

# Regulation and control of the pharmaceutical industry

Business



In the United States of America, five million people over the age of fifty-five say that they have to choose between prescription drugs and food (Rovner). If a drug is \$2, 000 a year, and a person is on three of them, that is \$6, 000 dollars a year on prescription medication alone, and the prices are still rising. Prescription drug prices have risen at three times the rate of inflation for the past (Rovner). In 2002, drug companies made the largest profits of any industry (Hatch). Many individuals are on more than three drugs, and few can afford all of the medications that they need.

The costs of research and development are substantial, but at the moment they are far outweighed by the profits of the drug companies. The advertising used by drug companies is misleading, and allows them to exploit those who buy drugs. These problems would be much less serious though, if there were other drugs on the market to combat this. However, this is not possible, because of a distortion of the patent laws. Some patent laws are necessary in order to reward innovation, however the current laws provide too much protection to the large pharmaceuticals. To combat exorbitant drug prices, the pharmaceutical industry should face much more stringent regulations on their clinical trials, advertising, and patents.

Research is the first stage of finding new drugs. This happens in several phases. First a disease is taken into a lab and studied by researchers. This part is relatively inexpensive, although it can take a long time, up to twenty years (Angell 22). It is generally carried out either by government labs or universities.

The researchers need to understand the disease completely before they can try to target it with medication. The next stage happens when the weaknesses of the disease are clearly understood. The researchers go into their banks of molecules, and try to find a drug which will target the disease and cure it or prevent its spread. Many substances, are tried and then found to be unsuccessful. These add to the price of the process of drug development. The unsuitable matches which have been rejected go back into the pharmaceutical companies' records, as they are potentially useful against other diseases.

Once a match is found, research for the drug is over. After this, testing occurs. Testing is the most expensive part of the entire process of drug development. There are three stages in most clinical trials required by the Federal Drug Agency (FDA). The first stage of the drug is tested on humans who do not have the disease which is being targeted. Its goal is to see how normal people react to the medication.

The second stage has a small group of people with the disease to see if the drug actually provides treatment. The third stage is with a larger group of people who have the disease in order to see if it is safe for a wider audience. If all of these are passed, the drug appears before the FDA. At that point the FDA can require a fourth set of trials, if they are not satisfied with the results from the first three. Some drug companies also choose to do stage four clinical testing for advertising purposes. The entire process of clinical trials are very expensive as a whole.

The reason for this is the lack of people willing to try out untested drugs. The ones who are desperate enough to do it require a lot of money for it. It is not uncommon for a company to have pay a single person \$75, 000 to participate in one study, and if the guinea pigs (people tested on) decide that they want more money, the company will generally have to give it to them (Elliott). According to one tester, “ guinea pigging has become a job” (qtd. in Elliot). However, delays occur in this stage, even for companies who have the money to pay testers.

The true expenses are hard to verify however, because almost all drugs receive government funding in the first stages of the process. The National Institute of Health (NIH) pays for most of the research. However, this does not meant that the government can keep the price of the developed drug down. The drug patent still belongs to the drug companies who did the actual research. Even when a drug is developed with tax dollars, a company may patent a drug for their own benefit.

This essentially forces the consumers of the drug to pay for it twice: once for its actual development and once for the drug when they buy it to take. For example, in the case of the drug Taxonal, the NIH provided thirty-two million dollars for the research and development (Brody 76). Nevertheless, the drug company involved was still the one to patent the drug, and the one who made most of the profits. Research and development of new drugs is cited by most drug companies as a major expenditure. The average drug costs around 213 million dollars to bring to market in research and development

alone (Angell 65). This is a hefty sum, but it is more than recovered by the pharmaceutical companies in profits.

The average profit margin of a pharmaceutical company is 15.5% (Rovner). While it is one of the factors in the pricing of drugs, the costs of research and development alone cannot account for the high costs of prescription drugs. Although the actual development of drugs costs drug companies a lot, the majority of money spent by pharmaceutical companies is used on advertising. Most phase four testing is done for advertising purpose and is used in highly misleading ways.

A common tactic is to perform tests on patients with the new drug and an older drug, which giving twice as much of the new drug than they do of the older drug. This makes their drug look twice as effective as it actually is. This is not regulated at all, which is why pharmaceutical companies can use these deceptive tactics. This causes consumers to continue to spend more on brand-name drugs when generics are just as effective (Marsa). Another way in which drug companies abuse advertising is the use of “me-too” drugs. Me-too drugs are drugs which are very similar to a previous drug, but a few molecules are manipulated.

These are then covered under a new patent, and marketed ferociously to try to transition the people who used to use the old drug onto the new.

Companies try to do this before generics appear and cut into their profits.

One of the best-known me-too drugs is Claritin. It replaced the previous drugs on the market for allergies but was actually less effective. This was achieved through 322 million dollars worth of advertising (Hall). However,

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the pharmaceutical companies do not only market their products to customers.

They also spend a great deal of money advertising to people in the medical profession who prescribe their drugs. Doctors benefit greatly from the current arrangement. They are often invited to “informational conferences” at exotic locations, which they are paid to attend. They then get to sit and listen to a one or two hour speech promoting a specific drug before flying home again. This leads to a clear conflict of interest in which doctors are rewarded by pharmaceutical companies for prescribing their products.

This raises the price for the consumer because it is in the doctor’s best interest to prescribe the more expensive drugs. Patent laws are another major factor in high drug prices. The law states that the basic time span for a drug patent to be in effect is seven years. Drug companies can stretch that as far as twenty years in some cases, without even having to resort to the advertising of a me-too drug. There are a wide variety of ways to do this.

If a drug must be tested on children, it extends the patent six months. If a corporation raises a lawsuit to challenge that patent, then a company gets another year for the assumed time that it took to settle the dispute. Often this company is a dummy corporation set up by the larger drug company specifically to challenge the patent, and thus extend it. This tactic was used very effectively by the AstraZeneca company when it was trying to extend the patents on its first drug, Prilosec, with its second me-too drug, Nexium (Angell, 80). All of these strategies allow pharmaceutical companies to be the sole distributor and control the prices for a longer period of time, thus

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increasing their profits. The patent time is crucial, because as soon as a drug comes out from under patent, another company can start to make generics of it.

When that happens, the price can drop down to as low as 20% of its original value (Angell 9). There is some debate as to the actual effectiveness of generics as opposed to brand name drugs, but for the most part, they do exactly the same thing as the original drug for a fraction of the price. Most generic drug companies make a much smaller profit than the companies which create patent drugs. That is because they sell drugs at a lower price with is much better for the consumer. The only reason for people to take brand-name drugs as opposed to generics is because they were recommended by their doctors. This ties back to the issue of advertising because doctors may recommend a more expensive brand name drug over a similar, cheaper generic because they have been paid by the drug company.

The main motivation of the pharmaceutical industry is profit. If the problems with the drug industry are to be fixed, first the loopholes which allow the drug industry to sit and do nothing, and yet retain all the financial benefits as if they were making new progress must be closed. However, because of the nature of drugs, this is difficult. If a pharmaceutical company wants to tell doctors more about their product, they should have to show the presentation in the doctor's office, without paying the doctor for it or handing out free gifts. There are many issues with the current patent laws, however there are also some benefits. The protection of intellectual property is important if a

company is to make money from its development of potentially lifesaving drugs, and thus provide an incentive to come up with new products.

The problem is that this system can be abused too easily. The me-too drugs have made patent laws into a protection which discourages the pharmaceutical industry from innovation. They reward the low-risk and still profitable development of drugs which are no improvement over their predecessors. At the same time, they make people pay substantially more. The process of research and development of new drugs is lengthy and very expensive. Testers must be paid, and the development itself is very costly.

However, the process alone cannot justify the prices which the drug companies attach to sometimes lifesaving medical care. The patent laws are distorted past recognition, and the obstacles involved in bringing generics to market is causing a healthcare crisis which cannot be ignored. The law must stop protecting large drug companies at the expense of consumers, and the misleading advertising which pharmaceutical companies often employ must be more closely regulated. Works Cited: Angell, Marcia. *The Truth About the Drug Companies : How They Deceive Us and What to do About It*. New York: Random House, 2004.

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