Oral Statement of Commissioner Christine S. Wilson, FTC

As Prepared for Delivery

Before the
U.S. Senate Committee on Commerce, Science, and Transportation
Subcommittee on Consumer Protection, Product Safety, Insurance, and Data Security

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Introduction

Thank you, Chairman Moran, Ranking Member Blumenthal, and distinguished members of the Subcommittee, for the opportunity to testify. It is an honor to appear before you for the first time since I joined the Commission two months ago.

I would like to highlight today one of the areas I identified as a personal and agency priority during my confirmation process—the healthcare industry. As you know, the healthcare industry impacts every American and takes a significant bite out of each paycheck. Given its importance, it should come as no surprise that the FTC is quite active in this segment of the economy.

I would like to briefly discuss two issues associated with healthcare, one related to consumer protection and the other related to competition.

Consumer Protection

On the consumer protection side, the marketing of unproven or ineffective treatments for serious health conditions is unfortunately all too common, and rightly remains a top priority for FTC enforcement.

One important area for the FTC is the marketing of products that claim to address opioid addiction. The CDC estimates that a staggering 115 Americans die every day – ***every day*** – from an opioid overdose.[1] People seeking lifesaving help for opioid addiction or withdrawal must get the right kind of help as soon as they are ready to receive it. Products that promise miracle cures or fast results can cost precious time and money, and can contribute to relapse or even death. It is illegal to advertise that a product or service can cure a condition without competent and reliable scientific evidence to back up those health claims.

The Commission has sued two companies that marketed bogus withdrawal and addiction treatment products.[2] The FTC also is conducting a number of non-public investigations in this

[1] *Opioid Overdose, Understanding the Basics*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/drugoverdose/epidemic/index.html (last visited Nov. 27, 2018).
[2] Compl., FTC v. Catlin Enterprises, Inc., No. 1:17-cv-403 (W.D. Tex. filed May 3, 2017), https://www.ftc.gov/system/files/documents/cases/withdrawal_ease_-_complaint_w_exhibit.pdf; Amended Compl.,

area. Thanks to the leadership of many of the members of this committee, including Senator Cortez Masto and Senator Capito, the FTC now has a new tool in its fight against the opioid epidemic – civil penalty authority to challenge false or misleading representations about opioid treatment products or services.

Earlier this year, the FTC also partnered with the Food and Drug Administration (FDA) to send warning letters to firms marketing products that claimed to help with opioid addiction.[3] Moving beyond enforcement to consumer education and advocacy, the FTC collaborated with the Substance Abuse and Mental Health Services Administration (SAMHSA) to release a fact sheet on getting the right help with opioid dependence or withdrawal.[4]

Armed with our expanded tools, the FTC will continue to support local, state, and federal law enforcement agencies as they work to confront the many challenges arising from the opioid crisis.

Competition

The Commission long has recognized and challenged false and unsubstantiated health claims. In contrast, REMS abuses, a problem we are seeing on the Competition side of the agency, are a relatively recent phenomenon.

The FTC continues to investigate allegations that branded pharmaceutical companies misuse Risk Evaluation and Mitigation Strategies, or "REMS," to impede competition. In theory, a REMS program is designed to protect patient safety by managing the known or potential risks associated with the use or distribution of certain medications. Oftentimes, that is also the practice. But sometimes branded manufacturers misuse REMS to thwart entry by would-be generic competitors, thereby upsetting the careful balance between competition and innovation that Congress established in the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (BPCIA).[5]

REMS abuses can take various forms. For example, a branded manufacturer may establish a restricted distribution system for a REMS product and then improperly invoke the REMS requirements to justify its refusal to make available samples of that product to firms seeking to obtain FDA approval of generic or biosimilar products. According to data reported by generic firms to the FDA, generic pharmaceutical firms have been unable to obtain samples of 52 branded pharmaceutical drugs despite making over 150 requests to branded pharmaceutical

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FTC v. Sunrise Nutraceuticals, LLC, No. 9:15-cv-81567-DMM (S.D. Fla. filed Jan. 8, 2016), https://www.ftc.gov/system/files/documents/cases/160108sunrisecmpt.pdf.

[3] The FDA and the FTC issued letters to companies that appeared to be making questionable claims in order to sell addiction or withdrawal remedies. *See* Press Release, FTC, *FTC, FDA Warn Companies about Marketing and Selling Opioid Cessation Products* (Jan. 24, 2018), *available at* https://www.ftc.gov/news-events/press-releases/2018/01/ftc-fda-warn-companies-about-marketing-selling-opioid-cessation.

[4] *Id.*

[5] A representative of the Commission has previously testified on this topic. *See* Prepared Statement of Markus H. Meier, Acting Director of the Bureau of Competition, FTC, Before the U.S. House of Representatives, Judiciary Cmte., Subcmte. on Regulatory Reform, Commercial and Antitrust Law: Antitrust Concerns and the FDA Approval Process, at 6-13 (July 27, 2017).

manufacturers.[6] Alternatively, if a competing firm applies for FDA approval of a generic, biosimilar, or interchangeable product, the branded manufacturer may improperly deny that competitor access to a single, shared REMS system, leaving the FDA unable to approve the competitor's application and labeling.[7]

Regardless of the precise method employed, concerns arise when branded pharmaceutical manufacturers subvert laws and regulations designed to protect the health and safety of consumers and instead use those frameworks to protect themselves from competition. By excluding competitors from the market, branded drug companies can price their products higher than they otherwise could. As a result, consumers – including both your constituents and government entities – risk paying more for these medicines.

Recognizing that REMS abuse is a competition problem, the FTC has used its existing powers to investigate potential antitrust violations. The FTC has also engaged in advocacy, including *amicus curiae* briefs filed in private litigation.[8]

We are grateful that members of the Subcommittee share our concerns and have proposed legislation that would more directly address this problem. To that end, FTC staff have been providing technical assistance on various bills, and we will continue to support legislative efforts.

Conclusion

In closing, the Commission recognizes the importance of healthcare in the daily lives of American consumers. Our targets include both longstanding challenges, such as the use of bogus claims to market unproven health treatments to consumers, and relatively new ones, such as REMS abuse.

I am happy to answer any questions you may have.

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[6] *See Reference Listed Drug (RLD) Access Inquiries*, FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm (last visited Nov. 27, 2018); *see also HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, 83 Fed. Reg. 22,692, 22,696-97 (May 16, 2018) ("In some instances for products that are subject to REMS that impact distribution, manufacturers continue to restrict access to generic developers even after the FDA issues a letter stating that it … would not consider the provision of drug samples to this developer for generic development to violate the applicable REMS.").

[7] Recognizing this potential problem, the FDA has issued two draft guidance documents on shared system REMS. *See* FOOD & DRUG ADMIN., DEVELOPMENT OF A SHARED SYSTEM REMS: GUIDANCE FOR INDUSTRY (June 2018), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609045.pdf; FOOD & DRUG ADMIN., WAIVERS OF THE SINGLE, SHARED SYSTEM REMS REQUIREMENT: GUIDANCE FOR INDUSTRY (June 2018), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609048.pdf

[8] Br. of FTC as *amicus curiae*, Actelion Pharms. Ltd. v. Apotex Inc., No. 1:12-cv-05743 (D.N.J. filed Mar. 11, 2013), *available at* https://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd.et-al.v.apotex-inc./130311actelionamicusbrief.pdf; Br. of FTC as *amicus curiae*, Mylan Pharms., Inc. v. Celgene Corp., No. 2:14-cv-2094 (D.N.J. filed June 17, 2014), *available at* https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf.