

THE HIGH COST OF INVENTING NEW DRUGS—AND OF NOT INVENTING THEM

by Merrill Matthews, Ph.D.

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 could extend a patient's life indefinitely?

That's not even a hypothetical question. The drug manufacturers poured money into finding a treatment for AIDS once it became clear the disease would take thousands of lives. The research and development was costly and didn't emerge overnight, but being diagnosed with AIDS is no longer a death sentence.

HOW MUCH DOES IT COST TO CREATE A NEW DRUG?

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.¹

And it can take 10 to 12 years for that new drug to get through the development process and hit the market—a process we refer to as “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 DiMasi's pre-approval out-of-pocket costs of \$1.395 billion with the post-approval cost estimate of \$312 million, you get \$1.707 billion spent to develop a new drug.

AVERAGE COST OF DRUGS APPROVED BY YEAR			
Year	R&D (Billions)	Approved per year	Cost per Approved Drug (Millions)
1994	\$13.4	22	\$609.1
1995	\$15.2	28	\$542.9
1996	\$16.9	53	\$318.9
1997	\$19.0	39	\$487.2
1998	\$21.1	30	\$703.3
1999	\$22.7	35	\$648.6
2000	\$26.0	27	\$963.0
2001	\$29.8	24	\$1,241.7
2002	\$31.0	17	\$1,823.5
2003	\$34.5	21	\$1,642.9
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	\$691.6	559	\$27,596.0

SOURCE: PhRMA, FDA

DiMASI'S METHODOLOGY

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.

A DIRECT WAY OF ESTIMATING THE COST OF CREATING A NEW DRUG

But there is another far less rigorous method of calculating the average cost of drug development that leads to remarkably similar results: 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, and include 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.

Total drug company R&D spending patterns have remained pretty steady over the years, with most years seeing a small increase over the previous years. However, U.S. Food and Drug Administration (FDA) approval is much more sporadic. A few delays one year can mean an artificially high number of approved drugs the next year. Incorporating 10 years into the overall estimate rounds out some of the FDA approval disparities of any given recent year. The numbers are also not adjusted for inflation, though there hasn't been much for the past decade.

THE GROWING COST OF DRUG DEVELOPMENT

Whether you prefer DiMasi's much more scientifically and academically rigorous approach or this 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, which are targeting Alzheimer's, arthritis, diabetes and a host of other diseases.

And in some cases drug makers are developing not just treatments, but cures (e.g., Sovaldi for hepatitis C) for some of the most difficult maladies.

THE GROWING ROADBLOCKS IN DRUG DEVELOPMENT

One factor that increases the costs of developing new drugs and the time it takes to get them to the market is the complicated and cumbersome approval process. And there is little reason to think the FDA, which has changed from being a checkpoint on the drug-approval road to a roadblock, will reform its ways without congressional and presidential pressure.

Nor is it clear the agency wants to. Whereas drug companies have an incentive to get a drug that has proven to be safe and effective to market as quickly as possible, bureaucracies are under no such imperative. Indeed, if they move a drug approval along quickly and someone is harmed by the new drug—or if a trial lawyer can convince a jury that someone was harmed—then the FDA catches lots of media and public grief. If the regulators take their time, even if they know they will approve the drug, they appear to have been more thoughtful.

CONCLUSION

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 return—if they ever do? 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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ENDNOTES

1. "Cost to Develop and Win Marketing Approval for a New Drug Is \$2.6 Billion," Tufts Center for the Study of Drug Development, Nov. 18, 2014.

Data for chart taken from:

PhRMA, "Reporter's Handbook: Key Industry and PhRMA Facts", <http://www.phrma.org/news-media/related-resources/key-industry-factsabout-phrma>

and
Food and Drug Administration, "Novel New Drugs 2014 Summary", <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DrugInnovation/UCM430299.pdf>

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