

Senate May Compromise on 'Biosimilars' But Length of Market Exclusivity Poses a Stumbling Block

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If nothing else, a Senate committee's passage of a bill allowing the Food and Drug Administration (FDA) to approve "near copies" of biotechnology drugs shows just how far Congress has come on that matter and just how far it has to go. No one disputes the fact the FDA needs congressional authorization to be able to approve the more complicated generic versions of genetically engineered drugs such as granulocyte-colony-stimulating factor (G-CSF) for stimulating white blood cells after chemotherapy, interferon-beta products for multiple sclerosis, and interferon alfa-2a for hepatitis C. Innovator versions of these drugs are already on the market, either in Europe or in the U.S., or both.

However, except for the category of human growth hormone (hGH) drugs (of which five or more are already on the market and which are structurally simple), the FDA has not approved any biologically similar agents, also known as "follow-on proteins." The FDA did approve a "biosimilar" version of Pfizer's Genotropin (somatropin of recombinant DNA origin)—Sandoz's Omnitrope. But it approved Genotropin (and other hGH products) plus insulins, both simple in structure, under the Food, Drug, and Cosmetic Act (the 1984 Hatch-Waxman Act); this made it easier for the agency's approval of Omnitrope.

The FDA approved another 50 or so biotech drugs such as rituximab (Rituxan, Genentech/Biogen Idec), adalimumab (Humira, Abbott), trastuzumab (Herceptin, Genentech), natalizumab (Tysabri, Biogen Idec), and interferon beta-1a (Avonex, Biogen Idec) for use in the U.S. under the Public Health Services (PHS) Act. This Act involves a much more rigorous approval process because of the complicated manufacturing conditions under

which biotech drugs are made. No provision exists under the PHS Act for approval of generic agents as there is for conventional chemical compounds under the Food, Drug, and Cosmetic Act.

The Biologics Price Competition and Innovation Act, which the Senate Health, Education, Labor, and Pensions Committee approved in June, would create an approval pathway for follow-on proteins under the PHS Act. However, although Senator Orrin Hatch (R-Utah) says that the committee, in establishing that pathway, reached "a balance" between the needs of the biotech industry on one side and the generic industry on the other, neither side is especially happy with the final legislative product. Moreover, according to an analysis by the Congressional Budget Office, the bill would result in fairly insignificant savings—from cheaper biosimilar drugs—for consumers and federal health programs such as Medicare and Medicaid.

From an innovator company's perspective, the most important point is to ensure that incentives for creating the first brand-name versions of these drugs are not lost; this means not making it too easy for generic companies to bring their products to market, which would reduce the innovator's market share. The key provision in the Senate bill says that the FDA cannot approve a generic application of a follow-on protein if the generic cites the innovator's scientific data unless the innovator drug has been on the market for 12 years. Some provisions also protect the patents of innovators, and another provision states that a pharmacist can switch a patient to a biosimilar agent without a physician's prior approval.

Jim Greenwood, President and Chief Executive Officer of the Biotechnology Industry Organization (BIO), considers the bill an improvement over an earlier version. However, he wants a data exclusivity period of 14 years, not 12, and he sees some problems with both patent and pharmacist prescribing provisions.

Michael Leavitt, Department of Health and Human Services Secretary, agrees with BIO about the pharmacist provision.

He wrote to the Senate committee:

In light of the current scientific limitations on the ability to make determinations of interchangeability, and because it is critical to protect patient safety, the Administration believes that patients should not be switched from the innovator biological product to a follow-on biological product (or vice versa) without the express consent and advice of the patient's physician, and legislation should not allow for determination of interchangeability at this time.

The Pharmaceutical Care Management Association (PCMA), the PBM trade group, prefers another bill—the Access to Life-Saving Medicine Act—sponsored by Representative Henry Waxman (D-Calif.) and Senator Charles Schumer (D-N.Y.). That bill confers no market exclusivity on innovator companies.

Charles Coté, PCMA spokesman, notes that the Hatch-Waxman Act allows only a five-year period of market exclusivity for small-molecule, conventional chemical drugs with the possibility of a three-year extension. He says:

"We think 12 years is too long. We also have a problem with the provision in the Senate bill which would allow the innovator company to make minor changes to its reference product and thereby extend its market exclusivity."

Mr. Coté doesn't think Congress will move this Senate bill along very far in 2008 but that it will be primed for action next year, especially if the Democrats enlarge their majorities. Even if a bill passes, the cost savings to consumers are likely to be far less than they are with generic versions of traditional drugs, such as antidepressants, antibiotics, and the like. For example, when Omnitrope was available for the first time in the U.S. in March 2008, Sandoz priced it at \$33.65 per milligram and said that this was 35% less than the published price of Genotropin, the comparative reference product. Although a 35% price differential is nothing to sneeze at, with biotech drugs running \$10,000 per year and upward, the cost of biosimilar agents will still be heavy. ■

