

United States Senate

WASHINGTON, DC 20510

December 13, 2017

The Honorable Maureen Ohlhausen
Acting Chairman
Federal Trade Commission
600 Pennsylvania Ave., NW
Washington, D.C. 20580

The Honorable Scott Gottlieb, M.D.
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Chairman Ohlhausen and Commissioner Gottlieb:

As individuals and families across the country continue to battle the national opioid epidemic and seek remedies to address the symptoms and underlying disease of a substance use disorder, we urge the Federal Trade Commission (FTC) to immediately investigate deceptive, illegal marketing practices by dietary supplement manufacturers, and the Food and Drug Administration (FDA) to take strong enforcement action against dietary supplements that target those with substance use disorders by claiming, without adequate evidence, that their products ease withdrawal symptoms or otherwise treat substance use disorders.

Addiction is one of the greatest public health crises of our time. According to the Centers for Disease Control and Prevention (CDC), drug overdoses are now the leading cause of injury-related death for Americans aged 25 to 64. Only 10 percent¹ of Americans who need specialty treatment for a substance use disorder receive it and nearly 100 Americans die as a result of opioid overdose every day.² The voracity of this indiscriminate and rapidly spreading epidemic has translated into desperation for many individuals and families, who are seeking help to free themselves or their loved ones from the grips of addiction. Given the size and scope of this epidemic and the resulting demand for treatment options, it is unconscionable that many Americans seeking relief for themselves or for their struggling loved ones have been targeted by insidious scammers looking to profit from their recovery efforts by marketing fraudulent dietary supplements to them.

Last week, the *New York Times* reported that the Center for Science in the Public Interest has identified eight dietary supplement retailers purporting to “ease withdrawal symptoms” and “shorten detox length, improve emotional well-being, [and] provide nutritional support to the brain during detox.” These claims are unfounded and not based on any conclusive, scientific evidence.³ Moreover, as an FDA spokesperson said, “Health fraud scams like these can pose

¹ https://www.samhsa.gov/data/sites/default/files/report_2716/ShortReport-2716.html

² <https://www.cdc.gov/drugoverdose/epidemic/index.html>

³ <https://www.nytimes.com/2017/12/08/health/FDA-opioids-supplement.html>

serious health risks, and the FDA cautions the public to instead seek out medication-assisted treatments that have met the scientific rigor of FDA approval.” As one can imagine, delaying critical treatment by turning to unverified dietary supplements could prove deadly for many Americans with opioid use disorders.

Currently, dietary supplements are not subject to premarket review by the FDA, or to the rigorous manufacturing practices required of prescription drugs. As these opioid treatment products illustrate, it is evident that far from enough is being done to protect consumers from misleading, dangerous dietary supplements. Given this glaring regulatory gap, the FTC has previously brought enforcement actions against dietary supplement marketers who are claiming to treat substance use disorders. Most recently, in September 2017, the FTC settled with Sunrise Nutraceuticals, LLC, the creator of the “opioid withdrawal” powdered drink supplement Elimidrol, and issued refund checks to over 5,000 consumers who purchased this fraudulent product.⁴

We strongly urge the FTC and FDA to swiftly use their full authority to hold such scammers accountable for their egregious actions that prey on already vulnerable consumers. The FTC should investigate and file charges against those making unfounded claims, and obtain refund checks for affected consumers. The FDA must take action against these products because they are making medical claims and should thus be subject to premarket approval as drugs. We encourage the FTC and FDA to coordinate efforts to ensure that these predatory products are removed from the market and that fraudsters are held accountable. These dangerous, unsubstantiated supplements have no place on store shelves, online websites, or in Americans’ homes. We stand ready and willing to work with both agencies to ensure that Americans battling the opioid epidemic are protected from predators.

Thank you for your attention to this critical matter. We respectfully request a response outlining what concrete actions you intend to take to address this issue by January 13, 2018.

Sincerely,



RICHARD BLUMENTHAL
United States Senate



EDWARD J. MARKEY
United States Senate

⁴ <https://www.ftc.gov/news-events/press-releases/2017/09/ftc-sending-refund-checks-totaling-more-210000-consumers-who>