IN THE PIPELINE

A Drug Pricing Proposal and its Effects

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The topic of drug pricing is never that far away in the news, and it's closer these days than it's been in a while. There's a series of questions, all of which can set off one sort of argument or another. **First**, are drug prices in the US too high? We will bypass the "Too high for what?" response, although that's not as stupid as it might sound. Note that for this one, you really have to say *prescription* drug prices - although a lot of people don't realize it, generic drugs tend to be cheaper in the US than they are in (say) the EU. That leads us to a **second** question: are all prescription prices too high, or are some of them well out of line with the others? **Third**, if you believe that the answer to those questions, one way or another, is "yes", should the government take steps the lower those prices? The **fourth** question follows immediately on that one: what steps are those exactly, and how politically and legally feasible are they? A **fifth** question follows as well: if you're on board with a "yes" to these last few questions and have some legislative or regulatory steps in mind, what are the potential downsides to such actions, and how do you balance those with the positive effects you're aiming for?

Longtime observers of the industry that pays my bills will know that when that fifth question comes up, pharma companies always talk about bad effects on drug development and innovation under a price-control system. One response to that is "Well, they would, wouldn't they?", but just as with the canonical Mandy Rice-Davies response, it doesn't necessarily mean that the objection is invalid *prima facie* (even if it would also be advanced if it were). This topic is especially pertinant given that the Congressional Budget Office has come up with a scoring system to try to quantify this exact effect. That would be useful, because otherwise you have the problem of trying to quantify things that might have existed, but now don't because a decision made years ago.

I mean, let's do the *reducio ad absurdum*: if you were to somehow forbid new drug approvals, and somehow mandate that everything now under patent protection will immediately go generic, the immediate effects for the medical consumer will be glorious. Drug prices will fall very quickly, and for a while, there will be no difference in the medical care available to the public. Only with time will the drugs that were in the immediate pipeline not show up. And with more time, all the things that were in earlier stages of development won't show up, either. Slowly, gradually it will become apparent that we had gotten used to a. . .well, let's call it a "pipeline" of new drugs - improvements on existing drugs, and totally new classes of therapies as well, and that this flow has stopped. But it would take several years before you'd notice for sure.

Now, we're not going to take those steps in my thought experiment. But the argument is that price controls will turn the dial in that direction. The problem is, the CBO model used to estimate these things may well be flawed, as Steve Usdin details here. The first thing to note is that the CBO explicitly agrees that yes, drug price controls will lower the number of drugs approved:

> *CBO's model estimates that price controls similar to those proposed in the Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3) would reduce pharmaceutical industry returns in the top quintile of Medicare Part D drugs by 15-25%. The bill would give HHS power to "negotiate" drug prices and impose civil and tax penalties on companies that fail to agree to prices CMS*

> *proposes. Revenue reductions similar to those envisioned by H.R. 3 would, CBO projects, "lead to 2 fewer drugs in the first decade (a reduction of 0.5 percent), 23 fewer over the next decade (a reduction of 5 percent), and 34 fewer drugs in the third decade (a reduction of 8 percent)."*

As it is, the model predicts 59 fewer drugs over the next 30 years, and an estimated savings of 900 billion dollars total. We could start by deciding if that's a good tradeoff or not; no doubt there are arguments to be made in both directions. But let's get to an issue that might confound any such calculation, because there are drugs and there are drugs. Usdin quotes one of the members of the CBO's health advisory panel, Harvard Business School's Amitabh Chandra, as saying that the more innovative drugs will be hit disproportionately hard by this proposal. His argument (and others - see this open letter) is that the CBO model is too one-size-fits-all and in particular, that it ignores venture capital investments in biopharma startups, where a substantial amount of game-changing stuff has its birth. This is surely going to be one of the most sensitive parts of the whole ecosystem when it comes to to price control ideas - the great majority of VC investments come to nothing, so the ones that work have to pay off pretty thoroughly.

This, I would say, is a substantial problem. For all the craziness of the VC world, the US biopharma venture capital system is (in my view) one of the glories of the US economy and a substantial contributor to global well-being. There is no place on earth where it is easier to get wild, interesting, and unusual ideas funded, launched, and staffed than in the US, and if we mess with that system too heavy-handedly, we will regret it greatly. I will not defend every company that's launched by VC money, nor every single venture capital shop. But taken as a whole, we have something very special and valuable, and we need to recognize that. As an aside, I spent quite a bit of time here a few years ago arguing against the idea that floats around that all drugs just come from the NIH, anyway, so I don't want to relitigate that one (although I understand that it's going to make more appearances during these very arguments).

There are more problems down in the details, when you look at the mechanics of the current bill. As the open letter says, the proposed legislation now contains a 95% tax penalty provision for any company that does not accept the government's price offer. This, its signers note, is not exactly what is meant by the word "negotiation". It would, in fact, seem to be a mechanism for the government to dictate prices by fiat. And yes, I know that that idea is politically popular with many groups - if we enacted it today there would be millions of people cheering for the drug companies to get it really good and hard. But just because a particular idea satisfies your urge for revenge does not make it the right decision - as with so many other things, the world would be a much simpler and easier to understand place if that were always true. And just because it would be nice if the prices for things that we want and need were always nice and cheap, that doesn't mean that it can always be that way. I realize that drug prices are (for many) a very different argument.

So let's see where this proposal goes. If it does make it into law in its present form - a prospect I find fairly unlikely - it will profoundly change the landscape of drug development in the country where the bulk of that work (one way or another) gets done. It seems impossible to me that it can change it any other way but for the worse.

ABOUT THE AUTHOR

Derek Lowe

Derek Lowe, an Arkansan by birth, got his BA from Hendrix College and his PhD in organic chemistry from Duke before spending time in Germany on a Humboldt Fellowship on his post-doc. He's worked for several major pharmaceutical companies since 1989 on drug discovery projects against schizophrenia, Alzheimer's, diabetes, osteoporosis and other diseases.

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