Generic Biotechnology Drugs Could Win Congressional Approval; FDA Approval Would Be Trickier

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The easiest way to get more generic versions of biotechnology (biogeneric) drugs onto the U.S. market would be to pass a law allowing the Food and Drug Administration (FDA) to approve them. The hardest part would then be the need for the FDA to figure out how to structure a sensible approval process.

There is no question that the current Congress will pass legislation authorizing the FDA to devise an approval process for these biogeneric drugs, which are now approved under the Public Health Service Act. These are very-large-molecule, hard-to-manufacture recombinant biologics such as products containing human insulin, somatropin, granulocyte–colony-stimulating factor (G-CSF), and erythropoietin. The FDA approves these under a statute that differs from the procedure applied for small-molecule, conventional drugs.

The 1984 Hatch–Waxman Act allowed generic copies of conventional drugs, but copies of biotech drugs, approved under the Public Health Service Act, have not been permitted. Congress is ready to change that.

In the past, the brand-name industry, represented by the Pharmaceutical Research and Manufacturers of America (PhRMA), had claimed that these biotech drugs could not be copied and that their manufacturing formulas would be impossible to recreate. That argument, however, will not hold sway with the Democrat-controlled Congress. Congress today is less influenced by the drug industry and is very concerned about drug costs, not only to consumers in general but also to the federal government via its payment for drugs under Medicare and Medicaid—and these biotech drugs are very pricey indeed.

Moreover, Congress will move forward, because almost no one is opposed to legislation opening the door to what could be called biotech comparables (technically, they cannot be called “copies”). In Europe, which already has a regulatory approval process in place, these are called biosimilars. Drug manufacturers call them follow-on biologics.

We now have a politically enviable situation in which employers and unions—two normally bitter antagonists—are both in favor of comparables; so are health insurance payers and physicians, two other groups who often tangle. The same can be said for pharmacy benefit managers (PBMs) and drugstores. Even the pharmaceutical manufacturers, who have opposed creating a means by which the FDA could approve biotech comparables, are on board, with a few caveats, of course.

Jay P. Siegel, M.D., Group President of Research and Development for Biotechnology, Immunology, and Oncology for the Johnson & Johnson family of companies, says:

While legislation on follow-on biologics has the potential to improve access to lifesaving medicines, that legislation should be well-founded in science and ensure that the lifesaving medicines to which access is provided are no less life-saving or safe than medicines already on the market. I believe that through the proper process, these critical ends can be met.

The legislative starting point is a bill introduced by Senator Charles Schumer (D-N.Y.) and Representative Henry Waxman (D-Calif.). The Access to Life-Saving Medicine Act (S. 623) would authorize the FDA to approve abbreviated applications for biological products that are comparable to previously approved brand-name biological products. The Act also gives the FDA the authority to require any additional clinical information it deems necessary.

“Safe and effective biogenerics will bring billions of dollars of savings to consumers, state and federal governments, and the health care community,” says Mark Merritt, President of the Pharmaceutical Care Management Association (PCMA).

According to a study conducted on behalf of the PCMA, creating a clear pathway for the approval of biogeneric agents would save an estimated $14 billion over 10 years for the Medicare Part B program alone. Dr. Merritt adds:

This amount represents the tip of the iceberg of potential federal savings and does not include the vast majority of medications covered by Medicare, Medicaid, the Federal Employees Health Benefit Plan and other publicly financed health programs. Moreover, businesses and workers covered by private health plans would stand to save billions of dollars as well.

The Schumer bill would pave the way for both comparable and interchangeable biotech drugs. Because comparable drugs would not be subject to clinical testing, they would not be allowed to claim equivalence with brand-name competitors. However, interchangeable drugs, via clinical testing, would have to prove that they produced the same medical results as the innovator drugs.

It is likely that the Schumer bill will be attached as an amendment to reauthorization of the Prescription Drug User Fee Act (PDUFA), which mandates that drug companies pay fees which are used by the FDA to speed the new drug-approval process. That law expires on September 30, 2007, unless Congress reauthorizes it. Both Democrats and Republicans consider the Schumer bill a
“must pass” piece of legislation.

However, although an approval amendment for biogeneric drugs will undoubtedly be attached to a PDUFA reauthorization, it may leave the FDA in a technical quandary if the amendment follows the Schumer bill. According to Dr. Siegel of Johnson & Johnson, which owns Centocor, this is because no amount of clinical testing can ensure that a biogeneric product would be *interchangeable*. He also argues that some clinical testing is needed before the FDA can call a biogeneric drug *comparable*.

In the end, we can expect the Schumer–Waxman bill to clear Congress with numerous gray areas that the FDA will have to sort out. ■