

Why One Drug Costs \$295K a Year

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There is now an approved prescription drug that costs \$295,000 a year.

Let's digest this for a moment. A prescription drug that costs twice as much as a college education. Every. Single. Year.

And it's not an outlier. Gattex, which is prescribed for short bowel syndrome, is the fourth drug approved in 2012 that's priced above \$200,000 per patient, per year.

The market for high-priced drugs meant to treat rare diseases, such as Gattex, is growing at a faster rate than the overall drug market. But even excluding these Rolls Royce drugs for uncommon diseases, brand-name pharmaceutical prices have risen faster than inflation. According to Express Scripts, a pharmacy benefits manager, brand-name meds increased more than 13% from September 2011 to September 2012.

You know, because they were just so cheap to begin with, right?

How Consumers Can Even Afford a \$300,000 Drug

The reason why Gattex is priced so high sheds light on how the market for pharmaceuticals works—that's to say in a way that hardly makes sense.

CFAD Exhibit 1068
CFAD v. NPS
IPR2015-00990

Gattex is considered an “orphan drug,” which has been a booming section of the pharmaceutical industry in the past decade. Targeting rare diseases is not only profitable, but it can even be seen as philanthropic. The current treatment for short bowel syndrome can cost well over \$100,000 a year, and additional costs may run as high as \$500,000. Gattex may allow patients to return to work and earn an income, amounting to a significant improvement on their quality of life. Ostensibly, Gattex costs as much as any other drug to develop, but short bowel syndrome is a rare disease, so the market will be very small—and hence why its maker, NPS Pharmaceuticals, priced it so high.

This said, no patient will have to pay out of pocket for it. Instead, the drug will be covered by a patchwork of insurance, coupons and charitable organizations. Commercial insurers will pay for part of the drug, around 70%. The remaining co-pay will be covered by NPS Pharmaceutical’s co-pay assistance plan or—in the case of Medicare patients—by rare disease organizations that get funding help from NPS Pharmaceuticals. About 15% of patients who can’t pay anything will get it for free. (NPS’s team of marketers work personally with everyone who wants to use the drug.)

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Until this strategy was picked up (and encouraged by a 1983 law), drug companies had no incentive to find cures for rare diseases with tiny markets. Now they do. According to a survey released on Thursday, drug companies are shifting away from developing drugs for common diseases toward doing so for orphan diseases. In 2011, they invested \$50 billion of their own money into research targeted to rare disease medicine—at the end of that year, 1,800 such drugs were being tested on patients.

So you can understand why the Rolls Royces of the drug world are expensive. But what about the Hondas—the everyman’s drugs that many people need?

How Pharmaceutical Companies Make Money

When you shell out \$295,000 for a drug, you're not paying for the chemical compounds in it, but the research, development and grueling approval process for the drug.

Estimates vary on how much each drug costs from inception to clinical trials to approval to selling, but the consensus is that it's in the billions, which doesn't account for drugs that never even make it to market. To recoup these costs, drug companies get a patent on the drug, giving them an (arguably deserved) monopoly. The profits on that high-priced drug in turn help fund development of future meds.

But, wait, there's more ...

The Pay-for-Patent Scheme

Eventually, the patent will expire, and a generic manufacturer or several can make and sell it for pennies on the dollar. To prolong its patent on a brand-name drug, a company will tweak the formula to "reset" the patent, so it can keep producing the drug exclusively for a few years longer. In theory, generic companies can challenge these tweaks in court, so they can start manufacturing the drug themselves, but it's an expensive legal process.

To make it easier for everyone (except consumers), pharmaceutical companies pay generic makers to withhold cheaper versions from the market. For example, Bayer paid \$400 million to generic drug makers to keep the generic version of the antibiotic drug Cipro off the market until 2003, when Bayer's patent expired.

A 2011 Congressional Budget Office report estimated that a Senate bill to outlaw these payments (now stalled) would lower drug costs in the United States by \$11 billion, as well as save the federal government \$4.8 billion over 10 years, since it would be able to pay for generic versions for Medicare and Medicaid patients.

There is still hope: A court case challenging these types of payments is up before the Supreme Court on March 25th.

America, Land of the Expensive Scripts

In many countries, governments have instituted price controls to keep medicine more affordable for their citizens. But, in the U.S., drug companies are free to raise prices as they see fit.

Zola P. Horovitz, Ph.D, a pharmaceutical and biotechnology industry consultant, told the authors of the Freakonomics blog, “Most people do not realize that when a prescription is paid for in the U.S., the payer (the patient, his or her insurance company, or the government) is subsidizing the cost of that same prescription in most countries outside the U.S.”

She claims that companies—whether American or Norwegian or anywhere else—have to offload the full price almost exclusively onto Americans, while patients in other countries get a discount. In November, India moved to bring more “essential” drugs, like HIV medication, under price controls. And China clamped down on prices just last week.

So couldn't the U.S. do the same? Not likely, since developing new drugs would no longer be profitable, and pharmaceutical research and development would drastically drop.

The War of the Coupons and Co-Pays

Generics have always been a cheap and safe alternative, and in the past year, their price has even dropped 22%. (Here's a helpful tip: Costco almost always has the lowest generic drug prices.) But even when generics are plentiful, pharma companies have another trick to get you to buy brand-name drugs: coupons.

Let's say that you need a prescription to treat cholesterol. Your doctor gives you two choices: Drug Brand Name or Drug Generic. They do the same thing, but Drug Brand Name costs more—\$500 versus \$100. The insurance company, which is covering most of the cost, obviously wants you to get the cheaper version. So it will charge you a co-pay of \$50 for Drug Brand Name, and a co-pay of \$10 for Drug Generic. You pick Drug Generic, the insurance company pays less and everyone is happy—except for Drug Brand Name's maker.

In response, pharmaceutical companies have started providing consumers with co-payment cards and coupons that bring the price of the brand name drug's co-pay below that of the generic version. So now there's no reason not to get Drug Brand Name. The pharmaceutical company picks up the \$40 difference, and the insurance company gets stuck paying the remaining \$450 for your designer drug.

According to IMS Health, an information company that tracks the pharmaceutical industry, use of co-payment cards, coupons and other discounts has more than tripled since mid-2006. As you can imagine, health insurers and consumer groups say this is one big reason why insurers have been raising rates. (People on Medicare don't get coupons because it's considered an illegal kickback.)

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A 2011 study by the Pharmaceutical Care Management Association, which represents companies that administer pharmacy benefits, estimated that discount cards and coupons will increase prescription drug costs nationally by \$32 billion over the next decade. The Pharmaceutical Care Management Association has argued that each one percentage point decrease in the “generic drug dispensing rate raises the amount that employers, unions, state governments and consumers spend on prescription drugs by \$3 billion annually.” So consumers do eventually get the bill for these pricier versions—and then blame insurers and the government for it.

Defenders of coupons say, in some cases, generic alternatives aren't exactly the same or aren't

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