Time to Throw In the Towel on Biosimilars

Biologic drugs don’t face strong competition, and Washington’s preferred solution slows innovation.

By Peter B. Bach and Mark Trusheim
Aug. 21, 2019 6:58 pm ET

A major reason drugs are even mildly affordable in the U.S. is that cheap generic copies can eventually flood the market. But first the Food and Drug Administration grants new drugs a few years of monopoly “exclusivity.” For decades this high-price-before-low-price model has fueled astounding pharmaceutical innovation while also providing long-term access to important treatments.

But today this model is in trouble. An entire class of high-priced medicines, called biologics, may never face strong competition from copycats. These drugs—which are used for cancer, rheumatoid arthritis, and other serious illnesses—accounted for 37% of all spending on drugs in 2017 even though they were only 2% of all medicines dispensed. While chemical drugs can be easily mimicked by generic drugs, biologic drugs are made in genetically engineered cells, a process that cannot be perfectly copied.

It wouldn’t be the end of the world if a few biologics—like the breast-cancer drug Herceptin, first approved in 1998—stayed overpriced. But now there are dozens of biologics that may command high prices in perpetuity. We estimate that Americans are spending $50 billion more each year than if the low-price part of the system were working for biologics.
We recently proposed that the government regulate the prices of older biologics while allowing the market to set prices for newer and more innovative ones like gene therapies. Scott Gottlieb, the Food and Drug Administration’s recently departed commissioner, disagreed. He tweeted in April that “it’s far too early to throw in the towel on biosimilars.”

Biosimilars are near-copies of the original biologic drug, similar but not the same. They are Washington’s favored way to introduce price competition for brand biologics. But because biosimilars aren’t and cannot be identical to the original biologics, the government appropriately requires that they undergo extensive testing before going on the market.

This creates two new problems. First, onerous testing requirements raise costs, delay market entry, and reduce the number of competitors. Even under ideal conditions a brand biologic might face only two or three competitors over many years. This would exert only
mild price pressure on the original drug—far less than the rapid and intense price pressure on chemical drugs from generics.

The average sales price of the brand biologic Neupogen, which increases white-blood-cell counts in cancer patients, is higher today than when it entered the market in 1991, though it has two competitors. Even the Biosimilars Council says biosimilars will only save around $50 billion over the next decade, about what we believe could be saved each year through price regulation.

The other problem is that large clinical studies of biosimilars themselves slow the pace of innovation by diverting patients from other studies of promising new treatments. Nearly 3,000 women had to undergo clinical trials of four biosimilars that may someday modestly dent the price of Herceptin. Meanwhile, clinical trials of cancer immunotherapies are short more than 100,000 patients.

The most valuable and scarce resource in pharmaceutical innovation is patients willing to participate in risky research. That resource shouldn’t be squandered on copycat medications that by definition cannot be better than drugs already available on the market.

Even today there are barely a dozen biosimilars on the U.S. market and no competitors on the horizon for dozens of biologic drugs. The barriers to entry are so high that even the hundreds of millions in sales these uncontested products generate isn’t enough to attract even one competitor.

Thus it is time to throw in the towel on biosimilars. After a biologic drug’s exclusivity period is over—the FDA currently protects biologic drugs for 12 years—government should regulate its price to provide a fair profit for its manufacturer. The pricing formula would incorporate all production and distribution costs, including reinvestment in manufacturing facilities and a reasonable profit benchmarked to other commodity manufactured products. Costs, margins and profits would be reported and then confirmed by an independent auditor, like the system used to pay hospitals for inpatient care. The manufacturer would be required to keep supplying the drug to the U.S. for that guaranteed profit or sell the business to a firm that will. Many investors would find such a business attractive.

Most issues in drug pricing are contentious. Ending monopoly pricing after a company has been rewarded for innovation isn’t. Pursuing biosimilars might seem like a solution,
but this approach is drawing patients away from studies of newer therapies even as it fails to control costs. Price regulation may be a tough sell in some quarters, but it’s the best way to keep the promise of America’s extraordinary pharmaceutical industry alive.

Dr. Bach is a physician and the Director of the Drug Pricing Lab at Memorial Sloan Kettering Cancer Center. Mr. Trusheim is a visiting scientist at the MIT Sloan School of Management and strategic director of MIT New Drug Development Paradigms.