

Pharmaceutical Drug Pricing and Ethics:
Identification of the Problem and the Exploration of Solutions

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21W.746: Humanistic Perspectives on Medicine

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12 May 2005

The pharmaceutical industry is facing many key issues today that have a huge impact on millions of people worldwide. The most prominent issue being debated, and that which is the focus of my paper, is the problem of high pharmaceutical drug pricing. This paper first establishes the existence of this problem of high drug prices by presenting evidence such as the marked increase in American health expenditure as a percentage of GDP (Figure 1) and the increase in pharmaceutical spending as a percentage of total health spending (Figure 2). The paper then proceeds to describe the complications this problem presents to the global community. These complications include, but are not limited to, problems resulting from people who are just not capable of paying the steep prices for prescription drugs. These people often resort to trading off their medication for food, apartment rent, or clothes. Other people are capable of buying some prescription drugs, but do not take them as often as they should because of the financial burden this high cost has on their life. Finally, the paper explores several solutions to the problem, and explains the benefits and drawbacks of the proposed solutions. Such proposed solutions include the weakening of patent protection, drug importation from neighboring countries, pharmaceutical price discrimination, the MEND Act, the pressuring of other nations to raise the prices of their drugs, the implementation of price controls, and the adoption of European drug pricing models. While I analyze the effectiveness of these possible solutions, I believe the true solution to this problem can only be attained through a combination of some of these solutions. This final solution must provide sufficient economic incentives for drug research and development, limit marketing costs, and provide drugs at affordable prices. Ethical questions exist at all three levels of this paper, and are addressed accordingly. For example, I question the ethicality of various issues such as taking advantage of physically vulnerable people, developing “me too” drugs, implementing a two-

tier pricing system, and exclusively providing cheap drugs to governments of developing nations.

My line of reasoning proceeds along pragmatic and religious lines. I am a consequentialist who uses cost-benefit analyses to determine the ethicality of various issues, and believes the government should fulfill the role of furnishing goods that improve social well being. However, I also follow transcendental ethical principles that I acquired from my Muslim heritage and believe there are certain normative rules that are universal and are inherently right or wrong. I analyze the ethicality of each issue on an individual basis by taking into account transcendental moral principles and considering the costs and benefits of that issue relative to pharmaceutical companies, governments, and most importantly, the people being affected.

Since pharmaceutical companies provide a great service to humanity by developing drugs for many diseases, some people expect them to adhere to the strictest moral guidelines. Others believe that pharmaceutical companies, like other businesses, have one ultimate goal in mind—to make money. I strongly disagree with the notion that since the only social responsibility of business is to increase profits, then charging people whatever they are willing to pay is acceptable. I disagree with this notion because pharmaceutical companies are intrinsically different from other normal businesses, and therefore have different responsibilities. Pharmaceutical companies are intrinsically different from most other businesses because many of their products are necessary for survival, which makes them providers of indispensable healthcare. The main responsibility of pharmaceutical companies is to combat disease by developing drugs. This should be their main concern, and any other

secondary responsibilities, such as maximization of profits, should not conflict with the main responsibility. Therefore, since maximizing profits by charging high prices makes it harder for people to treat their disease, pharmaceutical companies should refrain from charging people excessively high prices for drugs if they are making large profits.

The recent controversy over high pharmaceutical drug prices stems from the fact that drug prices have been steadily increasing in the U.S. In Figure 1, a graph shows how American health expenditure as a percentage of GDP has been steadily increasing over the past 30 years¹. High pharmaceutical drug spending is not a problem confined to the United States. People from around the world have specifically been spending more on pharmaceutical drugs than they ever had in the past (See Figure 2)².

The problem of high pharmaceutical drug prices is a very real one that is affecting millions of Americans. There are more than 45 million Americans, including 11 million children, who are currently un-insured³. However, high prescription drug prices are not just a problem for the poor and uninsured. Many middle-class, medically insured Americans are also suffering from the high drug prices. As the economy is struggling, many health insurance companies are decreasing the benefits of its members, thereby causing them to pay more for their drugs. In addition, many employers are even completely dropping medical benefits.⁴ Many people just are not capable of paying the steep prices for many of these prescription

¹ A Graph Showing Health Expenditure as a Percentage of GDP, <<http://www.pharmaceutical-technology.com/projects/grafon/grafon4.html>> (18 April 2005).

² Pharmaceutical Spending Graph, <http://www.oecdobserver.org/news/fullstory.php/aid/1170/pharmaceutical_spending_graph_large.html> (10 April 2005).

³ "Mr. Bush's Costly Silence on Drug Prices," *Chattanooga Times Free Press*, 31 January 2005, sec. B, p. 6.

⁴ Marcia Angell, M.D., *The Truth About the Drug Companies* (New York: Random House, 2004).

drugs. These people often resort to trading off their medication for food, apartment rent, or clothes. Other people buy the prescription drug, but do not take it as often as they should. This presents a huge problem for millions of Americans who are financially struggling to stay healthy.

Since prescription drugs are mainly a “need” rather than a “want”, customers are usually willing to pay any price to purchase their drugs. In the United States, there are no governmental price controls for prescription drugs and therefore pharmaceutical companies are free to charge whatever they want for their drugs. Pharmaceutical companies in the U.S. are taking advantage of their position of power, and are charging very high prices for their drugs. Ethical principles in the Qur’an (the Muslim holy book) forbid people from deceiving and harming people because it is inherently wrong to do so. This unique background has led me to believe that there are certain moral principles and ethical guidelines that people and companies should always abide by. These are normative rules that hold in all circumstances. One of those rules is the fact that it is unethical to take advantage of physically vulnerable people just because you have the power to do so. Therefore, taking advantage of sick people by charging very high drug prices is immoral, and pharmaceutical companies should refrain from this practice.

Pharmaceutical companies incur very high costs to develop a drug. For example, Pfizer claims to have spent more than \$700 million to develop its cholesterol-lowering drug, Lipitor⁵. In order to offset these very high research and development costs, pharmaceutical

⁵Investor Releases, <http://www.pfizer.com/are/investors_releases/2004pr/mn_2004_1130.cfm> (10 April 2005).

companies sell drugs at a price that is intended to sell the most amount of drugs at the highest price the market can bear⁶. In many cases, successful drugs garner hundreds of millions of dollars in profits for the pharmaceutical company. Last year, the average pharmaceutical company “earned \$36 million more than was needed to pay off R&D costs for each new drug. The excess profit was claimed to represent about 4.3% of the price of each drug.”⁷ However, in some cases, the pharmaceutical company fails to make enough revenue to cover the costs of producing a drug. In response to recent drug price hikes, Pfizer said it had to raise its prescription drug prices because it “is not immune to the costs of doing business.”⁸ I believe that Pfizer is deceiving the public when issuing such misleading comments. It is hypocritical to justify high drug prices by insinuating that the reason for high drug prices is high research costs when your company is making millions of dollars in profit. The aforementioned statement by a Pfizer representative came right after Pfizer reported in its annual report that its profits quadrupled in the last quarter⁹.

I believe that the cost estimates given by many pharmaceutical companies are inaccurate and misleading in part because a lot of the spending in pharmaceutical companies is squandered on the development of “me too” drugs that are not truly innovative. Pharmaceutical companies commonly change an existing drug slightly and then spend a large amount of marketing expenses to show people how the new drug is better even though the old one is just as effective¹⁰. In Figure 3 we can see that over the past 5 years, the Food and Drug

⁶Eduardo Porter, “Importing Less Expensive Drugs Not Seen as Cure for U.S. Woes,” The New York Times, 16 October 2004, sec. A, p. 1.

⁷ Ann-Marie McIntyre, Key Issues in the Pharmaceutical Industry (New York: Wiley, 1999).

⁸ “Mr. Bush’s Costly Silence on Drug Prices,” Chattanooga Times Free Press, 31 January 2005, sec. B, p. 6.

⁹ Pfizer Inc. 2004 Financial Report

¹⁰ Porter, “Importing Less Expensive Drugs Not Seen as Cure for U.S. Woes”

Administration (FDA) approved 427 new drugs. 80 out of 427 drugs (23%) were innovative, while the rest (77%) were “me too” drugs, which are classified as being no better than drugs already on the market to treat the same condition¹¹. I believe this practice of developing “me too” drugs is unethical because the costs outweigh the benefits. The only benefit derived from the development of “me too” drugs is the profitability of the pharmaceutical company. However, the costs are too great to justify the development of these drugs. First, if pharmaceutical companies spend a lot of money on developing “me too” drugs and their marketing campaigns, then they are deceiving their customers who actually think the new drugs are innovative and expensive to produce. Second, instead of spending money on trying to find cures for new diseases, pharmaceutical companies are wasting their money on drugs that offer little advantage to customers, thus not fulfilling their main responsibility of providing cures for diseases.

A major part of the humanitarian relief effort in developing nations is the provision of pharmaceutical drugs to people afflicted with disease. I believe it is morally irresponsible to charge both developed and developing nations the same price for drugs because there is a huge disparity in the wealth and standard of living of these two types of nations. I have arrived at this conclusion because I believe in the normative rule that all people should be treated equally. Therefore, it is unfair to charge the same price to different people with widely different means. Unsurprisingly, many pharmaceutical companies agree, and have implemented a two-tier pricing system. Under this system, developing nations received drugs from multinational pharmaceutical companies at lower prices than their developed

¹¹ CDER NDAs Approved in Calendar Years 1990-2004 by Therapeutic Potential and Chemical Type, <<http://www.fda.gov/cder/rdmt/pstable.htm>> (18 April 2005).

counterparts¹². I believe the two-tier pricing system is a fair compromise because people in most developing nations have very low income, and cannot afford to pay the high prices Americans pay for drugs. In addition, disease is more prevalent in many developing nations due to poor sanitation, inadequate healthcare systems, and lack of medications. Even though pharmaceutical companies might be benefiting from this two-tier pricing system by gaining sympathy from customers, they are nonetheless benefiting humanity by financially assisting poor, sick people in developing nations. Therefore, the implementation of the two-tier pricing system helps pharmaceutical companies fulfill their main responsibility of alleviating disease by providing drugs to people with diseases.

Many pharmaceutical companies have recently rescinded their earlier practice of offering lower prices for both governments of poor nations and humanitarian organizations, and are now only offering low prices to the governments of poor nations. By only offering the lowest prices to state-associated AIDS treatment facilities, the pharmaceutical drug companies have put these life-saving drugs even further out of reach for all other providers of care for disease-stricken people in developing nations¹³. I believe pharmaceutical companies should not exclusively provide cheaper drugs to the governments of developing nations. Following the Kantian lines of reasoning, I believe pharmaceutical companies have a moral obligation and responsibility to provide drugs to disease-stricken peoples because if they do not help these people, widespread disease and famine will spread. Since many developing nations do not have the necessary infrastructure and resources to efficiently provide medicines to the sick, often times the best way to reach the disease-stricken areas is through non-governmental

¹² Milton Silverman, et.al. Prescriptions for Death: The Drugging of the Third World (Berkeley: University of California Press, 1982).

¹³ "AIDS NGOs Protest 40% Hikes in Drug Prices," PR Newswire Europe. 12 October 2004.

humanitarian relief organizations. Therefore, by providing cheap drugs only to governments of developing nations while abandoning NGOs, pharmaceutical companies become indirectly responsible for the death of many poor, disease-stricken peoples.

While I do not oppose capitalism, I believe capitalism by itself is not enough. I think governments have social responsibilities that must be taken care of even if the country is mainly capitalistic. For example, just as defending one's country is an obligation, I believe providing healthcare to the sick is also an obligation for any country. Although pharmaceutical companies should do everything they can to provide pharmaceutical drugs to the sick, I also believe the governments of wealthy, developed nations should also assist this effort. It is unfair to let the pharmaceutical companies bear the brunt of the costs of all of these humanitarian efforts, and carry the large burden of providing drugs to sick people. It is the government's duty and obligation to serve its citizens by ensuring they are provided with decent healthcare. Just as pharmaceutical companies have a responsibility to provide drugs for many diseases, governments of nations have a moral responsibility to take care of their citizens.

The National Institutes of Health (NIH) proposed a solution to the problem of high pharmaceutical drugs and drug inaccessibility in the early 1990s. This announcement stated that those in need of new drugs developed in part by government funding should "not be denied access because of the price, and that pricing responsive to the health and safety needs of the public is the appropriate way of ensuring that access."¹⁴ However, in 1995, the head of

¹⁴ Baruch Brody, "Public Goods and Fair Prices: Balancing Technological Innovation with Social Well-Being," The Hastings Center Report, *Sociological Abstracts* 26, no. 2 (1996): 5-12.

the NIH eliminated this pricing clause, stressing its dangers to the development of new products.¹⁵ I believe this pricing clause was a great regulatory measure to limit the negative consequences of high drug prices because it was not consistent with the capitalist model and had socialist connotations in the sense that it provided drug access to anyone in need. It turns out that this was probably the reason this clause was eliminated, because of the antiregulatory mood in Washington after the elections of 1994.

One possible solution to the problem of high drug prices is the weakening of patent protection, which makes it easier for companies to legally copy and reproduce common drugs. One reason why pharmaceutical companies provide discounted drugs to developing nations is to prevent people from copying existing drugs and selling them to developing countries at discounted prices. Pharmaceutical executives criticize those who suggest patent protection should be weakened to make drugs more affordable or easier to copy. Novartis AG's CEO Vasella said, "From my perspective, it is unethical to fight patents."¹⁶ I also believe that fighting patents by illegally copying patented drugs is unethical. Pharmaceutical companies invest a lot of time and money into the research and development of a new drug. After all of this research, physically producing the drug is very cheap, and it would be unfair to allow a company to simply copy the drug and sell it at a very low price because their effort will be wasted. Another cost associated with weakening patent protection is the likely decrease in the research for innovative drugs. The benefit of weakening patent protection would be the widespread availability of cheaper drugs if companies are allowed to copy common drugs.

¹⁵ Brody, "Public Goods and Fair Prices: Balancing Technological Innovation with Social Well-Being"

¹⁶ Ross Kerber, "Novartis CEO: Easing Rules on Drug Imports May Loom," The Boston Globe, 18 November 2004, sec. E, p. 3.

Therefore, since the costs strongly outweigh the benefits, I do not believe weakening patent protection is a feasible solution to the problem of high drug prices.

Some members of the U.S. Government believe that the U.S. should solve the problem of high pharmaceutical drug prices by allowing drug importation from other countries where drug prices are lower. Currently, the FDA has banned the importation of pharmaceutical drugs from Canada due to safety concerns.¹⁷ Senator Olympia Snowe proposed the Pharmaceutical Market Access and Drug Safety Act which states, “We have an obligation and a responsibility to make sure we do everything we can to provide accessible and affordable prescription drugs, and one way to do that is through a safe and reliable drug importation system.¹⁸” I believe drug importation from Canada is an unethical and ineffective attempt to solve the problem of high drug prices in the U.S. Drug importation is unethical because this solution calls for patients in America to get prescription drugs from Canadian doctors who they never met. This is morally unacceptable because it is a breach of the normal practice of physicians, which is based on ethical principles. People could abuse this importation system and take advantage of it by asking Canadian doctors for drugs they do not need. People could also begin selling these prescription drugs to people who are addicted to various drugs and narcotics. Drug importation is ineffective for three reasons: First, using drug importation as a solution to high drug prices is like treating a bullet wound with a bandage: while it hides the problem, it does not fix it and only serves as a temporary solution. Secondly, drug importation scares away investors. If people stop buying drugs from America, investors will lose confidence in the pharmaceutical industry, and will divest. Thirdly, “parallel importers” buying drugs in one

¹⁷ Imported Drugs, <<http://www.fda.gov/importeddrugs/>> (10 April 2005).

¹⁸ “A Prescription for Lowering Drug Prices,” US Fed News, 4 February 2005.

country and distributing them in another capture profits based on the price differences rather than passing them along to consumers. This shows that even if importation is allowed, people in America will not gain much.¹⁹ Therefore, while some people might benefit from this system by getting cheaper drugs, the negative costs are much greater and will result in greater harm than good.

Pharmaceutical price discrimination, whereby pharmaceutical companies charge different prices to different individuals, is another proposed solution to the high price of pharmaceutical drugs. Although many people would like to see drug prices decrease for everyone, pharmaceutical companies would suffer too much from such a sudden measure because they will lose money. However, pharmaceutical companies can have a program where certain groups of people are given prescription drugs for lower prices. This system will be difficult to implement because it is hard to determine who should receive lower prices and who should not. However, if this system is indeed implemented, many people will benefit. The most needy patients will receive cheaper drugs and the wealthier patients will pay the normal prices for their drugs. This price discrimination would be justified because the poor and uninsured are usually not capable of paying for their healthcare, but are just as in need of medications as the wealthier insured people are. Since the only downside to this solution is lower profits for the pharmaceutical companies, price discrimination is an ethically acceptable solution to high drug prices if it can be efficiently implemented.

¹⁹ Ross Kerber, "Novartis CEO: Easing Rules on Drug Imports May Loom," The Boston Globe, 18 November 2004, sec. E, p. 3.

Some members of the United States Congress have another proposed solution to directly address the crisis of skyrocketing drug costs. The Medicare Enhancement for Needed Drugs (MEND) Act was introduced on February 1, 2005. This legislation would give the Secretary of the U.S. Department of Health and Human Services the specific authority to negotiate lower prices for drug purchases through the Medicare prescription drug benefit.²⁰ If implemented, the MEND Act would be great first step because it will decrease the cost of prescription drugs for the elderly. In a sense, this solution is a form of pharmaceutical price discrimination, and is therefore an ethically acceptable solution. Since the elderly are more price-sensitive and disease-prone than other age categories, they buy more prescription drugs and are affected the most by the current high prices of prescription drugs. This Act addresses this problem and will make it easier for the elderly to buy the prescription drugs they need.

The United States market for pharmaceutical drugs represented more than half of the global drug industry's sales of 410\$ billion last year and was the country in which drug companies made the bulk of their profits²¹. In Table 1, we can see that the U.S. sales as a percentage of total sales is very high²². It is unfair for U.S. citizens to pay exorbitant prices for their prescription drugs while people in other countries pay much lower prices. According to Mr. Love, a consumer advocate, American consumers are "subsidizing everyone's R&D...we're paying way more than everyone else...others should pay more."²³ One possible solution to high U.S. drug prices is for the U.S. to pressure other developed nations to slightly

²⁰ "A Prescription for Lowering Drug Prices," US Fed News, 4 February 2005.

²¹ Eduardo Porter, "Importing Less Expensive Drugs Not Seen as Cure for U.S. Woes," The New York Times, 16 October 2004, sec. A, p. 1.

²² L.J. Sellers, "Top 50 Pharmaceutical Companies of 1999," Pharmaceutical Executive, April 2000.

²³ Porter, "Importing Less Expensive Drugs Not Seen as Cure for U.S. Woes"

raise the price of their drugs, so they shoulder a higher share of the global research burden²⁴.

It is unfair and unethical for the U.S Government to allow consumers in the U.S. to pay exorbitantly high prescription drug prices just because the rest of the world does not want to slightly raise its prices. To understand is not to condone, and I believe it is understandable that pharmaceutical companies are making up for lost ground by charging high prices in the United States. By slightly lowering the price of pharmaceutical drugs in the U.S. and raising them in other developed nations, all developed countries will share the global research burden equally and Americans will not have to deal with the skyrocketing costs of prescription drugs. Christopher Harrison, author of The Politics of the International Pricing of Prescription Drugs, said, “One country, the U.S., was able to persuade more than 100 other countries that they, as net importers of technological and cultural information, should pay more for the importation of that information.²⁵” It is clear from this quotation that the United States is a very powerful negotiator, and can convince other countries to buy U.S. prescription drugs at higher prices. If the U.S. succeeds in doing so, it will be easier to lower drug prices here in the U.S. without harming the pharmaceutical industry. The downside to this proposed solution is that other countries will have to pay higher prices for their drugs, which I believe is a reasonable compromise since this price increase will be very small if many nations agree to this proposed solution. Therefore, since the benefits of this solution outweigh its costs, this proposed solution is both very feasible and ethically sound.

Some people believe that the best way to force pharmaceutical companies to lower the price of drugs would be to implement price controls. “Is it sensible for the United States to

²⁴ Porter, “Importing Less Expensive Drugs Not Seen as Cure for U.S. Woes”

²⁵ Christopher Harrison, The Politics of the International Pricing of Prescription Drugs. (Westport, CT: Praeger, 2004).

have price controls?” asked Jean O. Lanjouw, an economist at the University of California, Berkeley. “It is a real question. But we don’t discuss the real questions.²⁶” The European pricing model of setting price controls is good because it provides its citizens with cheaper drugs. However, this system fails to provide adequate economic incentives for research and development.²⁷ If the U.S. joins the rest of the world by setting price controls, I believe the pharmaceutical companies will end up spending less on the research and development of drugs. Since I think research and development is more important for the welfare of humanity in the long run, I do not think setting price controls is the best solution to the problem of high drug prices. Low research and development can have adverse effects on sick patients in the long run because companies would not be willing to invest in the innovation of new drugs. I think the people who will be hit hardest are those patients with rare diseases. For example, Genzyme charges about \$170,000 per person each year for the treatment of Type 1 Gaucher disease²⁸. The main reason Genzyme is developing drugs for rare diseases is because they have the freedom to sell their drugs at any price. Without this protection in the United States, companies like Genzyme will stop developing orphan drugs because their companies cannot be profitable without charging very high prices. As a result, since the costs outweigh the benefits, setting price controls in the U.S. is not an ethically acceptable solution to the problem of high drug prices.

Ireland has a unique healthcare system that provides free healthcare to all of its citizens. In addition, the poorer 35% of Ireland’s population do not have to pay for

²⁶ Porter, “Importing Less Expensive Drugs Not Seen as Cure for U.S. Woes”

²⁷ Brody, “Public Goods and Fair Prices: Balancing Technological Innovation with Social Well-Being”

²⁸ Clarissa Ceruti and Henry Chesbrough, “Genzyme: Engineering the Market for Orphan Drugs,” HBS Case No.9-602-147 (Boston: Harvard Business School Publishing, 2002).

prescription drugs.²⁹ I believe the United States should consider implementing a similar healthcare system where a certain percentage of the population does not have to pay for prescription drugs. This solution would be very costly for the U.S. and will require a huge budget. However, I still believe that this solution is possible if the U.S. decreases other expenditures, such as military and space research, and increase the budget for this initiative. I believe the healthcare budget should be higher than the military and space research budgets. If and only if there is extra money, should the U.S. Government start spending on these superlative expenditures that do not have a direct impact on the welfare of Americans. Therefore, since this solution has more benefits than costs, the implementation of Ireland's healthcare system in the U.S. is an ethically sound solution to high drug prices.

This research paper has established the existence of the problem of high pharmaceutical drug prices by mentioning empirical data and information from various sources. The complications this problem presented to people worldwide have also been thoroughly described and elaborated upon. Finally, several solutions to the problem of high pharmaceutical drug prices were analyzed, including the positives/negatives of the proposed solutions. I believe the main responsibility of pharmaceutical companies is to combat disease by developing drugs. This should be their main concern and they should focus their resources and efforts for the attainment of this goal. Therefore, since maximizing profits by charging high prices makes it harder for people to treat their disease, pharmaceutical companies should refrain from charging people excessively high prices for drugs if they are making large profits. While I presented many possible solutions to the problem of high pharmaceutical drug

²⁹ Susan P. Smith, "Warner-Lambert Ireland: Niconil," HBS Case No. 9-593-008 (Boston: Harvard Business School Publishing, 1993).

prices, I believe the ideal solution to this problem will only be attained by combining several of the proposed solutions mentioned in this paper. In order to be practical and ethically acceptable, this ideal solution must provide sufficient economic incentives for drug research and development, limit marketing costs, and provide drugs at affordable prices.

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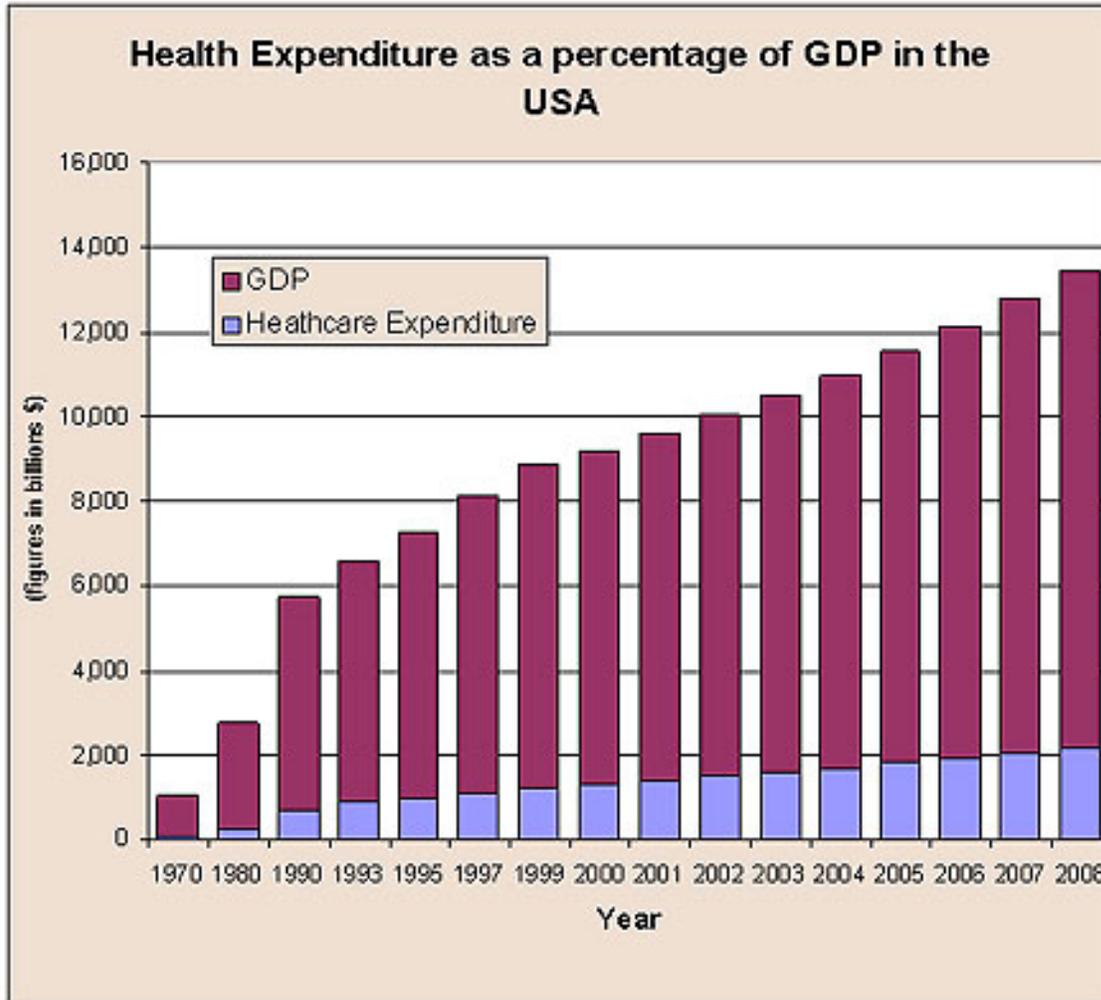
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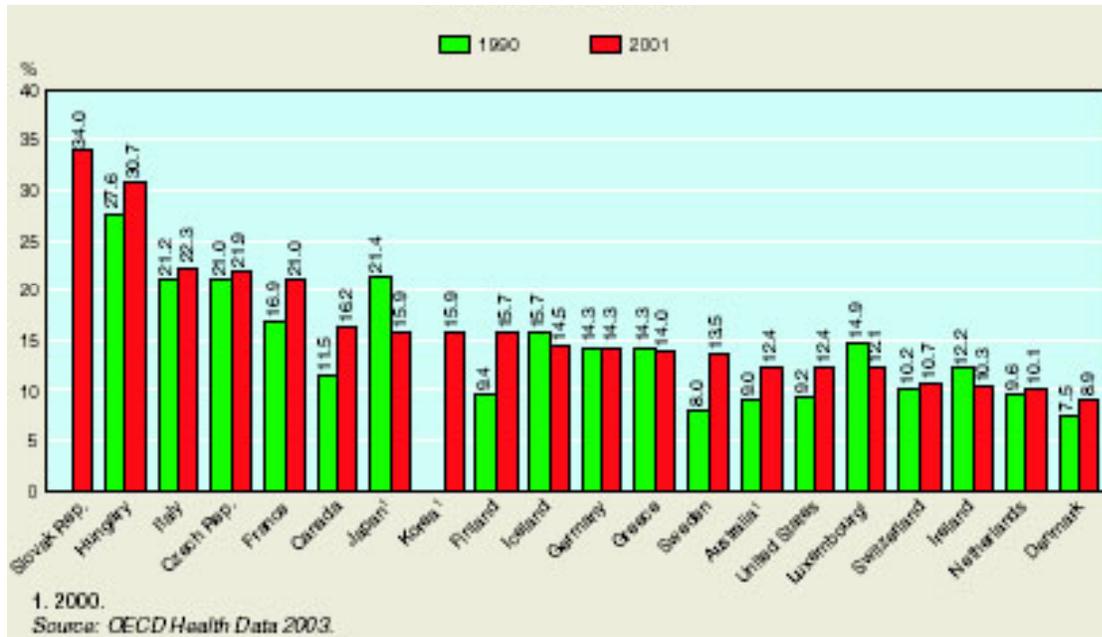
Appendix

Figure 1. Health Expenditure as a Percentage of GDP in the USA.



(Source: <http://www.pharmaceutical-technology.com/projects/grafon/grafon4.html>)

Figure 2. Higher Pharmaceutical Spending: Percentage of Total Health Spending



(Source: http://www.oecdobserver.org/news/fullstory.php/aid/1170/pharmaceutical_spending_graph_large.html)

Figure 3. CDER NDAs Approved in Calendar Years 1990-2004 by Therapeutic Potential and Chemical Type

Year	Therapeutic Potential - Priority Review* and Chemical Type***								Therapeutic Potential - Standard Review** and Chemical Type***								Total Approvals
	1	2	3	4	5	6	7	Total	1	2	3	4	5	6	7	Total	
1990	12	0	8	0	0	0	0	20	11	2	23	2	2	4	0	44	64
1991	14	0	5	0	0	0	0	19	16	1	15	2	10	0	0	44	63
1992	11	0	5	0	1	0	0	17	15	1	30	5	21	1	1	74	91
1993	13	0	6	0	0	0	0	19	12	0	18	1	18	2	0	51	70
1994	13	0	4	0	0	-	0	17	9	0	23	5	8	-	0	45	62
1995	9	1	5	0	0	-	0	15	19	5	30	2	11	-	0	67	82
1996	18	0	10	0	1	-	0	29	35	5	50	4	7	-	1	102	131
1997	9	1	6	1	3	-	0	20	30	2	52	12	4	-	1	101	121
1998	16	0	9	0	0	-	0	25	14	0	46	4	0	-	1	65	90
1999	19	1	7	1	0	-	0	28	16	2	32	3	2	-	0	55	83
2000	9	1	9	1	0	-	0	20	18	0	48	7	3	-	2	78	98
2001	7	1	1	0	1	-	0	10	17	1	23	9	5	-	1	56	66
2002	7	0	3	1	0	-	0	11	10	2	44	5	6	-	0	67	78
2003	9	0	4	1	0	-	0	14	12	5	31	7	3	-	0	58	72
2004	17	0	4	1	3	-	0	25	14	1	59	5	8	-	1	88	113

(Source: <http://www.fda.gov/cder/rdmt/pstable.htm>)

*Priority Review - Significant improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease.

**Standard Review - The drug appears to have therapeutic qualities similar to those of one or more already marketed drugs.

***Chemical Types:

- 1 - New molecular entity
- 2 - New ester, new salt, or other noncovalent derivative
- 3 - New formulation
- 4 - New combination
- 5 - New manufacturer
- 6 - New indication (Beginning in 1994, Type 6 NDAs were tracked as efficacy supplements)
- 7 - Drug already marketed, but without an approved NDA

Table 1. Top-Selling Pharmaceutical Companies by Sales, 1999

Pharmaceutical Company	Total Pharmaceutical Sales (U.S. \$ billion)	U.S. Sales as Percentage of Total	Research and Development (U.S. \$ billion)
1. Merck	\$17.4	60%	\$2.1
2. Pfizer	\$14.9	62%	\$2.7
3. AstraZeneca	\$14.8	48%	\$2.1
4. Bristol-Myers Squibb	\$14.3	65%	\$1.7
5. Glaxo Wellcome	\$13.8	42%	\$2.1
6. Aventis	\$13.5	26%	\$2.3
7. SmithKline Beecham	\$11.6	53.6%	\$1.6
8. Novartis	\$11.4	N/A	\$1.6
9. Johnson and Johnson	\$10.7	60%	\$1.6
10. Eli Lilly & Co.	\$10.0	62%	\$1.7

(Source: L.J. Sellers, "Top 50 Pharmaceutical Companies of 1999," Pharmaceutical Executive, April 2000.)