December 12, 2019

The Honorable Lamar Alexander, Chairman
The Honorable Patty Murray, Ranking Member
Senate Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington D.C. 20510

Dear Chairman Alexander, Ranking Member Murray, and Members of the Committee:

On behalf of National Taxpayers Union, I write encouraging you to reject efforts to include Section 407 of the updated Lower Health Care Costs Act in year-end legislation that Congress will consider this month, or at the very least substantially modify this provision.

We believe Section 407, originally Section 205, was written with the good intention of preventing manufacturers from 'parking' their first-to-file generic drug applications, which in turn can block subsequent generics from coming to market and creating competition for brand-name drugs. The provision as it currently stands in the compromise version of the Lower Health Care Costs Act, however, would unwittingly punish some generic manufacturers who are simply going through a lengthy and frequently cumbersome Food and Drug Administration (FDA) approval process. This, in turn, would punish patients and taxpayers, who pay the price when generic drug competition cannot come to market.

The provision says that the following condition needs to be met for a first generic drug to be forced into beginning its 180-day exclusivity period:

> "Thirty-three months have passed since the date of submission of an application for the drug by one first applicant, if there is only one first applicant, or, in the case of more than one first applicant, 33 months have passed since the date of submission of all such applications."[1]

According to the Pew Charitable Trusts, though, the *median* FDA review time for generic drug applications (abbreviated new drug applications, or ANDAs: from ANDA receipt to approval) has not been below 33 months since 2012.[2] In fact, the median review time climbed from 31.75 months in 2012 to 36 in 2013, then 42 in 2014 and 2015, before dipping to 39.42 months in 2016 and 37.26 months in 2017.

[1] "S.1895 - Lower Health Care Costs Act." Congress.gov, July 8, 2019. Retrieved from: https://www.congress.gov/bill/116th-congress/senate-bill/1895/text?q=%7B%22search%22%3A%5B%22lower+health+care+costs+act%22%5D%7D&r=1&s=1#toc-idc36cb432287a4bf2b10c00f962a13dd5 (Accessed November 25, 2019.)
[2] "FDA Approves More Generic Drugs, but Competition Still Lags." The Pew Charitable Trusts, February 2019. Retrieved from: https://www.pewtrusts.org/-/media/assets/2019/02/fda_approves_more_generic_drugs_but_competition_still_lags.pdf (Accessed November 25, 2019.)

If Section 407 becomes law as it is currently written, it is very possible that some generic manufacturers working through the regular FDA approval process will have their limited, six-month exclusivity period begin while they are still awaiting approval. If a manufacturer's wait time is 39 months, for example, their exclusivity period will be expiring just as they are receiving final approval from the FDA.

Congress has carefully reflected on lengthy FDA review periods before. For example, in 2012 Congress temporarily changed the length of the so-called "Failure to Obtain Tentative Approval Forfeiture Provision." This provision states a first-to-file generic applicant will forfeit their 180-day exclusivity if they have not obtained tentative approval for their drug within 30 months of the date their application is first filed.

According to draft FDA guidance on the 180-day exclusivity published in 2017, the temporary extension of the existing 30-month forfeiture period "to 40 months for certain ANDAs and to 36 months for certain other ANDAs," passed in 2012 as part of the Food and Drug Administration Safety and Innovation Act (FDASIA),

> "...reflects Congress's understanding that, even in the absence of a change in or review of the requirements for approval, FDA's review of an ANDA might take more than 30 months and might contribute to a first applicant's failure to obtain tentative approval or final approval by the 30-month forfeiture date and result in forfeiture of exclusivity."[3]

In the face of these prior amendments to law, and of the current median FDA review times for approval of generic drug applications, a 33-month period seems inadequate. Instead, what it could do is reduce the incentives generic manufacturers have to challenge a brand drug, and spend the time and money it takes to do so.

The FDA itself has written that the 180-day exclusivity period is "a very strong financial incentive."[4] Section 407 could have the (surely unintended) effect of reducing this strong financial incentive for generic manufacturers, thereby reducing the amount of generic drugs coming to market and reducing the downward impact that generic competition has had on drug prices.

Should lawmakers insist on including Section 407 in year-end legislation, there is an opportunity to modify this provision for the better using an amendment proposed by Sen. Tim Scott (R-SC). Sen. Scott's amendment would provide a clear exception to the new exclusivity period law for first generic applicants that are "actively pursuing final approval of an application for the relevant drug." The amendment defines "actively pursuing" as:

> "an applicant's good faith effort to pursue marketing approval in a timely manner, based on a consideration of all relevant factors, such as the applicant's compliance with regulations and the timeliness of its responses to the Secretary's questions or application deficiencies during the review period."[5]

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[3] Food and Drug Administration. (2017.) "Guidance for Industry: 180-Day Exclusivity: Questions and Answers." Retreived from: https://www.fda.gov/media/102650/download (Accessed November 26, 2019.)
[4] Food and Drug Administration. (2003). "Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day." Retrieved from: https://www.fda.gov/media/71304/download (Accessed November 26, 2019.)
[5] Amendment in the Senate of the United States—116th Cong., 1st Sess. S. 1895, To lower health care costs. Retrieved from: https://www.ntu.org/library/doclib/2019/12/Scott-Amendment-1-.pdf (Accessed December 11, 2019.)

While Section 407 is flawed for the reasons we outlined above, this amendment could at minimum protect generic drug makers who are simply doing right by the FDA approval process.

We encourage the Committee to reject Section 407 or substantially modify it in year-end legislation, and instead consider building on laws like Hatch-Waxman that helped create a robust generic drug market in the U.S. Thank you for your consideration, and should you have any questions, I am at your service.

Sincerely,

Andrew Lautz
Policy and Government Affairs Associate