Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
" FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics "
February 3, 2022

David Gaugh, Senior Vice President, Sciences and Regulatory Affairs, Association for Accessible Medicines

The Honorable Gus Bilirakis (R-FL)

1. Mr. Gaugh, your testimony specifically calls out the importance of competition in the drug marketplace, and how there is significant evidence of prices decreasing, in some cases by nearly 80 percent when four or more generics enter the market. FDA also mentions that the last GDUFA legislation had required Priority Review to become available for applications for generic drugs with limited competition, as well as for generic drugs in shortage. These provisions were a direct result of legislation I co-led with Rep. Schrader, the Lowering Drug Costs through Competition Act. This bill also created the Competitive Generic Therapy program, and I was pleased to see this past fall that FDA has approved over 100 generic drug applications with Competitive Generic Therapy designation. This means we are starting to see more competition in the marketplace, which will help alleviate prices. That's why it is critical we have a predictable review process at FDA to ensure smooth and quick approvals, particularly when we are dealing with complex generics. Can you explain how this next GDUFA commitment letter will build upon the successes of these programs for generics with little to no competition in the market, and can you explain how we can continue to ensure a transparent process for drug innovators?

The Competitive Generic Therapy (CGT) designation was established under the *FDA Reauthorization Act of 2017* (FDARA) to provide new incentives for generic manufacturers to develop and commercialize medicines in areas where there is inadequate competition. The CGT listed drugs are generally brand-name drugs that lack adequate competition despite the expiration of all patents and exclusivities that would otherwise block generic competition. Therefore, for various reasons, there is inadequate generic competition, which results in less access to more affordable medicines. The CGT pathway has been remarkably successful at generating competition in areas where it was previously lacking. Since 2018, FDA has approved 130 CGT products. AAM applauds your and Representative Schrader's leadership in developing this important program.

While there is nothing in GDUFA III specific to CGT products, there are several enhancements in the Commitment Letter that will also be helpful in facilitating the continued development of CGTs. For example, the "imminent action" enhancement will allow FDA to extend a goal date

by 60-days without triggering a new review cycle if an approval or tentative approval of the ANDA Application (including a CGT Application) will occur within these 60-days. This enhancement will help mitigate the need for additional review cycles, which could unnecessarily delay ANDA Applications (including CGT Applications) over imminently resolvable issues. CGTs that are complex generic medicines will also benefit from GDUFA III enhancements in the Commitment Letter, as FDA will be issuing more product-specific guidances for complex medicines, which will increase predictability for developers by creating more transparency over FDA's product development expectations.