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September 27, 2016

The Honorable Edith Ramirez
Chairwoman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20530

Dear Chairwoman Ramirez,

I write to request the Federal Trade Commission (FTC) use the full force of its authority to accelerate its investigation into whether the manufacturer Indivior (formally Reckitt Benckiser) has violated any antitrust laws in connection with the sale of Suboxone, a drug that is used to treat those with opioid use disorders.

With the prescription painkiller and opioid overdose epidemic claiming 78 American lives every day,[1] affordable treatment options for those suffering from opioid use disorders are of the utmost importance. It is estimated that of the 2.2 million patients who need treatment for an opioid use disorder fewer than 50 percent are receiving adequate treatment.[2] In light of this extensive "treatment gap," I have worked to expand access to evidence-based treatment options, including authoring a provision recently enacted into law that expands the types of qualified health professionals who can treat patients with medication assisted treatments such as Suboxone.[3] This provision, combined with recent action by the Secretary of Health and Human Services that nearly triples the existing cap on the number of patients that a physician can treat with Suboxone and related products[4], will mean that more patients can access this treatment, necessitating increased availability of the most affordable options. It is now more important than ever that the FTC vigilantly investigate allegations that pharmaceutical companies have thwarted competition, unlawfully increased profits, or illegally extended monopolies in connection with medication assisted treatments for opioid use disorders.

First approved by the Food and Drug Administration (FDA) in 2002, Suboxone is one of only three approved medications for the treatment of opioid use disorders. Manufactured by Indivior, Suboxone combines buprenorphine, an opioid used to treat addiction to heroin and prescription painkillers, with naloxone, which can cause intense withdrawal symptoms and is intended to prevent abuse. When the FDA first approved Suboxone, it granted the manufacturer exclusive rights to sell and market the drug, based on the manufacturer's claim to the FDA that, because

[1] https://www.cdc.gov/drugoverdose/epidemic/
[2] https://aspe.hhs.gov/sites/default/files/pdf/107956/ib_OpioidInitiative.pdf
[3] http://www.markey.senate.gov/news/press-releases/markey-statement-on-passage-of-comprehensive-addiction-and-recovery-act
[4] http://www.hhs.gov/about/news/2016/07/06/hhs-announces-new-actions-combat-opioid-epidemic.html

too few people were seeking treatment for opioid use disorders, the company would not otherwise be able to recoup its research and development costs.

As the end of Suboxone's exclusivity neared and the possibility of cheaper generic competition emerged, the company claimed that the pill formulation of its product posed a dangerous exposure risk to children and petitioned the FDA to delay approving any generic products. In the meantime, Indivior switched its formulation of Suboxone to a dissolvable oral film strip, which, the FDA noted could present a greater threat to children. Indivior then pulled its pill formulation off the market, replacing it with a more expensive film version whose patent does not expire until 2023, while maintaining claims to the physician and patient community that the film products were safer than the pills. Shortly thereafter, in early 2013, the FDA approved two generic pill versions of Suboxone. To date there are no generic versions of the film-strip formulation.

Recently, 35 states and the District of Columbia filed a lawsuit against Indivior alleging that the company violated antitrust laws by conspiring to block generic competition, extending its monopoly.[5] The states are seeking to recoup the billions of dollars in profits generated by the company's actions, which drove up prices and deprived states and consumers of lower costs.

Following Indivior's actions in 2012, the FDA referred the manufacturer to the FTC for investigation. In addition to investigating whether Indivior has engaged in unfair methods of competition, the FTC has also examined whether the manufacturer interfered with the FDA's development of a plan for the safe manufacturing and distribution of its drugs (Risk Evaluation and Mitigation Strategies, or REMS). Court documents show that Indivior has significantly impeded the FTC's investigation by attempting to deny the FTC access to thousands of pages of documents that are integral to its investigation.[6] But the court overseeing the Indivior litigation recently ordered the company to turn over all remaining nonprivileged documents.[7]

In light of the potential impact Indivior's actions delaying approval of cheaper generic competition have had on federal spending under both Medicare and Medicaid, and the impact on consumers, I respectfully request that the FTC accelerate its investigation to determine whether Indivior engaged in unlawful and anti-competitive behavior and to take any necessary enforcement actions.

Thank you for your attention to this important matter. I look forward to your response and to continuing to work together to ensure that those with opioid use disorders are able to access and afford the treatment they seek.

Sincerely,

Edward J. Markey

Edward J. Markey
United States Senator

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[5] http://www.ag.ny.gov/press-release/ag-schneiderman-sues-manufacturer-opioid-addiction-drug-illegally-blocking-competition
[6] Federal Trade Commission v. Reckitt Benckiser Pharmaceuticals, Inc., No. 3:2014mc00005 - Document 29 (E.D. Va. 2014)
[7] Federal Trade Commission v. Indivior, Inc., Misc. No. 3:14mc5 (E.D. Va. Aug. 1, 2016)