KILPATRICK TOWNSEND

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Two Bipartisan Bills Aim to Encourage Competition in the Biopharma Industry

by April Abele Isaacson

Drug pricing and innovation are hot topics in Washington right now with several bills making their way through the legislative process, many in a bipartisan fashion. On April 23, 2021, two of these bills were signed into law by President Biden. The first bill, the Ensuring Innovation Act, limits new drug exclusivity, thereby making it easier for generics to enter the market and spur competition. The second bill, the Advancing Education on Biosimilars Act of 2021, is designed to increase the availability of information about biologics and biosimilars in an effort to educate healthcare providers and patients and indirectly increase competition.

The Ensuring Innovation Act

The Ensuring Innovation Act, sponsored by U.S. Senators Bill Cassidy (R-LA), Tina Smith (D-MN), and Roger Marshall (R-KS), amends the Federal Food, Drug, and Cosmetic Act to make a drug eligible for the FDA-granted five-year New Chemical Entity (NCE) exclusivity on the basis of its active moiety only and not on the basis of its active ingredient. Thus, the exclusivity will now be based solely on the core molecule and new exclusivity periods will not be available for minor modifications of that molecule. According to Senator Cassidy, the bill will close loopholes through which companies claimed new innovations on the same drug to extend the exclusivity period and prevent cheaper generics from coming to market.

Historically, the FDA has interpreted the term “active ingredient (including any ester or salt of the active ingredient)” to mean “active moiety,” and excluded a number of noncovalent derivatives beyond salt and esters from eligibility for NCE exclusivity. But its approach has been rejected in 2015 in *Amarin Pharms. Ireland Ltd. v. FDA*, in which the court ruled against the FDA’s conflation of the terms “active ingredient” and “active moiety.” The court noted the FDA’s interpretation is contrary to “a cardinal principle of statutory construction that a statute ought, upon the whole to be constructed in a manner that ensures that no clause, sentence, or word shall be superfluous, void or insignificant.” (internal citations omitted). The court concluded the FDA’s interpretation could not be supported because it “would render the parenthetical clause in the exclusivity provision either redundant or incomprehensible.”

The Ensuring Innovation Act codifies the FDA’s interpretation of “active ingredient (including any ester or salt of the active ingredient)” and moots further challenges to this interpretation. Specifically, the bill replaces each

instance of the phrase “active ingredient (including any ester or salt of the active ingredient)” in the FD&C Act with “active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)).” This language, not only supports the FDA’s current position but also provides the FDA with the possibility of refining its definition in the future.

According to Senator Smith, a co-sponsor of the Ensuring Innovation Act, it will ensure the FDA has the ability to curb the practice of “evergreening” in which pharmaceutical companies extend patents and market exclusivity when making only minor changes to a drug.

The Advancing Education on Biosimilars Act of 2021

The Advancing Education on Biosimilars Act of 2021, sponsored by Senators Cassidy and Maggie Hassan (D-NH) is designed to increase patients’ and healthcare providers’ awareness of biosimilars as well as their comfort level with biosimilars’ use with the aim of their wider adoption. The push for wider adoption of biosimilars is premised on their promise for lowering healthcare costs. As Senator Hassan noted, biosimilars could save Americans approximately $54 billion in healthcare costs over the next decade.

The bill amends the Public Health Service Act to enable the Department of Health and Human Services to create a website with educational materials about various aspects of biologics and biosimilars, including the definition of the terms “biosimilar” and “interchangeable biosimilar,” the development of biological products, and a how the government ensures the safety and efficacy of biological products and biosimilars. The bill also calls on the HHS to advance education and awareness among healthcare providers about biological products and biosimilars.

Takeaway

The pharmaceutical industry continues to be in Congress’s crosshairs, with the goal of lowering drug prices and reining in healthcare costs. The Ensuring Innovation Act and the Advancing Education on Biosimilars Act of 2021 are modest steps toward this goal, but they demonstrate that Congress has a variety of approaches in its legislative arsenal.

Please, contact the author with any questions, and stay tuned for updates regarding this important topic.