New Directions in Health Care: Controlling Rising Drug Costs

This is New Directions in Healthcare, the Commonwealth Fund's podcast, and today we're looking at a significant driver of rising medical costs in this country: prescription drugs. In the fall of 2015, Turing Pharmaceuticals shocked the nation by raising the price of a 60-year-old drug urgently needed by people with compromised immune systems. The cost to treat a potentially life-threatening infection went from \$13.50 for a single dose of Daraprim to \$750. CEO Martin Shkreli told CBS:

"The drug was unprofitable at the former price, so any company selling it would be losing money, and at this price it's a reasonable profit—not excessive at all."

This case sparked outrage from politicians and the public, reviving discussion of why prices for prescription drugs in the U.S. are increasing. Dr. David Blumenthal is president of The Commonwealth Fund.

"In the period from about 2010 to 2014, drug costs were atypically slow in their increase. There were relatively few new drugs and many existing drugs went off patent, which meant that they had more competition from generic drug makers."

Then, several new, high-value drugs won FDA approval, and Dr. Mark McClellan, Director of the Duke-Margolis Center for Health Policy, says the overall cost of prescription drugs rose dramatically.

"Drugs don't make up most of health care costs, but they have grown faster than the overall rate of the economy in the last few years, and there have been a couple of notable years of prescription drug costs recently, particularly in 2014, associated with the introduction of some new cures for hepatitis C and new cancer drugs and other treatments as well."

When pressed to <u>explain</u> high prices, the <u>makers</u> of brand name drugs often cite the need to underwrite expensive research. Again, the Commonwealth Fund's Dr. David Blumenthal.

"They say, for example, that they try out a lot of new drug ideas. They spend a lot of money developing them, billions of dollars often, and then they fail because they're not safe and effective, and therefore it's only a fraction of all the drugs that they experiment with that make it to market and on which they can make revenue."

But some experts have begun to challenge that claim.

"The big drug companies have been notoriously ineffective in developing new drugs, and most of the new drugs that they develop are now being purchased or licensed from small biotech companies, so though they make a big point about research and development, their actual research and development is not very effective, and I think more transparency into what they do and how they do it would be useful."

At Johns Hopkins University's School of Public Health, Professor Gerard Anderson argues government should more aggressively regulate drug prices.

"There are no rules. There's no legislation. You just basically, as a drug company, have the ability to set the price, and if the government has given you a monopoly – and that's what a patent is – then there are no competitors for your drug, and so you can charge essentially whatever you want. You don't have to worry that a lot of people won't have access to the drug, because you're going to make a lot of money on a few people, and that's exactly what happens."

He adds that even generic drug makers may be charging too much.

"Five drugs companies—and soon it will be four—in the generic drug industry control over half of the market, and the reason why generic drugs have been inexpensive in the past is pure price competition. They're selling exactly the same product. That's what a generic drug is, but they're selling it on the basis of price competition, but if there's not a lot of competitors, then you don't get very good price competition."

But Mark McClellan warns against the imposition of price controls, since they may limit patient access to certain medications.

"In the United Kingdom, which has significantly lower drug prices than the United States, there is a government body set up that reviews whether or not the price set by a manufacturer is worth it for certain kinds of patients, and in some patients makes a decision that the price is not worthwhile. That's negotiating leverage. That means that unless the price comes down, people don't have as much access to the drug."

As that debate continues, Dr. Blumenthal says the federal government has found some ways to negotiate for better prices.

"The Veterans Administration and the Department of Defense negotiate drug prices and have the statutory authority to set an upper limit on drug prices—that is the lowest amount that any single purchaser can get from a drug company, and there are other drug price controls that are imposed, for example, by states on behalf of their Medicaid programs. When you put California and New York together—two blue states that often pioneer with these kinds of new programs—those are big parts of the national market."

Some health care providers also bring market pressures to bear, working through a federal program.

"The 340-B program is an authority that Congress has granted to the Department of Health and Human Services to assist certain providers of care—hospitals and clinics for example, or community health centers and has said to them, "You can demand a price that is no higher than the lowest price charged to any purchaser by that drug company for that drug."

In addition, experts say the Food and Drug Administration could play a greater role in promoting competition—an idea explained by Mark McClellan.

"FDA has a process for accelerating the approval of breakthrough medications. They get special treatment. They get extra attention from the FDA regulatory staff. They typically have a faster review process. One thing that could be helpful is making sure that the FDA does prioritize drugs that could help make less costly competitive treatments available for a particular condition when there is a breakthrough treatment."

And there is pressure to speed up approvals for so-called biosimilars, which are generic versions of biologic medications. Again, The Commonwealth Fund's David Blumenthal.

"They are biological molecules—usually proteins—often very, very effective but complicated to make, and they are harder to assure equivalence when you're talking about a newer agent that is meant to compete with a patented, existing agent, and the Europeans have been more effective at developing ways of enabling competitors to get those drugs to market than we have been. The FDA is working hard on that, and I think is doing a better job."

Looking ahead, McClellan predicts some slowing in the rise of drug costs over the next few years, but with the U.S. spending 17.5 percent of GDP on health care overall, he and David Blumenthal agree the nation will have to keep an eye on this and other sectors of the medical marketplace.

"The largest component of our spending in absolute terms are hospital costs and physician costs. Recently, drugs—though they are still a relatively modest amount—on the order of 12–15 percent in overall costs, have played an outsized role in the resurgence of healthcare costs."

"The expectation is that we won't see growth that is as rapid as we saw in 2014 and 2015. Overall, spending growth is down a bit this year, but it's still projected to be higher than the overall rate of growth for the economy, and it's still projected to be a significant part of overall health care spending growth, and with rising health care costs and concerns about affordability and access to cures, this is certainly going to be an important policy issue for the coming years."

That was Dr. Mark McClellan, Director of the Duke-Margolis Center for Health Policy. He joined the Commonwealth Fund's Dr. David Blumenthal and Johns Hopkins' Professor Gerard Anderson for this edition of New Directions in Healthcare, the Commonwealth Fund's podcast. I'm Sandy Hausman. Thank you for listening.