Washington Examiner

When cost saving is lifesaving: Expanding patient access to biosimilars

Orrin G. Hatch - Wednesday, March 4, 2020

That our nation has developed many, if not most, of the world's modern life-giving, lifesaving medical treatments is a shiny fiber that runs through the strong fabric of the American Dream. The astounding evolution of U.S. pharmaceutical development has progressed from early plant-based remedies, to basic, chemically synthesized "small molecule" drugs, to the exciting promise of tomorrow's cures with new therapies such as CAR-T and gene therapy.

Along the way, drug development was revolutionized when scientists harnessed the power of large molecule, living cells —genetically engineering them to create new "biologic" medicines. These treatments and their lower-cost counterparts, called "biosimilars," offer new promise to patients with a host of debilitating illnesses, including cancer, multiple sclerosis, and rheumatoid arthritis, to name a few.

Biologics are by necessity more expensive than chemical drugs. Their research and development costs are high, the raw materials costly, and their complex manufacturing process is lengthy and intricate. Biologic drugs comprise only 2% of all prescriptions in the country but represent over a third of net drug spending. In fact, they are the biggest driver of Medicare drug spending. With skyrocketing prescription drug costs continuing to burden patients, it's past time Congress delivers on the promise of affordable treatments.

Reducing pharmaceutical costs is something I happen to know about.

Thirty-five years ago, as chairman of the committee overseeing the FDA, I joined with influential House Democrat Henry Waxman to write a law, often called "Hatch-Waxman," which gave rise to the modern generic drug industry. This law, cited as one of the most significant consumer protection measures ever, carefully balanced a new pathway to speed delivery of lower-cost drugs to patients with incentives to spur innovation in pharmaceuticals. Today, over 90% of prescriptions are generic, saving consumers trillions of dollars over the last 35 years and an estimated $293 billion last year alone.

Early in 2007, when more and more patients were relying on the abundant promise of biologics, I began to think about how the proven model of Hatch-Waxman could be applied to these newly emerging products. Democrats and Republicans quickly agreed to work with me and

methodically crafted a bill — the Biologics Price Competition and Innovation Act — to create a regulatory pathway providing patients with lower-cost biosimilars.

This wasn't easy.

Democrats weren't eager to help the pharmaceutical industry. Republicans were leery of stifling innovation. Innovators were afraid of losing their intellectual property. Patients wanted next-generation therapies and lower costs. And there were serious policy questions about how to design the pathway for "follow-on biologics" — whose manufacturing must be highly controlled under the most rigorous of conditions known only to the innovator. That summer, when we considered the bill in committee, it was approved unanimously, showing the strength of our bipartisan alliance. Senators saw our powerful collaboration and largely followed, but not without a spirited debate over the bill's foundational 12 years of data exclusivity protection. That debate continues to this day.

It took two years for the bill to win final approval, aided immeasurably by the leadership of Rep. Anna Eshoo in the House, who insisted on the strong IP protections which were the foundation of the law's inherent balance.

Fast forward to 2020. At the decade mile marker, implementation of the BPCIA is well underway. Twenty-six biosimilars have been approved, and patients have access to lower-cost options of some of the most expensive biologics on the market. It's estimated that increased biosimilar use could save taxpayers as much as $150 billion over the next decade.

But our work is far from done. Barriers remain.

Implementation has been too slow. The highly technical work of assuring the follow-on copies are similar enough had to be crafted carefully. Legal challenges have kept over half the approved products off the market. Payment policy has also lagged behind — with legitimate questions raised about how to incentivize reimbursement of these high-cost medicines without providing a windfall to providers, insurers, or any others in the manufacturing-to-patient chain.

One option Congress, HHS, or CMS could consider is to increase patient access and save taxpayers billions by testing a "shared savings" model for biosimilars. This means Medicare savings associated with prescribing a biosimilar (as compared to the more expensive reference biologic) would be shared with patients, taxpayers, and providers. If written correctly, this sensible solution could save billions of dollars and answer the calls by millions of people asking for affordable treatment options.

There is a story here. It is one of the power of bipartisanship. It is a story of compromise, of forward-thinking, and cost-savings — and most importantly, of our getting the job done for patients.

Orrin Hatch served as a senator from Utah from 1977 through 2018.