STATEMENT

OF

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BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON HALTH

UNITED STATES HOUSE OF REPRESENTATIVES

COMBATTING EXISTING AND EMERGING DRUG THREATS

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RELEASE UPON DELIVERY

Dear Members,

Thank you for the opportunity to testify at this hearing and contribute to the discussion on this topic.

THE ISSUE

What Congress Can Do

As Congress grapples with how best to address opioid poisoning deaths, it should start by making permanent a proven strategy to eliminate the creation and supply of all new deadly fentanyl related substances (FRSs) by passing the SOFA Act or HALT Fentanyl Act. After FRS Class Scheduling was enacted in Wisconsin in 2017, the U.S. Drug Enforcement Administration enacted temporary FRS class scheduling federally in 2018, authorization of which has been extended multiple times since, and was passed in the US House of Representatives in May of 2025 in a bipartisan manner with 74 Dem votes. In short, these efforts have resulted in shutting down the creation and flow and very existence of new fentanyl related substances into the U.S. It's why Congress must act to finally make permanent this temporary policy.

The fact is, no one can die from ingesting something never created or be incarcerated for trafficking something that does not exist.

Background on Fentanyl Class Scheduling Legislation

By design, FRS class scheduling is preventative, not punitive. As the primary architect of current FRS class scheduling policy, my goal has always been to stop the creation and spread of deadly new fentanyl related substances from legal chemical companies and transnational drug trafficking organizations. It was not to incarcerate people with substance use disorder, or anyone for that matter- it was to keep them alive.

I am a full-time emergency physician and recent part-time medical regulator in Wisconsin. I've provided medical direction for a statewide peer-to-peer recovery program that provides naloxone training and I also prescribe medication-assisted treatment when needed. I'm past Chairman of the Wisconsin Medical Examining Board and a former member of the Wisconsin Controlled Substances Board (responsible for controlled substance scheduling at the state level) and was principal architect of the State of Wisconsin prescription opioid reform strategy. Since 2015, I have testified six times before the US House of Representatives and Senate in hearings focused on opioid reforms.

As well, I have been on the front lines in the opioid battle for more than 30 years. One of the most heartbreaking aspects of my job is to inform parents and other family members that their loved one is never coming home due to an opioid poisoning. Inspiration for the fentanyl class scheduling reform arose out of the tragedy of my friend Lauri Badura, whose son Archie died of an overdose. Archie was an altar server with my daughters. He got hooked on prescription medicine and then snorting heroin. I was able to resuscitate Archie on his second to last overdose. On that occasion, I showed him a body bag and warned he would end up in it if he didn't accept help. He attended rehab and stayed clean for six months. Sadly, fentanyl caught up with him once more. One of the last memories my friend Lauri has of her son Archie is his lifeless body being zipped up into a body bag.

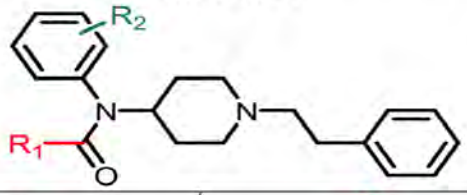
At the time I originated FRS class scheduling legislation over eight years ago, doctors and other health care professionals -- in Wisconsin alone -- were battling more than nine nearly identical fentanyl variants. While each was responsible for dozens or more poisoning deaths in our state and across the U.S., they were still considered "legal" substances, having not yet been scheduled federally by the DEA or at the state level by the Controlled Substance Board (CSB). In Wisconsin, when deaths result from new novel substances, the CSB can use its emergency scheduling authority. It was like a lethal game of "Whack a

Mole". We literally had to wait for the body count to pile up before we could find and schedule new fentanyl variants individually.

I knew something had to change, thus my idea to selectively schedule likely bioactive fentanyls as a class and remove the incentive foreign transnational drug trafficking organizations and chemical/drug manufacturers had in modifying the fentanyl molecule. Knowing these entities could simply add or change one minor chemical group and stay ahead of U.S. scheduling, my calculus was simple: stop the drugs at their source. If we could get it done in Wisconsin, we could then scale it nationally and internationally, thus impacting global production, with the end game of stopping it overseas in China and elsewhere where these lethal fentanyl variants have largely been legally manufactured.

Working with the DEA, FRS class scheduling language was created. In part, the Stopping Overdoses of Fentanyl Analogues (SOFA) Act, or Wisconsin Act 60, which passed unanimously in the state legislature, memorialized Archie Badura. It was named after the Saving Others For Archie organization (SOFA) that his mom Lauri created after his death to help other families in crisis. State Senate Leader (now US Congressman) Scott Fitzgerald (R-WI) shepherded the bill through the state process. It was signed into law on November 9, 2017. Within its first week on the books, the DEA published its intent to use emergency scheduling powers to temporarily schedule FRSs as a class federally. This took effect February 2018. US Senator Ron Johnson (R-WI) first introduced the law federally as the SOFA Act in 2017 before it was law in Wisconsin, and has introduced it every Congress since (now it's 5th time). The results have been incontrovertible: the creation of new fentanyl related substances has ground to a halt internationally.

Table 1. Examples of recent structural modifications to fentanyl observed on the illicit market.



Substance	R_1	R_2
fentanyl[14]	$-CH_2CH_3$	H
acetyl fentanyl	$-CH_3$	H
butyryl fentanyl	$-CH_2CH_2CH_3$	H
furanyl fentanyl	-furan-2-yl	H
4-fluoroisobutyryl fentanyl	$-CH(CH_3)_2$	*para*-F
acryl fentanyl	$-CH=CH_2$	H
ortho-fluorofentanyl	$-CH_2CH_3$	*ortho*-F
tetrahydrofuranyl fentanyl	-tetrahydrofuran-2-yl	H
methoxyacetyl fentanyl	$-CH_2OCH_3$	H
cyclopropyl fentanyl	-cyclopropyl	H
valeryl fentanyl	$-CH_2CH_2CH_2CH_3$	H
isobutyryl fentanyl	$-CH(CH_3)_2$	H
para-chloroisobutyryl fentanyl	$-CH(CH_3)_2$	*para*-Cl
para-methoxybutyryl fentanyl	$-CH_2CH_2CH_3$	*para*-OCH_3
cyclopentyl fentanyl	-cyclopentyl	H
ocfentanil	$-CH_2OCH_3$	*ortho*-F
para-fluorobutyryl fentanyl	$-CH_2CH_2CH_3$	*para*-F

To date, DEA has found 36 new FRSs which have caused thousands of poisoning deaths in multiple states across the country. The NFLIS (National Forensic Lab Information System) data show 7,058 encounters for FRSs in 2016-2017, and a decrease in 2018-19 to 758 encounters [a 90% decrease], and of these, the vast majority were for previously scheduled FRSs. Most importantly, the fentanyl/FRS flow from China has ground to a halt, and reports to NFLIS of overdose deaths related to new fentanyl-related substances have essentially ceased.

CONCERNS RAISED AND CONSIDERED

Increased Incarceration?

The goal of fentanyl class scheduling is singularly laser focused: to remove the incentive for the creation and therefore halt development of deadly fentanyl poisons at their origin, namely, in chemical labs overseas. Those opposed to fentanyl class scheduling initially suggested there would be a large increase in societal costs due to increased incarceration of people suffering from substance use disorder, but that has not proven to be the case. According to a 2021 GAO report, in the three years since FRS class scheduling was placed into regulation, there have been exactly eight prosecutions in the U.S. using the temporary scheduling language and half of these defendants had known ties to transnational criminal organizations. **It is important to note that removing the schedule I penalties and mandatory minimum sentencing for FRSs would actually incentivize their creation and significantly weaken the law's most powerful proactive and preventative effects**.

Opposition also mischaracterizes FRS scheduling as a partisan matter at the federal level given the years in which the policy has taken hold. I beg to differ. I have talked with federal and state policymakers across the political spectrum who care deeply about this issue and are determined to do what they can to help fix it. The HALT Fentanyl Act was put up to a vote last May in the House, there were 74 democratic house members that voted for it. Plain and simple, by halting the creation and existence of new fentanyl variants, there has been significantly less availability and supply, causing a reduction in harm, overdose deaths and incarceration.

This underscores the primary strategy of overdose prevention. When considering societal effects, we must also consider the impact on mortality rates. In New York City alone, in 2016 and 2017, there were over 900 deaths from FRSs. Since 2018, deaths in the US related to new FRSs have been almost nonexistent. As such, those who have opposed this policy because of concerns related to incarceration, now suggest it is unnecessary because of the low number of prosecutions. Their pivot proves the policy is working. We have already witnessed the positive societal impacts of the fentanyl class scheduling including that thousands more Americans are alive today who would otherwise not be had new fentanyl related substances been created and trafficked in the U.S. Not only are people with opioid use disorder not being incarcerated as a result of FRS scheduling, they are alive today, in part, because of this policy.

Another inaccurate claim used by opponents of FRS class scheduling is that deaths and incarcerations due to fentanyl and FRSs have sharply increased in recent years. As mentioned previously, deaths and incarcerations from new FRSs have ground to a halt. Increases are due to illicit fentanyl which FRS scheduling is not designed to stop. Rather, it is to prevent overdoses at the hands of new FRSs by removing the incentive for their creation and distribution at foreign points of origin. **FRS class scheduling is the ultimate form of overdose prevention: you can't die from ingesting something never created, nor can you be incarcerated for selling something that doesn't exist**.

Effect on General Research

Concern about not wanting to impede general research was thoughtfully considered, and great care was given to ensure the language would be specific and narrowly crafted. We looked at more than structural similarity when arriving at the definition of fentanyl related substances. Structure-Activity Relationship (SAR) considers the relationship between changes in chemical structure relative to changes in pharmacological activity; it was the basis of the definition to make sure substances meeting this definition have a high probability of retaining opioid-like pharmacological and psychoactive activity. The detailed scheduling language includes specific modifications to only those portions of the fentanyl molecule with an already documented high likelihood of bioactivity. The language is the equivalent of a surgical scalpel, not a hand grenade.

Concerns raised about the potential negative impact of FRS scheduling on research are **purely theoretical** and have already been addressed by discussions with stakeholders. These proposed research accommodations have been signed off on and are supported by the agencies and organizations representing academic scientific research in the US - including the National Institutes of Health, HHS, the FDA and the National Institute of Drug Abuse . Why would they all support FRS class scheduling if it would harm research? The agreed upon accommodations would significantly loosen research restrictions on all schedule 1 substances (not just FRSs) and open up wide areas of substance abuse research.

- ➢ Those who oppose FRS scheduling point to increased numbers of illicit fentanyl deaths as reason for why FRS scheduling is not working. Some have said that "Temporary scheduling is a failed experiment that hasn't curbed the devastation of the opioid crisis." At best, this is disingenuous and a misunderstanding of the issue. In fact, the opposite is true. FRS scheduling has accomplished the one and only thing it is designed to do: stop the creation and very existence of new FRSs and therefore shut down all new FRS related deaths.

- ➢ Tragically, poisoning deaths from illicit fentanyl have skyrocketed, but deaths from illicit fentanyl are a separate issue from FRSs and FRS scheduling, and one that could never be impacted by FRS class scheduling. Arguing that FRS class scheduling has not worked because illicit fentanyl deaths have risen is a confabulation and misrepresentation of the facts on the effects of FRS scheduling. The correct question should be about what has been the effect on deaths and trafficking arrests from new FRSs, which have ground to a halt, exactly as intended.

- ➢ The fact is, academic scientific research would actually be significantly advanced if research accommodations similar to the ONDCP proposal in the HALT Fentanyl Act were to be enacted allowing easier access to research on all controlled substances. The current strict regulations and limitations on schedule 1 research would be reduced, removing significant disincentives and encouraging research on all schedule 1 substances.

Similarly, some suggest research into new lifesaving treatments such as a FRS reversal agent or medication assisted treatment would be impeded.

- o The scientific basis for this argument seems to be based on one line in testimony by Dr. Throckmorton, Deputy Director of the Center for Drug Evaluation and Research at the FDA, at a December 2021 Energy and Commerce Committee hearing, "The Overdose Crisis: Interagency Proposal to Combat Illicit Fentanyl-Related Substances": "Among the

individual FRS for which pharmacological activity has been studied, FDA has identified examples of substances lacking in mu-opioid agonist activity, the presumed pharmacology that would lead to opioid-related harms."

- While it is true there is a single FRS encountered by law enforcement that is a predominant kappa receptor stimulator at low levels (which are thought to have lower abuse potential and theoretically beneficial antagonistic properties) as cited by Dr. Throckmorton, however at high levels it does stimulate mu receptors which typically cause euphoria and the respiratory suppression that kills.

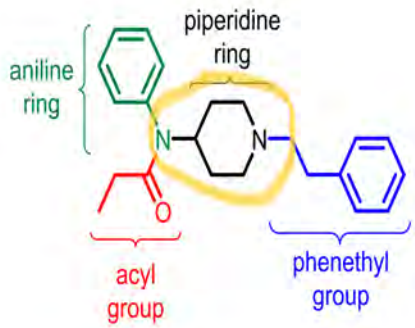
- However, when reviewing research into FRSs, every substance that has been encountered that is classifiable under the FRS class scheduling language has been found to have opioid receptor bioactivity. Almost all are dozens to hundreds and even thousands of times more potent than heroin and morphine. As of August, 2022 the DEA has encountered 36 FRSs and completed preliminary pharmacological investigations on 27 of them, with additional testing ongoing. It was found that all FRSs studied to date bind and activate at least one opioid receptor with varying affinities and efficacies. In short all FRSs are bioactive.

- Over the past 60 years of exhaustive structure-activity relationship studies on fentanyls, there has been no development of a fentanyl based antagonist/ reversal agent or medication assisted treatment.

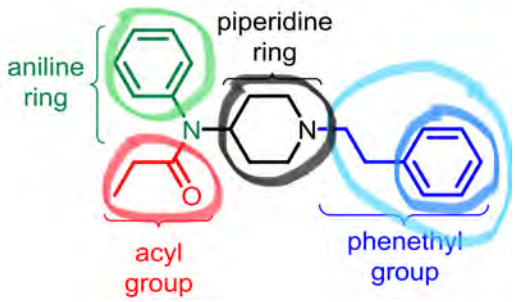
- In contrast, prior to FRS class scheduling, legal FRSs pouring across our borders took the lives of countless Americans.

Others have held up that FRS scheduling would impede research into new opioid versions of fentanyl. But seriously, is anyone arguing there is a need a new opioid more powerful than fentanyl?

Fentanyls fall into the 4-anilinopiperidine class (defined by the aniline ring in the 4-position of the piperidine ring). By definition, in order to structurally classify as a fentanyl related substance under the FRS language, the base chemical structure must be that with Nitrogen at the 4-position of the piperidine ring (highlighted in yellow below).



Any chemical without that exact base structure and without any of the specified modifications would not be included in the scheduling. All elements of the basic fentanyl molecular chemical scaffolding must be present. If there are any deletions from the scaffold, the chemical wouldn't be included, and if there are any substitutions not specifically included in the specific language, those chemicals would also not be included in scheduling. FRS Class Scheduling Language: must include one or more of the following-



(A) By replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

(B) By substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxy, halo haloalkyl, amino or nitro groups;

(C) By substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, ester, ether, hydroxy, halo, haloalkyl, amino or nitro groups;

(D) By replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle and/or

(E) By replacement of the N-propionyl group by another acyl group.

The targeted language was intentionally designed to capture only the modifications [already well described in the scientific and medical literature] being used by both legal chemical companies and transnational criminal organizations to exploit the legitimate research information on structure activity relationships. By staying one step ahead of the CSA and Analogues Act, they continued the spread of these deadly poisons in the U.S. and internationally. There is an excellent detailed discussion on the chemistry and history of fentanyl and fentanyl related substances in a statement from Michael Van Linn, PhD taken from testimony before the United States Sentencing Commission in December, 2017: https://www.ussc.gov/sites/default/files/pdf/amendment-process/public-hearings-and-meetings/20171205/Van-Linn.pdf

Fentanyl was first created in 1960 and has been studied extensively since then. As noted in the Van Linn testimony, many of the new FRSs responsible for recent overdose deaths in the U.S. are well described in the patent and scientific literature, often accompanied by pharmacological data and detailed instructions on synthesis. Essentially, these are precise maps or recipes that guide legal -- as well as illicit – drug labs and chemical manufacturers in creating new FRSs that are almost certain to be bioactive.

The pathway to synthesize fentanyl and FRSs is relatively straight forward and well-defined, and creation of a new FRS is as simple as plugging in or removing a different chemical at one step or another in the process of synthesis. The path to create new bioactive FRSs is easy straightforward to medicinal chemists and, unfortunately, also illicit chemists.

Reversing Overdoses and Medication Assisted Treatment

Some opposition in the research community suggest FRS class controls would hamper research into possible chemicals that could be used to reverse poisonings or treat opioid use disorder. To date, in over 60 years of extensive research done on fentanyls during which exhaustive structure activity relationship studies have been conducted, registered researchers and published research have failed to develop a fentanyl based antagonist/ reversal agent or medication assisted treatment.

It should also be noted that the pharmacological and poisoning effects including lethal respiratory depressant effects of fentanyl/FRSs are similar to those of other all other opioid agonists. Naloxone (Narcan) has been shown to be effective in reversing the respiratory depression that leads to death caused by opioids like heroin, as well as semisynthetic and synthetic opioids including fentanyl. In other words, Naloxone is a very effective reversal agent/ antagonist. Deaths do not occur because naloxone doesn't work or isn't strong enough. Rarely it can wear off and if it does, the solution is to give more. Poisoning deaths occur because of the ingestion of lethal doses of highly potent and toxic opioids, and not due to lack of potency or effectiveness of naloxone in reversing opioid toxicity when given in time.

With regard to medicinal treatment of opioid use disorder (medication assisted treatment/ MAT), relapse rates have no correlation with current MAT options. Relapse or drop-out rate of patients is attributed to many factors such as cost, access to doctors/ treaters and/ or lack of behavioral treatments among other factors, and are not related to the specific opioid being abused. Nor have there been discovered or created any fentanyl/FRS based medication assisted treatments**.** Almost all current research is focused on detection, analysis and understanding the harm of these substances.

Sufficient Oversight & Collaboration Across Agencies

In the normal sequence of scheduling, DEA reviews and investigates chemical compounds individually, then collaborates with HHS and the FDA in making a final decision in the scheduling process. Concerns about bypassing consultation with HHS and the FDA in this circumstance by which the DEA can schedule certain fentanyl-related substances based on the specific, limited, targeted criteria were thoughtfully considered. As a result, the language was narrowly crafted to only include likely bioactive modifications based on the already well known fentanyl structure activity relationship body of research.

Proactively, and also in response to research concerns raised by the Department of Health and Human Services (HHS) and other stakeholders, DEA has already addressed and significantly simplified the research requirements for FRSs including, for example, requiring a single registration for all chemicals in the fentanyl class instead of separate registrations for each individual substance like it does for all other substances. It is significant to note that the majority of research registrants for the new FRS class were for DEA subcontractor chemical analysis or submitted through the Department of Defense. Ultimately, research is driven by funding and there does not appear to be a current investment in FRS research after 6 decades of studying the class. A final point on this: nearly all development and production of new fentanyl-related substances has been done oversees [in China mostly] and not by American scientists and researchers.

The following table is a representation of the precise level of lethality [how much is required to kill an average human] of common narcotics and chemical weapons agents. It is almost incomprehensible how small a dose of fentanyl will kill someone: **2mg or approximately the equivalent of 4 grains of sand**.

Lethal Doses of Chemical Warfare Agents and Narcotics

Chemical Agent/Drug	Lethal Dose	Route
Botulinum Toxin	.00007mg	Inhaled/Ingested/Injected
Tetanus Toxin	.0001mg	Inhaled/Ingested/Injected
CARFENTANIL	**.02mg**	**Inhaled/Injected**
Tabun Nerve Agent	1-1.5mg	Inhaled/Ingested/Percutaneous
Ricin	1.78mg; 10mg	Inhaled/Injected;Percutaneous
FENTANYL	**2mg - equal to 4 grains of sand)**	**Inhaled/Injected**
VX Nerve Agent	2.1mg; 10mg	Inhaled/Injected; Percutaneous
Strychnine	70-140mg	Ingested
HEROIN	**70mg**	**Inhaled/Injected**
Cyanide	100-200mg	Ingested
MORPHINE	**200mg**	**Inhaled/Injected**
Methamphetamine	200mg	Inhaled/Injected
Cocaine	200mg	Inhaled/Injected
MDMA (Ecstasy)	1000mg	Ingested
THC/Marijuana	4000mg (pure THC)	***Not realistically achievable in humans by all methods of consumption per the WHO
	One teaspoon of Fentanyl is enough to kill 2,000 people	

Lethality and Potency, as Deadly as Chemical Weapons

The most accurate way to view fentanyl-related substances is as weapons of mass destruction, not as recreational drugs or intoxicants like marijuana, cocaine, and even heroin. In a 2019 paper by John P. Caves, Jr., a Distinguished Research Fellow in the Center for the Study of Weapons of Mass Destruction (CSWMD) at the Institute for National Strategic Studies at the National Defense University, called "Fentanyl as a Chemical Weapon" covers the topic well. https://www.hsdl.org/?view&did=832803. Opposition to fentanyl class scheduling has likened it to cocaine legislation in the 1980s and as an extension of the war on drugs, but this perspective fails to account for the chemical weapon-like level of lethality that exists with fentanyl and FRSs.

In September 2018, 52 members (including all 50 states) of the National Association of Attorneys General (NAAG) sent a letter urging Congress to adopt the Wisconsin law on scheduling FRSs . When Congress failed to act, in December 2019 a second unanimous letter from all 56 members of the NAAG was sent urging Congress to adopt FRS class scheduling showcasing the strong bipartisan support for this policy. https://1li23g1as25g1r8so11ozniw-wpengine.netdna-ssl.com/wp-content/uploads/2020/10/Letter-to-Congress-SOFA-Act-8.23-1.pdf , https://1li23g1as25g1r8so11ozniw-wpengine.netdna-ssl.com/wp-content/uploads/2020/10/NAAG-Support-for-FIGHT-Act-Letter.pdf.

A signatory of both letters included former HHS Secretary Xavier Becerra in his capacity as California Attorney General, who actually signed them both. This speaks to the importance of this matter as a critical national public safety measure which is completely non-partisan at it's core.

Theoretical Research Concerns

It is interesting to note that the main groups opposing FRS scheduling for reason of theoretical negative effects on research are in fact mainly criminal justice reform and drug legalization based activist organizations. These are the same organizations who initially opposed FRS scheduling due to concerns of theoretical effects of mass incarceration preferentially affecting of people of color - which did not happen. A report by the GAO in 2021 said there were eight prosecutions for drug trafficking in the U.S. in the 3 years FRS scheduling had been temporarily enacted, four of which were known cartel traffickers. As designed, "**No one can die from ingesting something never created or be incarcerated for trafficking something that does not exist."**

Targeted control of specific fentanyl-related substances as a class and not as discrete chemicals is not a minor change to the U.S. Controlled Substance Act (CSA). It has been carefully and thoughtfully crafted and wouldn't even be considered, but for its significant impact already seen in the worst drug epidemic in the modern era. Annualized deaths caused by illicit fentanyl and known analogues now far surpass heroin and are responsible for the overdose/poisoning death spike and lowering of the average life expectancy for Americans for the first time since development of immunizations and antibiotics.

Analogues Act of the CSA is Not Sufficient

Some suggest the Analogues Act of the CSA is sufficient to give DEA and DOJ the power needed to act against fentanyl-related substances. That is simply not accurate. In order to use the Analogues Act, a substance must be proven *substantially similar* to a listed schedule I or II, and also must be proven to be *intended for human consumption*. This is highly problematic because those findings must be adjudicated (and re-adjudicated) in court in each and every case, even when the substance has been proven to be an analogue in a previous case. In addition, the usual threshold to trigger looking at a substance as an analogue is purely reactive when it is found to be killing people, usually many people across multiple states. It is simply not preventative or proactive in any way. If the Analogues Act was sufficient, then the

thousands of Americans killed by FRS poisoning would be alive, and there would have been no need for me to come up with FRS class scheduling in the first place.

Between 2017 and 2018 **in New York City alone** there were over 900 deaths from FRSs. According to the 2019 Florida Medical Examiners Commission Report, deaths in the Sunshine State directly attributable to FRS overdose rose 65 percent in just one year: 965 in 2016 to 1,588 in 2017, that is over 2,500 lives lost in just 2 years from FRSs…in just one state. Untold thousands have already died due to the existence and availability of fentanyl related substances. It's why former Governor Cuomo of New York called for fentanyl class scheduling language in NY and why other states and nations including our neighbors to the north in Canada are following Wisconsin's lead. We cannot go back to the way it was before fentanyl class scheduling was put in place.

Concerns over Prosecutions for Non-Bioactive FRSs

Concerns raised about increased prosecution of people distributing non-psychoactive FRSs that would be inappropriately classified as schedule I is an extremely unlikely scenario for the following reasons:

1) First and foremost - **every substance encountered by law enforcement classifiable under the FRS class scheduling language has been found to have potent opioid bioactivity - dozens or more times more potent than morphine.**

2) Simple charges of possession and lowest level dealing of FRSs are simply not aggressively prosecuted by federal prosecutors.

3) FRSs do not exist naturally. They are synthesized in illicit clandestine overseas labs by chemist suppliers to transnational criminal organizations. The process of FRS synthesis is intentional and based on researched and readily available information of the roadmaps of the Structure-Activity Relationships: it isn't grown in a backyard; there is no bathtub lab manufacturing occurring; and, there is never going to be accidental synthesis, manufacturing and distribution of a new FRS.

4) The low likelihood of transnational criminal organizations/ drug cartels synthesizing, manufacturing, and distributing new FRSs that aren't bioactive/ psychoactive. It's simply not plausible they would decide not to test their product lest they put new FRSs in their distribution networks that were duds [non-psychoactive]. How long would they be able to sell them if they didn't have potent opioid bioactivity?

Due to the specific and targeted nature of the SOFA language based on stopping the exploitation of known fentanyl/FRS structure activity relationships, it is almost certain that a newly developed FRS covered under this fentanyl related substance class scheduling language that is then manufactured and internationally trafficked would be bioactive. If the bioactivity were similar to fentanyl, it would be at the level of chemical weapons lethality: one teaspoon deadly enough to kill 2,000 people.

Sentencing Guidelines

Under current federal guidelines, the sentence is 5 years for 10 grams of fentanyl/ FRS, and 10 years for more than 100 grams. On first glance, that may seem harsh, but it is important to remember the lethality and consider that 10 grams of a FRS is enough to kill 5,000 people, and 100 grams of a FRS could kill 50,000. I would venture to guess that most, if not all, physicians [and Americans too for that matter] would agree: if you could have only one class of drug with associated mandatory minimums, it would be fentanyl and FRSs. **As mentioned above, it is important to note that removing the schedule I mandatory minimums for FRSs would actually incentivize their creation and significantly weaken the law's proactive and preventative effects.**

There is information being disseminated that there have been prosecutions for FRSs that are not bioactive. This is not correct. As mentioned previously, every FRS encountered by law enforcement to date under the FRS language has been found to have opioid effect bioactivity far more potent than heroin and morphine. The most recent new FRS studied was found to be four to eight times more potent than fentanyl (400-800 times more potent than morphine), and another that is 7,000 times more potent than morphine.

Benzyl fentanyl has often been pointed to as an example of a fentanyl analogue that was scheduled under emergency order and then unscheduled [in 1985 and 1986 respectively]. In fact, it would not have qualified under the fentanyl class scheduling language as a FRS. The benzyl fentanyl modification and similar modifications were specifically excluded from the scheduling language because of their known non-bioactivity. It is also misstated by opposition that since 2018, prosecutions of the List 1 precursor benzyl fentanyl have occurred under FRS scheduling. In fact, they have occurred under precursor controls. [This is because benzyl fentanyl can be easily modified to create fentanyl, therefore it was controlled as a List 1 precursor]. **There have been Zero prosecutions for FRSs that are not bioactive.**

In addition, on several occasions, substances that do not fall under the FRS class scheduling language have been misclassified as such by those arguing against FRS Class Scheduling: benzyl fentanyl, remifentanil, Imodium and AT202 adding to the confusion on the issue of impact on research. In fact, all are not classifiable as schedule 1 under the FRS scheduling language.

International Coordination (with China Especially)

In trade negotiations with the Chinese government, the U.S. included targeted FRS class scheduling among its priorities. As a result, China permanently enacted similar scheduling language in May 2019. The United Nations includes it in its toolkit of model opioid legislation for member nations. Several other countries [including The United Kingdom and Canada] and many American states have adopted similar scheduling language. In this case of harm reduction to benefit American citizens, even China sees the value in permanent FRS class scheduling. It is not inconceivable -- and many would say likely -- that if the U.S. doesn't permanently enact FRS class scheduling, China may not continue its prohibitions on fentanyls. The incentives for the creation and distribution of new FRSs would re-occur and that some of the thousands of chemical companies in India could/would start on the FRS creation pathway that would re-open if FRS scheduling were to sunset.

CONCLUSION

It is incontrovertible that temporary targeted fentanyl class control has already been an extremely effective harm reduction tool and has eliminated the incentive for traffickers to create new FRSs, closing the FRS loophole at home and overseas and saving countless lives in the process. If Congress allows the FRS-class scheduling to expire, it's only a matter of time before other countries like China and India could restart the fentanyl-related substance creation machine and unleash the devastating consequences.

My roles as an emergency physician, parent of young adult daughters and a medical regulator, drove me to design a legislative solution to prevent the development of new FRSs by illicit overseas chemists, but at the same time not incarcerate people with substance use disorder or impede critical research. The FRS class scheduling language that has been embraced by SOFA Act and the HALT Fentanyl Act threads that needle.

I first testified on FRS scheduling at a US House of Representatives Judiciary Committee hearing 6 years ago, and my wife keeps asking me why it is necessary for me to keep coming out to Washington to get this simple legislation locked in place. I can't really give her an answer that would make sense to most Americans. Congress has in its power the ability to permanently enact this important FRS class scheduling legislation and continue to save countless lives. There is no question, if we turn our collective backs on the progress that's been made to stem the tide of the creation of new FRSs in America, thousands more deaths will occur annually from the reemergence, existence and widespread availability of these deadly chemical agents. **Now is the time to make this crucial reform permanent and pass the SOFA Act or HALT Fentanyl Act.**

Thank you for the opportunity to contribute to the discussion and thank you for your leadership on this critical public health issue.

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