

Significant price hikes for insulin and top selling US drugs

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Since 2011, the prices of four of the top 10 drugs in the United States have risen by over 100 percent, while the prices of the six remaining drugs increased by more than 50 percent, according to a recent analysis by Reuters.

The price of Humira, AbbVie's anti-inflammatory drug, rose by 126.4 percent, from \$1,677 to \$3,797. Amgen's anti-inflammatory medication, Enbrel, saw its price increase by 118.2 percent, from \$427 to \$932. The multiple sclerosis treatment, Copaxone, marketed by Teva, increased by 118 percent, from \$3,025 to \$6,593. AstraZeneca's cholesterol drug, Crestor, saw its price go up by 113 percent, from \$350 to \$745.

Reuters' research, which used 2014 sales figures to compile the list, is based on proprietary pricing data from Truven Health Analytics and looked at the average wholesale price of the drug. "Reuters shared its method and findings with the eight companies that sell the top 10 drugs," notes the news outlet, "none disputed the findings."

The Reuters' report coincided with the April 5 publication of a research letter in the *Journal of the American Medical Association* (JAMA), which found that between 2002 and 2013 the cost of insulin, the most widely used treatment for diabetes, rose nearly 200 percent—increasing from \$4.34 per milliliter to \$12.92. Annual spending on insulin by patients more than tripled, increasing from \$231 to \$736.

"I can tell you from seeing patients myself that there are many who can't afford their insulin and don't take it or take less of it and they're worse off for it," Dr. Robert Gabbay, chief medical officer of the Joslin Diabetes Center in Boston, told Reuters. Gabbay was not involved with the research published in the *JAMA*.

The researchers noted that the cost increases were largely due to the introduction of insulin analogs—insulin modified to be rapid or long acting—such as Lantus, Levemir, and Humalog.

A report by Bloomberg last year found evidence of "shadow pricing" among diabetes medication manufacturers, where competitors followed each other's price increases. For example, when Sanofi increased the

price of Lantus by 16.1 percent on May 30, 2014, Novo Nordisk increased the price of its competing drug, Levemir, the following day by the exact same amount. The two companies have increased the U.S. prices of their respective drugs 13 times in tandem since 2009. Similar shadow pricing was seen for Eli Lilly's Humalog and Novo Nordisk's Novolog.

Insulin has been available for over 90 years, yet there is still no generic alternative. A study published last year in the *New England Journal of Medicine* described how pharmaceutical companies made a series of patented improvements to the drug—longer-acting versions in the 1930s and 1940s, improved purity in the 1970s and 1980s, and synthetic analogs in subsequent decades—that they characterized as an example of patent "evergreening." Since doctors are hesitant to prescribe medicines considered obsolete, there has been no incentive to develop generic versions.

Diabetes is a chronic disease characterized by high levels of blood sugar as a result of the pancreas not producing enough insulin or the body being unable to effectively use the insulin produced. The disease caused 1.5 million deaths worldwide in 2012, and complications from the disease can lead to heart attack, stroke, kidney failure, and lower limb amputation.

According to a report by the World Health Organization (WHO) released on April 6, the prevalence of diabetes among the world's population has increased from 108 million (4.7 percent of the population) in 1980 to 422 million (8.5 percent) in 2014.

"Around 100 years after the insulin hormone was discovered, the 'Global report on diabetes' shows that essential diabetes medicines and technologies, including insulin, needed for treatment are generally available in only 1 in 3 of the world's poorest countries," said Dr. Etienne Krug, Director of WHO's Department for the Management of Noncommunicable Diseases, Disability, Violence and Injury Prevention.

The drug companies contacted by journalists for the stories

on the price hikes provided the standard excuses: the prices do not take into account the discounts and rebates offered by the drugmakers, and reflect the costs of producing new drugs, including lost income from drug failures. Neither excuse holds up to scrutiny.

It is true that the average wholesale price (AWP) of drugs is generally not the actual cost of the drug. The methods by which drugs are priced in the U.S. are complex and shrouded in secrecy. The Reuters report notes that data on discounts and rebates is “information [drugmakers] closely guard.” In this way, the drug industry attempts to deflect attention from its significant price hikes—allowing it to claim that patients and insurers pay less than the sticker price, but refusing to reveal the extent of the discounts.

“Even after discounts,” the Reuters article points out, “pharmacy benefit managers told Reuters they pay annual price increases on top medications of up to 10 percent. By comparison, the U.S. consumer price index rose an average of 2 percent annually over the last five years.”

One reason for the discrepancy between the AWP and the actual drug price paid by pharmacies is so that drug companies can “market the spread” to pharmacies. That is, insurers, including Medicare and Medicaid, generally reimburse pharmacies based on the AWP. Pharmacies stand to make more money if the price they pay for the drug is lower than the insurance reimbursement. Drug companies enable this practice by inflating the AWP and concealing the level of discounts and rebates. In return, pharmacies are more likely to prescribe their drugs—often in lieu of lower-cost alternatives.

These practices occasionally come to light in court cases brought by whistleblowers under Federal and State False Claims Acts. For example, in 2009 a jury found that Pharmacia violated Wisconsin’s Medicaid fraud statute 1,440,000 times by inflating the AWP to enable overpayment by Medicaid, although a circuit court later lowered the number to 4,758 violations.

The pharmaceutical industry also justifies the high prices based on the research and development costs of producing new drugs, including the cost of failures. “Our industry invests on average 20 percent of our revenues into research and development. It’s a fundamentally different business model,” Robert Zirkelbach, a spokesman for the industry trade group Pharmaceutical Research and Manufacturers of America (PhRMA), told Reuters.

According to the Tufts University Center for the Study of Drug Development, which was formed in the mid-1980s with financing from the drug industry, the average cost of producing a new drug in 2014 was \$2.6 billion. However, the findings of the study, which are endlessly touted by the industry, are based on assumptions that inevitably inflate the

price.

For example, the study arrived at a figure of \$1.4 billion for average out of-pocket costs, including failures. It then added \$1.2 billion in “time costs,” or returns that investors forgo while the drug is under development. Thus, in addition to other methodological limitations, the figure completely eliminates any risk for the drug company.

And while the pharmaceutical industry may invest 20 percent of its revenues on average in research and development (although this figure, too, is questionable), this is generally lower than the amount it spends on SG&A (sales, general, and administrative, which includes marketing).

A recent investigation by *CBS Money Watch* looked at the 2014 financial data for 16 publicly held pharmaceutical companies. “In all cases but one, corporate overhead was higher than R&D, and often significantly so. In half, after-tax profits were higher than the research-and-development expenses the industry typically points to as the major reason for high costs,” the article found.

In fact, pharmaceutical companies spent \$5.4 billion in 2015 on advertising, an increase of 19 percent over the 2014 figure and tying the previous industry record established in 2006, according to data from Kantar Media that was shared with *FiercePharmaMarketing*.

The costs associated with drug development, however, have not prevented the pharmaceutical industry from making a respectable return. Between 2003 and 2012, the eleven largest drugmakers made \$711.4 billion in profits, according to an analysis of corporate filings by the lobbying group Health Care for America Now (HCAN). In 2014, the world’s ten largest publicly held pharmaceutical companies had an average profit margin of 19 percent, according to an analysis by *Forbes*.

While drugmakers have attempted to cast the widely publicized price hikes by Turing Pharmaceuticals and Valeant Pharmaceuticals as exceptions to the rule, their activities are merely the most extreme examples of what is a common and widely shared practice in the pharmaceutical industry.

This was underscored by the price hikes at the start of the year by Pfizer and a number of other pharmaceutical companies. Last month, the pharmacy benefits manager Express Scripts published a report that found that U.S. drug prices had nearly doubled since 2011.



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