“Pay-For-Delay” Prescription Drugs

**Abstract**

Many Americans struggle to pay prescription drug costs today, despite access to health care being an intrinsic human right. Americans pay the highest drug prices for prescription drugs in the entire world, but why? Nearly one in five Americans between the ages of 19-64 (around 36 million people) refused to fill prescriptions because they were unable to afford it[[1]](#endnote-1). Does a life-saving drug benefit a consumer if one is not able to afford it?

Economic theory insists that sellers may participate in price discrimination if three conditions are met; the seller has a monopoly over production of the product, different buyers are willing to pay different prices from the same product, and buyers may not trade already purchased items amongst themselves. The makers of single-source drugs engage in a particular form of price discrimination called third-degree discrimination. This means that a seller may charge a different price to two or more separate classes of buyers, but must charge a single price to all members within each respective class[[2]](#endnote-2).

**Introduction**

There are numerous policies in place to prevent the production of generic drugs by name-brand pharmaceutical companies. Such acts prohibit the manufacturing of a generic drug for a specified period of time in order to allow a free and open trade market for the original drug. Generics are exactly the same in terms of dose, active ingredient, strength and quality, and must pass stringent standards before being approved by the FDA. Drug companies often resort to lawsuits that delay the production of the exact same generic drug in exchange for a cash payment, often regarded as “assistance” but intentionally used to delay the production to shelf time. In 2008 alone, spending in the United States for prescription drugs was $234.1 billion, almost six times more than the $40.3 billion spent in 1990, and that number is still climbing today[[3]](#endnote-3).

On average, a generic drug is 80 to 85 percent less expensive than the brand name product. According to the FDA, in 2010 alone, the use of FDA-approved generics saved $158 billion, an average of three billion dollars ($3 billion) every week.[[4]](#endnote-4)A generic drug that is produced through the FDA has rigorously met numerous standards in regards to identity, strength, quality, etc. Generic drugs are required to have the same active ingredient in the same strength and dosage form, identical route of administration (oral, etc.) as the brand name product, but do not need to contain the same inactive ingredient.

Prior to a generic drug being sold in America, it must pass a series of tests to prove it does not infringe upon the original brand-name drug’s copyright and intellectual property. Litigation has been increasingly successful for generic drug manufactures, as lawsuits have been settled via agreements in which the generic drug manufacturer promises to delay the production and distribution of said drug for a period of time in exchange for a cash payment. Such payments are argued by generic drug companies to be assistance to produce and process drugs and ensure that more generic drugs make it to the market quickly, however there are many arguments that these settlements are delaying the entry of cheaper drugs in the market, as well as infringing upon anti-trust laws.

Many argue that restricting these settlements would allow more affordable generics to be streamlined and quickly produced and introduced for the patients that need them. According to the Congressional Budget Office, restricting “pay-for-delay” would reduce the deficit by $5 billion over 10 years, in addition to generating further savings for private consumers[[5]](#endnote-5).

**Recent Progress**

According to a scientific study by the International Journal of Science, prescription drug prices are not likely to drop until generic drugs are readily available. Most drug manufactures place a patent on their specific chemical compound, and exclusively own the rights to produce said compound. Such lawsuits prevent generic drugs, possessing a similar genetic makeup and chemical compound, from entering the free market and driving prices down. “For drugs experiencing initial generic entry in 2011–2012, the MEP was 12.6 years for drugs with sales greater than $100 million (in 2008 dollars) in the year prior to generic entry, 12.9 years overall. After generic entry, the brand rapidly lost sales, with average brand unit share of 16% at 1 year; 11% for NMEs with pre-generic entry sales of at least $250 million (in 2008 dollars). Over 80% of NMEs experiencing 2011–2012 initial generic entry had faced at least one Paragraph IV challenge from a generic manufacturer.[[6]](#endnote-6)”

There are numerous benefits to increasing generic drug distribution among a free and equal market. Increasing generic drugs and lowering overall cost has the ability to greatly exceed static efficiency without hindering innovations in the pharmacy sector. There are numerous different launch times of generics versus their name brand counterparts, and the launch time differences separated geographically. Statistically, price regulation has the most profound effect on time of a launch of generic drugs, with reducing the time to launch generics and faster adoption in higher priced markets, which depends on the degree of competition, market size and demand for the drug.

There are similar drugs that are potentially cost saving in the United States, including biosimilar drugs. Biosimilar drugs are complex biologics that are protein based and provide for a large range of functions, including insulin, blocking inflammation in rheumatoid arthritis and expressed in a range of drugs to treat multiple sclerosis, cancer, and other chronic diseases. In 2011, eight of the top 20 drugs in the United States in terms of sale were biologics, according to IMS Health[[7]](#endnote-7). Unlike common prescription drugs, however, biologics typically do not face generic competition after the initial patent protection has expired. Biosimilar manufacturers can expect to face lower costs and less time to obtain approval while still maintaining no relative difference in effectiveness and safety. All biosimilar drugs will require clinical head-to-head trials to ensure effectiveness, which may limit competition in the field. Additionally, to lower the price of biologic drugs, new regulations could provide effective answers. Regulation to reduce the length of guaranteed protection of brand name biologics against generic competition from twelve years down to seven years will reduce the “exclusive” period where only the name brand drug can be produced, encouraging innovation, increasing market competition, and sending more affordable generics to the market[[8]](#endnote-8).

As with any new drug, there are many concerns for biotech companies. Recently there has been a push for provisions in new legislature that establish tighter time frames for listing patents with the FDA and potentially addressing new bioequivalence standards for generics. The aim of such standards is the development of generic topical creams and other alternate dosage forms of modern medicine. Many biotech companies, however, regard it as a move by the generic drug companies to open the door to a new wave of non-traditional generic products. Consumers must wonder what is so detrimental about newer, more effective forms of medicine, and why many drug manufactures oppose it?

Almost 80% of FDA-approved drugs have generic counterparts. In 2008, 22% of total prescription drug sales and 72% of total prescriptions dispensed were generic medicines[[9]](#endnote-9). Several high-sales brand name drugs have gone “off-patent” in the past 5 years, causing overall drug sales to decline, with competition from generic drugs lowering costs for patients. In a world ruled by common supply and demand method, prescription drug prices are largely unregulated. Drug manufactures set prices at whatever artificial level they choose and do not reveal the criteria on which they base price.

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3. Centers for Medicare and Medicaid Services, National Health Expenditure Accounts, Historical, <http://www.cms.gov/NationalHealthExpenddata/>. Accessed January 28, 2016. [↑](#endnote-ref-3)
4. FDA. "Food Drug Administration Generic Drugs."*FDA Resources*. FDA, 7 Aug. 2015. Web. 1 Feb. 2016. [↑](#endnote-ref-4)
5. IMS Health, “Shaping the Biosimilars Opportunity”, 2011. [↑](#endnote-ref-5)
6. U.S. Department of Health and Human Services. (2013, Apr 10). Fiscal Year 2014 Budget in Brief. Retrieved from <http://cbo.gov/sites/default/titlescbofiles/attachments>. [↑](#endnote-ref-6)
7. National coalition on health Care. (2010) Curbing Health Care costs, Improving Quality: Care for High Cost Beneficiaries (Policy Paper #9). Washington, DC. [↑](#endnote-ref-7)
8. Johnson, J.A. (2010, April 26). FDA Regulation of follow-On Biologics, Congressional Research Service; 7-5700:RL34043. www.crs.gov [↑](#endnote-ref-8)
9. IMS Health, “IMS Health Reports U.S. Prescription Sales Grew 5.1 Percent in 2009, to 300.3 Billion” (April 1, 2010), online at <http://ikmsheath.com> (Press Room, Press Releases) [↑](#endnote-ref-9)