

EXPLAINING THE HIGH COST OF PRESCRIPTION DRUGS

by Merrill Matthews, Ph.D.

If you are taking a prescription drug, there's an 86 percent chance it's a very affordable generic version of a brand name drug. But that still leaves millions of Americans taking new drugs, whose prices have become a political target.

Many brand name drugs are expensive; there's no disputing that. But there are reasons why some drugs—not all—cost so much, and why some of the proposed political “fixes” would either make those drugs even more expensive or ensure they are never developed for the patients who need them.

DRUGS ARE COSTLY TO DEVELOP

Drug manufacturers report their annual research and development expenditures—\$51.2 billion in 2014. Dividing that amount by the number of newly approved drugs renders an average cost for each year. But while R&D costs rise at a fairly steady rate, drug approvals vary significantly—usually between 20 and 30 per year, though there were 39 in 2012 and 41 in 2014. So to smooth out those peaks and valleys, we averaged those costs, including some post-approval expenditures, over the decade 2004-13, resulting in an average cost of about \$1.756 billion per newly approved drug. [See IPI's: *The High Cost of Inventing New Drugs—And of Not Inventing Them*]

Interestingly, that figure is almost identical to Tufts Center for the Study of Drug Development economist Joe DiMasi's much more rigorous conclusion of \$1.707 billion in direct out-of-pocket R&D and post-approval costs for a new drug.

THE TARGET PATIENT POPULATION IS OFTEN SMALLER TODAY

Over the past 20 years drug company R&D has increasingly shifted from developing relatively simple, small-molecule drugs that targeted widespread chronic diseases—where development costs would be spread over millions of patients—to large, complex molecules, often injectible biologics, that target much smaller patient populations.

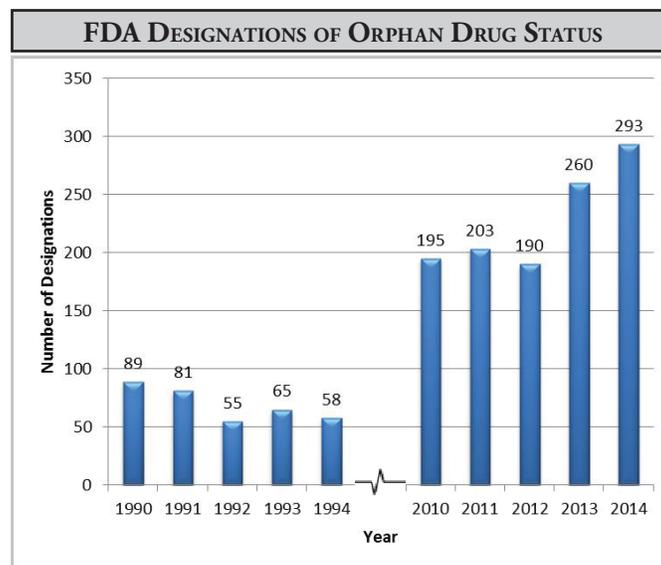
For example, between 1990 and 1995, the FDA approved between 55 and 89 drug company requests for rare (or “orphan”) drug disease status—i.e., diseases that affect fewer than 200,000 people. Those requests have exploded over the last decade, with the FDA granting orphan drug status to 260 new molecules in 2013 and 293 in 2014.

[See the figure.]

So while R&D spending is rising at a relatively steady pace, the number of potential patients who could benefit from many of the new drugs is shrinking, making the cost of drug development for each new patient rise exponentially.

RESTRICTING IP PROTECTIONS WOULD INCREASE THE COST

Some have suggested that reducing new drugs' 20-year patent life or 12 years of data exclusivity would allow a generic version to hit the market earlier, giving patients a less-expensive option. But reducing the intellectual property (IP) protections will likely raise prices, not lower them.



Once a drug manufacturer identifies a promising molecule, it must file for a patent and then start the R&D process. It can easily take a new drug 10 to 12 years for early testing, clinical trials and, hopefully, FDA approval. But the patent-clock is ticking during development, leaving the company perhaps eight to 10 years in which to recover its investment.

The cost of producing a new drug is the same whether its patent life is 10, 15 or 20 years. If that IP protection were shortened, the innovator company would either:

- Raise a drug's price in order to cover its costs and make a profit in less time; or
- Cancel the project all together because the company doesn't think it can recover its costs.

And while IP protections have not been reduced—at least in the U.S.—the growing number of regulations that increase the time from “inception to ingestion” have a similar impact, because it takes longer and costs more for a new drug to become available.

If lawmakers want to lower drug prices and encourage even more new drug development, they should allow innovator companies to receive more benefits from their current IP protections. How? One way would be to start the IP clock ticking later.

For example, let a company file a patent once it discovers a prospective molecule, but the patent or data exclusivity clock wouldn't start ticking until some later point, say, when the drug begins clinical trials, allowing manufacturers to spread their R&D costs over a longer period.

COMPETITION DRIVES COSTS DOWN

Drug company critics often claim that IP rights protect manufacturers from competition. Not so.

While it is true that IP protections prohibit competitors from rolling out an identical version of a new drug, companies may release different formulations treating the same disease. For example, Pfizer released its erectile dysfunction drug Viagra in 1998, while Eli Lilly rolled out its competing Cialis in 2003. And the FDA recommended approval in October 2013 of two new hepatitis C drugs, Gilead Sciences' Sovaldi and Johnson & Johnson's Olysio, and approved AbbVie's Viekira in 2014.

Competition gives physicians the option of prescribing a lower-cost drug if it is equally effective. Or companies with less popular drugs than the market leader may offer them to, say, the Veterans Health Administration at a deeply discounted rate in an effort to gain some market share.

The point is that competition, not regulation, is the best way to put downward pressure on prices. And with more than 7,000 new drugs in the testing pipeline, there is lots of potential competition. Thus the government's best course of action isn't price controls, but streamlining the drug-approval process to ensure that as many drugs can hit the market as quickly—yet still as safely—as possible.

SHOULDN'T WEALTHY COUNTRIES PAY HIGHER DRUG PRICES?

In general, the “list price” for brand name drugs is higher in the U.S. than in other countries—though Americans usually pay much less for generics. But the official figures can be misleading.

While critics focus on a drug's list price, very few if any actually pay that price. There appear to be no published data, but Center for Medicine in the Public Interest President Peter Pitts estimates that most brand name drugs are discounted between 30 percent and 50 percent, depending on the drug and level of competition. And the 90 percent of Americans with health coverage will only pay out of pocket a fraction of the discounted price. Finally, those without coverage are often able to get assistance with the most expensive drugs.

Ironically, some of the loudest critics of U.S. consumers paying more than other countries are the same people who claim that the wealthy should pay more (e.g., taxes). Well, the U.S. is arguably the wealthiest country.

For example, according to the World Bank, the per capita GDP—that is, the share of the economy per person—for the U.S. was \$54,629 in 2014. The United Kingdom was \$45,603, about 20 percent less. For Germany it was \$47,627 and France \$42,732. For Brazil it was \$11,348 and India \$1,585.

Do critics of U.S. drug prices really believe that U.S. residents should be paying the same price as residents of Brazil, whose per-capita GDP is one-fifth of the U.S.?

CONCLUSION

No one likes paying high prices. But there are reasons why some drugs are very expensive, and why the U.S. bears a disproportionate share of that cost. Without that revenue to develop and test new drugs—i.e., sustainable innovation—there would be no new drugs to criticize.

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