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115TH CONGRESS }
2d Session }

SENATE

{ REPORT
115-285 }

OPIOID ADDICTION RECOVERY FRAUD
PREVENTION ACT OF 2018

R E P O R T

OF THE

COMMITTEE ON COMMERCE, SCIENCE, AND
TRANSPORTATION

ON

S. 2842



JUNE 27, 2018.—Ordered to be printed

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SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

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SECOND SESSION

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OPIOID ADDICTION RECOVERY FRAUD PREVENTION ACT OF 2018

JUNE 27, 2018.—Ordered to be printed

Mr. THUNE, from the Committee on Commerce, Science, and
Transportation, submitted the following

R E P O R T

[To accompany S. 2842]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, Science, and Transportation, to which was referred the bill (S. 2842) to prohibit the marketing of bogus opioid treatment programs or products, having considered the same, reports favorably thereon with an amendment (in the nature of a substitute) and recommends that the bill (as amended) do pass.

PURPOSE OF THE BILL

The purpose of S. 2842, the Opioid Addiction Recovery Fraud Prevention Act of 2018, is to explicitly prohibit the deceptive marketing of opioid treatment programs and products. Section 5 of the Federal Trade Commission Act (FTC Act; 15 U.S.C. 41 et seq.) already prohibits such deceptive practices. The bill also would provide additional tools to the Federal Trade Commission (FTC) and States to enforce against these practices. Specifically, the bill would empower the FTC to seek the remedies currently available under the FTC Act for violations of a trade regulation rule, and empower States to seek appropriate relief in Federal court. By providing the FTC and States with these tools, the bill will facilitate enforcement and thereby better protect consumers from the deceptive marketing of opioid treatment programs and products.

BACKGROUND AND NEEDS

The term “opioid” includes prescription opioid painkillers like hydrocodone and morphine and illegal drugs like heroin. In July 2017, the Centers for Disease Control and Prevention (CDC) reported that the amount of opioids prescribed in 2015 was enough for every American to be medicated around the clock for 3 weeks.¹ According to a CDC report, there were 63,632 drug overdose deaths in the United States in 2016, and 42,249 deaths related to opioid overdoses.² The CDC’s 2017 Annual Surveillance Report of Drug-Related Risks and Outcomes highlights that opioid overdose death rates are largely a result of prescription or illicit opioids, including heroin and illicit fentanyl, a synthetic opioid.³

Heroin overdoses are closely linked to the opioid crisis. In 2015, more than 33,000 people died from an opioid overdose, with heroin deaths increasing over 20 percent from 2014 to 2015.⁴ A 2015 report by the CDC and the Food and Drug Administration (FDA) found the strongest risk factor for a heroin use disorder is a prescription opioid use disorder.⁵

To prevent overdose and death, the CDC recommends treatment for people struggling with opioid use disorder. To treat those with opioid use disorder, the CDC specifically recommends expanded access to evidence-based treatments, including medication-assisted therapy, a comprehensive approach to treatment that combines the use of medication (methadone, buprenorphine, or naltrexone) with counseling and behavioral therapies.⁶

In response to growing demand for treatment services, the Substance Abuse and Mental Health Services Administration maintains a behavior health treatment services locator which lists substance abuse and addiction treatment facilities that meet certain eligibility criteria.⁷

Given this demand, opioid treatment centers have become big business. The President’s Council of Economic Advisors estimated that prescription opioid misuse increased healthcare and substance abuse treatment costs by \$29.4 billion in 2015.⁸ In one Florida county alone, substance abuse treatment was estimated to be a \$1 billion business and a major economic engine, ranking only below tourism, agriculture, and construction.⁹

¹ CDC, Vital Signs (Jul. 2017). (<https://www.cdc.gov/vitalsigns/opioids/index.html>)

² Puja Seth et al., Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants—United States, 2015–2016, 67 *MMWR* 349–358 (Mar. 30, 2018). (https://www.cdc.gov/mmwr/volumes/67/wr/mm6712a1.htm?s_cid=mm6712a1_w)

³ CDC, Annual Surveillance Report of Drug-Related Risks and Outcomes (2017), (<https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf>)

⁴ Rose A. Rudd et al., Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015, 65 *MMWR*, 1445–1452 (Dec. 30, 2016). (https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm?s_cid=mm655051e1_w#T1_down)

⁵ Press Release, CDC, New research reveals the trends and risk factors behind America’s growing heroin epidemic (Jul. 7, 2015). (<https://www.cdc.gov/media/releases/2015/p0707-heroin-epidemic.html>)

⁶ CDC, Treat Opioid Use Disorder (<https://www.cdc.gov/drugoverdose/prevention/treatment.html>) (accessed May 17, 2018).

⁷ Substance Abuse & Mental Health Services Admin., Behavioral Health Treatment Services Locator (<https://findtreatment.samhsa.gov>) (accessed May 17, 2018).

⁸ Council of Econ. Advisors, The Underestimated Cost of the Opioid Crisis (Nov. 2017). (<https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf>)

⁹ Pat Beall, County’s \$1 billion gold rush: Addiction treatment draws FBI, Palm Beach Post (Aug. 14, 2015). (<https://www.mypalmbeachpost.com/news/county-billion-gold-rush-addiction-treatment-draws-fbi/JT3MyQwWckFyEzASfQnoTN>) (hereinafter Beall).

While legitimate treatment centers exist, media reports have uncovered various scam treatment centers operating in the United States and detailed the prevalence of questionable industry practices. One report explained how “[c]rooked” treatment centers partner with “body brokers” and sober homes to generate patient leads through various tactics, including “offer[ing] those trying to get clean free rent and grocery store gift cards, cigarettes and manicures in exchange for going to a specific treatment center, which pays kickbacks for every client.”¹⁰ The report further explained how these treatment centers, in turn, often provide “questionable counseling, costly and potentially unnecessary drug screens, and exotic laboratory tests. Some treatment centers not only overlook drug use—they encourage it. To Florida’s worst operators, relapse doesn’t mean failure. It means profit.”¹¹

Unscrupulous drug treatment centers have been the target of criminal law enforcement across the country. In July 2017, for example, State and Federal law enforcement conducted a sweep of arrests in South Florida targeting the owners of drug treatment centers.¹²

Opioid recovery scams are perpetrated not only by treatment centers, but also by companies promoting recovery treatment products with deceptive advertising claims. For example, in 2015, the FTC filed a lawsuit in Federal court to enjoin a dietary supplement marketer from making misleading claims that its product can help treat and even cure people who are addicted to opiates. In that case, the FTC alleged that a Florida-based company deceptively claimed that its dietary supplement Elimidrol contained a “proprietary blend” of herbs and other compounds to alleviate opiate withdrawal symptoms and increase a user’s likelihood of overcoming opiate addiction.¹³ Under the court order settling the FTC’s charges, the company is barred from making such unsubstantiated health and efficacy claims and agreed to pay \$235,000 for consumer refunds.¹⁴

SUMMARY OF PROVISIONS

Although the bill does not in any way expand the FTC’s jurisdiction, it does reaffirm the FTC’s jurisdiction over marketing practices also subject to the FDA’s jurisdiction, such as the advertising of drugs. The Committee notes that the Memorandum of Understanding Between The Federal Trade Commission and The Food and Drug Administration (MOU) approved and accepted by the two agencies in 1971, addresses how the two agencies will proceed

¹⁰Lisa Seville et al., Florida’s Billion-Dollar Drug Treatment Industry Is Plagued by Overdoses, Fraud, NBC News (Jun. 25, 2017), (<https://www.nbcnews.com/feature/megyn-kelly/florida-s-billion-dollar-drug-treatment-industry-plagued-overdoses-fraud-n773376>)

¹¹Id.

¹²Anna R. Schechter & Lisa Seville, Florida Drug Treatment Center Operators Busted in Crackdown, NBC News (Jul. 19, 2017), (<https://www.nbcnews.com/health/health-care/florida-drug-treatment-center-operators-busted-crackdown-n784326>)

¹³*FTC v. Sunrise Nutraceuticals, LLC*, No. 9:15-CV-81567 (S.D. Fla.) (complaint for permanent injunction and other equitable relief filed Nov. 16, 2015), (<https://www.ftc.gov/system/files/documents/cases/151117sunrisenutraceuticalscmpt.pdf>)

¹⁴*FTC v. Sunrise Nutraceuticals, LLC*, No. 9:15-CV-81567 (S.D. Fla.) (stipulated final judgment and order for permanent injunction and other equitable relief entered July 8, 2016), (<https://www.ftc.gov/system/files/documents/cases/160706sunrise-stip.pdf>)

where their jurisdictions overlaps.¹⁵ The MOU provides that, with the exception of prescription drugs, the FTC has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs, devices, and cosmetics.¹⁶ In contrast, the FDA has primary responsibility for preventing misbranding of foods, drugs, devices, and cosmetics, and with respect to the regulation of the truth or falsity of prescription drug advertising.¹⁷ In addition, the MOU provides that “[t]he initiation of proceedings involving the same parties by both agencies shall be restricted to those highly unusual situations where it is clear that the public interest requires two separate proceedings.” The Committee notes that the purpose of the MOU is to prevent unnecessary and wasteful duplicative enforcement by the FTC and FDA.

Section 2 would define the term “opioid treatment product” to mean a product, including any supplement or medication, for use or marketed for the use in the treatment, cure, or prevention of an opioid use disorder. It would define the term “opioid treatment program” to mean a program that provides treatment for people diagnosed with, having, or purporting to have an opioid use disorder. It would define the term “opioid use disorder” to mean a cluster of cognitive, behavioral, or physiological symptoms in which the individual continues the use of opioids despite significant opioid-induced problems, such as adverse health effects.

Section 3 would affirmatively establish that it is unlawful to make any deceptive representation with respect to the cost, price, efficacy, performance, benefit, risk, or safety of any opioid treatment program or opioid treatment product. Any such violation would be considered a violation of an FTC trade regulation rule, allowing the FTC to seek civil penalties under section 5 and the remedies set forth in section 19 of the FTC Act, in addition to injunctive relief and other equitable remedies. The maximum civil penalty amount the FTC may seek for violations of trade regulation rules is \$41,484 per violation, as currently adjusted for inflation. This section would also empower States to bring actions against entities for violations of this section and to obtain appropriate relief.

LEGISLATIVE HISTORY

S. 2842 was introduced on May 15, 2018, by Senator Capito (for herself and Senator Cortez Masto) and was referred to the Committee on Commerce, Science, and Transportation of the Senate. Senators Brown, Sullivan, and Nelson are also cosponsors of the bill. On May 22, 2018, the Committee met in open Executive Session and, by voice vote, ordered S. 2842 reported favorably with an amendment (in the nature of a substitute).

During the 115th Congress, the Committee has held hearings to examine both the opioid crisis and consumer scams generally. On March 21, 2017, the Subcommittee on Consumer Protection, Product Safety, Insurance, and Data Security held a hearing entitled “Staying a Step Ahead: Fighting Back Against Scams Used to De-

¹⁵ Mem. of Understanding Between The Fed. Trade Comm’n and The Food and Drug Admin., MOU 225-71-8003 (1971). (<https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115791.htm>)

¹⁶ Id.

¹⁷ Id.

fraud Americans” in which the subcommittee heard testimony about FTC and State attorneys general efforts to combat various consumer scams.

On May 17, 2017, Chairman Thune convened a full committee hearing entitled “Current Issues in American Sports: Protecting the Health and Safety of American Athletes” in which the Committee heard testimony about the opioid crisis and its impact on athletes and their families.

ESTIMATED COSTS

In accordance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate and section 403 of the Congressional Budget Act of 1974, the Committee provides the following cost estimate, prepared by the Congressional Budget Office:

S. 2842—Opioid Addiction Recovery Fraud Prevention Act of 2018

S. 2842 would authorize the Federal Trade Commission (FTC) to levy civil penalties on opioid treatment programs and products that make false or deceptive claims regarding their cost, price, efficacy, performance, benefit, risk, or safety. Under current law, the FTC already has the authority to prohibit such claims but does not have the authority to levy civil penalties. The bill also would authorize state attorneys general, or other state officials, to bring civil actions for violations such as deceptive claims.

Using information from the FTC, CBO estimates that implementing S. 2842 would have no significant effect on the agency’s administrative costs because the bill would not expand the scope of the FTC’s enforcement authorities.

S. 2842 would allow the FTC to levy civil penalties (which are recorded in the budget as revenues) to enforce the prohibition; therefore, pay-as-you-go procedures apply. However, CBO estimates that any increase in revenues would not be significant because we expect that few entities would be affected. Enacting S. 2842 would not affect direct spending.

CBO estimates that enacting S. 2842 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2029.

S. 2842 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act.

The CBO staff contact for this estimate is Stephen Rabent. The estimate was reviewed by H. Samuel Papenfuss, Deputy Assistant Director for Budget Analysis.

REGULATORY IMPACT STATEMENT

In accordance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee provides the following evaluation of the regulatory impact of the legislation, as reported:

NUMBER OF PERSONS COVERED

S. 2842, as reported, would not impose any new regulatory requirements on businesses.

ECONOMIC IMPACT

Enactment of this legislation is not expected to have an adverse impact on the Nation's economy.

PRIVACY

S. 2842 does not raise any issues relating to privacy.

PAPERWORK

S. 2842 would not impose any new paperwork requirements, other than an obligation on States to notify the FTC in writing before they file an action to enforce section 3(a) of this legislation.

CONGRESSIONALLY DIRECTED SPENDING

In compliance with paragraph 4(b) of rule XLIV of the Standing Rules of the Senate, the Committee provides that no provisions contained in the bill, as reported, meet the definition of congressionally directed spending items under the rule.

SECTION-BY-SECTION ANALYSIS

Section 1. Short title.

This section would provide that the bill may be cited as the "Opioid Addiction Recovery Fraud Prevention Act of 2018."

Section 2. Definitions.

This section would define the term "opioid treatment product" to mean a product, including any supplement or medication, for use or marketed for the use in the treatment, cure, or prevention of an opioid use disorder. It would define the term "opioid treatment program" to mean a program that provides treatment for people diagnosed with, having, or purporting to have an opioid use disorder. It would define the term "opioid use disorder" to mean a cluster of cognitive, behavioral, or physiological symptoms in which the individual continues the use of opioids despite significant opioid-induced problems, such as adverse health effects.

Section 3. False or misleading representations with respect to opioid treatment programs and products.

Section 3(a) would affirmatively establish that it is unlawful to make any deceptive representation with respect to the cost, price, efficacy, performance, benefit, risk, or safety of any opioid treatment program or opioid treatment product.

Section 3(b) would provide that any such violation would be considered a violation of an FTC trade regulation rule, allowing the FTC to seek civil penalties under section 5 and the remedies set forth in section 19 of the FTC Act, in addition to injunctive relief and other equitable remedies that it can already obtain under the FTC Act. The maximum civil penalty amount the FTC may seek for violations of a trade regulation rule is \$41,484 per violation, as currently adjusted for inflation.¹⁸ The section 19 remedies for trade regulation rule violations include "rescission or reformation of con-

¹⁸ See 15 U.S.C. § 45(m)(1)(A) and 16 C.F.R. § 1.98.

tracts, the refund of money or return of property, the payment of damages, and public notification respecting the rule violation . . . except that nothing in this subsection is intended to authorize the imposition of any exemplary or punitive damages.”¹⁹

Section 3(c) would empower States to bring actions in Federal court against entities for violations of this section and to obtain appropriate relief. It would also require a State to notify the FTC in writing before filing a case if possible, or if not feasible immediately upon filing the action. The FTC would have the authority to intervene in the State action. Once the FTC or the Attorney General on the FTC’s behalf files an action, States may not file during the pendency of the FTC action their own actions against a party named in the FTC action alleging the same violation. This section also addresses venue and service of process issues.

CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, the Committee states that the bill as reported would make no change to existing law.



¹⁹See 15 U.S.C. § 57b(b).