

The High Cost Of Inventing New Drugs -- And Of Not Inventing Them

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There is a financial cost to developing new drugs—and it’s a big one. There is also a big cost to not developing new drugs, and that cost can be both financial and human. People may be able to live with the pain that an undiscovered drug might have alleviated, but they may not be able to do all the things they would have. A cancer patient might still have a few productive years after a diagnosis, but how much would it be worth to the patient—and to society (think Steve Jobs)—if a new drug meant that extended life could be indefinite?

Economist Joe DiMasi of the Tufts [University] Center for the Study of Drug Development is probably the country’s leading expert on the cost of developing new prescription drugs.

His [most recent assessment](#), released last November and co-authored with economists Henry G. Grabowski of Duke University and Ronald W. Hansen of the Simon Business School at the University of Rochester, estimates that the total cost to develop and gain marketing approval for a new drug is about \$2.6 billion.

And it can take 10 to 12 years for that new drug to get through the Food and Drug Administration's (FDA) approval process and hit the market—a process I call “inception to ingestion”—if it ever does.

Moreover, once the drug has made it to market, there is often post-approval research and tests to evaluate dosing strength and a host of other factors. DiMasi et al estimate those efforts can add an extra \$312 million to the cost of a drug, for a grand total of \$2.87 billion (in 2013 dollars).

Included in that figure is what economists call “time costs,” which DiMasi defines as “expected returns that investors forego while a drug is in development.” He estimates those time costs to be \$1.163 billion. If we remove that figure, the actual out-of-pocket spending to create a new drug is \$1.395 billion. And if we combine that pre-approval out-of-pocket cost of \$1.395 billion with the post-approval cost estimate of \$312 million, you get \$1.707 billion spent to develop a new drug.

Over the many years that DiMasi has been releasing his drug-cost estimates, critics have complained they are too high, that it doesn’t cost that much to create a new drug. And they are especially critical of his inclusion of time costs.

DiMasi goes through an extensive investigative process, getting information from 10 drug manufacturers and tracking the progress of more than 100 experimental drugs in the pipeline in order to arrive at his estimates.

But there is another far less rigorous method of calculating the average cost of drug development: Dividing the drug manufacturers’ publicly reported research and development expenditures in a given year by the number of newly approved drugs. If we do that for the last

10 years we come up with an average cost of about \$1.756 billion per drug—remarkably close to DiMasi’s \$1.707 billion.

Average Cost of Drugs Approved by Year

Year	R&D (Billions)	Approved per year	Cost per Approved Drug (Millions)
2004	\$37.0	36	\$1,027.8
2005	\$39.9	20	\$1,995.0
2006	\$43.4	22	\$1,972.7
2007	\$47.9	18	\$2,661.1
2008	\$47.4	24	\$1,975.0
2009	\$46.4	26	\$1,784.6
2010	\$50.7	21	\$2,414.3
2011	\$48.6	30	\$1,620.0
2012	\$49.6	39	\$1,271.8
2013	\$51.1	27	\$1,892.6
Total	\$462.0	263	\$1,756.1

Source: PhRMA, FDA

Averaging the last 10 years—as opposed to looking at one year—rounds out some of the disparities of any given recent year, which can see a burst or a dearth of FDA approvals. And the numbers are not adjusted for inflation, though there hasn’t been much for the past decade.

But whether you prefer DiMasi’s much more scientifically and academically rigorous approach or my back-of-the-envelope method, it’s clear that drug development is very expensive—and likely to grow even more so.

One reason for those growing R&D costs is that drug manufacturers have been transitioning away from small molecule drugs, usually taken in a pill, to much more complex biologic drugs. And in some cases new drugs can cure (e.g., Sovaldi for hepatitis C) some of the most difficult diseases.

Plus the approval process has become more complicated and cumbersome, and there is little reason to think the FDA, which has changed from being a checkpoint on the drug-approval road to more of a roadblock, will streamline the process without congressional and presidential pressure.

There are ways to make drugs less expensive—i.e., cut down on some of the bureaucratic oversight or lengthening the patent life, which means the manufacturers would have more time to recoup their investment—but both efforts would require a major legislative push.

The good news is that drug companies are proceeding with their research to create new and innovative drugs; the bad news is that it costs a lot to do that—however you calculate the costs. But the public won't get more innovative drugs by imposing price controls, which is one of the critics' primary solutions to the high cost of drugs.

How many companies would invest nearly \$2 billion over 10 to 12 years before receiving a dime in returns—if they ever do—if politicians and bureaucrats, under pressure to lower costs, decided the price of a new drug? How many drugs would not be invented? More importantly, how many lives would not be improved or saved?

If the cost of creating new drugs is high, the cost of not having any new drugs is immeasurable.

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