Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Building 1, Room 2217
Silver Spring, MD 20993

Dear Commissioner Gottlieb,

We, the undersigned consumer groups, are committed to promoting access to affordable generic medicines, including by ending abuse of the Food and Drug Administration's (FDA) regulatory process to impede generic entry. We appreciate the FDA's continuing commitment to lifting harmful and unnecessary barriers to generic drug market entry and competition, as evidenced by your remarks at the public meeting held July 18, as well as your subsequent statements.

Generic drug competition has proven an effective way to help lower prescription drug prices and reduce overall healthcare costs. Unfortunately, some brand name drug companies have manipulated and twisted the FDA's rules to delay or inhibit availability of generic drugs. This has given these brand name drug manufacturers the power to charge unreasonable prices, which leads to greater healthcare costs, with higher premiums and increased out-of-pocket expenses, often for consumers who can least afford them. As a result, too many Americans cannot afford the prescription medicines they need.

Brand name drug companies have used various means to keep generic drugs off the market. In recent testimony, for example, Hastings Law Professor Robin Feldman stated that GlaxoSmithKline had made $2.5 billion over 23 months by abusing the citizen petition process to keep generic competition out of the market.[1] That amounts to over $3.5 million per day.

We would highlight three types of abuse from the discussions at the July 18 public meeting that we believe warrant the FDA's further attention: abuse of REMS (Risk Evaluation and Mitigation Strategies), abuse of the citizen petition process, and opportunistic reformulations/product hopping.

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[1] Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 500, 512 (2016). *See also* Seth C. Silber, Jonathan Lutinski & Rachel Taylon, *Abuse of the FDA Citizen Petition Process: Ripe for Antitrust Challenge?* ANTITRUST HEALTH CARE CHRONICLE, Jan. 2012 33– 35, https://www.wsgr.com/PDFSearch/silber0112.pdf.

1) REMS abuse. REMS programs have been an important regulatory mechanism for ensuring the safety of drugs that carry significant risks. However, some brand name companies have abused REMS requirements to stop generic competitors from obtaining samples for the necessary testing for FDA approval. Without these samples, generic companies cannot pursue abbreviated new drug applications (ANDAs). This practice, if it is allowed to continue, could raise prices on the 40% of new drug applications that are subject to REMS.[2]

Stopping REMS abuse will save significant money. For example, the CBO scored a proposed legislative solution – the Creating and Restoring Equivalent Access to Equal Samples (CREATES) Act – and found savings of $3.3 billion for government program drug purchases alone. The CREATES Act is a bipartisan solution that allows manufacturers of generic drugs to bring actions in federal court for injunctive relief to obtain the samples they need. It also authorizes judges to award monetary damages to deter future delaying attempts, and gives the FDA more authority to approve alternative safety protocols for a generic when it is having difficulty getting cooperation from the brand name drug maker to develop a shared safety protocol.

We encourage the FDA to support the CREATES Act, but also to look for steps it can take now to address REMS abuse.

2) Misuse of citizen petitions. The citizen petition process was established so that the public can participate in the FDA process and register any genuine concerns about a drug product before it is approved. But some brand name companies have abused this process by filing frivolous petitions as "citizens" for the purpose of delaying a generic drug's approval. Competition can be blocked for several months while the FDA reviews the petition, and qualified generic drugs are kept off the market for no good reason.

A recent study by Rutgers Law Professor Michael Carrier and Oncologist Carl Minniti found that brand name drug companies file 92% of citizen petitions, and only 8% of those petitions are granted.[3] Moreover, 39% of the petitions are filed within six months of the patent's expiration date or the end of the FDA exclusivity period – suggesting that these petitions are being used as a delay tactic. Notably, the average number of citizen petitions being filed per year is increasing, while the success rate is decreasing.

Antitrust cases have also been filed against brand companies for misusing petitions; in one such case, the company, ViroPharma, submitted 43 filings with the FDA

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[2] Alex Brill, *Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry.* Matrix Global Advisors. July 2014, http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf.

[3] Michael A. Carrier & Carl J. Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 Am. U. L. Rev. 305 (2016). Available at SSRN: https://ssrn.com/abstract=2832319

between 2006 and 2012 and failed to provide any data to support its arguments.[4] This case alone has been estimated to have cost consumers hundreds of millions of dollars.[5] We urge the FDA to examine how future citizen petition abuses could be deterred, including by increasing the transparency of the citizen petition process, as many experts and market participants have proposed.[6]

3) Product hopping. The third type of abuse is the practice of opportunistic reformulations, or "product hopping." This involves a brand name company making very minor changes to a drug as the end of its patent life approaches, and forcing patients to switch to a new patented formulation before they are able to access lower-priced generics.[7] These changes have nothing to do with real innovation for the benefit of patients, and instead are used strategically to extend product patent life-cycles by evading state generic substitution laws. Product hopping impairs competition from new entry by generic drugs, and forces consumers to continue paying higher prices. This violates the spirit of the Hatch-Waxman Act, which was enacted to promote generic competition after giving the brand name drug maker a reasonable time to sell under a patent.

To give one example: the pharmaceutical company Actavis attempted to remove an older version of Namenda, a drug used to treat Alzheimer's disease, whose patent was expiring, from the market and replace it with a supposedly improved version that was patented until 2029. The only change was that this "new and improved" version was to be taken once per day instead of twice per day; and it would have led to consumers paying $300 million more in costs, employers and insurers paying an additional $1.4 billion, and Medicare and related programs would have paid an additional $6 billion or more.[8] Fortunately, an injunction prevented Actavis from removing the older drug from market.[9]

While product hopping is primarily enabled by state substitution laws that require exact substitutions, we urge the FDA to also consider ways to help curb this problem. As a start, for example, the FDA could compile data on drug modifications, including the nature of the modification and how close to patent expiration it occurs. The FDA

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[4] Press Release, *FTC Charges That Shire ViroPharma Inc. Abused Government Processes Through Serial, Sham Petitioning to Delay Generics and Maintain its Monopoly over Vancocin HCl Capsules*, *available at* https://www.ftc.gov/news-events/press-releases/2017/02/ftc-charges-shire-viropharma-inc-abused-government-processes.

[5] *Id.*

[6] *E.g.*, Robin Feldman, Evan Frondorf, Andrew K. Cordova, & Connie Wang, *Empirical Evidence of Drug Pricing Games - A Citizen's Pathway Gone Astray*, 20 Stan. Tech. L. Rev. 39, 89-91 (2017).

[7] This strategy can also be used when a drug is off-patent, as in the case of the antibiotic Doryx. *See* Mylan Pharmaceuticals v. Warner/Chilcott, 838 F. 3d 421 (3d Cir. 2016). This means the strategy could be used by a generic company, although it would require a specific set of market circumstances.

[8] Gregory H. Jones, Michael A. Carrier, Richard T. Silver, and Hagop Kantarjian, *Strategies that delay or prevent the timely availability of affordable generic drugs in the United States.* PMC. US National Library of Medicine, National Institutes of Health. 2016 Mar 17; 127 (11): 1398-1402, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915805/.

[9] New York ex rel. Schneiderman v. Actavis plc, 787 F. 3d 638 (2d Cir. 2015).

could also conduct a study on whether there are health risks involved in the substitution of a lower priced generic that has the same active ingredient and therapeutic effect, but has other differences. This type of study could develop recommended safety protocols that states could use to modify their generic substitution laws to allow patients to still receive certain lower priced generics after a forced switch.

Helping bring new innovative drugs to market can and should work hand in hand with improving their availability and affordability without undue delay. We urge the FDA to continue its efforts to end these regulatory abuses, to better ensure that American consumers can have access to affordable generic prescription drugs. And if the FDA identifies areas in which it needs more authority to be able to effectively address these problems, we urge you to notify Congress and request appropriate legislation.

Sincerely,

Consumers Union
Patients for Affordable Drugs
Consumer Federation of America
Consumer Action