--of which they are the sole providers. That each patent granted for a specific drug provides a twenty-year monopoly to the patent holder creates the potential for severely inflated prices. Though many countries impose controls on drug prices, the U.S. does not, making it a good example of the degree to which patented medicines demand exorbitant fees from consumers. For instance, a year's supply of the drug tamoxifen, prescribed to survivors of breast cancer, cost $1,400 in the U.S. and only $125 in Canada (Leavitt 2003: 55). In 1992, the price of Zanax in the U.S. was 225 percent higher than in Canada, Premarin was 190 percent higher, and Zantac was 40 percent higher. A General Accounting Office study of 121 drugs found that only 23 were priced lower in the U.S., while 98 were higher, generally by about 50 percent (Bian 1997: 29-30). In general, Canadians pay about 62 percent of what Americans pay for the same medicines, and Italians, French, Swedes, Germans, Swiss and English pay between 53 and 69 percent of American prices (Greider 2003: 17). The price disparities between the U.S. and other countries are evidence of the giant mark-ups that occur with patented drugs, especially when the government does not regulate those prices. The actual cost of producing and distributing a drug, with a reasonable level of profit to keep a firm in

business, is estimated to be 25 to 30 per cent of the selling price during its patented period (Robinson 2001: 86).

Though high research and development costs are a constant source of worry for giant pharmaceutical firms, they also certainly contribute to the increasing concentration of the pharmaceutical industry. These research and development costs prohibit many small firms from entering the pharmaceutical market, perpetuating the monopoly-hold that large firms have established. Furthermore, small firms are at a disadvantage because they cannot meet the strict regulatory requirements or technical demands that are necessary for production innovations (Greider 2003: 161-162). Thus, large firms have been able to keep control of the market and increase their shares by having the capital necessary to fund research and develop innovative new products.

Before the mid-1960s large firms were not necessarily the most innovative (Comanor 1965; Grabowski 1968; Reekie 1969; Mansfield et al 1971). However, their efforts during that period to expand their research and development enabled those firms to increase their output in proportion to their sizes (Reekie and Weber 1979: 146-51). This trend continues today, as the pharmaceutical market is now dominated by so-called "blockbuster drugs." Large drug companies have shifted their approach from manufacturing a broad range of products to simply producing a small number of drugs with giant markets and huge profit margins. In 2001 the five biggest drug makers garnered between 48 and 80 percent of their profits from blockbuster drugs with at least $1 billion in sales, and blockbuster drugs account for over half of drug sales in the U.S. today. But this shift has left smaller firms unable to compete. Developing such drugs

requires a huge commitment of resources into sampling, detailing, advertising, and market research--one that is only feasible for the largest drug companies (Greider 2003: 163-166).

The high profits of the pharmaceutical industry can also be explained because it is relatively protected from price competition. Physicians, not consumers, determine which drugs should be purchased, and as Braithwaite notes, "doctors have little reason to be price-conscious" (Braithwaite 1984:161). Furthermore, effective medical care tends to be less price-elastic than other types of consumer products, due to a lack of available substitutions. At the same time, insurance coverage has given consumers more access to prescription drugs while making them less sensitive to high prices (Greider 2003: 162-163). As such, the pharmaceutical industry and the drugs it produces do not abide by the rules of free market competition.

One category of drugs long characterized by a remarkably high level of market concentration and oligopoly in the pharmaceutical industry is therapeutics (Slatter 1977: 48-9; Schwartzman 1976). In 1973 the therapeutic market in the United State was controlled by four pharmaceutical firms for nine different therapeutic drug categories. The level of market concentration has, historically, also been high for bulk drug production. In 1979, Ascorbic acid (Vitamin C) was sold by more than a hundred different companies in dosage form, but only three firms produce the entire output of the vitamin: Merck, Pfizer, and Roche (U.N. Center on Transnational Corporations 1979:38.) Today, however, the global growth of pharmaceutical markets, increasing dependence on blockbuster drugs, and a trend towards corporate mega-mergers have resulted in

unparalleled levels of oligopoly in the pharmaceutical industry. The top ten pharmaceutical companies accounted for 53% of global sales in 2003, and the top 20 companies accounted for over 75% (ETC Group 2003; see Scripps Pharmaceutical League Table 2003). This high level of industry concentration also enables pharmaceutical firms to avoid price competition (Braithwaite 1984: 162-163).

However, when patents expire, competition from generic drug makers appears almost immediately. When a drug comes off patent, generic competition will reduce its price initially by around 50%, and eventually by as much as 80% (Robinson 2001: 187). The antibiotic market has witnessed such activity; when U.S. patent protection expired in the late 1970s for most of this class, the antibiotic market witnessed price levels falling below those of the early 1960s (Reekie 1979: 100). This trend is extremely troubling for drug firms today, as many rely on one or two patented blockbusters for the majority of their profits.

With a lack of sure-fire blockbuster drugs in the research and development pipeline, R&D firms have resorted to a variety of tactics to extend patent life and the monopoly control that comes with it. By patenting some trivial feature of the drug, such as its pill coating or delivery method, just before the patent expiration date, drug companies prevent others from introducing generic equivalents (Leavitt 2003: 55). R&D firms will also put out the same drug in a new formulation, combine it with another drug, or claim some new, previously un-patented use for it. These altered versions receive three more years of patent life (Greider 2003: 29). Giant drug firms spend significant amounts of money lobbying for patent extensions, and some estimates suggest that up to 80

percent of their research and development costs are accrued not in the pursuit of new drugs but instead working on these kinds of "line extensions" (Robinson 2001: 11-12). R&D firms can even extend a drug's patent life for six months by agreeing to test that drug on children. Though the incentive of "pediatric exclusivity" has resulted in hundreds of new pediatric drug studies, it has also brought huge windfalls for drug companies willing to test all sorts of drugs on children, even those for hypertension, arthritis, and heartburn. While these trials cost a few million dollars, the resulting six-month patent extensions can yield upwards of $900 million extra in profits on a blockbuster drug such as Claritin (Greider 2003: 39).

In sum, the pharmaceutical industry is one of the most profitable in the world for a number of reasons. To start with, patent protection allows drug companies to monopolize new drugs and set very high prices for them. The high costs of research and development, regulatory testing, and product marketing make it increasingly difficult for smaller firms to compete, thereby allowing large firms to further consolidate the market and decrease competition. The fact that doctors choose drugs for their patients, often without an eye towards costs, and the fact that prescription costs are often paid by insurance companies both contribute to a greater public tolerance for high prices than would be the case with other products. Finally, drug companies are constantly finding new ways to extend patent protection on their most lucrative drugs, extending their monopolies and further increasing their profits.

Regulation in the United States

In most countries the price of a drug is determined by the government and a pharmaceutical firm at the time it enters the market and its price may not be altered unless the government approves it. Price levels are generally determined by taking into account the costs of raw materials, production, distribution, research, and profit margin, although this varies by country. For example, in Australia a detailed analysis of marketing costs is taken into consideration while in Italy a price is determined only by the costs of raw materials and production expenses. In Britain drug prices are set according to a predetermined profit margin by the government without any consideration of material, production, distribution or research costs. In contrast, the costs of drugs in many Third World countries depend on the prices set by the countries where they are manufactured, as governments in developing nations cannot afford to investigate the various factors that determine price levels (Braithwaite 1984: 170- 171).

The United States is the most permissive industrialized nation in terms of pharmaceutical price regulation, and the only large pharmaceutical market in the world where prices are not primarily controlled by the government (Greider 2003: xiv; Braithwaite 1984: 170). But while price regulation has been avoided, governmental regulation of the content of pharmaceuticals began early in the United States with the passage of the Pure Food and Drug Act of 1906, which prohibited the interstate trade of adulterated and mislabeled food and drug products. Passage of this Act was primarily secured due to the efforts of social reformers concerned with public health as well as the publicity generated from Upton Sinclair's horrific account of the meat-packing industry in his book *The Jungle*. Although food, more than drugs, was the focal point of the Act at

the time, its implications for the pharmaceutical industry of the future were evident. Before the Act, consumers could freely purchase any drugs without a prescription from a physician. Indeed, prescription drugs accounted for less than a third of all drugs consumed during this time, and many consumers were taken in by "quack" doctors selling patent medicines that were without scientific merit. The 1906 Act, which was amended in 1912, was the first step towards prohibiting such misleading, and potentially deadly, patent medicines (Grabowski 19xx:1-2.)

This piece of legislation proved to be ineffective at completely eliminating mislabeled and adulterated medicines from the market for several reasons. The first was a problem of enforcement. Only a small staff of chemists was provided to enforce the law. Second, a series of court decisions put the burden for prosecuting fraudulent producers on the government. The often exaggerated or false therapeutic claims of many drugs and patent medicines were generally seen as outside of FDA control, provided the substances' ingredients were correctly labeled (Daemmrich 2004: 22). While the law did grant the FDA the power to remove products that were improperly labeled from the market, this only applied to products that had traveled over state borders. Products manufactured and sold within one state were not covered under the Act (Grabowski 19xx: 2).

Responding to these weaknesses, FDA officials and USDA lawyers drafted a new bill in 1933 to expand government regulatory authority and require firms to carry out safety tests before putting their products on the market. A large but decentralized group of food, drug, and cosmetic manufacturers set out to lobby congress against this proposed

bill. But their efforts had minimal impact once the Sulfanilamide disaster became news in 1937. When one hundred people, mostly children, died from ingesting a syrup form of Sulfanilamide that contained a toxic diethylene glycol additive, Congress could scarcely afford to ignore the need for greater FDA oversight. The FDA gained a measure of authority over the medical profession then-- arguing in public that doctors were recklessly prescribing unnecessary new medicines-- and it was rewarded with the Food, Drug, and Cosmetic Act of 1938 (Daemmrich 2004: 22-23).

The Food, Drug, and Cosmetic Act greatly improved the government's control of drugs in the United States. Under this new law pharmaceutical firms were required to submit a new drug application (NDA) to the FDA before they could introduce a new drug to the interstate market. In this NDA firms had to provide a list of the uses of the new drug and make evident that the drug was safe if consumed under specified guidelines. FDA officials were responsible for determining testing protocols for these drugs, and were able to inspect factories to make sure their preparation met safety requirements (Daemmrich 2004: 23). All NDAs were automatically approved within sixty days of submission unless the firm failed to adequately demonstrate that the drug was safe. Another provision of this new law allowed the FDA to differentiate pharmaceuticals into ethical drugs that could only be obtained with a physician's prescription, and proprietary drugs that could be purchased by all consumers over the counter (Grabowski 19xx: 2).

While these new regulations made pharmaceuticals in the United States much safer, they did not address issues of pricing. It was not until 1959, when Senator Estes Kefauver launched an investigation into price-fixing in the pharmaceutical industry, that

the high prices of pharmaceuticals and the possibility of government intervention in drug pricing engendered serious public scrutiny (Daemmrich 2004: 25).

Initially, the market for the anti-infective drug penicillin that developed during WWII was characterized by competition between a large number of firms and, thus, by low prices. However, the second generation of more powerful anti-infective drugs that hit the market during the Korean War was controlled by a few firms that conspired to artificially set prices and avoid competition (Harrison 2004: 44). Unlike penicillin, for which no company held a patent, the broad-spectrum antibiotics chlortetracycline and oxytetracycline were patented by Pfizer and Cyanamid, companies that maintained high prices and earned huge profits in the antibiotic market as a result. When the therapeutically superior, and seemingly un-patentable, tetracycline came on the scene in 1953 and threatened the Pfizer-Cyanmid monopoly, those companies negotiated a deal to restrict sale of the drug to themselves and three other pharmaceutical companies, all of whom recognized Pfizer as the patent holder. The companies were able to avoid a competitive market structure and began fixing prices with such uniformity, despite highly variable production costs, that it eventually resulted in a 1961 grand jury indictment of all five companies (Braithwaite 1984: 175-182). Though these companies were found innocent of collusion, the case brought national attention to the cartel-like pricing of the industry and would soon provide Tennessee Senator Estes Kefauver with ammunition for a crusade against these practices (Harrison 2004: 45-46).

In the U.S. Senate Sub-Committee on Anti-Trust and Monopoly, referred to as the Kefauver hearings, it was discovered that the average production costs for fifteen major

drug firms were only 32.3 percent of the price at which drug manufacturers sold their products to the public. This was compared to fifty companies from other industries, not one of which was found to have production costs less than 42.6 percent of their ex-manufacturer sales (Braithwaite 1984:161). Kefauver proposed a system of compulsory licenses that could circumvent exclusive patents, allowing other firms to produce patented medicines in the name of increased competition and lowered prices. These licenses would allow time for a company to recoup research and development expenditures before competing firms were allowed to enter the market, after which time profits had to be derived from competitive pricing rather than monopolization (Harrison 2004: 47-48).

Unfortunately, another pharmaceutical disaster diverted public attention away from these issues and back towards concerns over safety. A drug called Thalidomide that was under FDA review at the time began to cause a rash of serious birth defects in European children whose mothers had taken the drug during pregnancy. The R&D pharmaceutical industry capitalized on the public fear created by the Thalidomide scandal and shifted the terms of debate back towards safety. Suddenly taking the lead, they made several far-reaching proposals to give the FDA increased inspection and market-removal powers as well as more funding. They did, however, oppose Kefauver's compulsory licensing system. With the regulatory discourse now skewed towards safety, any attempts to alter the pharmaceutical market structure were dropped, and the 1962 amendments to the Food, Drug, and Cosmetics Act were signed into law. Kefauver's demands for fair pricing had been subverted by the drug companies, and though the 1962 amendments brought with them the increased costs of more pre-market testing and FDA oversight, the

R&D industry correctly assumed that these high initial costs would dissuade smaller, competing firms from entering the market (Harrison 2004: 48-50).

While the 1962 amendments to the Food, Drug, and Cosmetics Act represented a big win for the R&D pharmaceutical firms, it was in some ways their last major domestic policy victory in the U.S. The success of increased FDA oversight soon left consumers feeling safe about medical drugs, and free to once again question the market structure of the pharmaceutical industry. Despite industry lobbying efforts to prevent these changes, states began repealing "anti-substitution" laws that had been on the books since the 1950s. These anti-substitution laws prevented pharmacists from filling prescriptions with generic alternatives. Previously, to receive a generic drug it had to be prescribed by name, but with anti-substitution laws coming off the books in more and more states, pharmacists were able to fill prescriptions with generic equivalents of patent-expired medicines. By 1979 the majority of states had repealed these laws, and by 1984 all had, resulting in increased competition from generic drug producers and lower prices on off-patent medications (Harrison 2004: 51-54).

At the same time, the Pharmaceutical Manufacturers of America (PMA) led a movement to change drug patent laws so that time spent in research and development did not count towards patent expiration. The proposed Drug Competition and Patent Term Restoration Act of 1984, which would have meant a windfall for the R&D firms, died in the House of Representatives thanks to the lobbying and public relations efforts of the Generic Pharmaceutical Industry Association (GPIA), the American Association of Retired Persons (AARP), and many powerful labor unions and advocacy groups

(Harrison 2004: 56-58). Though the bill was later resurrected and compromises were reached between the generic drug industry and its research and development counterparts, the R&D industry's failure to secure across-the-board patent extensions, and the increased public support for generic competition, led the biggest pharmaceutical firms to shift their strategies and pursue legislation involving patent protection in emerging international markets (Harrison 2004: 3, 60).

There is, however, some evidence to suggest that the pharmaceutical industry has had more success with its domestic agenda in recent years. The Medicare reform bill of 2003 was widely seen as a windfall for drug companies. In addition to pursuing Medicare reform, the Bush administration has vigorously opposed the price-cutting measure of importing prescription drugs from Canada, with FDA Commissioner Lester Crawford going so far as to suggest that al-Qaeda terrorists may be planning to tamper with these Canadian pharmaceuticals (CNN.com, Aug. 12, 2004). While the Bush family's ties to giant pharmaceutical firms like Eli Lilly represent one explanation for the industry's recent legislative success (Hogshire 1999: 56-57; Robinson 2001: 48-49), a more obvious factor is the money that drug companies spend on lobbying. In 2002, the pharmaceutical industry spent $91.4 million on lobbying activities, hiring 675 different individual lobbyists-- more than the number of Congressman and nearly seven lobbyists for every Senator. And this figure doesn't even include money spent on issue ads, telemarketing, direct mail, grants to advocacy groups, and all the other ways in which the industry attempts to sway public opinion on domestic legislation (Public Citizen 2003: 7-8).

So although it has not been successful in steering every piece of legislation, the industry has used its powerful influence to avoid any kind of price regulation in the US, and compromised on increased safety measures only when some highly visible public health crisis made such reforms inevitable. Yet increasingly costly safety measures also drive out smaller firms that might have offered price competition. As such, a handful of US pharmaceutical companies continue to charge exorbitant prices and reap massive profits, free from much regulation and competition.

International Controls

The United States has a long history of leading the campaign for international anti-drug controls. By 1900, opposition to the opium trade from religious groups, temperance societies, and missionaries in the U.S. and Great Britain became increasingly vocal. But it was not until 1902, with the discovery of a large population of opium addicts in the newly- acquired Philippines, that the U.S. government took up the cause of international opium prohibition (Stares 1996: 17). Moral entrepreneurs like Bishop Charles Brent helped steer the course of early regulatory efforts. Brent's ideas meshed well with those of Teddy Roosevelt and the country's preoccupation with manifest destiny in the Pacific, and soon the U.S. had completely banned opium in the Philippines for anything other than medical and scientific uses. But the country soon realized that these measures needed to be coupled with international efforts, particularly in opium exporting nations such as China (Bewley-Taylor 1999: 19). With an addict population in the U.S. of 250,000, and a strong desire to improve relations and promote investments in China, the

United States found it had much motivation to champion international drug regulation (Bewley-Taylor 1999: 32).

The U.S. took the initiative in 1909 of sponsoring the formation of the International Opium Commission at a conference in Shanghai. Though very little was accomplished at this conference, the twelve opium exporting nations did sign a non-binding resolution to take measures towards curbing opium use and export in their own territories and possessions (Stares 1996: 17). This was the beginning of international drug regulation.

Another conference was held shortly thereafter at The Hague in 1911. With forty-two countries in attendance and more countries, especially Great Britain, in favor of regulation, the scope of the conference was widened to include morphine and cocaine. While the majority of countries were still either unsure of or directly opposed to international regulation, the final resolution committed each signatory to enact domestic legislation controlling the manufacture of medicinal opium, heroin, cocaine, and any other derivative of similar properties. This conference also succeeded in shifting the approach of international regulation from reliance on voluntary national laws to mandatory international controls supervised by international bodies. Thus the League of Nations established the Opium Advisory Committee, which later became the Opium Control Board, to monitor compliance with the terms of the Hague Convention (Stares 1996: 17-18).

U.S. pharmaceutical firms have been heavily represented on these regulatory bodies since their inception. When a 1925 convention in Geneva reconstituted the Opium

Control Board as the Permanent Central Opium Board and placed it in charge of the accounting system to which states had to submit statistics on production and consumption of drugs, its first chairman became Herbert May. May had been a successful executive in the pharmaceutical trade. Though in theory the Board was to be free from government influence, May remained in constant contact with the U.S. State Department during his entire tenure (Bewley-Taylor 1999: 33).

Manufactured drugs in Europe have always been a greater threat to the United States than opium from the Orient, and at the Geneva Conference this threat was emphasized in articles calling for the restriction of the manufacture, sale, and use of drugs to purely medicinal and scientific purposes (Taylor 1969:233-4). Along with the quotas on medical production established at Geneva, opium production was limited to state-run monopolies with the intent of gradually decreasing and finally eliminating this trade over a period of fifteen years (Stares 1996: 18).

This plan amounted to “an international cartel of European narcotic drug manufacturing" (Taylor 1969: 235). Rather than contributing to a decline in the drug trade, power had merely been consolidated between states and legitimate pharmaceutical companies. "The colonial administrations came to view the government monopolies more as profitable sources of revenue than as mechanisms to control production, the import restrictions were easily circumvented via non-signatory states, and pharmaceutical companies continued to oversupply the world market for manufactured drugs" (Stares 1996: 18).

After adopting the Geneva plan, the League of Nations invited 25 major producing, manufacturing, and consuming countries to participate in a conference that would become the Narcotics Limitation Convention of 1931. Britain requested that a preliminary conference of the government of manufacturing countries convene in order to establish an agreement on the proposed plan and on the quota allocation for national firms. The U.S. government was urged by the Council to attend. American pharmaceutical firms had been pushing for a comprehensive set of international quotas on medical drug production since the passage in the U.S. of the Import and Export Act of 1922. American firms maintained that they would never be able to effectively reduce their prices enough to compete against European firms unless the Act's import duty on raw opium, then a major ingredient in pharmaceuticals, was decreased (Taylor 1969: 235-237). However, it was the hope of these American firms that they could gain a larger share of the international drug market if their European competitors had to work under regulatory systems similar to those of the United States. These American companies believed that a large portion of European factories' profits were derived from drugs that went into illicit traffic, and so they supported stringent international regulation of pharmaceutical distribution and production (Taylor 1969: 243).

The preliminary conference in Britain focused on two main issues: the allotment of quotas among manufacturing countries and the construction of an appropriate apparatus that would guarantee a fair distribution of drugs among consuming countries. This preliminary conference was postponed for two weeks at the request of the British delegation so that attending manufacturers could arrive at an agreement regarding quota

standards. Ironically, all governments accepted these agreements except the British, who refused to accept the proposed quota arrangement because they believed the morphine quota assigned to British firms was too small (Taylor 1969: 237-38).

Regardless, the main effort at this preliminary conference was to try to draft a proposal that the United States would agree to at the Narcotics Limitation Convention. The U.S., along with China, had felt that the Geneva measures did not go far enough and, as a result, both countries had refused to sign that agreement (Stares 1996: 18; Bewley-Taylor 1999: 30-32). A representative for the American pharmaceutical industry was present at some of the preliminary conference, but he did not participate in proceedings regarding European manufacturers. When it became clear to this representative that the position of the U.S. drug industry was not going to improve unless it began producing a large amount of product for export, he left the conference (Taylor 1969: 238-9).

But a change in personnel at the U.S. State Department and the diplomatic rise of Harry Anslinger led to a more moderate attitude on the part of U.S. representatives by the time the Narcotics Limitation Convention actually took place. Anslinger, a representative at Geneva in 1925 and again at the Narcotics Convention in 1931, was determined that the U.S. become the leading force in crafting international drug policy, even if it meant some concessions at the early stages. This new attitude helped make the Convention "one of the cornerstones of the international control system. Its basic principle was the limitation of three dangerous drugs, morphine… heroin, and cocaine, strictly to amounts required for medical and scientific purposes, in addition to the restriction of the quantity of these drugs available to each country. Consequently, the convention finally succeeded

in formalizing American-initiated ideas concerning manufacturing quotas" (Bewley-Taylor 1999: 41). Many American doubts were assuaged by this new agreement, which the U.S. signed, and by 1934 some real results began to show, with worldwide opium production falling to 82 percent of its 1906 levels (Stares 1996: 18-19).

The onset of World War II severely limited both licit and illicit drug trades. As Stares put it, WWII "did more to restrict illicit traffic than any existing statue or convention" (Stares 1996: 20). The drop in supply caused an increase in falsified prescriptions and drug store thefts, but generally it forced a number of addicts into a period of involuntary abstinence (Ibid.). The war also imposed many difficulties on the drug control machinery of the League of Nations and thus provided the U.S. with an opportunity to further increase its influence on international regulation. With safety concerns and a lack of funds throwing the existence of the League's Permanent Central Opium Board and Drug Supervisory Board in jeopardy, the U.S. offered to relocate those agencies to Washington and found two American foundations to donate the necessary funds. Those boards established their headquarters in Washington in 1941, thereby affording American public opinion and Anslinger's Federal Bureau of Narcotics a much more direct influence on international drug policy (Bewley-Taylor 1999: 43-44).

After the war, the League of Nations gave way to the United Nations, and the Commission on Narcotic Drugs replaced the old Opium Advisory Committee. The U.S. had emerged as the single world power, and it saw the UN as a malleable tool for the implementation of American policy. Though subsequent events would prove this perspective somewhat naïve, the U.S. has been able to use the Commission on Narcotic

Drugs as a means to apply intergovernmental pressure, especially by linking less powerful countries' acquiescence to American-backed drug policies with the receipt of economic aid and political support (Bewley-Taylor 1999: 58-61).

Debate exists regarding how effective pharmaceutical firms have been at influencing drug control policies. Much of the literature suggests that drug firms have been successful in shaping the international drug control of narcotics (see Musto 1973; Taylor 1969.) However, during the days of the League of Nations, these controls worked to remove pharmaceutical firms from illicit trading practices (Bruun 1975: 156). This, of course, was not an issue with legitimate firms who wanted to block competitors from profiting off illicit trade (Bruun 1975:158-9). Moreover, most American firms, already subject to domestic regulation, were in competition with the less-regulated European firms that had more opportunities to profit from illicit trade (Taylor 1969: 243). This increased regulation attests, then, to the influence of American concerns on the course of international drug policy. Some companies were even in favor of creating a black list of pharmaceutical firms that trafficked in illicit drugs, but after suggesting this to the Opium Advisory Committee it was struck down by the German, Swiss, Japanese, and Portuguese delegates. However, a black list of individual dealers engaged in the illicit drug market was retained (OAC: 3d, 1923 in Bruun 1975: 226).

As international drug regulation became more and more established, and as the lines between legal purveyors of medicines and criminal dealers of drugs became more clearly codified in international law, pharmaceutical industry lobbying efforts shifted increasingly towards restricting further regulation. Before the 1960s, debate over

international regulation never mentioned addicts, addiction, or treatment (Stares 1996: 46). But all this began to change, perhaps because the industry was worried that more regulation would hinder growth, and perhaps because new pharmaceutical treatments for addiction, particularly methadone, were being developed by the industry. As such, this era would witness a marked change in industry stances towards drug policy, one that began to favor a slackening of the very controls which had previously helped consolidate and legitimize the international pharmaceutical trade.

The Pharmaceutical Industries Association (PIA) adopted a resolution at a meeting in Stockholm in June 1968 that called for legislation of drug controls to occur on a national level and that suggested the international drug market not be burdened by complex import/export rules. It was also suggested that investigations of the risks of certain drugs be conducted before unnecessarily harsh controls were established (Bruun 1975:253-4.) The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) adopted a similar resolution in May 1969, expressing concerns regarding an international draft agreement by the Narcotics Commission and arguing that it gave the commission too much power over drug control policies. Of course, the IFPMA preferred a policy of international drug control that it had crafted itself (Bruun 1975:254.)

Criticisms raised over a proposed treaty at the 29th International Congress on Alcoholism and Drug Dependence in February 1970 further exemplify the shift in drug industry rhetoric. Walter von Wartburg, legal advisor to pharmaceutical giant Hoffman-La Roche, presented a paper that argued for issues of "administrative practicability" and "medical availability" to be considered. When creating drug controls the Council needed

to be cognizant of the fact that many drugs were in "extensive medical use and administered daily to an untold number of patients all over the world." He also made a point that the differences between psychotropic and narcotic drugs should be taken into account. According to von Wartburg, psychotropic drugs did not pose "ill effects to the individual and to society" like narcotic drugs did; therefore controls regarding these two types of drug categories should be developed independently (von Wartburg 1970 in Bruun 1975:254-55.) Furthermore, von Wartburg claimed that only in rare cases did psychotropic drugs lead to physical dependency. In terms of drug dependency or abuse von Wartburg suggested that controls were not necessarily a solution and that control of narcotics "sometimes even discourages the use of narcotic drugs for medical purposes." The best drug controls, according to von Wartburg, were those that would be directed at dependence-related abuse instead of the misuse of drugs used by medical professionals (Bruun 1975: 255).

Debates regarding drug controls continued at the International Institute of the Prevention and Treatment of Drug Dependence in June 1970, a conference organized by the International Council on Alcohol and Addictions (ICAA). Representatives from the pharmaceutical industry and the U.S. medical science community expressed their discontent with the use of criminal sanctions in drug legislation as well as their concern with how controls interfered in scientific research and the freedom of medical practice. A paper entitled "Principles of Effective Drug Abuse Control" was presented at the close of the conference by a panel of speakers. It was suggested in this paper that drug laws should target the "evil-minded" rather than the weak and that they should not impede the

capacity of societies to search for therapeutic cures. Like von Wartburg, the panel called for a distinction between narcotic and non-narcotic drug controls and claimed that subjecting the latter to narcotic control standards would "constitute an irresponsible interference with established medical practice on an international scale" (Bruun 1975:255-6). Furthermore, the paper argued that an international treaty would not be able to abolish drug abuse as well as national-level controls (Bruun 1975:255-256).

In 1971, the UN Convention on Psychotropic Substances contained the first provision in the history of international drug regulation that dealt with harm reduction. Though still based on the system of control established in 1961's Single Convention, this convention called for early identification of drug problems, treatment, and rehabilitation. This is perhaps due to the fact that the convention was designed largely by drug manufacturing nations, and therefore, it represented the interests of Western pharmaceutical companies. Its final provisions favored nations that produced synthetic drugs, and its focus on harm reduction instead of demand reduction may have been another way to avoid further restriction of industry growth (Bewley-Taylor 1999: 166-167).

Thus it seems that pharmaceutical companies, American firms in particular, have been successful in influencing international regulation since its inception. The early regulatory efforts successfully drew both legal and symbolic boundaries between licit and illict drugs and drug producers. Essentially, the American model of limiting drug production to purely scientific and medical uses provided drug companies with a legal

monopoly over mind and mood altering substances. Once this monopoly was firmly in place, however, the industry began to lobby against further international regulation.

Recently, U.S. drug firms have adopted a new strategy for controlling the international pharmaceutical trade. With a lack of major domestic legislative victories in the United States since the 1960s, the U.S. research pharmaceutical industry has sought to achieve its policy objectives through international institutions of economic policy-making (Harrison 2004: 4). Once safety was no longer available as an issue to distract the public from high domestic prices, the R&D drug industry and its lobbying group, the PMA, were able to stress the threat posed by international piracy of intellectual property. Beginning in the mid 1980s, the US Congress became convinced that stronger intellectual property protection abroad was of vital importance to overall economic competitiveness (Harrison 2004: 81-83). Important legislation in the late 1980s enabled the United States Trade Representative's (USTR) office to declare economic sanctions against any country that was found to inadequately protect U.S. intellectual property (Harrison 2004: 90).

Between 1988 and 1996, this new legislation allowed the USTR to threaten sanctions against five countries for alleged lack of pharmaceutical patent protection: Brazil, Argentina, Thailand, Pakistan, and India. All eventually acquiesced to U.S. demands (Harrison 2004: 100-101). The US continues to use international trade agreements like GATT, NAFTA, and TRIPS, and international organizations like the World Trade Organization, to enforce the adoption of strict intellectual property protection in developing nations (Robinson 2001: 59). This strategic shift allows the big drug firms to consolidate market control of international markets in what amounts to "a

massive redistribution of wealth from the Third World to the First World" (Harrison 2004: 175). It also presents a win-win situation for US politicians, a majority of whom support this new strategy. These legislators can please their constituents by railing against high domestic drug prices "without alienating an industry known for its generosity around campaign time" (Harrison 2004: 176). So campaign contributions keep coming, the pharmaceutical industry gains international political-economic power, and the US continues to dominate international regulatory efforts concerning both drug safety and trade.

Drug Companies and the Third World

Multinational drug companies have long been known for their unscrupulous practices in the third world. For example, Silverman (1976) and Medawar (1979) found wider drug indications and recommend dosages in Latin American medical publications compared to those approved in the U.S. Physician's Desk Reference, and in the former there were fewer mentions of side-effects and contra-indications (cited in Braithwaite 1984: 248, 251). In addition to misleading and dangerous indications, the lower safety standards in the developing world often allow companies to simply promote harmful drugs there that they would never sell in the developed world—in 1981 in Bangladesh, for instance, one company was selling a mixture of anabolic steroids and glucose as a remedy for children with slow growth (Robinson 2001: 4).

An even more widespread type of unethical practice by multinational pharmaceutical firms in the third world is "dumping." Dumping involves moving products that would be declared unsafe in industrialized nations to parts of the world with

less stringent regulation. Types of dumping include removing a product from markets in which it has received bad publicity and selling it under a new name in another country; withdrawing application for registration of a drug that looks like it will not receive U.S. approval and selling it in the Third World instead; and exporting the ingredients of a banned drug separately only to recombine them later in another country and sell them there. Of course, the worldwide spread of manufacturing plants is perhaps the most pervasive means of dumping, as it allows pharmaceutical companies to source potentially hazardous drugs to a region from plants located in other regions with little or no drug regulation, and thereby to claim that the drugs are "approved in the country of manufacture" (Braithwaite 1984: 259).

Another kind of dumping occurs when pharmaceutical companies donate drugs to the developing world under humanitarian auspices. In addition to tax deductions and favorable publicity, companies often donate expired or overproduced drugs to avoid the hefty destruction fees that their disposal would otherwise entail (Robinson 2001: 99-105; Leavitt 2003: 49). Such was the case during the war in Bosnia and Herzegovina in the mid 1990s, where 50 to 60 percent of the 34,800 metric tons of pharmaceuticals donated were inappropriate, and included products such as Chap Stick, Preparation H, and anti-smoking inhalers (Leavitt 2003: 49).

Western pharmaceutical firms have also been known to test dangerous, high-risk drugs in developing countries, choosing these locations because as Braithwaite points out, "Peasants do not sue global corporations for injury. Informed consent regulations for drug testing do not exist in the Third World" (Braithwaite 1984: 266). In one instance, when

Pfizer went to Nigeria to test an antibiotic that had not yet gained US approval, it used 200 children as guinea pigs. The fact that these tests were poorly administered and that unresponsive patients were not switched to proven medicines left eleven children dead and others permanently disabled. A similar trial in Buenos Aires by Aventis that caused thirteen patient deaths was found, upon investigation, to have relied upon forged consent signatures and to have altered medical records to make more patients appear eligible (Leavitt 2003: 50-51).

Yet the most controversial involvement of the pharmaceutical industry in the Third World has to do with HIV/AIDS in Africa. In 2004, 39 million people were living with the virus worldwide, and more than 25 million of those lived in sub-Saharan Africa. More than 12 million children in the region have lost one or both parents to AIDS, and in some sub-Saharan countries one in three adults is infected (UNAIDS/WHO 2004, cited in Gillespie and Kadiyala 2005: 1). While the virus spread to epidemic proportions and ravaged the continent's social and economic fabric, the major drug companies were at best slow to act and, at worst, downright hostile to efforts to alleviate the crisis. It is here that inherent contradictions between the R&D pharmaceutical industry's humanitarian concerns and its need to profit really come to light. The cost of a year's supply of patent-protected AIDS drugs in the United States is roughly $12,000, but in countries like South Africa the average annual income is less than $3,000. When South Africa passed legislation to allow the production of low-cost generic versions of patented AIDS medications, industry lobbying groups pressured the Clinton administration into threatening South Africa and other countries with trade sanctions if they followed through

on their plans. In 1997, thirty nine large international drug companies even filed suit against South Africa over this issue, although the suit proved to be such a public relations disaster that it was withdrawn four years later (Leavitt 2003: 50, 262). It wasn't until 2000 that bad press and public pressure forced some concessions toward the AIDS epidemic on the part of "Big Pharma," with some companies donating large quantities of medicine and others dramatically lowering prices for sub-Saharan Africa. Glaxo Wellcome, for one, lowered the cost of its AIDS drug Combavir from $16.50 per day—its U.S. price—to $2 a day in Africa. Of course, the fact that this drastic price-break was even feasible suggests that the company had initially been operating at an 800 percent markup (Robinson 2001: 2, 95-98). But price breaks and donations are not permanent solutions, and the bigger issue remains the inability of a system based on increasingly long patent life and increasingly stringent international patent protection to adequately address epidemics and health crises, especially in the poorest parts of the world.

The unethical practices of pharmaceutical companies in the Third World attest to the limits of existing international drug policies, and perhaps, to the impossibility of adequately policing these companies in an increasingly global economy. On the other hand, the pharmaceutical industry continues lobbying for international consensus on and enforcement of drug patents, while using the same kinds of loopholes in and disparities between the laws of countries to outsource drug production, test potentially hazardous drugs, and dump unwanted or unsafe products. In the end, the existence of such legal and ethical transgressions is almost necessarily correlated with the hegemonic control that these companies exercise over drug regulation and trade in the first place. As such, the

presence of transnational pharmaceutical companies in the developing world is likely to remain problematic for the foreseeable future.

Advertising and Drug Promotion

Free from the legal barriers and social stigmas facing those who deal in "recreational" drugs, the producers of medical drugs spend billions promoting their products to physicians and, in the U.S., directly to consumers. Drug companies are increasingly able to influence not only the treatment of diseases but also their very diagnoses. Using a host of promotional techniques, and buttressed by gigantic budgets, the pharmaceutical industry exercises tremendous control over our perceptions of health and illness, and the role that drugs play in achieving and maintaining physical and mental well-being.

According to industry estimates, drug companies spent $19.1 billion on promotional activities in 2001 (GAO 2002: 3). While this figure is smaller than the estimated $30.3 billion spent by these companies on research and development, other studies have concluded that the pharmaceutical industry actually spends more on advertising than on research and development. Bian (1997) states that in 1991 drug companies spent 10 billion on promotion and only 9 billion for research. Furthermore, she argues that actual costs of promotion and advertising may be hidden in other accounting categories like "other," "cost of sales," and "miscellaneous" (Bian 1997: 30-31). According to Public Citizen (2003), in 2002 Fortune 500 drug companies channeled

30.8 percent of their revenues into marketing and administration, compared with 14 percent of revenues spent on research and development. Furthermore, pharmaceutical firms such as Pfizer and Johnson & Johnson spent more on ads in 2002 than advertising giants like Coca-Cola and McDonalds (Public Citizen 2003: 6). Clearly, marketing and promotion are top priorities for today's large pharmaceutical companies, with advertising budgets comparable to and in some cases exceeding those allocated for the actual discovery of new drugs.

The drug industry focuses much of its promotional efforts on physicians. As the sole decision-making body determining the consumption of prescription drugs for all of their patients, doctors are an obvious target. In 2001, despite the growing importance of direct-to-consumer (DTC) advertising, promotion to physicians accounted for more than 80 percent of the industry's promotional spending (GAO 2002: 3). The pharmaceutical industry reaches physicians through both advertisements in medical journals and personal visits made by drug representatives or "detail men" who promote new medicines and particular brands.

Medical journals have long been heavily dependent for revenue upon drug advertising (Silverman 1974: 56-69). These medical journal ads differ little in method and substance from other kinds of consumer advertisements. "They play upon the fears and hopes any human feels, while paying particular attention to the anxieties a doctor gets from standing on his pedestal all day" (Hogshire 1999: 30), and they are effective. Doctors are faced with dozens of virtually identical drugs to choose from, and their pharmacological training occurs early in medical school. Thus, with little time to evaluate

new drugs and no formal training about those drugs, doctors rely heavily on the studies and advertisements in medical journals (Leavitt 2003: 45). Another source of information for physicians, the Physicians' Drug Reference (PDR), is simply a giant advertising flyer for brand-name companies who actually pay to have their products listed (Hogshire 1999: 155). For many years physicians were unaware of this fact and believed that the products in the PDR were selected or screened by a professional review board (Silverman 1974: 75).

Journals that are dependent on pharmaceutical advertising money are likely to slant their editorial stances. For instance, the *Journal of the American Medical Association* (JAMA) did not condone prescribing generic drugs and it also took a stand against the FDA's attempts to regulate misleading advertising and warning labels on drug products in the 1970s (Silverman 1974:72). Furthermore, these journals very frequently publish the results of studies that are funded by drug companies or by researchers with other financial ties to those companies, often without disclosing such information. In 1984 the *New England Journal of Medicine* (NEJM) became the first major medical journal with a policy to prevent such conflicts of interest. Yet it relied on researchers themselves to disclose their corporate ties, and in the late 1990s the Los Angeles Times found that many NEJM articles were still being written by researchers who had failed to disclose their financial links to drug companies (Robinson 2001: 131-132). Thus even the clinical studies in academic journals, on which so many physicians rely, are often subject to undue industry influence.

To compliment their influence in the world of medical journals, drug companies employ an army of "drug reps" who visit doctors face-to-face, promoting a given company's newest drugs and treatments. Individual drug companies may employ as many as one rep for every eight physicians in the country. These drug reps are highly skilled at finding out particular doctors' prescribing habits, either by chatting up local pharmacists or through the use of information technology. Some drug companies donate computers to doctors' offices that will keep track of such information (Hogshire 1999: 24). They also keep detailed dossiers on the physicians they visit, tracking personal details and conversations in the hopes of building familiarity and rapport (Robinson 2001: 269; Hogshire 1999: 25). Representatives leave trails of gifts emblazoned with the names of the drugs they are pitching in every office they visit. More than that, they and the companies they represent frequently offer tickets to sporting events, pay for dinners at fancy restaurants, sponsor trips to lectures or symposia at expensive hotel resorts, and even kick back frequent flyer miles or money to doctors who prescribe their drugs (Greider 2003: 70-71; Leavitt 2003: 46-48; Robinson 2001: 275-279). And once again, these practices seem to work-- a recent study in JAMA concluded that doctors who regularly saw drug reps were associated with higher prescription costs, decreased prescription of generic drugs, rapid adoption of new drugs, and "nonrational" prescribing habits (Greider 2003: 73; Robinson 2001: 263).

While drug companies have always been free to advertise their over-the-counter medicines to any and all, the most important industry development in the last decade has been the growing importance of direct-to-consumer advertising for prescription drugs.

The FDA decided to lift its ban on direct-to-consumer advertising for prescription drugs in 1985 (Hogshire 1999: 31), but such advertising increased exponentially after a 1997 FDA rule made it much easier for drug companies to do so. Spending on consumer ads surged from $266 million in 1994 to $2.7 billion in 2001 (GAO 2002: 2; Greider 2003: 88). Drug companies are now banking on the idea that patients can persuade their doctors to write prescriptions for specific drugs that they want, and so far the drug companies have been correct. Between 1999 and 2000, prescriptions for the fifty most heavily advertised drugs rose at six times the rate of all other drugs (GAO 2002: 3; Greider 2003: 89; Leavitt 2003: 43). Thirty percent of consumers in a 2001 survey reported having talked with their doctor about a drug they'd seen advertised, and nearly half came away from the visit with a prescription for the drug (Greider 2003: 88-89). And in one study, 84 percent of doctors surveyed said they would consider prescribing a drug requested by a patient (Leavitt 2003: 43-44). As Hogshire points out, "On a business level, the doctor knows that the patient is ultimately his customer… Turn away the patient just because you don't want to give him a lousy pill and no doubt (you will) lose the steady income the patient's follow-up visits will bring in" (Hogshire 1999: 32). Doctors are seeing more and more patients who simply want to inquire about a drug for which they have seen an advertisement, and they are finding that an increasing number of these patients will consider switching doctors if they don't get the drug they want (Robinson 2001: 232, 237). It seems that direct-to-consumer advertising simultaneously increases doctors' income, by increasing their number of patients, and erodes a measure of their authority, by encouraging the public to make its own decisions about drugs.

But many drug advertisements are far from educational. Drug ads aimed at consumers frequently exaggerate benefits, minimize side effects and risks, and make unapproved claims. What's more, alternative treatments or lifestyle changes that might improve the condition are never mentioned (Leavitt 2003: 44). The FDA is supposed to oversee these advertisements and to halt the dissemination of false ads, but according to the General Accounting Office, its program has some serious limitations. The FDA has not been able to prevent some companies from repeatedly disseminating misleading advertisements, and some companies continually fail to submit new ads for FDA review in a timely fashion (GAO 2002: 4). Furthermore, consumer advertising has long been designed to elicit emotional responses rather than reasoned analyses (Ewen 1996), and the visual style and emotional appeal of DTC drug ads exist somewhat outside of the FDA's domain. Images such as "a flower opening, an old person frolicking like a colt, people of all colors linking arms" or "an apparently healthy middle-aged woman suddenly dropping from the frame" (Greider 2003: 87) have definite implications above and beyond an ad's direct textual content.

One of the earliest direct-to-consumer ad campaigns was run for Eli Lilly's Orthaflex, an anti-inflammatory that did not significantly differ from other arthritis drugs on the market. Its ads, however, implied that it could reverse the process of arthritis, and within six weeks more than half a million people were taking the drug. Several deaths resulted from the drug's side-effects, and it was taken off the market within three months of its release (Bian 1997: 36-37). An ad for Merck's drug Fosamax implied that women over 50 should take the drug to avoid broken bones caused by osteoporosis, despite the

fact that most osteoporotic fractures occur after age 75 and that the effects on a fifty year old woman of taking Fosamax for 25 years were not known (Robinson 2001: 243). Eli Lilly also sponsored a 1993 promotional campaign that reached 93 percent of American adults. It was designed to encourage the public to seek medical help for depression, but this public service campaign was little more than a means to recruit new patients for Prozac, the world's best-selling antidepressant and a product of Eli Lilly (Bian 1997: 36-37). Such "help-seeking" advertisements that do not mention drugs by name are not even regulated by the FDA (GAO 2002: 8), yet they clearly operate in order to boost drug sales.

Advertising like Lilly's depression campaign is also an example of the process of medicalization, "the implication… that a normal function of the body should be treated" (Bian 1997: 35). Pre-Menstrual Syndrome (PMS), childbirth, menopause, stress, anxiety disorders, and Attention Deficit Disorder (ADD) are all examples of medicalized conditions that can now be treated by a host of pharmaceutical products. People who were formerly labeled as shy are now sufferers of Social Anxiety Disorder (SAD), and are being prescribed blockbuster drugs like Paxil, Zoloft, Celexa, and Prozac (Gammage 2004). "Medicalization creates a market for its products by labeling the condition as something that needs treatment even when the condition is a normal part of life and even though treating the condition with powerful drugs often causes more severe side effects than those of the condition itself" (Bian 1997: 35). Of course, proponents of these drugs argue that disorders like SAD are much more severe than simple shyness, often preventing the afflicted from leading anything resembling normal lives. Even so,

cognitive behavior therapy has been found to work much better than medications in these situations (Gammage 2004: M4), though one would never know it from the torrent of advertising promoting pharmaceutical solutions to anxiety disorders. Furthermore, conditions such as shyness are only seen as problematic in certain very specific social and historical contexts, and are often tied to prevailing (and fleeting) expectations about gender roles (McDaniel 2001). As such, the continued medicalization of these conditions represents the pharmaceutical industry's increased hegemony over popular and professional perceptions of what constitutes "normal" behavior.

The Placebo Effect

In many clinical pharmaceutical trials, new drugs are tested against placebos, substances with no specific pharmacological activity for the conditions being treated. In these studies, patients are never told whether they are receiving a placebo or an active drug, and if as many patients improve by taking the placebo as do with the active drug, that drug is thought to be ineffective. Interestingly enough, between 35 and 75 percent of patients receiving only placebo will typically benefit during these studies (Leavitt 2003: 254; Talbot 2000: 4). Factors that have been found to influence placebo effectiveness include the shape, size, and color of the pill being taken, the perceived monetary costs of the medicine, and the ways in which doctors describe that medicine and its effects (Hogshire 1999: 44). In one study of 579 patients with sore throats randomly assigned to receive either antibiotics or no antibiotics, about two thirds of each group got better within five days (Leavitt 2003: 256). Similarly, an article that reviewed the results of 19 clinical trials of anti-depressant medication involving 2,318 patients found that inactive

placebos produced improvement that was 75 percent of the effect of the active drug (Kirsch and Sapirstein 1998). Clearly, more than simple chemical reactions are at work in the practice of pharmacy.

Medical explanations for the placebo effect vary. One is classical conditioning: those who are used to experiencing relief in medical settings or by ingesting a pill have been primed to do the same again. Another is that placebos stimulate the brain to release endorphins, which relieve pain. A third explanation is that taking a placebo relieves stress, which is known to aggravate the symptoms of many medical conditions (Talbot 2000: 13). But whatever the reasons, placebos do more than simply placate those who are suffering from imagined or psychosomatic ailments—they have been shown in numerous studies to produce actual physiological changes in patients (Talbot 2000: 7).

Placebos are nothing more than symbols, chemically negligible but imbued with the power of patients' expectations. That these symbols often work as well as actual medicine reminds us that the construction of meaning can have actual physiological consequences—an insight which sheds new light on pharmaceuticals as well. The prevalence of placebo effects shows that the social and legal status bestowed on pharmaceuticals affects not only the industry's political, economic, and rhetorical power, but its actual power to heal as well. From this perspective, the increasing importance of medical drugs in the overall practice of health care and the ubiquity of pharmaceuticals in everyday life would seem to contribute to their effectiveness. As such, the control of public opinion about legal, medical drugs—as well as any illegal alternatives—is absolutely essential to the continued success of the international pharmaceutical industry.

Conclusion

Today, a small number of drug companies control legal access to most of the world's mind and mood altering substances, garnering gigantic profits from this monopoly in the process. Over the past century these companies have established themselves as the only licit, legitimate option for drugs thanks to a series of interconnected economic, political, and rhetorical maneuvers. They are now so firmly entrenched that even a host of illegal or unethical practices have failed to call into question, in both international law and public parlance, the status of these companies and the status of the many natural substances that the pharmaceutical industry has helped suppress.

Originally, many legitimate drug companies were as involved in the underground international drug trade as any organized crime racket. So too were many states that sanctioned, taxed, and in some cases monopolized the trade in illicit drugs. But American companies faced strict regulation at home, and thus encouraged the proliferation of international regulation as a way to better compete against foreign drug firms. Furthermore, the designation of medical and scientific uses as legitimate and legal, and recreational use as illegitimate and illegal, cemented the place of pharmaceutical companies by providing a huge new barrier to purveyors of non-pharmaceutical drugs—the threat of state-sanctioned violence and arrest.

The economic results of this monopoly are incredibly high prices for drugs and huge profit margins for drug companies, necessarily calling into question the claims of the industry that it is primarily concerned with helping people. The political results are

the steering of regulation away from domestic price fixing and the industry's many misdeeds in the third world, and instead a focus in international law on attacking and arresting those defined as criminals for producing illegal drugs such as heroin, cocaine, and cannabis. Finally, the semiotic results are an entrenched classificatory system in which traditional and natural substances are generally regarded as recreational, illegal, and evil, while synthetic pharmaceuticals are considered medical, legal, and good, and this despite much evidence to the contrary. Thus the western pharmaceutical industry continues to employ not only economic monopoly but also political and rhetorical hegemony.

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