Additional Questions for the Record

Subcommittee on Consumer Protection and Commerce
Hearing on
"Profits Over Consumers: Exposing How Pharmaceutical Companies Game the System"
September 9, 2019

Responses of Mr. Jeff Francer
Senior Vice President and General Counsel
Association of Accessible Medicines

The Honorable Cathy McMorris Rodgers (R-WA)

1. When a brand company discontinues its branded drug, and takes it off the market for reasons unrelated to safety or efficacy, can a generic drug company file a generic drug application for such a discontinued drug and go to market?

When a brand-name drug company discontinues its drug for reasons unrelated to safety or efficacy, a generic drug company typically may seek and obtain approval of a generic version of the discontinued drug, but the brand company's actions may still create several significant regulatory hurdles for the generic drug company.

First, the generic drug company cannot submit an application for a generic version of a discontinued drug unless it is accompanied by a petition seeking a determination by FDA that the brand drug was not discontinued for safety or effectiveness reasons. A generic drug application cannot be approved unless and until FDA makes a determination that the marketing withdrawal was not for safety or effectiveness reasons. This additional regulatory requirement can result in delays in approval of generic drugs, particularly if the brand-name drug is withdrawn late in the review cycle for the generic version.

Second, when a brand-name drug company withdraws a reference listed drug (RLD), generic drug manufacturers may have difficulty obtaining samples of the brand-name drug on which to conduct bioequivalence and other testing, because the brand-name drug is no longer being sold. And if the generic company cannot demonstrate that its proposed product is bioequivalent to the brand version, the generic drug will not be approved by FDA.

Finally, withdrawal of a brand-name drug from the marketplace often has the intention and effect of destroying the market for potential generic competitors. This is because the main engine of generic competition is automatic substitution of lower-cost generic alternatives. If the brand company withdraws its original drug from the market and begins promoting and selling a new version exclusively, then the market for the withdrawn drug may shrink significantly, likewise diminishing any potential market for generic drug substitution.

The Honorable Michael C. Burgess, M.D. (R-TX)

1. As you mentioned in your testimony, changes in existing pharmaceutical products can result in substantial health benefits. Can you explain the benefits that patients may receive due to these improvements and give some examples?

AAM supports innovation and believes it is a key driver in improving the lives and health of American patients. Accordingly, AAM recognizes that some changes to existing pharmaceutical products can result in substantial health benefits to patients. For example, modifying a drug that must be injected every day to a new dosage form, such as a tablet, that can be taken orally could provide benefits to patients who have difficulty administering, or experience pain from, daily injections. For this reason, AAM has cautioned Congress to tread carefully when regulating "soft switches," which do not result in the removal of prior versions of the brand drug and thus allow patients and physicians weigh the true benefits of a new product against its costs. AAM believes it is important to encourage innovation, but to do so in a way that does not impair competition and patient access to more affordable generic and biosimilar medicines.