April 14th, 2021

Thank you Chairwoman Eshoo, Ranking Member Guthrie and members of the Committee for your leadership and this opportunity to testify on this critical public health epidemic.

In 2020, the temporary extension of the emergency scheduling of fentanyl related substances (FRSs) was signed into law. Unless Congress takes immediate action, this extension will expire on May 6, 2021. It's the reason for this testimony: to present the facts in support of a permanent legislative solution to ensure that deadly fentanyl variants can be scheduled and, as a result, thousands of lives continue to be saved. The death toll at the hands of opioids -- especially illicit fentanyl -- is on the rise. According to the CDC, from July 2019 to July 2020 in the United States there were over 50,000 deaths attributable to illicit fentanyl/synthetic opioids. The global pandemic has only served to exacerbate and accelerate what was already a horrific situation. Now is <u>not</u> the time to eliminate proven strategies in the fight to save lives.

<u>Background on Fentanyl Class Scheduling Legislation</u>

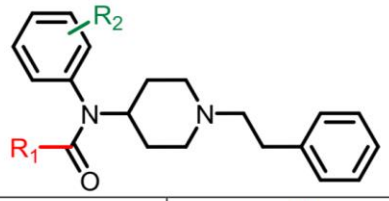
Fentanyl class scheduling by design is preventative, not punitive, it is in reality the ultimate expression of harm reduction. As a primary architect of the fentanyl class scheduling legislation, my goal was to stop the creation and spread of deadly new fentanyl related substances from transnational drug trafficking organizations, not to incarcerate people with substance use disorder. I am a full-time emergency physician and part-time medical regulator in Wisconsin. I provide medical direction for a statewide peer to peer recovery program that provides naloxone and training, in addition I prescribe medication assisted treatment when needed. I'm the immediate 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 architect of the Badger State's prescription opioid reform strategy.

As way of background, I have been on the front lines in the opioid battle for more than 30 years and have been deeply saddened by having to tell far too many parents and families their loved one was never coming home due to an opioid overdose. As an emergency physician, I was beyond weary and broken-hearted at times having to tell parents (sometimes even friends of mine) they would never see their child again after a lethal overdose. The inspiration for the fentanyl class scheduling reform arose out of the tragedy of my friend Lauri's son Archie Badura. Archie was an alter server with my daughters in church. Archie got hooked on prescription and then IV opioids. I resuscitated Archie on his second to last overdose. We showed him a body bag and warned that he would end up in it if he didn't get help. He got into rehab and stayed clean after that for 6 months, but then fentanyl caught up with him and snuffed his life out like it has for hundreds of thousands of other kids in our country.

At the time I came up with fentanyl-class control legislation over four years ago, Doctors and other health care professionals in Wisconsin alone were battling at least nine almost identical fentanyl variants. Each was responsible for multiple overdose deaths in state and across the U.S., but 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 had to literally wait for the body count to pile up before we could find and schedule the new fentanyl variants one at a time.

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

After countless heartbreaking times telling yet another family their child was never coming home, I knew something had to change. Hence came 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. For too long, these entities would simply add or delete one minor chemical group to stay ahead of US scheduling. They would develop new legal drugs that could not be stopped until they killed many young Americans -- until the Wisconsin law, whose provisions were embraced by the DEA nationally, stopped this deadly cycle.

My calculation was simple. If we could get it done in Wisconsin, we could then scale it nationally so it would have global implications, including in China and elsewhere where these lethal fentanyl variants have largely been manufactured. Working with the DEA, DEA then modified and updated the fentanyl-class scheduling language being used in the UK to work in the U.S. This targeted fentanyl-class scheduling language (the Archie Badura memorial fentanyl

class scheduling language) was the basis of the Stopping Overdoses of Fentanyl Analogues (SOFA) Act, or Wisconsin Act 60, which was passed unanimously in the state legislature under then WI Senate Leader and current US Rep Scott Fitzgerald (WI 5th) and signed into law in Wisconsin on November 9, 2017.

Within the first week of this new law being on the books in the Badger State, the DEA published the intent to use emergency scheduling powers to temporarily schedule fentanyl as a class federally. This took effect February 2018. The results have been incontrovertible: the creation of new fentanyl related substances has ground to a halt internationally. From 2016-2018 there were 32 new fentanyl related substances (FRSs) found to have caused thousands of overdose deaths in multiple states across the country. Since 2018, 12 new fentanyl related substances were found and with significantly fewer deaths attributed; it is suspected that many of these new FRSs may have already been in development prior to the temporary scheduling. NFLIS (National Forensic Lab Information System) data show 7,058 encounters for FRSs in 2016-2017, and a decrease in 2018-19 down to 758 encounters [a 90% decrease], and of these, the vast majority were for already 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 nearly ceased altogether.

CONCERNS RAISED AND CONSIDERED

Increased Incarceration

The goal of fentanyl class scheduling isn't to lock up low-level drug users, but to stop the development of deadly fentanyl poisons at their origin, namely, in drug labs overseas. Those opposed to fentanyl class scheduling initially suggested there would be an large rise in the societal costs due to increased incarceration of people suffering from substance use disorder, but that has just not proven to be the case. In the three years since fentanyl class scheduling was first placed into regulation, throughout the entire U.S. there have been 8 prosecutions using the temporary fentanyl class scheduling language; with half of these defendants having known ties to transnational criminal organizations/drug cartels.

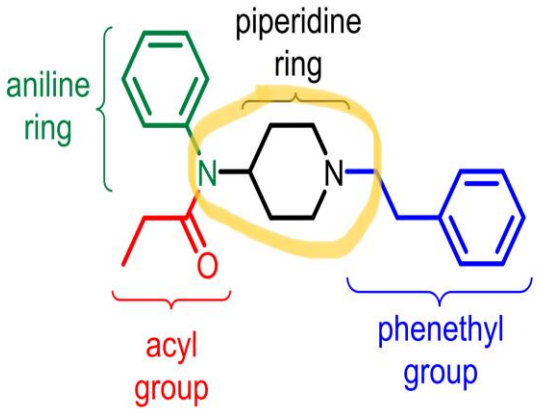
Opposition also mischaracterizes fentanyl class scheduling as a flawed law enforcement-first approach. This is a fundamental misunderstanding of the point that halting the creation of new drugs naturally results in decreased existence and thus supply which results in a decrease in harm, deaths and incarceration. This underscores the primary strategy of harm reduction. When considering societal effects, it is also critically importantly consider the effects on mortality. In Florida alone in 2016 and 2017 there were over 2500 deaths from FRSs, since 2018 FRS deaths in the US are almost nonexistent. Now, instead of opposing because of concerns for over incarceration, (after 3 years of data proving otherwise), it is being argued that fentanyl class scheduling is suddenly unnecessary because of the low number of prosecutions to date (8). This line of thinking actually proves the point of the importance of continuing the class scheduling, because without it, there would doubtlessly be more arrests, prosecutions and (as I have seen far too often up close and personal) inevitably more overdose deaths.

We have already been seeing the positive societal impact 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 US. Not only are people with opioid use disorder not being incarcerated, they are actually being kept alive. **Fentanyl-class scheduling is the ultimate form of harm reduction and prevention: you can't die from ingesting something never created, nor can you be incarcerated for selling something that doesn't exist**.

Impeding General Research

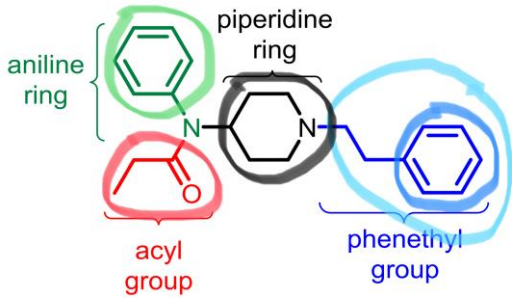
Concern about not wanting to impede general research was thoughtfully considered, and great care was given to insure the language would be specific and narrowly crafted. The DEA looked at more than structural similarity when arriving at the definition of fentanyl-related substances (FRSs). Structure-activity relationship considers the relationship between changes in chemical structure relative to changes in pharmacological activity and 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. In fact, the detailed scheduling language includes specific modifications to only those five portions of the fentanyl molecule with documented high likelihood of structure-activity relationship. The FRS language is the equivalent of a surgical scalpel, not a hand grenade.

Fentanyls fall into the 4-anilidopiperidine class (defined by the analine 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 any of the specified modifications would not be included in the class 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.

(The Archie Badura Memorial) Fentanyl Class Scheduling Language:



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 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 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 precursor at one step or another in the process of synthesis. The ease of creating new FRSs is attractive to medicinal chemists and, unfortunately, also illicit chemists.

Reversing Overdoses and Medication Assisted Treatment

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

It should also be noted that the pharmacological and overdose effects including lethal respiratory depressant effects of fentanyl/FRSs are similar to those of other opioid agonist drugs such as morphine, heroin and oxycodone etc. 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. Pharmacologically, naloxone's ability to reverse the adverse effects of opioid toxicity is influenced by the receptor's binding affinity and ligand-receptor association and dissociation kinetics, and are not related to the particular chemical agonist structure. 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. Overdose deaths occur because of the ingestion of lethal doses of highly potent and toxic opioids, and are not due to a 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. **To recap, not one reversal agent/antagonist or MAT has ever been found or investigated in the six decades of research done into fentanyls.** All current research is focused on detection, analysis and understanding the harm of these substances, the fentanyl class is just not being researched as a possible therapeutic prior or since the DEA emergency control in 2018. Currently, there are over 30 researchers studying FRS and many are DEA contract researchers, who will evenly study all of the FRSs encountered to date.

Most if not all of the academic and research concerns regarding FRSs appear to be theoretical in nature and fall into the category of general concern about doing schedule I research writ large. These mostly include the hurdles of coordinating the three layers of regulatory oversight required to conduct schedule I research -- academic institutions, state and federal government -- and include the most common complaints about the process being "time consuming and confusing." When analyzed, many, if not most, process delays are due to incomplete

applications by the researchers themselves. All researchers that have applied to study FRSs have been granted registrations in a reasonable amount of time, a few months at most. According to DEA the median overall review time to approval of a completed application was 53 days.

Sufficient Oversight & Collaboration Across Agencies

Another opposition area of concern voiced by some is the potential for decreased oversight into research on schedule I substances altogether, and seems not to be a particular concern with fentanyl class scheduling itself. There seems to be no distinction regarding what type of schedule I research is being undertaken. Marijuana and hallucinogens do not have the same risk profile of FRSs. A main general reason given by academics for needing to study schedule I substances is to "find out what makes these substances dangerous." Yet this is already well studied with fentanyl/FRSs. The danger comes from the known high affinity for the mu opioid receptor and the resulting respiratory suppression.

In the normal sequence of events, the 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 narrow 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 known structure-activity relationships. Furthermore, ongoing research accommodations have been negotiated to the point that HHS, NIDA, FDA, and NIH all signed off in an administration interagency position statement in December 2019 based on the sought after accommodations for researchers and criminal justice reform advocates.

Proactively, and also in response to research concerns raised by HHS, the DEA has already addressed and significantly simplified the research requirements for FRSs, 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. Currently, there are in total 28 research registrations for fentanyl-related substances. It is significant to note that more than half of the 11 new research registrants for the new fentanyl class since 2018 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 of new fentanyl-related substances has been done oversees [in China mostly] and not by American scientists and researchers.

A vocal few have voiced concern about the lack of research on other chemicals in certain schedule I drugs like marijuana and hallucinogens. Marijuana and the thousands of chemicals that compose it are organic molecules found in nature, and are non-lethal, except for near non-consumable levels of THC. FRSs are not natural substances and only exist due to intentional and already well researched chemical synthesis. Comparing marijuana research to fentanyl research is not apples to apples. Proper perspective in framing the discussion is critical. One cannot

reasonably consider all schedule 1 drugs in the same light. If we had have one and only one drug class to be scheduled as a schedule 1, it would be fentanyls. Fentanyl is slightly less deadly than VX nerve gas and almost as deadly as the nerve toxin Ricin. FRSs that are less potent than fentanyl are even still dozens of times more potent than morphine or heroin.

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**	**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 marijuana consumption per the WHO

Lethal Doses of Chemical Warfare Agents and Narcotics

Chemical Agent/Drug	Lethal Dose	Route
	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 just simply 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 1980's and as an extension of the war on drugs, but this perspective does not consider the differences in the chemical weapon like level lethality that exists with FRSs and the resulting mortality.

In September 2018, 52 members of the National Association of Attorneys General (NAAG) sent a letter urging Congress to adopt the Wisconsin law on scheduling FRSs . The unanimous bipartisan support of all 50 State Attorneys General, as well as from Washington DC and Puerto Rico, is unheard of in today's political climate. https://1li23g1as25g1r8so11ozniw-wpengine.netdna-ssl.com/wp-content/uploads/2020/10/Letter-to-Congress-SOFA-Act-8.23-1.pdf. Signors included current HHS Secretary-designate Xavier Becerra in his former role as California Attorney General. It speaks to the non-partisan importance of this matter as a critical national public safety measure.

Targeted control of specific fentanyl-related substances as a class and not as discrete chemicals is not a minor change to the US 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 surpass heroin and are responsible for the overdose death spike and lowering of the average life expectancy for Americans in the modern era 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 and that fentanyl class scheduling would only make it

easier to incarcerate people. That is patently 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 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 even trigger looking at a substance as an analogue is purely reactive and not proactive or preventative when it is found to be killing people, usually many people across multiple states.

According to the 2019 Florida Medical Examiners Commission Report, deaths in the Sunshine state directly attributable to FRS overdose rose 65% in just one year from 965 in 2016 to 1,588 in 2017. That is over 2,500 deaths, or 3.4/families losing a loved one/day every day for 2 years. Between 2017 and 2018 in New York City alone there were over 900 deaths from FRSs. Thousands have already died due to the existence and availability of fentanyl related substances. It's why Governor Cuomo called for fentanyl class scheduling language in NY and why other states and nations 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-Psychoactive 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 single FRS ever encountered and researched to date has been found to have potent opioid effect bioactivity, dozens or more times more potent than heroin and 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 back yard. There is no bathtub lab manufacturing occurring. 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 go to the trouble of not in some fashion testing their product and risk putting new FRSs in their distribution networks that were duds (non-psychoactive). How long would they be able to sell them if they didn't get users high?

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 the Archie Badura memorial fentanyl class scheduling

language that is then manufactured and then internationally trafficked would be bioactive. If the bioactivity was similar to fentanyl, it would be at the level of chemical weapons lethality- one teaspoon deadly enough to kill 2,000 people. Of all the new FRS's studied between 2018 and 2020 (11 in total), all have been found to be psychoactive with high abuse potential, and no FRS's have been non-psychoactive. In fact there has never been an FRS found that did not exhibit highly potent opioid bioactivity.

Those opposed use the implausible rationale for not enacting permanent fentanyl class scheduling that theoretically a drug trafficker could be incarcerated for distributing a FRS that was actually beneficial or an antagonist like naloxone. Even though as has been previously mentioned, in the over 60 years of research done on fentanyls, not one substance with antagonistic properties has ever been researched. Of importance to note is that rescheduling can also be done rapidly in the highly unlikely circumstance where the substance being trafficked turns out to be non-psychoactive, as has been addressed in the Administration Interagency Position agreement previously mentioned with the research and criminal justice communities.

Mandatory Minimum Sentencing

Under current federal sentencing 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. In comparison, the lethal doses for THC and many hallucinogens [upon which much opposition to schedule I research restrictions from academia seem to be based] are hundreds or thousands of time higher.

FRS Bioactivity

There is incorrect information being disseminated that there have been prosecutions for FRSs that are not bioactive. This is just not factually correct. As mentioned previously, every single FRS ever encountered and researched to date has been found to have potent opioid effect bioactivity, dozens or more times more potent than heroin and morphine. The newest most recent new FRS studied was just found to be 4-8 times more potent than fentanyl.

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), but in fact it would not fall under the fentanyl class scheduling language to qualify as a FRS. In fact 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 fentanyl analogue and List 1 precursor benzyl fentanyl have occurred under FRS scheduling, but in fact they have occurred under precursor controls. (This is because benzyl fentanyl can be easily modified to create fentanyl, therefor it was controlled as a List 1 precursor). To restate clearly, **there have been Zero prosecutions for FRSs that are not bioactive.**

Remifentanil

There is also a factual error that needs to be corrected in the recent GAO report. In the discussion of possible negative effects on FRS research it is noted that remifentanil would have fallen under FRS scheduling language, and theoretically it's development could have been hampered. However, remifentanil in fact does not have a chemical structure that falls under FRS classification under the fentanyl class scheduling language.

International Coordination (with China Especially)

In recent trade negotiations with the Chinese government, the U.S. included targeted fentanyl-class scheduling among its priorities. As a result, China permanently enacted fentanyl class scheduling language in May 2019. The United Nations includes it in its toolkit of model opioid legislation for member nations. Several other countries and many American states have adopted similar fentanyl-class scheduling language. In this case of harm reduction to benefit American citizens, even the Chinese Communist Party sees the value in permanent fentanyl class scheduling. It is not inconceivable and many would say likely that if the US doesn't permanently enact fentanyl class scheduling, then China may not continue their prohibitions on fentanyls.

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 fentanyl-related substance loophole at home and overseas and saving countless lives in the process. If Congress allows the fentanyl-class scheduling to expire in May 2021, it's only a matter of time before other countries like China and even India could restart fentanyl-related substance creation and unleash the devastating consequences.

As an emergency physician, parent of young adult daughters and medical regulator, that is what drove me to design a legislative solution to prevent the development of new FRSs by illicit overseas chemists. We absolutely needed to shut down the FRS mine but at the same time not incarcerate people with substance use disorder or impede critical research. The Archie Badura memorial fentanyl class scheduling language found in 2017 Wisconsin Act 60, the SOFA Act, the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, and now the FIGHT Fentanyl Act threads that needle. It already has a track record as a powerful proven harm reduction/preventative solution.

Congress has in its power to extend this important fentanyl class scheduling legislation through the FIGHT Fentanyl Act and SOFA Act 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 opioid abuse 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.

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

Timothy Westlake, MD, FFSMB, FACEP
Wisconsin Medical Examining Board, Immediate-Past Chairman
Wisconsin Controlled Substance Board, former Member
Governor Walker's Task Force on Opioid Abuse

(Following is a one page take home summary).

SUMMARY

April 14th, 2021

Background

In 2020, Congress enacted a temporary extension of the emergency scheduling of fentanyl related substances (FRSs). This closed a loophole in federal law which drug cartels had been exploiting for years to legally create and then distribute these deadly substances. This scheduling language by design is not punitive, it is the ultimate expression of prevention and harm reduction. Unless Congress takes immediate action, this extension will expire on May 6, 2021. With the death toll at the hands of opioids the highest ever recorded and on the rise due specifically to an increase in illicit fentanyl overdoses, now is not the time to eliminate a proven strategy in the urgent fight to save lives:

- Between July 2019 and July 2020, over 50,000 deaths were attributable to illicit fentanyls – a horrific situation made significantly worse by the global pandemic.

- Unlike marijuana, hallucinogens, cocaine or even heroin, Fentanyl/FRSs are so toxic and deadly that they can be classified -- and actually have been used -- as chemical weapons.

- A lethal dose is 2 mg, meaning one teaspoon can kill 2,000 people and 24 pounds is more than enough to kill all 5.4 million residents in metropolitan Washington DC.

Findings to Date

In the three years since the emergency temporary scheduling order took effect, the intended results are incontrovertible: the creation of new fentanyl-related substances and flow of fentanyl and FRSs from China and elsewhere have ground to a halt; most importantly, overdoses related to FRSs have effectively ceased altogether. So too, concerns about potential negative consequences whether on research or increased incarcerations have not materialized:

- To date and as a consequence of the temporary scheduling order, there has been no dampening or restricting of research. Significant accommodations regarding fentanyl research have been reached. Most remaining concerns are theoretical and seem to be focused on schedule I research writ large, and are not specific to FRS research itself. As well, there is an exceedingly small number of researchers who have registered to study the FRS class -- 28 in total with many of these being DEA and Department of Defense subcontractors. FRS research is focused exclusively on the analysis, detection and understanding the harm of these substances. Fentanyl has been exhaustively researched since its discovery in 1960, and not one fentanyl based reversal agent or medication assisted treatment agent has been found in the 60 years since.

- Regarding concerns about increased incarceration, in the 3 years since the emergency fentanyl class scheduling has been in place, there have been less than 10 federal prosecutions of defendants, half of whom have known ties to drug cartels.

Solution

Instead of allowing the temporary extension of the emergency scheduling of FRSs to expire, Congress should enact the FRS scheduling language from the bipartisan ***Federal Initiative to Guarantee Health by Targeting (FIGHT) Fentanyl Act*** and the ***Stopping Overdoses of Fentanyl Analogues (SOFA) Act,*** and make these critical reforms permanent. We must employ every effective harm reduction tool in our arsenal. **The fact is, you can't die from ingesting something never created, nor can you be incarcerated for selling something that doesn't exist.**