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Congress of the United States

House of Representatives

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March 5, 2020

The Honorable Stephen M. Hahn, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Commissioner Hahn:

We write to learn more about the Food and Drug Administration's (FDA) implementation of the FDA Reauthorization Act of 2017 (FDARA), with a focus on a specific provision in FDARA relating to marketing status reporting requirements.

Enacted in 2017, FDARA reauthorized four critical user fee programs to improve the review process for drugs, biosimilars, and medical devices.[1] Numerous provisions in FDARA enhance generic drug competition and lower drug prices, and this important bipartisan legislation has already boosted generic competition. For example, FDARA created an expedited approval process for a generic version of a product that does not have adequate competition—referred to as the Competitive Generic Therapies (CGT) pathway. Last August, the Committee applauded FDA when they approved the first generic drug under this authority.[2] As of February 13, 2020 FDA had approved 31 drugs under the CGT pathway.[3]

Promoting a competitive marketplace depends in part on FDA's timely approval of generic drugs and biosimilars, and in part on transparency about the marketing status of approved products. FDARA therefore required holders of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) to: (1) notify FDA before withdrawing an approved drug from sale, either 180 days before withdrawing it or as soon as practicable; (2) notify FDA

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[1] H. Comm. on Energy and Commerce, 115th Cong., H.R. 2430, *Factsheet: The FDA Reauthorization Act (FDARA) of 2017* (Jun. 7, 2017), *available at* https://republicans-energycommerce.house.gov/news/fact-sheet/h-r-2430-fda-reauthorization-act-fdara-2017/.

[2] H. Comm. on Energy and Commerce, 115th Cong., *FDARA is Boosting Generic Drug Competition* (Aug. 9, 2018), *available at* https://republicans-energycommerce.house.gov/news/blog/fdara-is-boosting-generic-drug-competition/.

[3] U.S. Food and Drug Administration, *"Competitive Generic Therapies," May 23, 2019 Issue* (May 23, 2019), *available at* https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/competitive-generic-therapies-may-23-2019-issue.

within 180 days of approval if a drug will not be available for sale within 180 days of the date of approval; and (3) provide a one-time report on marketing status.[4]

We appreciate FDA's efforts to implement this provision with the issuance of a draft guidance document in January 2019 entitled "Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format."[5] On January 30, 2019, former Commissioner Scott Gottlieb highlighted the importance of having information about circumstances where generic competition is lacking:

> The guidance provides approved drug application holders with clarity on the specific categories and descriptions of the information they're required to share with FDA on the marketing status for their brand and generic drugs and how to provide it in a timely and consistent manner. Having timely, accurate information about what drugs are being actively marketed helps provide transparency around circumstances where generic competition is lacking. It helps us also better understand circumstances where generic medicines are being approved, but not marketed so that we can better consider any policy reasons why this may be occurring.[6]

In the guidance, FDA explains that "the Agency has previously indicated that withdrawal from sale is not limited to a permanent withdrawal of a product but can also include 'any decision to discontinue marketing of [that] product.'"[7] More specifically, FDA explains that under the Agency's policy, the Agency determines that a product has been "withdrawn from sale" if "the applicant has ceased its own distribution of the drug, whether or not it has ordered recall of previously distributed lots of the drug. A routine, temporary interruption in the supply of a drug product would not be considered a withdrawal from sale, however, unless triggered by safety or effectiveness concerns."[8]

Since this provision in FDARA was passed into law, we have heard about additional ways that some drug manufacturers may be manipulating the market to harm competition and raise prices. A complaint filed by the Attorney General of Connecticut and a 44-state coalition in May 2019 details instances where generic manufacturers allegedly exited the market temporarily to suppress competition and fix prices.[9] The complaint alleges that certain

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[4] FDA Reauthorization Act of 2017 (FDARA), P.L. 115-52.

[5] U.S. Food and Drug Administration, *Draft Guidance: Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format; Draft Guidance for Industry; Availability* (Jan., 31, 2019), *available at* https://www.federalregister.gov/documents/2019/01/31/2019-00458/marketing-status-notifications-under-section-506i-of-the-federal-food-drug-and-cosmetic-act-content.

[6] U.S. Food and Drug Administration, *FDA Statement: Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's efforts to enhance the utility of the Orange Book to foster drug competition* (Jan. 30, 2019), *available at* https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-efforts-enhance-utility-orange-book-foster-drug.

[7] *See supra* note 6.

[8] *Id.*

[9] State of Connecticut, Attorney General William Tong, *Press Release: Attorney General Tong Leads 44-State Coalition in Antitrust Lawsuit Against Teva Pharmaceuticals, 19 Other Generic Drug Manufacturers, 15 Individuals In Conspiracy to Fix Prices and Allocate Markets for More Than 100 Different Generic Drugs* (May 12, 2019), *available at* https://portal.ct.gov/AG/Press-Releases/2019-Press-Releases/TONG-LEADS-LAWSUIT-

companies temporarily removed specific products from the market to engage in anti-competitive behavior:

> Unlike their branded counterparts, generic drugs are commodities and generic manufacturers are constantly making decisions to enter new markets and leave existing markets. Often these decisions are made, at least in part, based on who the competitors are and how strong the relationship is between the two companies. As one example, in July 2013, Defendant Sandoz was looking to implement a "Taro Strategy" that involved temporarily delisting ten products that they overlapped on with Defendant Taro. This strategy would allow Taro to raise price on these products while Sandoz was out of the market, and then Sandoz could re-enter later at the higher price.[10]

Shortly after the lawsuit was filed, the generic drug industry emphasized the importance of competition and its support of policies that promote competition and help speed the availability of generic medicines to patients.[11] Moreover, many of the generic drug companies implicated in the lawsuit have denied the claims and said that the claims are meritless. For example, Novartis issued a statement in May stating that the suit against its generic unit, Sandoz, was without merit and that the company would contest the allegations.[12] Similarly, Sun Pharmaceuticals said that, according to their subsidiary Taro Pharmaceuticals, the allegations made against its subsidiary Taro Pharmaceuticals were without merit and that the subsidiary would defend against them.[13] Three generic manufacturers—Heritage Pharmaceuticals, Rising Pharmaceuticals, and Sandoz—have admitted to engaging in a price-fixing scheme with their competitors.[14]

There are legitimate reasons that manufacturers enter new markets and leave existing markets. For example, at a December 2017 hearing on the prescription drug supply chain before the Committee's Subcommittee on Health, the President and Chief Executive Officer of the Association for Accessible Medicines (AAM) testified that generic drug manufacturers evaluate

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AGAINST-GENERIC-DRUG-MANUFACTURERS-IN-CONSPIRACY-TO-FIX-PRICES-FOR-OVER-100-DRUGS.

[10] Complaint at 48, *Connecticut v. Teva Pharmaceuticals USA, Inc.* (District Court, D. Connecticut), https://portal.ct.gov/AG/Press-Releases/2019-Press-Releases/DRUG-PRICE-FIXING-COMPLAINT-UNSEALED.

[11] Association for Accessible Medicines (AAM), *Response to 60 Minutes May 12, 2019: AAM Statement on the Importance of Competition to Promote Accessibility and Affordability of Medicines* (May 12, 2019), *available at* https://accessiblemeds.org/resources/press-releases/response-60-minutes-may-12-2019-aam-statement-importance-competition.

[12] Reuters, *Novartis vows to fight U.S. price-fixing claims against Sandoz unit* (May 13, 2019), *available at* https://www.reuters.com/article/us-usa-drugs-lawsuit-novartis/novartis-vows-to-fight-u-s-price-fixing-claims-against-sandoz-unit-idUSKCN1SJ0U6.

[13] *Pharma majors deny US price fixing allegations*, Economic Times (May 15, 2019), *available at* https://economictimes.indiatimes.com/markets/stocks/news/pharma-majors-deny-us-price-fixing-allegations/articleshow/69334480.cms?from=mdr.

[14] U.S. Dep't of Justice, *Second Pharmaceutical Company Admits to Price Fixing, Resolves Related False Claims Act Violations* (Dec. 3, 2019), *available at* https://www.justice.gov/opa/pr/second-pharmaceutical-company-admits-price-fixing-resolves-related-false-claims-act; John Commins, *Generic Drug Maker Heritage Pharmaceuticals Admits to Price Fixing*, HEALTHLEADERS (May 31, 2019), *available at* https://www.healthleadersmedia.com/generic-drug-maker-heritage-pharmaceuticals-admits-price-fixing

the sustainability of the competitive market in any therapeutic area in determining whether they will bring a product to market once they obtain FDA approval, and if the company will keep the product on the market after approval.[15]

Given the important role of marketing transparency in our efforts to help promote generic competition, we request that FDA provide us with a briefing to discuss the types of temporary market withdrawals that are being reported to the Agency under section 506I of FDARA and how FDA is monitoring and tracking such marketing status information. We also ask that the briefing include information on actions FDA is taking, if any, to address any gaps or overlaps in reporting requirements for manufacturers that withdraw a product from the market.

Thank you for your prompt attention to this request. If you should have any questions, please contact Kimberlee Trzeciak of the Majority Committee staff at (202) 225-2927 or Kristin Seum of the Minority Committee staff at (202) 225-3641.

Sincerely,

Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce

Greg Walden
Republican Leader
Committee on Energy and Commerce

Anna Eshoo
Chairwoman
Subcommittee on Health

Michael C. Burgess, M.D.
Republican Leader
Subcommittee on Health

Diana DeGette
Chair
Subcommittee on Oversight
and Investigations

Brett Guthrie
Republican Leader
Subcommittee on Oversight
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[15] H. Comm. on Energy and Commerce, 115th Cong., Hearing on "Examining the Drug Supply Chain," (Dec. 13, 2017), *available at* https://docs.house.gov/meetings/IF/IF14/20171213/106730/HHRG-115-IF14-Transcript-20171213.pdf.