SOFA: a Legislative Measure Attempting to Curb the Fentanyl Epidemic

The overwhelming national opioid abuse crisis has been exacerbated by the introduction of illicitly-manufactured fentanyl and fentanyl analogues into the world market. This is of particular relevance with the impending expiration of S.1553 in 2020 as described below.

Fentanyl, a Schedule II synthetic opioid, is used medically for analgesia and anesthesia. Its effects are similar to those of other opioids including morphine, heroin, and prescription pain medications including oxycodone and hydromorphone. The opioid abuse crisis, a significant contributor to morbidity and mortality in the U.S. and abroad, persists despite multiple public health, medical, and law enforcement strategies established over the last several years. In 2017, the White House issued a directive to declare the opioid crisis a national public health emergency. While the Centers for Disease Control and Prevention (CDC) report that numbers of overdose deaths in the US have stabilized overall, deaths associated with synthetic opioid exposures continue to rise. This correlates with US Drug Enforcement Administration (DEA) seizure reports of these chemicals and autopsy reports indicating the increasing prevalence of illicitly-manufactured fentanyl and fentanyl analogues.

The members of this class of chemicals (i.e. fentanyl analogues; all structurally similar to fentanyl with multiple, minor structural variations) were assumed to act similarly to fentanyl: that is, they would produce the same clinical effects if ingested, injected, or snorted (i.e. insufflated). Illicit drug manufacturers exploited this concept, incorporating these chemicals into their products as they were relatively cheap and easy to produce. While heroin production requires significant resources including a steady supply of opium

Continued next page
plant material, fentanyl and its analogues can be produced from chemical precursors using moderately unsophisticated laboratory techniques. Multiple reports trace the origins of these chemicals to China. The Department of Justice and the DEA, although authorized to prosecute those in possession of heroin and opium, were limited in their ability to address manufacturers and distributors of these fentanyl analogues as they did not meet the conditions required by the Controlled Substances Act. For these prosecutions, the government was required to prove that the substance in question was meant for human consumption and was structurally similar to a Schedule I or II controlled substance (i.e. fentanyl) and either had similar clinical effect or was intended to or represented as having such an effect. This burden of proof, in the setting of a growing opioid crisis and seizure of these fentanyl analogues, significantly impeded the government’s efficiency in these cases. Alarminglly, many of these analogues are more potent than fentanyl itself (whose potency far exceeds that of morphine or heroin). As such, they have been associated with outbreaks of overdoses leading to hospitalization or death in users of not only intravenous or insufflated heroin, but also of counterfeit pills (e.g. oxycodone and alprazolam) and cocaine.

In response, in February 2018, the Department of Justice announced the enactment of S.1553: the “Stopping Overdoses of Fentanyl Analogues Act” or SOFA. This bill, initially presented to the Senate July 13, 2017, amends the Controlled Substances Act to list fentanyl analogues as Schedule I controlled substances. Specifically, it allows the DEA temporary permission to prosecute those manufacturing and distributing illicitly-produced fentanyl and fentanyl analogues according to Schedule I guidelines. This emergency authority expires February 6, 2020.

The SOFA Act has not passed unnoticed or unopposed. In July 2019, a coalition of 52 organizations – including the American Civil Liberties Union, the Harm Reduction Coalition, and Human Rights Watch – submitted a letter to the Chairman and Ranking Member of the Senate Judiciary Committee opposing the continuance of SOFA. Specifically, it notes that the broader mandate afforded to the DEA with this bill “contradicts [the] Committee’s recent work to advance criminal justice reform and public health approaches to the overdose crisis.” It argues that the expertise of the Department of Health and Human Services and the medical community required for prosecution under the initial Controlled Substances Act is absolutely necessary to ensure appropriate justice.

Despite knowledge of illicitly-manufactured fentanyl and fentanyl analogues, exposures continue. For example, in January 2019, a California group published a case series of patients unknowingly

The Blue Ridge Poison Center faculty were well-represented at the North American Congress of Clinical Toxicology, held in September in Nashville, TN. Pictured with their posters below, top to bottom:

Dr. Heather Borek: Cosmetic or Coma: Pentobarbital masquerading as an herbal product.

Dr. Jennifer Ross: Decreasing Opioid Information and Identification Calls to the National Poison Data System.

Dr. Marissa Kopatic: National Estimates of Marijuana-Related Poison Center Calls.
dosed with fentanyl when insufflating cocaine; there were multiple deaths (MMWR, Jan 2019). Danuiulaiyte and colleagues analyzed drug users’ self-reported experiences with non-pharmaceutical fentanyl-type drugs (NPFs) and compared their responses to urine drug screens provided by the patients (Int. J. Drug Policy 71 (2019) 3-9). They found that almost 90% of study participants – mostly Caucasian females residing in Dayton, Ohio – tested positive for NPF-type drugs with 47% testing positive for at least 3 different NPFs. While some users reported seeking out NPF-type drugs specifically, some reported using heroin only and were unaware that they had been exposed to NPFs.

The ultimate effect of SOFA on the prevalence of illicitly-manufactured fentanyl and fentanyl analogues remains to be seen and as February 2020 approaches, the debate of its efficacy and propriety is likely to continue. In the meantime, multiple public health and harm reduction campaigns continue to increase awareness of the dangers these chemicals pose.

For questions regarding fentanyl, fentanyl analogues, or other substances of abuse, please contact the Blue Ridge Poison Center. Medical toxicologists are standing by 24 hours a day, every single day. Consultations are free and confidential. Call 1-800-222-1222. The poison center can provide assistance in the evaluation and potentially management of patients. Additionally, cases reported to poison centers will be catalogued in the National Poison Data System which will greatly strengthen the public health response to this potential threat.

References for this article are available upon request.

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The Blue Ridge Poison Center receives funding from University of Virginia Health, the Virginia Department of Health, and the U.S. Health Resources Services Administration (HRSA). We are accredited by the American Association of Poison Control Centers. We’ve been proudly serving the Commonwealth since 1978.