COMMITTEE ON
ENERGY & COMMERCE
CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

March 8, 2019

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"

On **Wednesday, March 13, 2019, at 10 a.m. in the John D. Dingell Room, 2123 of the Rayburn House Office Building,** the Subcommittee on Health will hold a legislative hearing entitled, "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition."

I. BACKGROUND

Prescription drug spending has risen rapidly in the past 50 years. On a per capita basis, inflation-adjusted retail prescription drug spending in the United States increased from $90 in 1960 to $1,025 in 2017.[1] In fact, per capita prescription drug spending in the United States was double the cost of per capita drug spending in 19 other industrialized countries in 2013.[2] Drug spending projections for the U.S. market are projected to climb higher through 2020.[3] The growth of spending is also concentrated among a handful of brand and specialty medications. In 2017, only 10 percent of drugs were responsible for 72 percent of consumer spending on drugs.[4]

---

[1] Kamal, Rabah, et al, Kaiser Family Foundation "What are the recent and forecasted trends in prescription drug spending?" (2017) https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-start.

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

[3] Pew Charitable Trusts, *A Look at Drug Spending in the U.S.* (2018) (https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/02/a-look-at-drug-spending-in-the-us).

[4] Association for Accessible Medicines, *Generic Drug Access & Savings in the US* (2017) (https://accessiblemeds.org/resources/blog/2018-generic-drug-access-and-savings-report).

Drug prices in the United States see considerable reductions through market availability of multiple generic drugs following expiration of exclusivity.[5] In its own analysis, the Food and Drug Administration (FDA) found that generic competition helps decrease prices most significantly when a third competing product is introduced into the market. FDA further found that drug prices continue to decrease with additional market entry—even up to the seventh competing product.[6] Today, generic drugs represent every 9 out of 10 prescriptions.[7] The Association for Accessible Medicines (AAM) released a report in June 2018 estimating that generic market entry saved $265 billion in 2017, including $82.7 billion for Medicare alone, or $1,952 per enrollee.[8] In 2015, IQVIA estimated that the average drug price decreased by 50 percent in the first year of generic entry, with an 80 percent reduction in five years.[4] These reductions were even more pronounced for oral pills, decreasing by 74 percent within 8 months, and 90 percent in 2.5 years.[9] These decreased prices lead to real cost savings for consumers.

II. GENERIC DRUGS AND BIOSIMILARS: PATH TO MARKET

Congress has acted on several occasions to ensure that the incentives for drug and biological product development are sufficient. The Hatch Waxman Act (1984) set out the requirements and incentive structures for developing and marketing generic drugs, and the Biologics Price Competition and Innovation Act (BPCIA) formalized a similar process for biosimilars. In order to ensure that generic applicants are meeting those requirements, FDA reviews each application to confirm that the proposed generic drug product contains the same active ingredient, has the same strength, uses the same dosage form (e.g. capsule, tablet, or liquid), and uses the same route of administration (e.g. oral, topical, or injectable) as the innovator drug.[10] Biosimilar products have similar requirements, including that such product has no clinically meaningful differences in safety, purity, and potency (safety and effectiveness)

---

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

[6] Food and Drug Administration (FDA), "*Generic Competition and Drug Prices*." (https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm).

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

[8] Id.

[9] Price Declines after Branded Medicines Lose Exclusivity in the US. 2016. Report by IQVIA, IMS institute for Healthcare Informatics. Parsippany, NJ.

[10] FDA, *Generic Drug Overview & Basics* (https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm567297.htm).

from an existing FDA-approved reference product.[11] Generic applicants must also provide a "certification" related to whether patents listed by the branded drug sponsor in FDA's Orange Book are invalid, unenforceable, or will not be infringed by the generic product.[12] If this process results in patent litigation, FDA is required to postpone approval of the generic application for thirty months, or until the parties resolve the litigation. As part of the biosimilar development process, biological product developers are required to provide a list of unexpired patents for which a claim of infringement could be made.

All branded and generic drug products currently marketed are included on a list commonly referred to as the "Orange Book," which is on FDA's website and includes, among other details, the patents that protect each product, the product's application number, and related exclusivities. Biological products are included on an analogous list known as the "Purple Book."

First generic applicants are those applicants who are first to file their applications with the FDA. As a reward for their efforts, the first generic applicant is granted 180 days of market exclusivity.

In the Food and Drug Administration Reauthorization Act of 2017 (FDARA), Congress again revisited the incentive structure for generic drug products to come to market. Among other things, this bill created a new 180-day exclusivity period for "Competitive Generic Therapies"—or those targeted to areas with inadequate generic competition.

III. BARRIERS TO COMPETITION

It is estimated that patients and payers lose out on at least $5.4 billion in savings, annually, from tactics that delay generic competition.[5] Such tactics work as barriers to generic entry at all stages of production, from drug development to market introduction. Examples of such tactics include: strategic patent listing, withholding of samples needed for product testing, extending single-shared system REMS negotiations for unnecessarily prolonged periods, gaming of the 180-day generic exclusivity, and pay-for-delay patent settlement agreements. These barriers can be categorized in the following way: patent listing barriers, drug development barriers, and market entry barriers.

---

[11] FDA, *Biosimilar Development, Review, and Approval* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580429.htm#process.

[12] FDA, *Patent Certifications and Suitability Petitions* (www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm047676.htm) (accessed March 7, 2019).

A. Patent Listing Barriers

Drug manufacturers are required to list with FDA patent information related to their drug. This listing in the Orange Book is used by generic manufacturers to make development decisions as it provides information about when patents or exclusivities associated with an approved drug will expire. Some branded drug manufacturers are not including all of their patents in the Orange Book. Further, some stakeholders have been critical that the patent information included in the Orange Book is not as accurate or up-to-date as it could be. Similar concerns have been raised regarding the Purple Book, as the current format is a static document that is not easily searchable or frequently updated.

H.R. 1503, the Orange Book Transparency Act of 2019, introduced by Rep. Kelly (D-IL), would help to ensure that the Orange Book is accurate and up-to-date, by requiring manufacturers to share complete and timely information with FDA, as well as ensuring that patents listed in the Orange Book are relevant to the approved drug product. Patents found to be invalid through a court decision or a decision by the Patent Trial and Appeal Board would be required to be removed promptly. FDA is also directed to reconsider the types of patents that should be listed in the Orange BookF within one year of enactment.

H.R. 1520, the Purple Book Continuity Act of 2019, introduced by Subcommittee Chair Eshoo (D-CA), would amend the Public Health Service Act to codify publication of approved biological products in the Purple Book in a similar format and with similar requirements to the Orange Book, specify that the Purple Book should be published electronically on FDA's website and updated routinely, and direct FDA to consider the types of patents that should be listed in the Purple Book.

B. Drug Development and Market Entry

Some branded drug manufacturers are using restricted distribution systems— including safety protocols known as Risk Evaluation and Mitigation Strategies, or REMS—to delay or impede generic competition on both the front end of generic drug development, through the delay or denial of the sales of samples needed to conduct testing necessary for purposes of FDA approval, and on the back end of market entry, through the delay of negotiations on single, shared protocols.[13] [14]

[13] Brill, Alex, *Unrealized Savings from the Misuse of REMS and Non-REMS Barriers* (2018)(https://accessiblemeds.org/sites/default/files/201809/REMS_WhitePaper_September2018%5B2%5D.pdf).

[14] Carrier, Michael, *Sharing, Samples, and Generics: An Antitrust Framework* (2017) (http://cornelllawreview.org/files/2017/11/1.Carrierfinal.pdf).

H.R. 965, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019, introduced by Reps. Cicilline (D-RI), Sensenbrenner (R-WI), Nadler (D-NY), Collins (R-GA), Welch (D-VT), and McKinley (R-WV), would establish a process by which generic manufacturers could request that FDA authorize them to obtain sufficient quantities of samples for testing. The bill would allow a generic manufacturer facing delay tactics to bring an action in federal court to obtain the samples it needs. Courts would be authorized to award monetary damages sufficient to deter future gaming. It would also clarify FDA's discretion to allow generic manufacturers to operationalize equivalent safety protocols in a separate system instead of entering a shared safety protocol with brand manufacturers, provided that such separate protocol meets the same safety standard as the original system.

H.R. 985, the Fair Access for Safe and Timely (FAST) Generics Act of 2019, introduced by Reps. Welch, McKinley, and Cicilline, establishes an authorization process by which generic manufacturers can gain access to samples of approved drug products that they are trying to genericize. As a condition of approval, brand manufacturers would also have to agree not to restrict access to the covered product, through REMS or otherwise, for development and testing purposes. The legislation defines restricted distribution programs generally, including abuse of a REMS program, as anticompetitive behavior. Additionally, FDA would be given the authority to waive the requirement for a single, shared system if the generic manufacturer has been unable to come to an agreement with the brand manufacturer. Further, the legislation allows generic manufacturers who have been impacted by these abuses to sue the license holder for injunctive relief and damages.

C. Market Barriers

Delay may also result from tactics of generic manufacturers.[15] For example, some first generic applicants are delaying market entry of their products—also known as parking—thus delaying the trigger for their market exclusivity and all subsequent generic competition. Stakeholders have raised concerns that the original generic 180-day exclusivity has morphed from an incentive to challenge patents to a tool for brand firms to pay first-filing generics to delay entering market.[16]

H.R. 938, the Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act of 2019, introduced by Reps. Schrader (D-OR) and Carter (R-GA), would discourage parking of 180-day exclusivity by a first generic applicant by allowing FDA to approve a subsequent generic application prior to the first applicant's first date of commercial marketing when the following four conditions have all been met: (1) the subsequent application is ready for full approval; (2) a minimum of 30 months has passed since at least one

[15] U.S. Health and Human Services, *Fiscal Year 2019 Budget in Brief*, (https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf)

[16] Carrier, Michael, *Four Proposals to Enhance Generic Competition* (https://www.fda.gov/downloads/Drugs/NewsEvents/UCM567752.pdf).

first applicant submitted their application for the drug; (3) any related patent litigation has been fully resolved; and (4) no first applicant is approved.

H.R. 1499, the Protecting Consumer Access to Generic Drugs Act of 2019, introduced by Rep. Rush (D-IL), would make it illegal for brand-name and generic drug manufacturers to enter into agreements in which the brand-name drug manufacturer pays the generic manufacturer to keep a generic equivalent off the market.

H.R. 1506, the Fair and Immediate Release (FAIR) of Generic Drugs Act, introduced by Rep. Barragán (D-CA), would allow any generic filer who wins a patent challenge in court or is not sued for patent infringement by the brand manufacturer to share in the 180-day exclusivity period of first applicants that enter into patent settlements that delay entry. It would also hold such first applicants to the launch date that was agreed to in any patent settlement agreement.

IV. WITNESSES

Lou Kennedy
CEO and Owner
Nephron Pharmaceuticals

Anthony Barrueta
Senior Vice President, Government Relations
Kaiser Permanente

Michael Carrier
Distinguished Professor
Rutgers Law School

Kurt Karst
Director
Hyman, Phelps & McNamara, P.C.

Jeff Kushan
Partner
Sidley Austin LLP

Marc M. Boutin, JD
Chief Executive Officer
National Health Council