Congress Enters Contentious Debate on Biosimilar Naming

Bill Provision Sides With Brand-Name Companies Over USP

Stephen Barlas

Mr. Barlas is a freelance writer in Washington, D.C., who covers issues inside the Beltway. Send ideas for topics and your comments to sbarlas@verizon.net.

With the Food and Drug Administration (FDA) starting to move a little more quickly on biosimilar applications, a key unanswered question about biosimilar naming has taken on added importance. Brand-name companies want names that distinguish the biosimilar from the innovator companion, making it easier for physicians to prescribe the latter, at least theoretically. The FDA released a draft guidance document in August 2015 that suggested a biosimilar would have the same nonproprietary name as the biologic it compared with, but would also have a distinguishing four-letter suffix.1 Even so, that guidance had detractors from both sides of the industry.

Now Congress has entered the debate. Sitting on the floor of the Senate awaiting a vote is the FDA and NIH Workforce Authorities Modernization Act.2 It is one of 19 bills packaged together in the Innovation for Healthier Americans legislative package. That package is the companion measure to the 21st Century Cures Act that the House of Representatives passed with strong bipartisan support in 2015.3 Both bills attempt to reform some aspects of FDA and National Institutes of Health (NIH) organization and programs. The House bill and the Senate package have some similarities and some differences.

One controversial difference is that the Senate package has a provision in the FDA and NIH Workforce Authorities Modernization Act with no counterpart in the 21st Century Cures Act. It amends Section 351(j) of the Public Health Service (PHS) Act by adding that the provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act that refer to an “official compendium” as developed and published by the U.S. Pharmacopeial Convention (USP) would not apply to biological products regulated under the PHS Act Section 351. It is not clear how that provision ended up in the bill.

In a letter to Senators Lamar Alexander (R-Tennessee), Chairman of the Senate Health, Education, Labor, and Pensions (HELP) Committee, and Patty Murray (D-Washington), Ranking Member of the HELP Committee, 10 national pharmacy organizations wrote:

This provision is unrelated to the other sections of the legislation and appears not to have received meaningful discussion with the broader stakeholder community prior to its inclusion. It would exempt biological medicines from the requirement to adhere to U.S. Pharmacopeial public standards for quality. If enacted, this provision would have potentially grave consequences for public health and would hinder, rather than support, our shared goal of getting safe and effective biosimilars to market.

The provision’s supporters include the Alliance for Safe Biologic Medicines (ASBM), composed of manufacturers such as Amgen and Genentech, along with some patient advocacy groups. Michael Reilly, Executive Director of the ASBM, says it is not appropriate for biosimilars to fall under the same USP monograph as the brand name they compete with, nor for both to have the same name. Reilly explains:

The biologics provision included as part of the FDA and NIH Workforce Authorities Modernization Act allows biosimilars to have distinguishable names and separate and distinct compendial identities. This is critical to ensure that all those who reference USP-NF [National Formulary] for information on medications, from physicians and pharmacists to insurance providers, gain a clear understanding that biosimilars are not generics and cannot be safely switched back and forth with the original medicine unless the FDA has deemed the biosimilar interchangeable with the reference biologic.

The FDA apparently feels the same way. In a written answer provided to the Senate HELP committee after hearings in 2015, the FDA said:

FDA has significant concerns that enforceable monographs for biological products may impede or delay approval of a biological product that meets the scientific requirements for approval, but does not meet the related compendia standards established by USP, an independent, nongovernmental organization. If a proposed biosimilar product was required to comply with same USP drug product monograph as its reference product, it effectively would require the applicant to demonstrate that its product contains the ‘same’ drug substance as the reference product, evaluated using the same tests and assays, notwithstanding the standards set forth in the statute. We anticipate that this may complicate licensure of biosimilar (and interchangeable) products that meet the requirements of the BPCI [Biologics Price Competition and Innovation] Act, but may not comply with the provisions of the FD&C Act regarding USP compendia standards.

Ronald Piervincenzi, Chief Executive Officer of USP, opposes the provision:

In the media, this provision has been characterized as one that would spur innovation by removing the requirement that biologics adhere to public standards. But the proposal strips biologics of the protections provided by public quality standards and unravels a critical piece of the overall safety net for these drugs. Without public standards, biosimilar product developers would have no common quality benchmark, which could potentially slow down the progress of new entrants into the market and impact patient access.

The Senate had passed a similar “anti-USP” provision in 2007 in an FDA reform bill. The House version of the bill omitted that provision, as did the final, conferenced bill. Given the closeness of the November election and the short time left for Congress to enact any legislation, continued on page 561
chances are that even if the Senate passes its 19 bills, that package will never get combined with the 21st Century Cures Act. Even if it does, there is no indication the House is any more willing to ditch USP standards this year than it was in 2007.

REFERENCES