September 18, 2019

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

Dear Chairman Alexander and Ranking Member Murray,

On behalf of the more than 1 million members and supporters of the Council for Citizens Against Government Waste (CCAGW), I am writing to express our concern about the effect of Section 205 of S. 1895, the Lower Health Care Costs Act, on generic drug abbreviated new drug applications (ANDA) and ask that it be removed. Section 205 would allow the Food and Drug Administration (FDA) to trigger the first applicant’s 180-day exclusivity if it has not received final approval within 33 months of submitting its application and a subsequent applicant could get final approval but not for the 180-day exclusivity. This may provide a short-term surge in generic drug approvals and help the agency’s performance goals, but in the long term the provisions of Section 205 would discourage Paragraph IV certifications and reduce the number of new generic drugs.

The Drug Price Competition and Patent Term Restoration Act of 1984, more commonly referred to as the Hatch-Waxman Act, was instrumental in establishing the abbreviated approval pathway for generic drugs. Prior to 1984, generic drug manufacturers had to prove the safety and efficacy of their drugs. As a result, only 35 percent of brand-name drugs had any competition and only 15 percent of prescriptions were for generic drugs. The delicate balance created under Hatch-Waxman protects brand-name drug patents and provides limited exclusivities while generic entry is encouraged by requiring a manufacturer to only prove that their product is bioequivalent to a brand drug through an ANDA, relying on the pioneering company’s safety and effectiveness studies.

Hatch-Waxman has made it much less expensive and more efficient for generic firms to get their products approved by the FDA. As a result, generic drugs now account for 90 percent of all prescriptions, with 93 percent of generic prescriptions being filled at $20 or less. This has saved patients and taxpayers $2 trillion in the last decade, including $293 billion in 2018 alone.

A generic drug company must file certifications regarding existing patents for the brand drug listed in the FDA’s Orange Book, a publication of approved drugs with therapeutic equivalence evaluations, when it submits its ANDA to the FDA. While there are four certifications, the Paragraph IV Certification will likely lead to patent litigation between the generic and brand name company. If a generic manufacturer settles its patent litigation, its product enters the marketplace an average of 81 months before the end of the patent term.
A September 10, 2019 *Bloomberg Law* article stated that litigating under Hatch-Waxman rose from $3 million in 2015 to $3.5 million in 2019, with $10 to $25 million at risk. The generic manufacturer that is first to file a substantially complete ANDA containing a Paragraph IV certification to a listed patent and gets FDA approval for its ANDA is eligible for a 180-day exclusivity period, a strong incentive to take on this difficult and expensive task to get its drug into the market more quickly.

The Health, Education, Labor, and Pensions Committee appears to be concerned that a generic company may decide to deliberately delay or “park” its ANDA, thus tying up ensuing ANDAs of other generic manufacturers. While Section 205 of S. 1895 is meant to address this issue by allowing the FDA to give approval to another applicant’s ANDA if the first applicant has not received final approval within 33 months of submitting its ANDA, this arbitrary deadline will have the opposite effect.

There could be many reasons why a company has not been able to receive approval over which it has no control, like the failure of the FDA to inspect or re-inspect its facility, or an unwarranted citizen’s petition. Furthermore, there is nothing in the legislation that would require the second applicant to market its generic drug immediately once it receives approval.

In 2017, it took on average 37.3 months for the FDA to approve an ANDA according to a February 2019 PEW issue brief enacted, “FDA Approves More Generic Drugs, but Competition Still Lags.” If this legislation should be enacted and the 180-day exclusivity is triggered through no fault of the first applicant, generic manufacturers will be reluctant to spend the millions of dollars required to pursue a Paragraph IV certification.

Section 205 is unnecessary as current law states, “If FDA concludes that a first applicant is not actively pursuing approval of its ANDA, FDA may immediately approve an ANDA(s) of a subsequent applicant(s) if the ANDA(s) is otherwise eligible for approval.” We urge you to eliminate Section 205 from S. 1895.

Sincerely,

Thomas Schatz

cc: Senate HELP Committee Members