

# Monopolization and the costs of drugs - Standard-Examiner

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The patent system in U.S. has existed since 1790, but it has expanded substantially since 1836. It is designed to protect new inventions by establishing property rights to holders. On one hand the patent system is designed to encourage inventions, but at the same time it confirms monopoly power to the inventors. Since uncontrolled monopoly power is an inefficient market structure, Congress has to balance it with the incentive for inventions. At present this right is generally granted for 20 years.

After the 20-year brand-name monopoly is over, pharmaceutical companies have to face competition from generics. A recent news story in The Wall Street Journal, Jan. 13, points out that, "Brand-name drug companies are fighting to weaken a provision of the health care overhaul that was designed to open up generic competition in biotechnology medicines and save billions."

Biologic drugs are biologically synthesized, as opposed to chemically based drugs. The health care law of 2010 made the entry of generics relatively easy in the market place for generic biologics (biogenerics) to provide effective competition to brand-name biologic drugs. Biologic drugs are very expensive and thus have a very high profit margin. A February 2008 study by economist Dr. Robert Shapiro (Chairman of Sonecon, LLC, a private consulting firm and former undersecretary of Commerce for Economic Affairs) and his co-authors, shows that across all treatments the average cost of biologics is \$16,425, which is 20 times the average cost of traditional drugs. Therefore, drug companies like Genentech, Amgen, and Merck are very much concerned about losing their market share and profits with the advent of generic biologic drugs.

At present, fortunately for brand-name drug companies, Food and Drug Administration has not come up with an evaluation process for biogeneric drugs. Hence, in the meantime, biologic drug companies, who control close to 20 percent market share, are working on two fronts to maintain their monopoly power and profits. They are partnering with other companies to develop "biosimilar" drugs, which are copies of their brand name drugs. They are also engaged in intense lobbying efforts to convince FDA to grant them exclusivity rights for 12 years; it is a cheaper way to preserve monopoly power. Sens. Orrin Hatch of Utah and Kay Hagan of North Carolina, both Republicans, sent a letter to FDA requesting, "to interpret the law in ways favorable to the brand-name makers." These efforts to block the entry of biogeneric drugs is in addition to barriers to entry posed by complexity and cost of developing biogenerics as opposed to developing traditional drugs.

Biologic name-brand companies are asking FDA for 12 years of exclusivity rights to market their drugs, as opposed to five years pushed by counter groups like insurance companies and generic biologic companies. Drug companies argue that exclusivity rights will permit more inventions of these complex drugs. However this argument is not supported by convincing evidence on their research and development efforts in relation to profits. Supporters of generics would argue that the development of generics would save patients billions of dollars. At present many patients cannot afford these lifesaving drugs. The research by Dr. Robert Shapiro and his co-authors shows that competition from biogeneric drugs across 12 treatments will result in an average price discount of 35 percent and will save a total of \$378 billion over 20 years. Sen. Hatch, who claimed that health care legislation would be very costly to the nation, is now trying to push FDA to maintain the monopoly power and profits of these large biologic drug companies. Government action is the cheapest way to acquire monopoly power to control output, prices and profits.

According to Kaiser Family Foundation Americans spent \$234.1 billion on prescription drugs. The pharmaceutical industry is the third most profitable industry. Prices of prescription drugs have increased at the average rate of 3.6 percent per year, much higher than the general inflation rate during 2000-2009. The average brand-name prescription drug price was four times the average price of a generic and manufacturers received almost 78 percent of the retail price. A

Congressional Budget Office study in 2006 found that median return on assets of pharmaceutical companies was close to 12 percent, almost double the return for other Fortune 500 companies.

It is about time that politicians, including Sen. Hatch, pay attention to their voter-patients' concerns about high drug prices, health insurance cost and medical care cost. Protecting exorbitant profits of drug companies by promoting monopoly power does not benefit this nation, given the very high fraction of spending on prescription drugs by private and public sectors. Efforts should be made to open the drug market for all types of drugs for more competition, including importation of drugs from Europe and Canada.

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