COMMITTEE ON
ENERGY & COMMERCE
CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

September 16, 2019

To: Subcommittee on Consumer Protection and Commerce Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on "Profits Over Consumers: Exposing How Pharmaceutical Companies Game the System"

On **Thursday, September 19, 2019, at 10:30 a.m. in room 2322 of the Rayburn House Office Building,** the Subcommittee on Consumer Protection and Commerce will hold a legislative hearing entitled, "Profits Over Consumers: Exposing How Pharmaceutical Companies Game the System."

I. BACKGROUND

It was estimated that the United States spent $480 billion on pharmaceutical drugs in 2016.[1] Further, research suggests that $323 billion was returned to manufacturers as net revenue.[2] Per capita spending on prescription drugs in the United States was $858 in 2013 compared with an average of $400 for 19 other industrialized nations.[3] Yet, profit made from drug sales is concentrated around only a few drugs with no competition; in 2017, only 10 percent of drugs were responsible for 72 percent of consumer spending on drugs.[4]

A. Generic Drugs and Biosimilars Regulation

The requirements for developing and marketing generic drugs and biosimilars are made and enforced by the Food and Drug Administration (FDA). FDA reviews each application to confirm that proposed generic drug products meet the requirements to come to market, including that such product contains the same active ingredient, has the same strength, uses the same

[1] Health Affairs, *Spending on Prescription Drugs in the US: Where Does All the Money Go?* (July 31, 2018) (www.healthaffairs.org/do/10.1377/hblog20180726.670593/full/).

[2] *Id.*

[3] AS Kesselheim et al, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform* (2016) (www.ncbi.nlm.nih.gov/pubmed/27552619).

[4] Association for Accessible Medicines, *Generic Drug Access & Savings in the US* (2018) (accessiblemeds.org/resources/blog/2018-generic-drug-access-and-savings-report).

dosage form (e.g., capsule, tablet, or liquid), and uses the same route of administration (e.g., oral, topical, or injectable) as the brand drug it is meant to copy.[5] Biosimilar products have parallel requirements, including that such product has no clinically meaningful differences in safety, purity, and potency (such as safety and effectiveness) from an existing FDA-approved reference product.[6] Generic applicants must also certify whether each of the patents listed by the branded drug sponsor are invalid, unenforceable, or will not be infringed by the generic product.[7] If the applicant certifies that the patent is invalid or will not be infringed, the applicant is required to notify the owner of the patent subject to the certification. If this process results in patent litigation, FDA is required to postpone approval of the generic application for 30 months, or until the parties resolve the litigation. As part of the biosimilar development process, biological product developers are also required to provide a list of unexpired patents for which a claim of infringement could be made.

B. Effects of Increased Competition on Drug Prices

Drug prices in the United States see considerable reductions through market availability of multiple competing products, including generic drugs, following expiration of patents and exclusivity.[8] FDA found that generic competition has the greatest downward effect on prices when there are three competing products on the market. FDA further found that drug prices continue to decrease with additional market entry—even up to the seventh competing product.[9]

Patients and payers lose out on at least $5.4 billion in savings annually from tactics that delay generic competition,[10] including patent and exclusivity abuse known as "evergreening," as well as the strategic timing of product reformulations to block generic competition, known as "product hopping." Such tactics work as barriers to generic entry at all stages of production, from drug development to market introduction.

II. PRODUCT HOPPING

Product hopping, also known as line extension and sometimes referred to as evergreening, refers to the reformulation of a pharmaceutical drug product by a brand drug

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[5] Food and Drug Administration, *Generic Drug Overview & Basics* (Sept. 13, 2017) (www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm567297.htm).

[6] *See* note 3.

[7] Food and Drug Administration, *Generic Competition and Drug Prices* (Nov. 20, 2017) (www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm).

[8] *See* note 3.

[9] *See* note 7.

[10] *See* note 3.

manufacturer for the purpose of delaying competition.[11] This behavior can include many types of reformulations, such as a change from a capsule to a tablet, a change in dosing or strength, or a reformulation to an extended-release drug. Sometimes manufacturers combine two or more previously approved drug compounds to create a new product.[12] Any of these reformulations, if timed correctly, can be used to prevent a generic from being substituted at the pharmacy for the redesigned brand product.[13] This practice impairs a generic's most cost-efficient (and only commercially feasible) means of competing.[14] Many reformulated products do bring medical or other benefits to consumer, but some are "undeniably inferior" to the original brand product and can significantly impair consumer access to the lower priced generic.[15] Nothing in the regulatory review and approval process expressly forbids this practice, yet it frustrates the efforts to facilitate price competition in pharmaceutical markets.[16]

Once a reformulated product has received approval from FDA, manufacturers can begin marketing the product. Manufacturers have engaged in a wide variety of actions to ensure that physicians and prescribers switch to the new product: some remove their original products from the market altogether and others find ways to enhance the appeal of their reformulated product relative to their previous product. Some manufacturers have relied heavily on their sales forces to promote the alleged benefits of the new product. For example, in the case of the drugs Provigil and Nuvigil, the manufacturer relied on its sales force to create a "great deal of excitement" in the marketplace for the "cheaper, more effective" Nuvigil, while revealing little about its role in increasing Provigil's price.[17] At the same time, no other party has the incentive and ability to promote the old product, which leads to doctors receiving "an entirely one-sided presentation" of the relative merits of the products.[18]

A study published in 2009 reviewed more than four hundred reformulations between the years 1995 and 2009.[19] A subset of the reformulations studied were linked with the timing of prospective generic market entry. These "suspect" reformulations included 32 minor reformulations, such as "changes from a capsule to a tablet or vice versa; changes in chemical structure that, according to independent researchers, yielded little or no consumer value; and

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[11] Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping* 62 Fla. L. Rev. 1009, 1015 (Apr. 11, 2010).

[12] *Id.*

[13] Steve D. Shadowen et. al, *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 Rutgers L.J. Numbers 1 & 2 (2009).

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *See* note 11.

[18] *See* note 13.

[19] *Id.*

multiple, seriatim product reformulations."[20] This research suggested that just among these 32 products with minor reformulations, competition against brand drugs was impaired by annual sales of more than $28.1 billion.[21] Yet another 22 reformulations that may have been product hops, including switches to extended release products or combinations of previously approved products, led to another $15.8 billion in annual sales.

III. CURRENT AUTHORITY

The Federal Trade Commission (FTC) has brought some cases arguing that pharmaceutical product redesigns, or reformulations, are anti-competitive and sometimes constitute exclusionary conduct in violation of FTC's statutory authority. In other situations, generic manufacturers have sued branded drug companies claiming that the branded companies violated antitrust laws in their efforts to exclude generic drugs from the market.

Some have argued that product hopping should not be subject to antitrust authority because marketing a new drug is "generally pro-competitive."[22] Making minor changes to a drug's physical form, however, is not innovation.[23] Some courts have said that a monopolist's products that gain acceptance in the market are free of antitrust liability only as long as "that success was not based on any form of coercion."[24] They have recognized that reduction of consumer choice through coercion can, among other things, cause harm to social welfare and should be subject to antitrust scrutiny.[25]

IV. WITNESSES

The following witnesses have been invited to testify:

Michael A. Carrier
Distinguished Professor, Rutgers Law School
Co-Director, Rutgers Institute for Information Policy and Law

Jeff Francer
Senior Vice President and General Counsel
Association for Accessible Medicines

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[20] *Id.*

[21] *Id.*

[22] Vikram Iyengar, *Should Pharmaceutical Product Hopping Be Subject to Antitrust Scrutiny*, 97 J. Patent & Trademark Office Soc. 663 (2015).

[23] *Id.*

[24] *Id.*

[25] *Id.*

David Mitchell
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Joanna M. Shepherd
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Emory University School of Law