FDA Commissioner Outlines New Plan to Increase Biosimilars by Balancing Innovation and Competition

By Eileen Koutnik-Fotopoulos

FDA Commissioner Scott Gottlieb, MD, has been outspoken about the critical need to reign in drug prices. Biosimilars are crucial for improving patient access to biologic drugs at an affordable cost. Biologics are now key in the treatment of cancer and autoimmune conditions. But cost remains an obstacle to access to drug therapy. As part of a larger shift to lower drug prices across the healthcare system, the FDA recently unveiled an 11-part action plan to boost the biosimilar industry as a way to lower drug costs through increased innovation and competition.

Scott Gottlieb, MD

During a speech at the Brookings Institution on July 18, 2018, announcing the release of the FDA's Biosimilars Action Plan: Balancing Innovation and Competition, Dr Gottlieb outlined 2 main reasons that biosimilar competition is currently "anemic," noting that of the 11 biosimilars that have so far been approved by the FDA, only 3 have gained significant market share.

"It's anemic because consolidation across the supply chain has made it more attractive for manufacturers, pharmacy benefit managers, group purchasing organizations and distributors to split monopoly profits through lucrative volume-based rebates on reference biologics—or on bundles of biologics and other products—rather than embrace biosimilar competition and lower prices," Dr Gottlieb said in a prepared statement (www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613881.htm).

"It's anemic because litigation has delayed market access for biosimilar products that are, or shortly will be, available in markets outside the U.S. several years before they'll be available to patients here," he continued. "These delays can come with enormous costs for patients and payers."

Dr Gottlieb pointed out that less than 2% of Americans use biologics, but biologic drugs account for 40% of all prescription drugs in the United States.

"To make sure that the next generation of breakthroughs remains affordable, it requires vibrant competition from biosimilars. But it also means that we must consider new payment approaches. Models that allow us to take advantage of the competition that biosimilars offer," Dr Gottlieb said.

In fact, "If Americans had the opportunity to purchase successfully marketed, FDA-approved biosimilar prescription drugs, they could have saved more than $4.5 billion in 2017," he said.

Drug Makers Squash Competition

He criticized drug makers who manufacture costly biologic medicines of using unacceptable tactics to keep competitors off the market and keep the high cost of their exclusive medicines.

"Rebating schemes or patent thickets that are purely designed to deter the entry of approved biosimilars are spoiling this sort of competition. Long-dated contracts are another toxin. The branded drug makers thwart competition by dangling big rebates to lock up payers in multi-year contracts right on the eve of biosimilar entry," he said.

Dr Gottlieb said that the FDA is also concerned that volume-based rebates "may encourage dysfunctional clinical treatment pathways. We've heard from multiple sources that some payers are requiring step-therapy or prior authorization on the reference biologic before patients can access a biosimilar. We see no clinical rationale for these practices, since a biosimilar must demonstrate, among other things, that it has no clinically meaningful differences from the reference product as a part of demonstrating biosimilarity."

"The branded drug industry didn't build its success by being business naïve. They are smart competitors," Dr Gottlieb continued. However, he said, "Some of these tactics should be unacceptable to every member of the drug supply chain."

Expand Access to Biologic Medicines

Dr Gottlieb underscored that expanding access to affordable biosimilars, and slowing the rise of healthcare

inflation, is an even more important issue today than it was in 1984 after the passage of the Hatch-Waxman Act.

"The higher costs, and longer timelines, required to develop biosimilars relative to generics means that these delaying tactics can make it uneconomical for biosimilar sponsors to postpone entry for extended periods of time. I'm worried that the biosimilar manufacturers may pull out of these endeavors altogether if the brand drug makers are able to lock up markets even in cases where there's a fully interchangeable competitor."

"We need to adopt a different approach to paying for these drugs. An ideal system would reimburse biologics in a competitively bid scheme, where we could take full advantage of the multi-source competition. Even without these policy changes, right now savings estimates from expected biosimilar competition are large."

Dr Gottlieb outlined 4 strategies in the Biosimilars Action Plan to accelerate biosimilar competition:

1. Improve the efficiency of the biosimilar and interchangeable drug development and approval process
2. Maximize scientific and regulatory clarity for the biosimilar drug development community
3. Develop effective communications to improve patients', providers', and payers' understanding of biosimilars
4. Support market competition by reducing gaming of FDA requirements or other attempts to unfairly delay market competition to follow-on medicines.

Action Plan Steps

Dr Gottlieb briefly touched on some of the steps in the Biosimilars Action Plan, saying, "I believe some of these actions can be transformative for sponsors' ability to bring high quality biosimilars." These steps include:

- Seeking to strengthen the FDA's partnership with regulatory authorities in Europe, Japan, and Canada
- Enhancing the Purple Book to include more information about approved biologic drugs
- Updating guidance to provide more clarity on how biosimilar manufacturers can carve out indications from their labels where a branded drug maker may still maintain some intellectual property
- Implementing new FDA review tools, such as standardized review templates that are tailored to marketing applications for biosimilar and interchangeable agents
- Taking steps to challenge gaming tactics, including new efforts to coordinate with the Federal Trade Commission to address anticompetitive behavior.

Reimbursement Reform

Dr Gottlieb highlighted that biologic drugs are very competitive, with many drugs available in the same clinical category, but paying for these drugs is not competitive. Biosimilars can introduce the needed cost competition.

"We need to adopt a different approach to paying for these drugs. An ideal system would reimburse biologics in a competitively bid scheme, where we could take full advantage of the multi-source competition," he said.

"Even without these policy changes, right now savings estimates from expected biosimilar competition are large. They range from $54 billion from 2017 to 2026 according to a study by RAND, to as much as $250 billion from 2014 to 2024 from just 11 biosimilars expected to be approved and marketed according to a survey by Express Scripts."

"There's active work under way on bold reforms, like shifting biologics from Medicare's Part B scheme into a competitively bid system like Part D, where we can take full advantage of price and therapeutic competition," explained Dr Gottlieb.

"These types of approaches can delink physician reimbursement from drug prices and inject more competition into the market, while increasing the incentives to create the next great innovation that's going to advance human health," he added.

Educating Patients and Providers

He also emphasized that, as was the case with generic drugs, the FDA cannot do it alone. "Competition requires all of us to shine a light on the anti-competitive impact of tying rebates and bundling biologics with other products to protect biologics' market share. And it requires us to educate providers and patients about biosimilars, and why people should have confidence in the safety and effectiveness of these FDA-approved products."

Without these steps, Dr Gottlieb believes, the common goal of more affordable drugs in the form of biosimilars will not be possible.