April 29, 2019

The Honorable Jerrold Nadler, Chairman
The Honorable Doug Collins, Ranking Member
Committee on the Judiciary
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Nadler and Ranking Member Collins:

Consumer Reports writes in support of four bills the Committee is considering today:

- H.R. 2375, the "Preserve Access to Affordable Generics and Biosimilars Act"
- H.R. 965, the "Creating and Restoring Equal Access to Equivalent Samples Act" or "CREATES Act"
- H.R. 2374, the "Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics Act" or the "Stop STALLING Act"
- H.R. 2376, the "Prescription Pricing for People Act of 2019"

These bills would all promote more effective competition, increasing the power of consumer choice in the marketplace, and making medications available to consumers at more affordable cost. We are very encouraged that all four bills are bipartisan.

H.R. 2375 would prohibit, as an unfair method of competition, anti-competitive "pay for delay" schemes, in which brand-name prescription drug makers effectively pay off manufacturers of more affordable generic and biosimilar alternatives to stay out of the way, so the brand-name drug maker can prolong its monopoly profits – perversely gaming a system designed to *promote* expedited entry of generics and biosimilars. By blocking competition and consumer choice, these schemes cost consumers billions of dollars. After a sustained decade-long effort, the Federal Trade Commission obtained a Supreme Court ruling that pay-for-delay deals are subject to the antitrust laws and can be found unlawful.[1] But drug makers have continued to resist that ruling, and to look

[1] FTC v Actavis, Inc., 570 U.S. 136 (2013).

for ways to evade it. Having to bring a new full-fledged antitrust challenge each time is costly and time-consuming.

H.R. 965 would remove two anti-competitive roadblocks imposed by brand name drug manufacturers – one blocks access to samples that generics need for testing, and the other blocks participation by generics in FDA-required protocols for safe distribution and use. Both these tactics take unfair advantage of FDA requirements designed to ensure that medications are safe and effective. In both instances, a legitimate FDA safeguard is being exploited by the brand-name drug maker to block competition, artificially prolonging its monopoly profits at the expense of consumers. The CREATES Act would give generic drug companies a clear path to keep these competition-blocking tactics from succeeding – by giving generics a straightforward legal right to obtain the samples they need, and by allowing generics to establish their own safe distribution protocols.

H.R. 2374 would prohibit the abusive use of so-called "citizen petitions" by brand-name drug makers to raise concerns that stall progress on developing generic alternatives. This petition process was established to provide citizens to have an opportunity to bring concerns to the FDA's attention in a timely fashion. But the procedure has been commandeered by brand-name drug makers to raise dubious concerns, often numerous times, that require the FDA to suspend while it investigates and responds. One brand-name drug company reportedly filed 43 such petitions against a single generic applicant.[2] H.R. 2374 would prohibit submitting a citizen petition for the purpose of preventing or delaying the approval of a generic or biosimilar drug, as an unfair method of competition.

H.R. 2376 would direct the FTC to conduct a thorough study on the effects of the way pharmacy benefit managers operate. As originally conceived, they can perform a valuable function as intermediaries between drug makers and health plans, helping negotiate lower wholesale prices. But their opaque operation makes it difficult to know whether they are acting in the interests of the health plans they ostensibly serve, or if they are operating in their own interests and taking kickbacks from drug makers in exchange for favoritism that keeps prices inflated and choices restricted. These concerns have grown more pronounced as the PBMs have become more consolidated, and have merged with other parts of the healthcare marketplace in ways that further increase the potential for conflicts of interest. A thorough study by the FTC will be very useful in helping determine what needs to be done to ensure competition and transparency.

We have long supported and informed consumers about constructive efforts to bring down the high prices consumers pay for prescription drugs – in our advocacy work, as well as in our journalism, most recently in our August 2016 article, "Is There a Cure for High Drug Prices?",[3] and

[2] https://www.ftc.gov/news-events/press-releases/2017/02/ftc-charges-shire-viropharma-inc-abused-government-processes

[3] Consumer Reports, "Is There a Cure for High Drug Prices?" (July 29, 2016). Available at https://www.consumerreports.org/drugs/cure-for-high-drug-prices.

our April 2018 follow-up, "How to Pay Less for Your Meds."[4] Both articles reported on the results of nationally representative telephone surveys we conducted. The April 2018 article re-confirms that escalating prescription drug costs are forcing many consumers to choose between cutting back on needed medications or on other basic necessities.

These four bills will all significantly advance efforts to improve competition in the development and sale of medications, so that consumers who need them will be better able to afford them. We urge the Committee to approve these bills and send them promptly to the full House for consideration.

Sincerely,

Dena Mendelsohn
Senior Policy Counsel
Consumer Reports

George P. Slover
Senior Policy Counsel
Consumer Reports

cc: Members, Committee on the Judiciary

[4] Consumer Reports, "How to Pay Less for Your Meds," (April 5, 2019). Available at https://www.consumerreports.org/drug-prices/how-to-pay-less-for-your-meds.