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To lower prices for prescription drugs, use more data

By Stephanie Zaremba | October 7, 2016

It seems that every week brings news of another drug price scandal and another pharmaceutical company scrambling to justify significant price increases. The details of each story differ wildly—from cutting-edge drugs to drugs that have been used for decades; from niche companies to pharmaceutical giants; from ground-breaking cures to run-of-the-mill treatments.

Yet each narrative contains a common thread: At some point, the cost of drug development and FDA approval is cited as a contributing factor to rising prices.

Truth be told, no one readily agrees on the cost of drug development. While one recent study from Tufts University pegged the cost of getting a drug approved at $2.6 billion, a 2006 study from Health Affairs found a wide degree of variation, estimating that the cost could be anywhere from $500 million to more than $2 billion, depending on the drug and developing firm.

Meanwhile, in Washington, D.C., lawmakers are certain of one thing: When it comes to the cost of both developing and purchasing drugs, the price tag is too high. So Congress has been considering different ways to bring those prices down.

One major legislative package, dubbed the 21st Century Cures Act, aims to increase the rate at which we develop and approve drugs and medical devices through, among other things, reforms to the FDA approval process and funding for the National Institutes of Health. Other proposals directly target price setting and market exclusivity in an attempt to more directly force prices down.

All of these approaches may leave on the table a vital tool: information technology. Because it's quite possible that the real savings in drug development will be realized not through additional NIH research, tweaks to FDA processes, or draconian price setting, but through a wholesale technological revolution in how emerging drugs are tested in the first place.

The FDA has only recently begun to seriously talk about using "real world evidence" in its review of drugs and devices. Regulatory experts will understand this phrase to mean that the FDA is thinking about incorporating data from outside the strict walls of a clinical trial into its reviews.

But a lay person would be forgiven for wondering what kind of evidence the FDA has been reviewing all of these years if it isn't from the real world.

The reality is that clinical drug trials, like the rest of the healthcare industry, are still operating by the rules of a paper-based world. Part of the reason these trials take years to complete is because participants and information must come through strictly-defined collection processes — and data that falls outside those parameters is ignored.

To regulators, these processes are known and predictable — and known and predictable is safe. When we're talking about drugs we are going to give our children or devices to be implanted in our parents' bodies, it's important to have a high bar for proving safety and efficacy.

But the FDA could be leaving new, efficient mechanisms untapped. Now that we can measure increasing amounts of data about our health — from wireless scales to electronic health records, to consumer-facing genome sequencing — we shouldn't be afraid to incorporate that kind of information into drug reviews.

One could envision certain trials in which data from a Fitbit or Apple's ResearchKit would be useful. But the most obvious example is data contained in electronic health records. That's a virtual treasure trove of health information, particularly about side effects after a drug is on the market, that still sits largely untapped.

When we dig into expansive networks of data, we can derive powerful insights. Other industries understand this: Waze knows, in real time, the best way around traffic jams, and Mint provides insights into spending and saving across multiple accounts. But healthcare still doesn't operate like the "real world," nor do pharmaceutical trials -- researchers and companies are still largely restricted to information contained in disparate silos.

The crisis of rising drug prices is like any problem. We can address it through a series of band-aid measures, or we can attack some of the underlying causes. And while many of the underlying causes of high drug prices are thorny and complicated, the idea that we could make better use of modern information technology to approve drugs is pretty simple.

In the 21st century, there's no reason we can't expect the drug approval process to be safe and effective — and efficient, too.

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