From: Tim McKibben
To: Public Comment
Subject: re: Fentanyl and fentanyl analogues
Date: Monday, November 13, 2017 3:18:14 PM

Dear Sentencing Commission:

This letter details concerns and comments as requested by the commission concerning the issues listed in the Federal Register Document Citation #82 FR 47322; page: 47322-47324 (3 pages); and document number 2017-21820 with a public comment deadline of November 13, 2017.

It may be helpful to know some of my professional background while reviewing my comments.

Synthcon is a current DEA registered bulk manufacturer and forensic/law enforcement instructor and consultant with:

10 years as a sworn laboratory agent for state law enforcement agency
>7 years as a DEA research chemist
>6 years as a forensic chemist for a large metropolitan city laboratory
4 years as a synthetic organic chemist manufacturing human antibiotics for Pfizer, inc.

Synthcon personnel have investigated illicit drug manufacturing sites in Asia, Europe, South America, Central America, and the United States

Have represented the U.S. as a delegate to the United Nations on two occasions, with one of those occasions dealing with illicit drug manufacturing.

Have testified in two foreign countries concerning illicit drug manufacturing cases and have processed many drug manufacturing sites and seized evidence.

Issues for Comment.—

1. The Commission invites general comment on fentanyl and fentanyl analogues, particularly on their chemical structures, their pharmacological effects, potential for addiction and abuse, the patterns of abuse and harms associated with their abuse, and the patterns of trafficking and harms associated with their trafficking. How are fentanyl and fentanyl analogues manufactured, distributed, possessed, and used? What are the characteristics of the offenders involved in these various activities? What harms are posed by these activities? How do these harms differ from those associated with other opioids such as heroin, morphine, hydrocodone, or oxycodone? How, if at all, do the harms associated with pharmaceutical fentanyl differ from the harms associated with non-pharmaceutical fentanyl? To the extent the harms posed by these substances are different, should the guidelines provide different penalties for pharmaceutical fentanyl and non-pharmaceutical fentanyl?

2. Fentanyl, when identified as N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propenamide, and analogues of that specific chemical, are subject to mandatory minimum penalties under current law, with analogues punished four times more harshly than fentanyl itself. Those penalties have shaped the guidelines provisions related to fentanyl since 1987. The Commission seeks comment on whether there are controlled substances that might commonly be regarded as “fentanyl analogues” that are not analogues of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propenamide and therefore do not meet the statutory definition of an “analogue.” If so, should the guidelines provide penalties for such controlled substances consistent with the mandatory minimum provisions applicable to fentanyl analogues that meet the statutory definition? Should the guidelines instead account for such substances in a different manner than substances to which the mandatory minimum penalty applies?

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The “ fentanyl analogues" that are being encountered are closely related in chemical structure to fentanyl and so we don’t see “non-fentanyl” fentanyl analogues. You may be referring to other narcotic drugs such as U-47700, W-18, and MT-45 but they are not “ fentanyl analogs” they are just additional, illicit narcotic drugs or opioids. One aspect that needs to be brought to the commission’s attention is differences between drug manufacturing in the pharmaceutical industry and illicit drug manufacturing. Illicitly there is no requirement for pharmacological activity and if the compound has never been made before there will be no information on its activity, safety, or

potency. In the pharmaceutical industry “analogues” are simply structural modifications of an existing or target drug’s chemical structure that get manufactured and tested to see if there is any activity and if so, then further tested for human safety and other characteristics. There is no guarantee of pharmacological activity based on structure similarity and conversely, dissimilar structures are not automatically eliminated from having activity at the same receptor sites. DEA has done a good job of individually scheduling novel drug classes or structural types that are being abused and there is no reason other opioid drugs should all be lumped into a “fentanyl analogue” group if they are not structurally similar to fentanyl or one of its known analogues.

3. The Commission invites general comment on whether and, if so how, the guidelines should be amended to account for fentanyl and fentanyl analogues. How, if at all, should the guideline provisions related to fentanyl and the fentanyl analogues specifically listed in § 2D1.1 be amended? For example, should the Commission revise the marihuana equivalencies already provided for fentanyl, Alpha-Methylfentanyl, and 3-Methylfentanyl? If so, what equivalency should the Commission provide for each substance, and why?

Should the Commission amend § 2D1.1 to account for other unlisted fentanyl analogues? For example, should the Commission establish marihuana equivalencies for fentanyl analogues currently not listed in § 2D1.1? If so, what specific fentanyl analogues should the Commission include in the Drug Equivalency Tables and what equivalency should the Commission provide for each such substance? What factors should the Commission consider when deciding whether to account for these substances?

The commission should establish TWO different equivalency table entries, one for fentanyl and all other currently accepted, FDA-approved, C-II fentanyl analogue products that are used in humans and a second marijuana equivalency level for all animal-only approved fentanyl analogs and all illicit fentanyl analogs.
Here is the rationale for doing so, first FDA approved, schedule II fentanyl products and fentanyl analog products have been through the long FDA approval process so their pharmacology, safe profiles, and human potencies are known with a high degree of certainty. For those fentanyl analogs not currently approved for human use in the United States, but used in animal studies or immobilization have much less if any human pharmacological data or safety data (Carfentanyl and Thiafentanyl). Because these analogues are used to immobilize large/wild or exotic animals (elk, rhino, elephants), they are USUALLY MUCH MORE POTENT than any current fentanyl analogue used for human use. This lack of human safety profiles and pharmacological data also extends to all illicit fentanyl analogues that have no approved human or animal use. Because there are many previously published fentanyl analogues which have been manufactured, but not yet seized as illicit drugs, this current drug trend mirrors that of the illicit synthetic cannabinoids which represents one of the largest potential number of illicit drugs that can be manufactured based on existing published scientific papers and patents.

1 gram of fentanyl and any current FDA-approved schedule II fentanyl analog (approved for approved human use) should equate to 200 Kg marijuana equivalents. It should equate to a higher marijuana level than LSD (100 Kg) because of the similar dosage level, but much more toxic nature of fentanyl and approved fentanyl analog products compared to LSD. The marijuana equivalence for fentanyl needs to be increased to be brought up to a more realistic level that more accurately reflects the danger to the public for this particular drug.

It should be noted and taken into consideration that much of the illicit fentanyl that is manufactured, trafficked and abused is NOT OF A PHARMACEUTICAL ORIGIN. Mexico is known to be a large producer of illicit fentanyl, whereas China is known to manufacture and distribute Fentanyl analogues into the United States. There is little domestic fentanyl production compared to foreign production. Much of the domestic fentanyl production is counterfeit pill production and not actual chemical synthesis of fentanyl itself. Because the majority of fentanyl is illicit and not of pharmaceutical origin, its purity, safety profile, and actual content is not known and varies on a case by case basis. Therefore a higher penalty should be warranted for the manufacturing, distribution, and use of illicit fentanyl versus pharmaceutical fentanyl, because it poses a higher likelihood to be more dangerous to the persons using or involved that form of fentanyl.

1 gram of illicitly produced fentanyl (Non-pharmaceutical origin); 1 gram of any fentanyl analogue product which is only approved for use in animals (carfentanyl and Thiafentanyl); and 1gram of any other unapproved, illicit fentanyl analogue should be an equivalency level equal to 800 Kg of marijuana.

Since much of the pharmacological data and obviously the human safety profile information is non-existent for these illicit fentanyl analogs, it should be assumed that the illicit analogue could be as potent as the known potency of Lofentanil or Ohmefentanyl. Unlike the super potent hallucinogen LSD, fentanyl analogues all have the potential to be lethal with a single dose which should be reflected in the penalty given to a suspect convicted of manufacturing, possessing, and or distributing such material.

4. The Commission has received anecdotal information about the availability of several fentanyl

analogues. How are these novel fentanyl analogues developed, manufactured and trafficked? To what extent are these substances legally manufactured for pharmaceutical purposes and then diverted for illicit trafficking and use, as opposed to having been manufactured illegally? How complex is the procedure to develop these substances and how frequently are they introduced into the illicit drug market?

The currently encountered fentanyl analogues, for the most part are not ones previously published in scientific literature. Fentanyl analogues can easily be manufactured by substituting one or more chemicals in the last step or previous steps to provide many different fentanyl analogues. For this reason, the commission should be aware that it is quite easy to manufacture and there are multiple "synthetic equivalents" chemicals which could be substituted in the beginning of the manufacturing process which can ultimately result in the manufacture of the same desired final product.

Instead of providing marihuana equivalencies for individual fentanyl analogues, should the Commission consider establishing a single marihuana equivalency applicable to all fentanyl analogues? Are fentanyl analogues sufficiently similar to one another in chemical structure, pharmacological effects, potential for addiction and abuse, patterns of trafficking and abuse, and associated harms, to support the adoption of a broad class-based approach for sentencing purposes? If so, what marihuana equivalency should the Commission provide for fentanyl analogues as a class and why? What factors should the Commission account for if it considers adopting a broad class-based approach for fentanyl and its analogues? Should the Commission define "fentanyl analogues" for purposes of this broad class-based approach? If so, how? Are there any fentanyl analogues that should not be included as part of a broad class-based approach and for which the Commission should provide a marihuana equivalency separate from other fentanyl analogues? If so, what equivalency should the Commission provide for each such fentanyl analogue, and why?

Much of what is asked for in this last question has been previously answered above. Here is a summary of those recommendations.

1. Update and increase fentanyl's marijuana equivalency to better reflect the similar, but much more lethal dosage level when compared to LSD. Increase fentanyl's marijuana equivalent from 2.5 Kg of marijuana to 200 Kg of marijuana.

2. Create just two separate sentencing categories for fentanyl and fentanyl analogues, distiguishing between FDA-approved, pharmaceutical products containing fentanyl or approved fentanyl analogues versus illicitly produced fentanyl, fentanyl analogues, and animal use only fentanyl analogues. Because of the very high potency of some fentanyl analogues, increase the marijuana equivalents for any illicit fentanyl analogue, illicitly produced fentanyl, or animal use fentanyl analogue to 800 Kg of marijuana (keeping the original 4:1 analogue to fentanyl equivalency ratio). Finally, this would prevent the need to readdress the sentencing issue each time a new fentanyl analogue is encountered and would better reflect the already known hazard potential of this drug class to the public.

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Synthcon