Debate 1:

Is it ethical for Big Pharma Companies to discourage generic drugs' access to the market?

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"There's a saying, that it costs a billion to produce the first pill, and 10 cents to produce the second," says Rachel Sachs, a fellow at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School[1]. Big pharmaceutical research has gotten a pretty bad rap over the last few years, but it is not all its chalked up to be. In 2005 the average cost of developing a new drug and getting it to market was $800 million[2], (Shanley, 2005), however, according to a NEWER study conducted in 2014, the average cost to develop and get a new drug to market has increased from $800 million to $2.6 BILLION[3] (Tufts Center for the Study of Drug Development) and only 1 out of 10 drugs developed will make it to market[4] (Berkot, Success rates for experimental Drugs Falls: Study).

So, that one drug that does make it to market has to make up for the other 9 that were not able to – so 9x $2.6 billion… is A LOT. Big pharmaceutical companies spend hundreds of millions of dollars a year on development and research for new drugs and compounds. They need to be able to recoup some of that cost before generics are allowed to flood the streets and cut into their profits. If they cannot earn some of the capital back that they spent, then we can have huge research and development centers going dark because there would be no point in continuing research and development if a company who didn't do the work, can steal your intellectual property right away. A lot of people could lose their jobs.

A research study conducted by the BMC Clinical Pharmacology in Finland shows the impact of generic drugs on the pharmaceutical companies over five-year examinations. The research was done to explore "the impact of generic drugs on the number of employees, the amount of prescription medicine marketing, the prescription medicine representatives' visits to pharmacies and to physicians, the number of different packages of pharmaceutical products for sale, R&D of new pharmaceutical products and storage of pharmaceuticals,"[5] after they enter the market and

the results can speak for themselves.

Based on the research:

- The number of the brand drug company employees decreased in total of 800-900 people between 2003 and 2008 (these are small companies in Finland that consist 19 employees or less).
- More than half of the brand name companies reported that generic drugs had impacted the amount of prescription medicine marketing; most of which had decreased the amount of promotional activities after generic drugs came into the picture.
- Sales volume of original products have decreased
- Generic drugs affected the storage of pharmaceutical products in most brand drug companies; led to overstocking due to reduction of sales volume
- Reduction in the number of packages for sale
- Reduction in the R&D of new pharmaceutical products

These results show that the impact of generic drugs is bigger than anyone had anticipated. Most of the research and publications that have been published in the U.S. talk about generic drugs and how they can help the people, but very few talk about how it will impact not only Big Pharma, but their employees and the spending on research for new, potential, life savings drugs. Nor do they mention how generic drug companies piggy back off the time, effort, and money spent by brand name companies, without having to invest much themselves.

The Hatch-Waxman Act “gives the first company to seek FDA approval for a generic drug the exclusive right to market the non-branded medication for 180 days. The six-month exclusivity is seen as giving the generic company needed financial incentives to bring the drug to market. The FDA ruled in 2004 that the company that owns patent rights to a drug can also sell

an unbranded version during the 180-day period."[6] So-called "pseudogenerics", "ultragenerics", or "authorized generics" are generics drugs that are made by firms controlled by brand-name companies. Generic drug companies are trying to fight this new law by the FDA saying "such 'authorized generics' either reduce or kill the market for the generic firm"[6]. Which leads one to wonder: why are the majority of people trying to fight big pharma for trying to make revenue off their medicine after spending more than $2bn on R&D, and no one is fighting generic drug companies for trying to steal that revenue without putting much work or money into it?

Additionally, the generic drugs that are put out on the market are often touted as "identical", but often are quite different. According to the FDA, a generic drug must have the same active ingredients, same label strength and dosage and must be bioequivalent (more on this in a minute) to its counterpart[7]. However, this means that the inactive ingredients, or excipients, and the process in which the drug is manufactured do not need to be the same, leading to pills that are not only different in sizes and colors, but ones that react differently in patients, causing inconsistent results and different side effects than brand name drugs. According to Joe Graedon, M.S., a pharmacologist, "the physical characteristics or release properties of a brand name drug often stay under patent even after the active ingredient becomes available generically… Generic manufacturers may have to come up with different technologies to deliver the active ingredients. This means that the products are not always 'indistinguishable or one and the same.'"[8] In other words, generic drug companies to do not have the master plan to identically remake a name brand drug. They need to reverse engineer the formula and try to recreate the drug in as close a way as possible to the original. However, close as possible may be a loose term where the FDA is concerned.

According to the FDA, a generic drug must be bioequivalent to that of a brand name drug in that there is an "equal rate and extent of drug absorbed [in] the bloodstream". However, the FDA has "established bioequivalence limits... for the generic/reference comparison of both AUC and Cmax be within 80% to 125% [of the brand name drug]."[9] That means that generics that are being labeled identical to brand name drugs have a 45% range in which they can be declared "equal" to their counterpart. That very large disparity is not the only one.

In addition, different generics often have different ranges of potency. In an article found in Fortune Magazine, Dr. James Hennesey, clinical director of the division of endocrinology at Beth Israel Deaconess Medical Center in Boston, explains how three different forms of levothyroxine (a drug used to fight hypothyroidism) were presented to the FDA's advisory committee and "all were more potent than the branded version and varied from one another. One was 12.5% above, another 9% above, and another 3% above the brand name's potency. All had been approved as bioequivalent. Noting that 'less than 10% dose intervals make clinical differences.'"[10] In other words, a patient that was talking a name brand drug that switches to one of these generics may find that their symptoms come back, the dosage exceeds what is needed, or the drug affects them in a completely new, unexpected way.

Finally, an example of a generic drug failing to meet brand name execution is Budeprion XL 150, the generic version of Wellbutrin XL 150, an antidepressant. According to the FDA (see Figure 1), the time it took for each drug to reach maximum blood concentration with Budeprion XL 150 was 1.5 to 2.5 hours, while it took 5 to 6 hours with Wellbutrin XL 150.[9] Yet, because the FDA does not measure hour to hour blood absorption as part of its standards for generics, this drug was deemed viable, resulting in numerous complaints from patients who switched to the generic, so much so, that the drug eventually had its approval withdrawn.

In conclusion, due to low success rate of new drugs and the high costs of R&D and getting successful products to market, Big Pharma companies need to have the opportunity to recoup their costs through discouragement of generic drug access to the market. If they are unable to do so, according to the research, these companies will eventually have to lay off employees and cut funding of research for new, potential lifesaving drugs. Further, despite being labeled as “identical” to brand name drugs by the FDA, there are in fact significant differences and wide ranges of acceptability that ultimately bring into question the safety of generic drugs to consumers.

Appendix

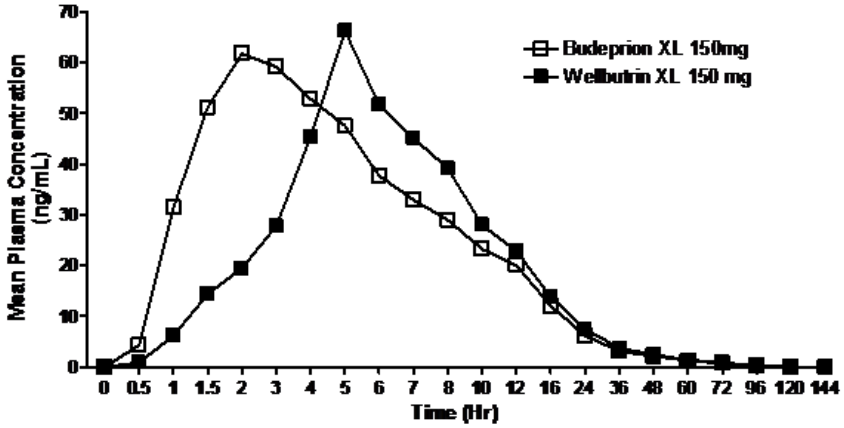

Figure 1.

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