The Balance Between Affordable Drugs and New Research

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Abstract

Generic drugs play an important role in reducing health care costs. Historically, Congress has attempted to maintain a balance between providing affordable medicine in the form of generics, while protecting the income of pharmaceutical companies who spend millions of dollars and years of research to launch a new drug. If too much emphasis is placed on producing generic drugs, there will not be incentive for investors to fund new research. In short, there will be no drug for the generic to imitate. In the field of biologics, the United States does not have a legal option to produce generics. Currently, generic drugs are not an option in the high priced sector of biologics. This paper examines the impact of legislation on drug pricing and how an entire class of cost-saving generic drugs has been excluded from the consumer.

Where are the Biosimilars: The Balance between Affordable Drugs and New Research

The American public has a vital interest in assuring new medical research remains vital and strong. If medicines become too costly, only a select few will have access. If medicine becomes too cheap, research and development for new medicines suffer. Where do we set the parameters between profitability and access? With traditional pharmaceutical drugs, procedures and laws are in place to assure pharmaceutical companies recoup research and development costs, while allowing generics to thrive in the marketplace. The situation is different with a class of drugs called biologics.

Biologics, a relatively new type of drug, offers enormous promise. Biologics are drugs created from living cells or organisms. Because biologics treat cancer, immune disorders and many diseases, they are sometimes called miracle drugs. The Food and Drug Administration takes a different stance on biologics, and requires a different approval process than traditional pharmaceuticals. Because of this one legal snafu, generic biologics, called biosimilars, are not available in the United States.(Dinh, 2007).

A brief history of the laws of pharmaceutical approval is necessary. With traditional drugs, a patent application is made, and then clinical trials are done. Ultimately, the goal is to get FDA approval via the NDA (new drug approval) process. Once the drug is approved as safe and effective, the innovated pharmaceutical company has approximately twelve years of exclusive sales, without competition. (Grabowski & Vernon).

Once the patent(s) on the original drug has expired, generic companies may wish to develop and sell their version of the drug. Generic companies must get FDA approval. Normally, to get FDA approval, a company must complete years of clinical trials. This cumbersome task seems duplicative for a drug that is the bioequivalent of the original drug. Likewise, if the generic

manufacturer must complete the same clinical trials as the original manufacturer, the cost savings would be non-existent.

The Hatch-Waxman Act was enacted to solve this problem. Rather than go through the NDA process, the Act allowed generic companies to apply for FDA approval via ANDA, which is an abbreviated new drug application. If the generic manufacturer proved its drug was bioequivalent to the original, then it could be expedited. This process saved enormous costs and allowed the consumer to get quality medication at affordable prices. The cost saving generic was allowed on the market, but not before the brand company was allowed approximately twelve years of monopoly sales. This type of system assures proper financial incentives for research and development, while eventually bringing down the cost of medicine for the consumer. (Mossinghoff, 1999)

Because biologics are different from traditional medicines, the FDA does not accept applications for approval via the NDA process. Biologics are approved pursuant to the Biologics Licensing Application (BLA), not the NDA. Under the BLA, Hax-Waxmann does not apply; therefore, there is no ANDA, or expedited process for proven bioequivalent drugs to bypass clinical trials. (Dinh, 2007) At present, generic manufacturers of biosimilars would not get the benefit of ANDA; rather they must redundantly go through the rigorous and costly NDA process.

Until congress approves some type of generic process for biologics, the U.S. will not have affordable generic biologics. The high cost of biologic medicine will continue indefinitely. This unique legal situation has caught the attention of lawmakers and the pharmaceutical industry.

PhRMA (Pharmaceutical Research and Manufacturers of America), is a trade group representing U.S. biotechnical companies and pharmaceutical research. Billy Tauzin, a former congressional representative, is the CEO of PhRMA. Mr. Tauzin touts biologics as the cutting

edge medicine that offers our brightest hopes for new treatments. He states the cure for cancer will come from biologics.

Acting before legislation has been issued regarding biologics, Mr. Tauzin argued that drug companies need protection from congress to provide incentives for pharmaceutical companies to continue to research and develop life-saving drugs. In his agency's web-site publication, he called for a twelve-year reprieve, which would allow pharmaceutical companies that develop biologic drugs, a twelve-year monopoly on the product before generic companies may compete. (Tauzin, 2009).

Mr. Tauzin's wisely looked into the future to take a proactive stance for his organization. In 2006, biologic sales reached $40.3 billion, which is fifteen percent of all U.S. prescription drug sales. The biologics market is the fasting growing market, with twenty percent growth, compared just eight percent growth for all pharmacy sales. (Frank, 2007) Biologics are expensive, not only because of the cost to manufacture, but because of the lack of generic biosimilars on the market.

Although there is currently no method for a generic biologic (biosimilar) to hit the market and compete with the biologics in the U.S., it is no secret congress is working toward a solution. With the cost of biologics skyrocketing, a generic approval process for biosimilars will play an important role in reducing health care spending. (Kelly, Jd, David, & Jd, 2009)

With the cost of health care at the heart of the current discussion, the pharmaceutical industry has been wise to secure a proactive role in attempting to propose regulations.

This issue is too complicated to address fully within the sound bites of modern persuasion. We must hope that consumer advocates and elected officials stand up for the citizens

and create a balance that will encourage continued investment into pharmaceutical research and development, while allowing the sale of cost-saving biosimilars.

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