

**Statement of Kevin Butler**  
**Before the United States Sentencing Commission**  
**Public Hearing on Synthetic Drugs**  
**March 14, 2018**

I am Kevin Butler, the Federal Public Defender for the Northern District of Alabama. I also am a member of the Federal Defender Sentencing Guideline Committee. I thank the Commission for providing me the opportunity to testify on behalf of Federal Defenders.

This statement addresses many of the issues the Commission currently raises in its proposed amendments and issues for comment on synthetic cathinones, synthetic cannabinoids, fentanyl, and fentanyl analogues. Defenders' previous submissions on the drug quantity table, synthetic drugs, fentanyl, fentanyl analogues, MDMA, and THC are still relevant to the issues and are incorporated into this statement.<sup>1</sup>

Defenders are gravely concerned about the Commission's proposal to increase the ratio for fentanyl and adopt a class-based approach and overly high ratios for synthetic cathinones/cannabinoids and fentanyl analogues. The differences between the drugs within each class are too significant to be overlooked. While a class-based approach would eliminate hearings to determine the "most closely related substance" under Note 6 of §2D1.1, treating them the same and adopting overly high ratios will lead to extensive litigation to encourage courts to exercise their discretion under *Kimbrough v. United States*<sup>2</sup> to reject the disproportionate ratios and account for the different potencies and harms of synthetic drugs. Consequently, a class-based approach is likely to result in unwarranted disparity as some courts reject the new guideline recommended sentences.<sup>3</sup> These problems are compounded because the selected marijuana ratios are inappropriate and will result in advisory guideline ranges that are unjustifiably severe.

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<sup>1</sup> Letter from Marjorie Meyers, Chair, Federal Defender Guideline Committee to the Honorable William H. Pryor, Jr., Acting Chair, U.S. Sentencing Comm'n (Mar.10, 2017); Letter from Marjorie Meyers, Chair, Federal Defender Guideline Committee to the Honorable William H. Pryor, Jr., Acting Chair, U.S. Sentencing Comm'n (Oct. 26, 2017); Letter from Marjorie Meyers, Chair, Federal Defender Guideline Committee to the Honorable William H. Pryor, Jr., Acting Chair, U.S. Sentencing Comm'n (Nov. 13, 2017).

<sup>2</sup> 128 S.Ct. 558 (2007) (finding that court could deviate from crack-cocaine ratio and conclude that the crack cocaine/powder disparity yields sentences "greater than necessary").

<sup>3</sup> See, e.g., *United States v. Malone*, 828 F.3d 331, 334 (5th Cir. 2016) (defendant request court to reject the 1:167 ratio for THC).

We have previously urged the Commission to undertake a comprehensive study of the drug guidelines and adopt a consistent approach to ranking drug harms and accounting for dosage weight and potency. And we renew that suggestion here. The proposed ad hoc comparison that considers “chemical structure, pharmacological effects, potential for addiction and abuse, patterns of trafficking and abuse, and/or associated harms,” without consistently considering each factor in setting drug quantities will exacerbate disproportionality and disparity. For example, a higher guideline recommended penalty for trafficking synthetic cathinones than trafficking cocaine does not consistently apply “associated harms” given that cocaine places a user at greater risk of an emergency room visit than synthetic cathinones.<sup>4</sup> A more proportionate guideline that considers “associated harms” would treat synthetic cathinones less harshly than cocaine.

For reasons stated in our earlier comments, we also believe the Commission should 1) amend Note 6 so that it considers the most significant factors—potency and typical dosage amount; and 2) correct current problems with the equivalencies for MDMA and THC.<sup>5</sup>

The Commission’s recent data shows why even the lowest proposed ratios fail to consider feedback from courts on the severity of the drug guidelines.<sup>6</sup> This data reveals that the average sentence for synthetic cannabinoids, synthetic cathinones, fentanyl, and fentanyl analogues is much lower than the average guideline range

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<sup>4</sup> Letter from Marjorie Meyers, Oct. 26, 2017, at 22.

<sup>5</sup> Letter from Marjorie Meyers, Oct. 2017, at 23-30.

<sup>6</sup> See 28 U.S.C. § 994(o) (directing the Commission to review and revise the guidelines in light of sentencing data and comments coming to its attention). “[T]he very theory of the Guidelines system is that when courts, drawing upon experience and informed judgment in such cases, decide to depart, they will explain their departures. The courts of appeals, and the Sentencing Commission, will examine, and learn from, those reasons. And, the resulting knowledge will help the Commission to change, to refine, and to improve, the Guidelines themselves.” *United States v. Rivera*, 994 F.2d 942, 949-50 (1st Cir. 1993) (Breyer, J.). See also *United States v. Booker*, 543 U.S. 220, 263-64 (2005) (noting that the Commission will “modify its Guidelines in light of what it learns” from “actual district court sentencing decisions”). “[D]epartures were considered an important mechanism by which the Commission could receive and consider feedback from courts regarding the operation of the guidelines,” which “would enhance its ability to fulfill its ongoing statutory responsibility under the Sentencing Reform Act to periodically review and revise the guidelines.” USSC, *Report to Congress: Downward Departures from the Federal Sentencing Guidelines* 5 (Oct. 2003).

because the rate of below-range sentences is so high.<sup>7</sup> No evidence supports the notion that the current guidelines result in sentences for these drugs that are too low.

If the Commission finds it necessary to set forth ratios for synthetic drugs rather than focus on more comprehensive changes to the drug guidelines and Note 6, Defenders suggest the following:

- conduct and gather empirical research into relative potency, effects, and comparative harms;
- adopt specific ratios to account for potency and effects because a one-sized-fits-all solution is not appropriate for synthetic drugs with widely varying potencies, effects, and harms;
- if the Commission chooses a class-based approach, use a ratio no greater than 1:100 for the most common synthetic cathinones and identify the substances the Commission specifically considered in adopting a class-based ratio;
- a presumption of 1:1 for a smokable synthetic cannabinoid sprayed onto psychologically inactive organic matter and a distinction between a synthetic cannabinoid in “actual” form and a mixture;
- lower the ratio for THC to have a more meaningful comparison to synthetic cannabinoids;
- if the Commission chooses to define synthetic cannabinoids based upon the effect on the CB1 receptors, make it clear that it must directly activate or be a full agonist of the CB1 receptors;
- do not adopt minimum base offense levels;
- leave the fentanyl ratio as it is, 1:2,500;
- if the Commission chooses enhancements, adopt only specific offense characteristics or enhancements that incorporate a *mens rea* element based upon

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<sup>7</sup> USSC, *Public Data Presentation for Synthetic Cathinones, Synthetic Cannabinoids, and Fentanyl and Fentanyl Analogues Amendments* (Jan. 2018). While some of the below range sentences are based on substantial assistance, a great percentage is based on other government sponsored or non-government sponsored below range sentences.

knowing conduct that truly demonstrates a level of culpability higher than the average individual involved in the offense; and consider actual empirical evidence prior to fashioning an appropriate solution.

## **I. Synthetic Cathinones**

The Commission's proposal to use a class-based approach for synthetic cathinones (including methcathinone but not Schedule III, IV, or V substances) with a marijuana ratio of [200]/[380]/[500] gm is not supported by the available empirical evidence. It also ignores evidence that the ratios used for synthetic cathinones found most closely related to MDMA, but half as potent (resulting in a ratio of 250gm), are still too high because the guidelines for MDMA are too high.<sup>8</sup>

### **A. Class-Based Approach**

The Commission requests comment on whether it should provide a class-based approach for synthetic cathinones. The available evidence shows that a generic class-based approach would be like treating apples as oranges, resulting in disproportionate guideline ranges that do not account for how various substances differ. For example, for reasons discussed below, if one person sells four grams of MDPV and another sells four grams of methylone, giving the same sentence to the methylone trafficker as the MDPV trafficker would be grossly unfair because methylone is less harmful or addictive than MDPV.

As previously discussed, we believe that chemical structure or pharmacological effects of synthetic cathinones, like other drugs, are relevant only to the extent they affect comparative harms of different drugs. But we understand from the request for comments that the Commission is not yet willing to limit the significance of chemical structure and pharmacological effects and adopt a consistent approach to assessing drug harms and setting ratios. As the Commission remains interested in this issue, it is important to note that not all synthetic cathinones are sufficiently similar in chemical structure, pharmacological effects, potential for addiction and abuse, or associated harms to fit a class-based sentencing model.<sup>9</sup>

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<sup>8</sup> Letter from Marjorie Meyers, Mar. 10, 2017.

<sup>9</sup> See, e.g., A.R Green, et al., *The Preclinical Pharmacology of Mephedrone: Not Just MDMA by Another Name*, 171 Br. J. Pharmacol. 2251 (Apr. 2014) ("current data suggest that mephedrone not only differs from MDMA in its pharmacological profile, behavioral and neurotoxic effects, but also differs from other cathinones"); Mariana Angoa-Perez, et al.,

## 1. Different pharmacological effects

Significant evidence shows that synthetic cathinones do not all have the same effects. The available *in vitro* and *in vivo* studies show that “many synthetic cathinones produce an array of effects linked to differential impacts on the regulation of dopamine, serotonin, and norepinephrine,” which “may be regarded as methamphetamine-like, MDMA-like, cocaine-like, etc., depending on whether the substance primarily interacts with DAT [dopamine], SERT [serotonin], or both (like cocaine), respectively.”<sup>10</sup>

Dr. Michael Gatch’s testimony to the Commission also acknowledged the different effects of synthetic cathinones – describing some as having MDMA-like subjective effects and others having effects less severe than those of cocaine.<sup>11</sup> And other research comparing the uptake inhibition potencies of ethylone to methylone shows that ethylone has an approximately 3.5x lower affinity for the serotonin transporter than methylone.<sup>12</sup>

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*Neurotoxicology of Synthetic Cathinone Analogs*, in *Neuropharmacology of New Psychoactive Substances (NPS): The Science Behind the Headlines* (Michael Baumann, et al., ed., 2017) (“despite their commonalities in chemical structure, synthetic cathinones possess distinct neuropharmacological profiles and produce unique effects”).

The Commission’s synopsis of the proposed amendment states that it received testimony indicating “that whether a substance is properly classified as a synthetic cathinone is not generally subject to debate, as there appears to be broad agreement that the basic chemical structure of cathinone remains present throughout all synthetic cathinones.” Experts, however, have debated the similarity of the chemical structure. *See, e.g.*, Gregory Dudley, Ph.D., *Scientific Considerations Relevant to the Analogue Statute* (Jan. 6, 2014) (concluding that bupropion did not have substantially similar chemical structure to methcathinone) (on file with Federal Defender Sentencing Resource Counsel).

<sup>10</sup> Letter from Candace Hom in Response to Court’s Order Dated 7/6/16, Ex. A, at 11 (statement of Gregory Dudley Ph.D., Sentencing Guideline Considerations for Methylone) *United States v. Pedro Arroyo*, No. 2:14-26-00186-KSH-1 (D.N.J. July 11, 2016). *See also* Linda Simmler & Matthias Liechti, *Interactions of Cathinone NPS with Human Transporters and Receptors in Transfected Cells*, in *Neuropharmacology of New Psychoactive Substances (NPS): The Science Behind the Headlines*, at 1779-1780 (Michael Baumann, et al., ed., 2017) (“All cathinone NPS inhibit transporter-mediated monoaminergic uptake but with different selectivity and relative potencies.”).

<sup>11</sup> Statement of Michael Gatch Before the U.S. Sentencing Comm’n, Washington, D.C., at 5 (Oct. 4, 2017).

<sup>12</sup> Simmler & Leichti, *supra* note 10.

## 2. Different potency and dosage weights

The Commission's guidance to courts to consider dosage and potency calls into question whether a class-based approach for synthetic cathinones is appropriate given the wide variance in potency and dosage within the class. Note 6 to §2D1.1 provides that, "to the extent practicable," in determining the most closely related substance, courts should consider "[w]hether a lesser or greater quantity of the controlled substance not referenced in this guideline is needed to produce a substantially similar effect on the central nervous system" and may consider "whether the same quantity of analogue produces a greater effect on the central nervous system than the controlled substance for which it is an analogue."<sup>13</sup> Even though Note 6 does not encourage courts to consistently look at potency and dosage, the Commission should follow its own advice, and reject a class-based approach because it fails to account for significant variations in potency and dosage. For example, the available literature shows that even though ethylone "is largely similar to methylone in its effects,"<sup>14</sup> it is less potent than methylone, which means that it would take a greater dosage of ethylone to have a similar effect on the central nervous system as methylone.<sup>15</sup>

Other evidence shows that methylone should not be treated like MDMA because it is less potent. After an extensive review of available research, Anthony DeCaprio, Ph.D., concluded that "[t]he bulk of pharmacological evidence . . . supports a conclusion that methylone is on average, 5-fold less potent than MDMA for a variety of endpoints relevant to the psychoactive effects of this class of drugs of abuse."<sup>16</sup> And the DEA, government experts, courts, and prosecutors have

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<sup>13</sup> USSG §2D1.1, comment. (n.6).

<sup>14</sup> Transcript of Sentencing Hearing, *United States v. Caldwell*, No. 8:14-cr-387-&-33TBM, at 29, 37-38 (M.D. Fla. Jan. 27, 2015) (testimony of Gregory Dudley, Ph.D.).

<sup>15</sup> See Transcript of Proceedings, *United States v. Austin-Ernest Kaholo Holmes*, No 1:15-cr-00245-SOM, at 28 (D. Haw. Apr. 7, 2016) (No. 78-1) (testimony of Dr. John Halpern discussing *inter alia* a study in *British Journal of Pharmacology* that "lists a larger milligram dose equivalent for ethylone over methylone").

<sup>16</sup> Declaration of Dr. Anthony DeCaprio, at 9, *United States v. Chin Chong*, No. 1:13-cr-00570-JBW (E.D.N.Y. July 24, 2014) (attached as App. G to Letter from Marjorie Meyers, Mar. 10, 2017).

acknowledged that methylone is half as potent as MDMA.<sup>17</sup> Accordingly, the proposal that a synthetic cathinone like methylone have the same ratio as MDMA (500gm) is unsupported by any evidence.

## **B. Marijuana Equivalency Ratios**

### **1. Individualized Ratios**

If the Commission chooses to set ratios for synthetic cathinones rather than amend Note 6 and undertake a more comprehensive review of the drug guidelines, it should set different ratios for each synthetic cathinone to account for the differences in potencies and effects. For example, the ratio for methylone should be lower than mephedrone and MDPV because methylone is less harmful. As Dr. Charles Grob explained: methylone, compared to “the prototype psychostimulant cocaine . . . is much milder, less likely to be habit forming or addictive, far less likely to be associated with violent behavior and implicated in far fewer fatalities.”<sup>18</sup> In contrast, a proportional ratio for MDPV and mephedrone would be 1:200 because MDPV has “far greater similarities to cocaine’s effects on the monoamine dopamine than does methylone” and “mephedrone induced much higher levels of drug self-administration than did methylone.”<sup>19</sup> Dr. Travis Worst—a witness before the Commission—also explained that “MDPV has a profile far more similar to cocaine.”<sup>20</sup>

The ethylone ratio should be lower than methylone for two reasons: (1) the available literature “suggests that it is largely similar to methylone in its effects, but with

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<sup>17</sup> See, e.g., *United States v. Marte*, 586 F. App’x 574, 575 (11th Cir. 2014) (relying on DEA pharmacologist’s testimony that “methylone is half as potent as MDMA,” the district court properly used a 1:250 ratio); *United States v. Chin Chong*, 2014 WL 4773978 (E.D.N.Y. Sept. 22, 2014) (1:200 ratio for methylone); Drug Enforcement Administration, Office of Diversion Control, *3,4-Methylenedioxymethcathinone (Methylone)* 1 (Oct. 2013) (noting that methylone was half as potent as MDMA in animal studies).

<sup>18</sup> Declaration of Charles S. Grob, M.D., at 5, *United States v. Thannavongsa*, 2:13-CR-00255-JADGWF (D. Nev. July 16, 2014) (attached as App. E to Letter from Marjorie Meyers, Mar. 10, 2017).

<sup>19</sup> *Id.* at 3.

<sup>20</sup> Statement of Travis J. Worst, Ph.D, Before the U.S. Sentencing Comm’n, Washington D.C., at 4 (Sept. 27, 2017).

slightly lower potency;”<sup>21</sup> and (2) the serotonin transporter of ethylone is much smaller than methylone.<sup>22</sup>

If the Commission chooses to adopt different ratios to account for the known differences in synthetic cathinones, but then place other synthetic cathinones in a generic class, the class-based ratio should not exceed 1:100 for reasons discussed below.

## 2. Class-Based Ratio

If the Commission chooses a broad class-based approach, it should adopt a ratio of 1:100. The ratios proposed by the Commission are too high given the current overly harsh ratio for MDMA and the fact that government experts, courts, and prosecutors have agreed that prevalent synthetic cathinones (methylone) are 50% as potent as MDMA. A 1:100 ratio would acknowledge that the emergency room risk ratios for synthetic cathinones are less than that for cocaine.<sup>23</sup>

It would also balance the vastly different expert opinions on synthetic drugs and help the Commission avoid the kind of errors made with the crack cocaine guideline, which resulted in disproportionately long sentences. And a 1:100 ratio would also acknowledge that the animal studies DEA relies upon to support higher ratios are inadequate to reliably determine the pharmacological and psychoactive effects of various drugs.<sup>24</sup>

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<sup>21</sup> Transcript of Sentencing Hearing, *United States v. Caldwell*, No. 8:14-cr-387-&-33TBM, at 29, 37-38 (M.D. Fla. Jan. 27, 2015) (testimony of Gregory Dudley, Ph.D.).

<sup>22</sup> Simmler & Leichti, *supra* note 10.

<sup>23</sup> See Letter from Marjorie Meyers, Oct 26, 2017 (risk ratio for emergency room visits by past-year “bath salts” users is .016 -0.32 and .131 for cocaine users).

<sup>24</sup> See *United States v. Stockton*, 2016 WL 10257478, at \*4 (D.N.M. May 2, 2016) (finding that in vitro and in vivo studies “have not been scientifically validated, singly or in combination, as a reliable method for unqualifiedly determining the hallucinogenic effects of synthetic cannabinoids on the human CNS.”). See also Transcript of *Daubert* Hearing, *United States v. Stockton*, No CR-13-05-0771-MCA, at 165, 200-203 (D.N.M. July 8, 2015) (Anthony DeCaprio, Ph.D. testified that DEA expert’s testimony was just a hypothesis “as to pharmacological effects and potency” of substances deemed “synthetic cannabinoids”; animal studies alone do not provide “a reliable quantitative judgment on relative potency”). See also Expert Report of Anthony P. DeCaprio, Ph.D., Prepared for James E. Felman, Esq: Kynes Markman and Felman, Tampa, FL., at 2-3 (Dec. 19, 2013) (Appendix).



### **C. Methcathinone**

The Commission requests comment on whether methcathinone is “sufficiently similar to other synthetic cathinones in chemical structure, pharmacological effects, potential for addiction and abuse, patterns of trafficking and abuse, and/or associated harms to be included as part of a class-based approach for synthetic cathinones.”

Methcathinone is not sufficiently similar in chemical structure. While these drugs share the same core structure, they “differ in the presence or absence of the methylenedioxy ring fusion, which is relevant to the “overall size, electronic structure, and reactivity profile of the molecule.”<sup>25</sup> Based on chemical structure and the manner in which the guidelines treat amphetamine, the most logical solution is to treat methylone “40x less harshly than the corresponding non-methylenedioxy-cathinone (i.e. methcathinone).”<sup>26</sup>

Nor is methcathinone sufficiently similar to methylone for the drugs to be treated the same. While animal testing can be problematic in determining the pharmacological effects and potency of drugs in humans, the available research of animal testing shows that methcathinone was “2x-3x more effective (lower dose, more potent) than methylone at producing subjective ‘cocaine-like effects.’”<sup>27</sup> Pharmacology data regarding the potency and efficacy of drug interactions with human monoamine transporters also shows that methcathinone and methylone are significantly different.<sup>28</sup>

### **D. Guidance on Class-Based Approach**

The Commission seeks comment on whether it should amend the commentary to §2D1.1 to provide guidance on how to apply a class-based approach. The most helpful information the Commission can provide is to identify the specific substances it considered in deciding to adopt a class-based approach. Specific examples are important because no matter the generic definition, experts do not often agree on whether or not a substance is a cathinone. If the Commission

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<sup>25</sup> Letter from Candace Hom, *supra* note 10, Ex. A, at 7.

<sup>26</sup> *Id.* at 8.

<sup>27</sup> *Id.* at 13.

<sup>28</sup> *Id.* at 16.

specifies which drugs it considers a cathinone, then it would make guideline application less complicated.

In addition, if the Commission opts to define a class-based “synthetic cathinone,” it should specify the pharmacological effects and typical effective dosage weight rather than simply adopt a definition based upon chemical structure as the DEA Division Control Division has suggested.<sup>29</sup> Similarity of chemical structure should be relevant only insofar as it affects “the pharmacological effects . . . potential for addiction and abuse. . . and harms associated with abuse.”<sup>30</sup>

The Commission should also include a departure provision for potency and direct harms. For example, if a particular drug is less potent, or has more limited addiction potential and lower risk for emergency room visits or overdose than the typical class-based drug, then it should be punished less harshly. Because it is impossible for the Commission to constantly track and add equivalencies for analogue drugs, and some drugs will differ from the “class-based” approach that the Commission might define, an invited departure will help promote greater uniformity in sentencing.

Recommending that the court consider the potency of a particular drug is consistent with a proposal that the DOJ made in 2004 for courts to account for the “greater or lesser potency of a substance compared to the most closely related substance.”<sup>31</sup> DOJ noted that “controlled substance analogues can be more or less potent than the scheduled substances to which they are similar” and thought it appropriate to give courts an opportunity to “‘account’ for potency upwards or downwards as they deem appropriate, based on evidence including expert testimony.”<sup>32</sup>

### **E. Minimum Base Offense Level**

The Commission has proposed an amendment that would set 12 as the minimum base offense level for synthetic cathinones. Defenders do not believe it appropriate

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<sup>29</sup> See Statement of Terrence Boos and Cassandra Prioleau Before the U.S. Sentencing Comm’n, Washington, D.C., at 12 (Oct. 4, 2017).

<sup>30</sup> USSC, Issues for Comment, 81 Fed. Reg. 92021 (Dec. 19, 2016).

<sup>31</sup> Letter from Deborah Rhodes, Counsel to the Assistant Attorney General to the U.S. Sentencing Comm’n, at 30-31 (Mar. 1, 2004).

<sup>32</sup> *Id.*

to set an offense level that would recommend a period of imprisonment for any non-violent offense. As we have previously discussed, imprisonment does not deter and minimum base offense levels tend to contribute to prison overcrowding – a problem that the Commission is obligated to consider when promulgating amendments.<sup>33</sup>

The Commission also has not released data on the offense levels and sentences imposed for synthetic cathinones for public commenters to meaningfully address this proposed amendment. For example, if any persons convicted of synthetic cathinones received a time-served or probationary sentence, such information would be relevant to whether a minimum offense level of 12 is appropriate. Also relevant is the drug quantity determination for persons who fell within OL 12 and below, and whether the individuals who had a base offense level of 12 or lower received a sentence below the guideline range.

## II. Synthetic Cannabinoids

Defenders do not support the Commission's proposal to adopt marijuana equivalency ratios for synthetic cannabinoids because those drugs, like synthetic cathinones, cannot be rationally incorporated into the fundamentally flawed Drug Quantity and Drug Equivalency Tables.

The Commission's proposal to use a class-based approach for all synthetic cannabinoids (except Schedule III, IV, or V substances) with a marijuana ratio of [167]/[334]/[500] grams ignores data showing that the current THC ratio is too high. It also fails to take into account the different potencies of synthetic cannabinoids and a lack of consensus in the chemical community about the nature of certain substances the DEA has characterized as synthetic cannabinoids.

The proposed definition of synthetic cannabinoid is also problematic because it bases the definition on unspecified effects on the CB<sub>1</sub> receptors even though the effects of different drugs can vary dramatically. It also is inconsistent to exclude THC from the definition even though it has a partial effect on CB<sub>1</sub> receptors, but include any other substance that only has a partial effect on the CB<sub>1</sub> receptors. Such an ad hoc approach that does not meaningfully distinguish drugs of different potencies, effects, and direct harms will unquestionably result in more litigation and unwarranted disparity.

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<sup>33</sup> Letter from Marjorie Meyers, Oct. 26, 2017, at 2-7.

Adopting an overly high marijuana ratio also is likely to result in more below guideline sentences. As with synthetic cathinones, the Commission's data indicates the current procedures for identifying closely related substances result in sentences that courts consider too high. The data shows a sizable percentage (43.3%) of persons convicted of trafficking synthetic cannabinoids received a below range sentence.<sup>34</sup> That no court imposed an above range sentence, even with a ratio of 167 grams for synthetic cannabinoids, is alone sufficient evidence for the Commission to reject ratcheting up the ratios to 334 or 500 grams.

The available public health data should be an important consideration for ranking drug harms. It shows that synthetic cannabinoids have a much lower risk of emergency room visits, given the number of past-year users, than almost every other drug for which data are available. This includes drugs with lower marijuana equivalencies than the ratios of 334 or 500 grams in the Commission's proposed amendment.<sup>35</sup>

#### **A. The Commission Should Lower the Ratio for THC Before Adopting Ratios for Synthetic Cannabinoids.**

The Commission seeks multiple comments on the appropriate ratios for synthetic cannabinoids and whether, if it adopts a 1:167 ratio for synthetic cannabinoids, it should apply that ratio to synthetic THC and include it in the definition of synthetic cannabinoids. Rather than use the 167 ratio or set even higher ratios for synthetic cannabinoids, the Commission should address the unsound ratio for THC and seek to establish drug quantity and equivalency tables that recommend proportional punishment. As discussed in Defender's previous comments, the current marijuana equivalency for THC fails to reflect actual concentrations of THC in marijuana and is unsupported by empirical data.<sup>36</sup> Dr. Nicholas Cozzi explained the problem in

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<sup>34</sup> USSC, *Public Data Presentation for Synthetic Cathinones, Synthetic Cannabinoids, and Fentanyl and Fentanyl Analogues Amendments* (Jan. 2018).

<sup>35</sup> See Letter from Marjorie Meyers, Oct. 26, 2017, at 22 (emergency room risk ratios show a lower ratio for synthetic cannabinoids (.003-.007) than "Bath Salts" like methcathinone (.016-.032), which has a marijuana equivalency of 380 grams, and MDMA (.009), which has an equivalency of 500 grams).

<sup>36</sup> Letter from Marjorie Meyers, Oct. 26, 2017, at 28-29; Letter from Marjorie Meyers, Mar. 10, 2017, at 13. See also Brad Gershel, *Sentencing Synthetic Cannabinoid Offenders: "No Cognizable Basis"*, 54 Am. Crim. L. Rev. 50 (2017) (discussing ratio's lack of scientific and empirical support).

*Hossain*, a case in which the court was deeply concerned about the lack of empirical data supporting the 167 ratio:

[S]aying that one gram of THC is equal to 167 grams of marijuana is like saying 167 grams of marijuana contains a gram of THC. That's what equivalence means. But if you calculate what percentage of THC that is on the weight, you take the one [and] divide it by 167, you get 0.6. So 0.6 percent of the total weight [of the marijuana] is THC. That's completely unrealistic in terms of psychoactive marijuana. We know from Government studies that the average THC content in marijuana today is over 14 percent. So that ratio should be one to seven, not one to 167.

*United States v. Hossain*, 2016 WL 70583, \*6 (S.D. Fla. Jan. 5, 2016).<sup>37</sup>

A district court in New Mexico agreed that the “1:7 ratio argued by Dr. Cozzi appears to have more scientific basis than the 1:167 ratio in the Guidelines.” *United States v. Abuzuhrieh*, 2017 U.S. Dist. LEXIS 59113, \*20 (D.N.M. Apr. 18, 2017).

Because the most recent data on range and average potencies of marijuana on the market today shows that the ratio for THC is far too high, the Commission should amend that ratio before setting any ratio for synthetic cannabinoids.

## **B. Class-based approach**

A class-based approach to all synthetic cannabinoids is not supported by the evidence and fails to consider how the chemical composition of different synthetic cannabinoids can cause vastly different effects<sup>38</sup> and result in different harms. Although it has pushed for a class-based approach, the DEA Office of Diversion

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<sup>37</sup> See also Mahmoud ElSohly et al., *Changes in Cannabis Potency Over the Last 2 Decades (1995-2014): Analysis of Current Data in the United States*, 79 *Biological Psychiatry* 613 (2016) (extensive study showed that average potency of marijuana in 2014 was about 12 percent).

<sup>38</sup> See, e.g., National Institute on Drug Abuse, *Synthetic Cannabinoids (K2/Spice)* (Feb. 2018) (noting that because chemical composition of synthetic cannabinoids can change, “these products are likely to contain substances that cause dramatically different effects”), <https://www.drugabuse.gov/publications/drugfacts/synthetic-cannabinoids-k2spice>. See also Cynthia Santos, *Synthetic Cannabinoids, emDocs* (Mar. 2014) (noting how “[f]irst generation synthetic cannabinoids are believed to be more benign than the newer generation cannabinoids”), <http://www.emdocs.net/synthetic-cannabinoids>.

Control has acknowledged that synthetic cannabinoids “may have less, equivalent or more pharmacologic (psychoactive) activity than THC.”<sup>39</sup> Research, discussed in more detail in the following section, shows that “[n]ot every new synthetic cannabinoid, which is used by consumers, provides higher CB<sub>1</sub> affinity than THC.”<sup>40</sup> Other resources show that the broad category of synthetic cannabinoids significantly vary in common dosage amounts.<sup>41</sup> And the Drug Enforcement Administration has acknowledged that “[e]ach synthetic cannabinoid variety has differing effects, potencies, and toxicities.”<sup>42</sup>

A class-based approach is also called into question by the wide variety of opinions on the characteristics of the various synthetic cannabinoids.<sup>43</sup> In addition to the different opinions presented to the Commission in public comments and hearings, DEA experts do not always agree on the characteristics of various substances. The disagreement between DEA experts is not widely known because various Assistant United States Attorneys and DEA experts have avoided disclosure of such information. For example, in *United States v. Fedida*, defense counsel sent a *Brady*<sup>44</sup> request for documents that “reflected any concern, doubt, contrary or

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<sup>39</sup> Alan Santos, Deputy Ass’t Administrator, Operations Division, Office of Diversion Control, *Synthetic Drug Trafficking & Abuse Trends* (July 2013), [https://www.deadiversion.usdoj.gov/mtgs/pharm\\_awareness/conf\\_2013/july\\_2013/asantos2.pdf](https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2013/july_2013/asantos2.pdf).

<sup>40</sup> Alexander Paulke et al., *Synthetic Cannabinoids: In Silico Prediction of the Cannabinoid Receptor 1 Affinity by a Quantitative Structure-Activity Relationship*, 245 *Toxicology Letters* 1 (Mar. 2016).

<sup>41</sup> The common pure dosages for smoked synthetic cannabinoids range from 1-2mg for THJ-2201 to 5-10mg for JWH-073—a difference of a factor of five. <https://psychonautwiki.org/wiki/Cannabinoid>.

<sup>42</sup> Drug Enforcement Admin, *2017 National Drug Threat Assessment Summary*, at 118.

<sup>43</sup> It is noteworthy that not all DEA experts have met the legal standards for testifying about synthetic cannabinoids at the trial level. See, e.g., *United States v. Stockton*, 2016 WL 10257478, at \*1 (D.N.M. May 2, 2016) (finding inadmissible DEA expert (Jordan Trecki, Ph.D.) testimony “relating to the issue of whether the “hallucinogenic effect on the central nervous system,” 21 U.S.C. § 802(32)(A)(ii), of each of five alleged controlled substance analogues commonly known as AM-2201, AM-694, JWH-250, UR-144 and XLR-11 is “substantially similar or greater than,” *id.*, the hallucinogenic effect of JWH-018, a scheduled controlled substance”).

<sup>44</sup> *Brady v. Maryland*, 373 U.S. 83 (1963) (requiring the prosecution to turn over all evidence favorable to the defendant that is material either to guilt or punishment).

conflicting opinions, or questions by anyone” in the DEA regarding whether UR-144 and XLR-11 are controlled substance analogues.<sup>45</sup> The government did not disclose any such information before or at the evidentiary hearing. Nor did the DEA Section Chief of the Diversion Control Division (Terry Boos) reveal any such disagreement among DEA staff when he testified that XLR-11 and UR-144 are substantially similar to JWH-018.<sup>46</sup> When cross-examined about whether his methodology for making that decision had general acceptance in the scientific community, he stated that the individuals within his “shop” arrived at the same conclusion.<sup>47</sup> He did not disclose a dissenting opinion from the DEA Forensic Science unit. Following an extensive hearing, where the government sought to limit the scope of any required disclosures to Diversion Control,<sup>48</sup> the prosecutor wrote to defense counsel that the Diversion Control unit consulted with Forensic Science regarding UR-144 and that “[o]ne SF chemist opined that UR-144 and JWH-018 were not substantially similar in structure because JWH-108 was a naphthyl structure group while UR-144 has a tetramethylcyclopropyl group.”<sup>49</sup> The letter also stated that the Diversion Control unit had “conducted its analysis and determination that XLR-11 meets the definition of a controlled substance analogue without consulting SF (DEA’s Office of Forensic Science).”<sup>50</sup> After the disclosure in *Fedida*, the Associate Chief Counsel of the Criminal Law Policy and Division Counsel Program released a memo advising agents and investigators to notify prosecutors of the different views of the Office of Diversion Control and the Office of Forensic Science because such information may be considered *Brady* material.<sup>51</sup>

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<sup>45</sup> Motion to Compel Production of Brady Material, *United States v. Fedida*, Case No. 6:12-cr-00209-RBD-DAB, (M.D. Fla. July 11, 2013) (letter of defense counsel to AUSA requesting *Brady* material), Doc. 90-1.

<sup>46</sup> Transcript of Motion Hearing, at 221, 232, *Fedida*, Doc. 52.

<sup>47</sup> *Id.* at 250.

<sup>48</sup> Transcript of Motion for Clarification, *Fedida*, Doc. 119.

<sup>49</sup> Motion to Compel Production of Brady Material, *Fedida*, Doc. 90-2.

<sup>50</sup> *Id.*

<sup>51</sup> Memorandum of Jane Erisman, Associate Chief Counsel, Criminal Law Policy & Division Counsel Program to “All Agents and Investigators with investigation and/or Prosecutions of UR-144”) (on file with Federal Defender Sentencing Resource Counsel).

Given the significant differences in synthetic cannabinoids and the lack of consensus in the scientific community about the nature of such substances, Defenders recommend that the Commission not adopt a class-based approach. Instead, the Commission should amend Note 6, as Defenders previously suggested,<sup>52</sup> to give courts a simpler and harms-based analysis for determining the appropriate ratio.

If the Commission, however, chooses to adopt a class-based approach, it should give specific examples of what substances it has concluded fall within that class. More information about what the Commission classifies as a synthetic cannabinoid for sentencing purposes is critical to avoid disparity in sentencing and help courts solve the inevitable dispute among the scientific community about whether the drug fits within the class.

### **C. Definition of Synthetic Cannabinoids**

The Commission requests comment about its proposed definition of “synthetic cannabinoid (any synthetic substance (other than synthetic tetrahydrocannabinoid) that [acts as an agonist at] [binds to and activates] type 1 cannabinoid receptors (CB<sub>1</sub> receptors).” That definition fails to distinguish drugs based upon the extent to which they impact the CB<sub>1</sub> receptor. For example, UR-144 (TMCP-018, KM-X1, MN-001, YX-17) is a drug invented by Abbott Laboratories that has a “lower affinity for the psychoactive CB<sub>1</sub> receptor.”<sup>53</sup> Other drugs may have a minimal effect on the CB<sub>1</sub> receptor, which is a psychoactive receptor, but primarily focus on the CB<sub>2</sub> receptor, which binds to the immune system, has therapeutic applications, and is “devoid of central side effects.”<sup>54</sup> To reduce the chances of unwarranted disparity and to focus on drugs with high CB<sub>1</sub> receptor affinity, which have the greatest abuse

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<sup>52</sup> Letter from Marjorie Meyers, Mar. 10, 2017, at 15-20.

<sup>53</sup> See Wikipedia, *UR-144*, (citing J.M Frost, et al., *Indol-3-ylcycloalkyl Ketones: Effects of N1 Substituted Indole Side Chain Variations on CB<sub>2</sub> Cannabinoid Receptor Activity*, 53 J. Medicinal Chemistry 295-315 (2010).

<sup>54</sup> See, e.g., Paula Morales, et al., *Cannabinoid receptor 2 (CB<sub>2</sub>) Agonists and Antagonists: A Patent Update*, 26 Expert Opinion on Therapeutic Patents 843 (2016); Amey Dhopeswarkar and Ken Mackie, *CB<sub>2</sub> Cannabinoid Receptors as a Therapeutic Target—What Does the Future Hold?*, 86 Mol. Pharmacol 430 (2014) (“CB<sub>2</sub> receptors have been the subject of considerable attention, primarily due to their promising therapeutic potential for treating various pathologies while avoiding the adverse psychotropic effects that can accompany CB<sub>1</sub> receptor-based therapies.”).



liability,<sup>55</sup> the Commission should define a synthetic cannabinoid as one that [directly activates] [is a full agonist of] the CB<sub>1</sub> receptors.

Using the term “full agonist” in defining a synthetic cannabinoid is extremely important if the Commission chooses to have different guideline amendments for THC and synthetic cannabinoids and/or adopts a marijuana equivalency greater than 167 grams.<sup>56</sup> We assume that the Commission wants to either exclude THC from the definition of “synthetic cannabinoid” or create higher ratios for synthetic cannabinoids because THC is only a partial agonist to the CB<sub>1</sub> receptors.<sup>57</sup> To treat THC differently because it is less potent as a partial agonist, but include other synthetic cannabinoids that are only partial agonists to the CB<sub>1</sub> receptors would create unwarranted disparity.

#### **D. Distinction Between Synthetic Cannabinoid in “Actual” Form and a Mixture**

The Commission seeks comment on whether it should make a distinction between a synthetic cannabinoid in “actual” form (*i.e.*, as a powder or crystalline substance) and a synthetic cannabinoid as part of a mixture (*e.g.*, sprayed on or soaked into a plant or other base material, or otherwise mixed with other substances), by establishing a different marijuana equivalency for each of these forms in which synthetic cannabinoids are trafficked.

Defenders strongly encourage the Commission to more closely track drug purity when determining base offense levels. A meaningful analysis of drug purity would help avoid the arbitrary, disparate, and excessive sentences that result from

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<sup>55</sup> Jenny Wiley, et al., *Combination Chemistry: Structure-Activity Relationships of Novel Psychoactive Cannabinoids*, in *Neuropharmacology of New Psychoactive Substances (NPS): The Science Behind the Headlines* (Michael Baumann, et al., ed., 2017) (“Cannabimimetic psychoactivity of the compounds, and their consequent abuse liability, is most closely associated with their high CB<sub>1</sub> receptor affinities.”).

<sup>56</sup> See, *e.g.*, *PsychonautWiki*, JWH-018 (“JWH-018, like many synthetic cannabinoids, is a full agonist of the CB<sub>1</sub> receptors in contrast to the partial agonist-Δ<sup>9</sup>-THC.”).

<sup>57</sup> The Commission’s synopsis of the proposed amendment suggests the Commission believes THC should be treated differently because some synthetic cannabinoids are more potent than THC. But if the Commission is considering potency in determining the ratio for synthetic cannabinoids compared to THC, then why doesn’t it meaningfully consider potency for all drugs rather than adopt an overly broad class-based approach for drugs with different potencies – a significant issue with synthetic cathinones and cannabinoids?

including the weight of adulterants and other inert ingredients mixed with the drug. This problem is acute with synthetic cannabinoids, which are routinely sprayed onto inert plant material to create a synthetic smokable marihuana (aka “spice”). The weight of the active ingredient is just a tiny fraction of the weight of the mixture or substance. Using the THC marihuana equivalency on the full weight of the plant material results in treating one dose of synthetic cannabinoid the same as 1000 to 2000 doses of marihuana.<sup>58</sup>

For the Commission to avoid another inconsistent approach to determining drug quantities that result in unwarranted disparity and disproportionality, Defenders strongly support guidelines that distinguish between pure form of a substance and a mixture. Just as the guidelines have different ratios for THC (167g) and marihuana/cannabis, granulated, powdered, etc. (no matter whether a low grade or high grade marijuana) (1g), new guidelines on synthetic cannabinoids (aka synthetic marihuana) should distinguish between pure synthetic cannabinoids and a mixture.<sup>59</sup>

Treating a mixture with a synthetic cannabinoid the same as a pure substance would treat dissimilar defendants the same and perversely punish defendants more harshly for trafficking less potent forms of the drug.<sup>60</sup> For example, if Defendant A is convicted of possessing with intent to distribute a kilogram of a mixture with XLR-181 sprayed onto plant leaves and Defendant B is convicted of possession with intent to distribute a kilogram of pure XLR-11, treating them both the same would be grossly disproportionate. By spraying the controlled substance onto leaves, defendant A diluted the potency. To allow the weight of the leafy substance to determine the guideline range is without reason. Accordingly, the highest ratio the Commission adopts should be applied only to a pure synthetic cannabinoid and a

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<sup>58</sup> Letter from Marjorie Meyers, Mar. 10, 2017, at 13.

<sup>59</sup> Defenders question the Commission’s proposed definition of “actual” as it appears to include both synthetic cannabinoids in pure form as well as when that drug is mixed with a solution such as acetone before it is sprayed onto any plant material. We strongly agree, however, with providing a different ratio where the synthetic cannabinoid has been “sprayed on or soaked into a plant or other base material, or otherwise mixed with other substances,” and that it should be 1:1, equivalent to marihuana.

<sup>60</sup> The court in *Abuzuhrieh*, 2017 U.S. Dist. LEXIS 59113, \*43-44 gave a downward variance in a “spice” case, noting that “one defendant’s mixture could be more potent than another defendant’s mixture” and “[a]pplying the weight of the whole spice mixture to the base offense level calculation does not address this potential for inconsistent results.”

significantly lower ratio should be used for a mixture. The best approach to dealing with synthetic cannabinoids mixed into psychologically inactive organic matter is to treat it the same as THC mixed in plant material (marijuana), i.e. a 1:1 ratio.

If the Commission does not want to set different marijuana equivalencies for pure synthetic cannabinoids and cannabinoids mixed with inert ingredients the way it treats THC and marijuana, then it should make clear that when a cannabinoid is mixed with another substance (e.g. plant materials ) a court should not use the weight of the entire mixture. Instead, a court should determine the purity of the synthetic cannabinoid and use the purity to determine the drug quantity. For example, if a mixture containing synthetic cannabinoid weighs 500 grams, but has a purity of 2%, then the drug quantity should be based upon 10 grams. If the purity of the drug cannot be determined, then base the guideline on the [DEA findings that synthetic marijuana is generally formed by mixing 1 gram with 13 grams of inert material so if a mixture weighs 14 grams, then the ratio should be based upon 1 gram] [research showing that the typical concentration of synthetic cannabinoids in herbal blends is 5-20mg/g, or .5-2% by weight].<sup>61</sup> If the Commission wants to adopt the most extreme weight of 2%, then if a mixture containing synthetic cannabinoid weighs 500 grams, the drug quantity should be 10 grams.

#### **E. Minimum Base Offense level**

The Commission requests comment on whether it should provide a minimum base offense level of 12 for synthetic cannabinoids. Defenders strongly oppose such an amendment. A guideline that encourages a court to imprison any person, including one with no criminal history, who happens to have trafficked a drug that is often considered the functional equivalent of marijuana is inappropriate. Those individuals who commit more serious offenses and play a greater role in drug trafficking will already receive an enhancement for aggravating role under §3B1.1. In addition, Commission data indicates setting a minimum base level of 12 is likely to result in more below guideline sentences. Specifically, 24.7% of the individuals included in the Commission's data analysis received sentences of either probation only, or probation and confinement.

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<sup>61</sup> Barry K. Logan, et al., *Identification of Synthetic Cannabinoids in Herbal Incense Blends in the United States*, 57 J. Forensic Sc. 1168 (2012) ("The recipes usually call for the addition of 1g of active ingredient to 50g of leaf material for a final concentration of 20mg per gram of substrate.").

### **III. Fentanyl and Fentanyl Analogues**

Defenders have repeatedly encouraged the Commission to undertake a comprehensive review of the direct harms caused by particular doses of all drugs in the guideline and amend the guidelines to create proportionate sentences. We have cautioned that increasing sentences for whatever drug is the current subject of public attention, with no evidence that increased penalties will reduce or deter distribution, will generate disparity. Yet that is precisely what the Commission proposes to do with its amendments for fentanyl and its analogues. We urge the Commission not to adopt the proposed changes that will result in disproportionate and unduly long recommended sentences.

#### **A. The Current Ratio for Fentanyl Should Not Be Increased.**

The Commission has proposed an amendment that would make the marijuana equivalency for fentanyl four times higher and the threshold quantity for the base offense levels four times lower. Available federal sentencing data, current guideline provisions, lessons from crack cocaine, and the purposes of sentencing indicate that the Commission should not increase penalties for fentanyl.

##### **1. The Current Guidelines Recommend Sufficiently High Penalties.**

###### **a. Commission Data Shows the Current Ratio for Fentanyl and Its Analogues Is (More Than) Sufficiently High.**

Commission data shows that the current ratio is sufficient. Only three individuals sentenced for fentanyl or fentanyl analogues in fiscal year 2016 received above-guideline sentences.<sup>62</sup> This amounts to a rate of 6%. In contrast, almost two-thirds (63%) received below guideline sentences.<sup>63</sup> This data falls far short of demonstrating a need for stricter penalties, and actually demonstrates the opposite: courts find the current guidelines are too high even when fentanyl is involved. Should the Commission act on its proposed amendment to increase the recommended sentences for fentanyl and its analogues, the Commission should not

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<sup>62</sup> USSC, *Public Data Presentation for Synthetic Cathinones, Synthetic Cannabinoids, and Fentanyl and Fentanyl Analogues Amendments* (Jan. 2018).

<sup>63</sup> *Id.*

be surprised to see an increased rate of below-guideline sentences as courts rightly cast aside the new ratios that lack empirical bases.

Ignoring this data has risks. And we urge the Commission to use caution to avoid repeating past mistakes. The public frenzy over crack cocaine in the 1980's resulted in hasty political measures that produced gross disparities in sentencing and disproportionately affected minorities.<sup>64</sup> There is a real danger of repeating those mistakes today given the current attention on fentanyl.

That we are in a similar time of public concern, with people grasping for solutions that elude them, is evident by the variety of actions being considered on the federal level. The DEA just recently employed its emergency scheduling authority to render all analogues Schedule I.<sup>65</sup> Congress recently passed the INTERDICT Act to enhance customs screening abilities at the border to combat fentanyl imports.<sup>66</sup> Numerous other bills are pending in Congress that would alter the state of the law on fentanyl and its analogues.<sup>67</sup> A variety of bills would take a more holistic approach and bolster treatment, testing, and data collection efforts in lieu of criminal policy reform.<sup>68</sup>

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<sup>64</sup> Ben Fabens-Lassen, J.D., *A Cracked Remedy: The Anti-Drug Abuse Act of 1986 and Retroactive Application of the Fair Sentencing Act of 2010*, 87 Temple Law Rev. 645, 645-46 (2015) (describing public fear of crack-cocaine, exacerbated by sensationalist media coverage and political discourse, and Congress' recognition of crack-cocaine as a public health crisis after the overdose death of Len Bias, a newly drafted basketball player for the Boston Celtics, as well as the Commission's conclusions about the disparity created by the 100-to-1 ratio disparity only a decade later).

<sup>65</sup> DEA Headquarters News, *Department of Justice Announces Significant Tool in Prosecuting Opioid Traffickers in Emergency Scheduling of All Fentanyls* (Nov. 9, 2017), <https://www.dea.gov/divisions/hq/2017/hq110917.shtml>.

<sup>66</sup> INTERDICT Act, Pub. L. No. 115-112, 131 Stat. 2274 (2018).

<sup>67</sup> Stopping Overdoses of Fentanyl Analogues Act, H.R. 4822, S. 1553, 115th Cong. (2018); Stop Trafficking in Fentanyl Act, H.R. 1354, 115th Cong. (2017); Comprehensive Fentanyl Control Act, H.R. 1781, 115th Cong. (2017); SITSA Act, S. 1327, 115th Cong. (2017); Sentencing Reform and Corrections Act, S. 1917, 115th Cong. (2017).

<sup>68</sup> Respond NOW Act, H.R. 4938, 115th Cong. (2018); Fentanyl and Heroin Task Force Act, H.R. 3883, 115th Cong. (2017); HELP Act of 2017, H.R. 664, S. 2008, 115th Cong. (2017); Stop OD Act of 2017, H.R. 664, S. 2008, 115th Cong. (2017); INFO Act, H.R. 4284, 115th Cong. (2017); Combating the Heroin Epidemic Through Forensic Drug Testing Act of 2017,

Proceeding now, without evidence that the increased ratios are necessary and appropriate, will likely lead to a future moment where the Commission revisits the issue and concludes as it did with the 100-to-1 crack-cocaine ratio that it “overstated the relative harmfulness,” “swept too broadly and applied most often to lower level offenders,” and “overstated the seriousness of most crack cocaine offenses and failed to provide adequate proportionality.”<sup>69</sup>

**b. The Guidelines Already Impose Severe Sanctions When There is Death or Serious Bodily Injury.**

The guidelines already cover the dangers posed by trafficking fentanyl. The Commission’s proposed amendments attempt to address concerns raised by DOJ that §2D1.1 “does not adequately reflect the serious dangers posed by fentanyl and its analogues, including their high potential for abuse and addiction.”<sup>70</sup> These concerns derive from the “proliferation and ease of availability” of fentanyl and its analogues, which has resulted in an increased number of overdose deaths.<sup>71</sup> The Commission’s proposal to increase marijuana equivalencies and lower the thresholds to account for such dangers fails to acknowledge that the guidelines already cover the dangers posed by drug trafficking.

The guidelines set a base offense level of 38 for an individual with 0 criminal history points who was convicted under 21 U.S.C. § 841(b)(1)(A), (B), or (C), where death or serious bodily injury resulted from the use of a substance.<sup>72</sup> In such cases, the guidelines subject the individual to a high guideline range—235-293 months.<sup>73</sup> This particularized base offense level means that any increased penalties in the drug quantity table or base offense levels pertaining to fentanyl or its analogues will not apply to the cases providing the very animus for the Commission’s proposed amendments. Rather, changes in the drug quantity and offense levels will only affect individuals who have caused no bodily harm.

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S. 1355, 115th Cong. (2017); Combating the Opioid Epidemic Act, H.R. 4501, S. 2004, 115th Cong. (2017).

<sup>69</sup> USSC, *Report to Congress: Impact of the Fair Sentencing Act of 2010*, 3 (2015).

<sup>70</sup> 83 Fed. Reg. 3869, 3874 (Jan. 26, 2018).

<sup>71</sup> *Id.*

<sup>72</sup> USSG §2D1.1(a)(2).

<sup>73</sup> USSG, Ch. 5 Pt. A, Sentencing Table.

## **2. Enhanced Penalties for Fentanyl Will Not Serve the Purposes of Sentencing.**

Congress has charged the Commission with creating guidelines that advance the purposes of sentencing set forth in 18 U.S.C. § 3553(a)(2).<sup>74</sup> Raising the fentanyl marijuana equivalency from 2.5 KG to 10 KG and lowering thresholds will do little, if anything, to serve those purposes.

### **a. Deterrence**

No evidence shows that sentence increases have a deterrent effect on drug trafficking or use.<sup>75</sup> To the contrary, research shows that changes in penal law have no demonstrable effect on trafficking or use.<sup>76</sup> Neither the imposition of the 100-to-1 ratio in the Anti-Drug Abuse Act of 1986 (ADAA), nor the passage of the Fair Sentencing Act had any demonstrable impact on the distribution or use of crack cocaine.<sup>77</sup> If sentence increases do not deter, or otherwise affect the prevalence of the drug, then increasing the ratio and lowering the threshold for fentanyl does nothing productive to address public health concerns. Increasing sentence length will also increase prison overcrowding and impact BOP's staffing ratio in a way that will hinder its ability to provide drug treatment and other rehabilitative services.

### **b. Just Punishment**

Across the board increases in recommended sentences for all fentanyl cases will not result in just punishment. First, instead of being narrowly targeted toward serious

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<sup>74</sup> See 28 U.S.C. §§ 991(b)(1)(A) & 994(f).

<sup>75</sup> Letter from Marjorie Meyers, Oct. 26, 2017.

<sup>76</sup> See, e.g., Lauryn Saxe Walker & Briana Mezuk, *Panel Paper: Mandatory Minimum Sentences: The Impact on Crack and Powder Cocaine Use*, APPAM DC Regional Student Conference (2017), <https://appam.confex.com/appam/sc17dc/webprogram/Paper19844.html> (assessing the impact of the Anti-Drug Abuse Act of 1986 and the Fair Sentencing Act of 2010 on crack-cocaine use, and finding no differential impact) (*Panel Paper: Mandatory Minimum Sentences*).

<sup>77</sup> USSC, *Report to the Congress: Impact of the Fair Sentencing Act of 2010*, 11-12, 27 (2015) (finding that half as many individuals were sentenced in 2014 in the federal system as had been in 2010; that crack-cocaine represented the most commonly-sentenced drug in only 9 federal districts in 2014, down from 36 districts in 2010; and that passage of the Act did not disrupt the ongoing decline of crack-cocaine users according to survey data). See also *Panel Paper: Mandatory Minimum Sentences*.

or major drug traffickers, the proposed amendments will increase guideline recommended sentences for individuals the Commission has considered less culpable, such as street-level dealers, couriers/mules, renter/loader/lookout/enabler, and users. This is evident from Commission data showing that a majority of defendants sentenced for fentanyl offenses are low-level dealers.<sup>78</sup> And this across the board increase is particularly pernicious because Commission data shows that most persons convicted of trafficking fentanyl did not seem to know they had fentanyl.<sup>79</sup>

Second, setting the same ratio for all fentanyl and fentanyl analogues, without consideration of purity, and including the weight of the entire mixture or substance will not advance proportionate sentencing. We know that with fentanyl, purity levels are varied and that, often, miniscule amounts of fentanyl are involved. The Drug Enforcement Administration (DEA) reported that in one seizure, a fentanyl-laced kilogram of heroin contained only one teaspoon of fentanyl, or 5.69 grams, along with other adulterants and diluents such as quinine.<sup>80</sup> In 2016, seized fentanyl ranged from only trace amounts of fentanyl to nine percent pure as part of a mixture.<sup>81</sup> Earlier reports regarding seized fentanyl in 2014 and 2015 indicated purity levels from four to seven percent.<sup>82</sup> But, “[b]ecause fentanyl is so powerful, these purities are wholesale-level, and the drug must still be diluted several times before being distributed in user quantities at the retail level.”<sup>83</sup> The Commission’s proposal to increase the severity of the recommended sentence across the board will

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<sup>78</sup> USSC, *Public Data Presentation for Synthetic Cathinones, Synthetic Cannabinoids, and Fentanyl and Fentanyl Analogues Amendments* (Jan. 2018) (showing that a majority of defendants sentenced for fentanyl offenses are low-level dealers; of the 51 persons convicted of a fentanyl-related offense in FY 2016, 29 served “street-level dealer” “courier/mule” and “employee/worker” functions). See also USSC, *Report to the Congress: Cocaine and Federal Sentencing Policy* 18 (2007) (listing culpability based on function in the offense).

<sup>79</sup> *Public Data Presentation* (of the 51 individuals only 8 of them clearly knew they had fentanyl, 27 of them did not seem to know, and in 16 cases the Commission could not tell).

<sup>80</sup> DEA, *2017 National Drug Threat Assessment*, 65 (2017) (*DEA 2017 Summary*), [https://www.dea.gov/docs/DIR-040-17\\_2017-NDTA.pdf](https://www.dea.gov/docs/DIR-040-17_2017-NDTA.pdf).

<sup>81</sup> *Id.* at 68.

<sup>82</sup> DEA *National Drug Threat Assessment Summary*, 43 (2015) (*DEA 2015 Summary*), <https://www.dea.gov/docs/2015%20NDTA%20Report.pdf>.

<sup>83</sup> *Id.*



result in those with more diluted mixtures being treated more harshly than those with the most potent, pure form of the drug.<sup>84</sup>

### **3. Increasing the Ratio for Fentanyl Perpetuates and Exacerbates the Problems From The Commission's Ad Hoc Approach to Drug Sentencing.**

Adopting a ratio above the quantities set by the ADAA—as the Commission proposes—does not merely perpetuate, but actually exacerbates the problems arising from the Commission's ad hoc approach to drug sentencing. The current guideline thresholds for fentanyl are linked to the mandatory minimum penalties set by Congress in the ADAA. The ADAA provides for a ten year mandatory minimum for 400 grams or more of a mixture containing a detectable amount of fentanyl and the same penalty for 100 grams or more of a fentanyl analogue depicting a ratio of four to one.<sup>85</sup> The current guidelines mirror the statutory ratio.<sup>86</sup>

The ADAA, however, is not empirically based.<sup>87</sup> Since its passage, the Commission abandoned its work developing drug offenses based on empirical data and instead linked base offense levels to the ADAA's quantity thresholds for mandatory minimum penalties.<sup>88</sup> Amendment of the drug guidelines since the ADAA has been piecemeal, often directed by Congress and encouraged by DOJ, based on fluctuating

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<sup>84</sup> That fentanyl is unique in its potency may be the reason why forty-three states punish fentanyl either equal to or less than heroin. (a memorandum on state law is on file with Federal Defender Sentencing Resource Counsel). While fentanyl in its *pure form* is more potent than heroin, sentences based on the total weight of the entire substance should reflect the small amount of fentanyl the substance is likely to contain.

<sup>85</sup> 21 U.S.C. § 841(b)(1)(A)(vi). *See also* § 841(b)(1)(B)(vi) (setting a similar four-to-one ratio for a five-year mandatory minimum, forty grams of fentanyl and ten grams of analogue).

<sup>86</sup> USSG §2D1.1, comment. (n.8(D)) (punishing fentanyl at an equivalency of one gram equals two and a half kilograms of marijuana, and fentanyl analogues at ten kilograms of marijuana).

<sup>87</sup> *See Kimbrough v. United States*, 552 U.S. 85, 96 (2007) (“The Commission did not use this empirical approach in developing the Guidelines sentences for drug-trafficking offenses. Instead, it employed the 1986 Act’s weight-driven scheme.”).

<sup>88</sup> Letter from Marjorie Meyers, Nov. 13, 2017, at 3 (citing Ronnie Skotkin, *The Development of the Federal Sentencing Guidelines for Drug Trafficking Offenses*, 26 Crim. Law Bull. 50, 52 (1990)).

criteria.<sup>89</sup> The result is a patchwork guideline that fails to sentence drug crimes proportionately, fairly, or effectively.<sup>90</sup>

Defenders have long urged the Commission to serve as an expert body and reject thresholds that fail to achieve just and proportionate sentences.<sup>91</sup> But the Commission has remained committed to the ADAA quantities, taking the position that linkage to the federal statute is legally required by the ADAA provision that the guidelines establish sentencing ranges “consistent with all pertinent provisions of title 18, United States Code.”<sup>92</sup>

Yet, now, the Commission proposes breaking with the ADAA quantities to set guideline thresholds *above* those identified in the ADAA, without evidence that such penalties are necessary to serve the purposes of sentencing.

If the Commission is willing to adopt guidelines different than the statutory framework to which it usually adheres, the better approach is to follow what the Commission did with LSD. With LSD, the Commission correctly determined that the ADAA threshold quantities failed to ensure proportionate sentencing.<sup>93</sup> Under the ADAA, just one gram of a mixture or substance containing a detectable amount of LSD results in a five-year mandatory minimum penalty.<sup>94</sup> Common oral doses for LSD are 75-150 micrograms (.000075-.00015 gms),<sup>95</sup> making it one of the most

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<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> See Letter from Marjorie Meyers, Mar. 10, 2017; Statement of Molly Roth Before the U.S. Sentencing Comm’n, Washington, D.C., addendum (Mar. 13, 2014) (discussing problems with how the ADDA and the drug quantity tables have not served the purposes of sentencing).

<sup>92</sup> Letter from Marjorie Meyers, Nov. 13, 2017, at 4 (citing Hon. Patti Sarris, *A Generational Shift for Federal Drug Sentences*, 52 Am. Crim. L Rev. 1, 5 (2015) (citing 28 USC § 994(a) as a mandate that the guidelines be “consistent with all pertinent provisions of any Federal statute”); USSC, *An Overview of Mandatory Minimum Penalties in the Federal Criminal Justice System* 16-17 (2017) (“the Commission has incorporated mandatory minimum penalties into the guidelines since their inception, and has continued to incorporate new mandatory minimum penalties as enacted by Congress”).

<sup>93</sup> USSG App. C, Amend. 488 (Nov. 1, 1993).

<sup>94</sup> 21 U.S.C. § 841(b)(1)(B)(v).

<sup>95</sup> <https://psychonautwiki.org/wiki/LSD>.

potent of commonly misused drugs. In 1993, the Commission found that “the weights of LSD carrier media vary widely and typically far exceed the weight of the controlled substance itself . . . As a result, basing the offense level on the entire weight of the LSD and carrier medium produces unwarranted disparity among offenses involving the same quantity of actual LSD but different carrier weights, as well as sentences that are disproportionate to those for other, more dangerous controlled substances.”<sup>96</sup> To address the problem of disproportionate sentences, the Commission designed a dose system.<sup>97</sup> Under this system, each dose of LSD is assigned a standardized weight, which is greater than the weight of the pure drug, but far less than the combined weight of the LSD and carrier medium. This system successfully eliminated much of the unwarranted disparity in sentencing arising from arbitrary variations in the weight of inert “mixtures and substances” combined with the drug.

The proposed amendments for fentanyl and its analogues carry the same potential for disproportionality as the original LSD guideline. Not only do fentanyl and its analogues vary widely in potency, but they are most often a small fraction of a mixture or substance. The remainder of the mixture could also include inert ingredients, which produces the same disproportionality as the weighing of LSD carrier media. Thus, instead of increasing the ratio and lowering the threshold quantities across the board for fentanyl, which all but guarantees disproportionate sentences, the Commission should consider a dose-based approach like it took with LSD.

## **B. Fentanyl Analogues**

The Commission’s proposed amendments to define fentanyl analogues and treat them as a single class appears to be based in part on the false premise that there is a significant problem with fentanyl analogues requiring “courts to hold extensive hearings to receive expert testimony” to determine the marijuana equivalency.<sup>98</sup> To date, there has not been a single reported case regarding the appropriate drug equivalency or whether a substance was a fentanyl analogue.<sup>99</sup> Fentanyl and its

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<sup>96</sup> USSG App. C, Amend. 488 (Nov. 1, 1993).

<sup>97</sup> This dose system was subsequently affirmed by the Supreme Court for guideline purposes. *Neal v. United States*, 516 U.S. 284 (1996).

<sup>98</sup> 83 Fed. Reg. at 3875.

<sup>99</sup> Letter from Marjorie Meyers, Nov. 13, 2017, at 1.

analogues are involved in only a few cases, representing a tiny fraction of the federal case load.<sup>100</sup>

Indeed, the lack of litigation—and the information gathering that has not yet occurred—regarding fentanyl analogues and their comparative harms, combined with still-developing scientific research, means not enough information is available to support the Commission’s proposed definition of fentanyl analogue or its proposal to treat all fentanyl analogues as a single class. Not enough evidence is available regarding the comparative harms of fentanyl or its analogues, the typical dosage weight, its marketing forms, relative potencies, and other factors that are important to setting just punishments. To be sure, researchers have not even determined the average lethal dose for a human yet.<sup>101</sup> Little of the testimony presented to the Commission during its December 5, 2017 public hearing addressed the *relative* potency of different fentanyl analogues or their corresponding comparative pharmacokinetics.<sup>102</sup> Yet as with other opiates and semi-synthetic opioids listed in the DQT and DET, the relative potency of fentanyl and fentanyl analogues varies widely. According to the DEA, fentanyl is 50 to 100 times more potent than morphine and by extrapolation—25 to 50 times more potent than heroin (which is twice as potent as morphine).<sup>103</sup> Recently scheduled U-47700, by comparison, is 7.5 times more potent than morphine, 3.25 times more potent than heroin, and thereby

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<sup>100</sup> *Compare* USSC, *2016 Sourcebook of Federal Sentencing Statistics* tbl. 33 (19,788 defendants were sentenced under the drug guidelines in 2016) (hereinafter *2016 Sourcebook*); *with* USSC, *Public Data Presentation for Synthetic Cathinones, Synthetic Cannabinoids, and Fentanyl and Fentanyl Analogues Amendments* (Jan. 2018) (Only 51 defendants were sentenced for fentanyl or its analogues in 2016). *See also* USSC, *Quick Facts: Drug Trafficking Offenses* (June 2017) (in FY 2016, crack cocaine, methamphetamine, powder, heroin, oxycodone, and marijuana accounted for 96.3% of drug trafficking offenses).

<sup>101</sup> Source: NCBI, PubChem, 12.1.7 Toxicity Summary (citing DrugBank, <http://www.drugbank.ca/drugs/DB00813>) (“Fentanyl has an LD50 of 3.1 milligrams per kilogram in rats, and, 0.03 milligrams per kilogram in monkeys. The LD50 in humans is not known.”), <https://pubchem.ncbi.nlm.nih.gov/compound/fentanyl#section=Top>.

<sup>102</sup> Transcript of Public Hearing before the U.S. Sentencing Comm’n, Washington, D.C., at 54-55 (Dec. 5, 2017) (Dr. Tella) (Explaining that seven recently tested analogues were slightly less potent than fentanyl but still more potent than morphine. Concluding that some analogues are less potent and some are more potent than fentanyl, and many of them are close to fentanyl in potency.).

<sup>103</sup> *DEA 2017 Summary*, at 58.

significantly less potent than fentanyl.<sup>104</sup> Carfentanil, on the other hand, is 10,000 times more potent than morphine, 5,000 times more potent than heroin, and by extrapolation—100 to 200 times more potent than fentanyl.<sup>105</sup> Other known fentanyl analogues such as  $\alpha$ -methylfentanyl, 3-Methylfentanyl, Acetylfentanyl, Acetylmethylfentanyl, and Butyrfentanyl (there are many more than listed here) have varying potencies ranging between U-47700 and carfentanil.

### **1. The Commission’s Proposed Definition of Fentanyl Analogue Is Both Too Narrow and Too Vague.**

The Commission’s proposed definition of fentanyl analogue, by looking only at whether the substance has a “chemical structure that is similar to fentanyl,” or “substantially similar to fentanyl,” is too vague and will result both in significant litigation and unwarranted disparity. For example, how similar need the chemical structure be? Will experts disagree about whether various chemical structures are, or are not similar? Does the addition of “substantially” to the definition provide any further degree of clarity?

The Commission received a measure of guidance during testimony on this issue. Dr. Logan testified that when viewing the “chemical composition of the substances, they have three characteristic domains. . .[or] chemical constituents on the molecule, [and] if all three of them are present, then a chemist can recognize them as being related to or derived from fentanyl.”<sup>106</sup> Yet the proposed definition omits the requirement that all three of these domains be present (and does not name those domains in terms the legal community could understand) and instead replaces that clearly recognized scientific requirement with a nebulous similarity standard.

The Commission’s proposed definition of “fentanyl analogue” also fails to provide adequate guidance because, as discussed above, it relies solely upon chemical structure for a group of drugs with vastly differing harms and effects.<sup>107</sup> The

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<sup>104</sup> *Id.* at 57.

<sup>105</sup> *Id.* at 63.

<sup>106</sup> Transcript of Public Hearing before the U.S. Sentencing Comm’n, Washington, D.C., at 53 (Dec. 5, 2017) (Dr. Logan).

<sup>107</sup> The proposed definition is also another example of the ad hoc approach the Commission takes to the drug quantity table. How is proportional sentencing possible if the guideline range for one class of drugs depends primarily upon pharmaceutical effects (e.g. synthetic cannabinoids), but the range for another class of drugs depends upon chemical structure?

Commission's suggestion in its issue for comment that the definition include not only a "[substantially] similar" chemical structure, but also some additional factor such as "an effect on the central nervous system that is substantially similar to [or greater than] fentanyl," would be an improvement. Though such a definition still fails to include the critical component of comparative harms. But the Commission's suggested additional factor includes not only substances with actual effects similar to fentanyl, but also substances "represented or intended to have such an effect." This alternative to actual effects guts any value the additional prong might offer. It is vague and leads to far more questions than it answers. For example, what exactly does "be represented or intended to have such an effect" mean? Will it sweep in those individuals who think they have purchased heroin? After all, heroin is an opiate and has similar depressive effects. Will an individual need to tell someone something to the effect of, "this will feel like fentanyl" or should "this will feel like Oxy" suffice? What about simply saying "you'll feel real good" or "it'll take your pain away," is that sufficient? This vague prong carries the potential for vastly differing interpretations and should not be included as part of the definition. It further places the onus on the defendant to disprove any and all statements made by confidential informants, that are often uncorroborated and who often boast and embellish their statements to satisfy and fall in the favor of law enforcement. With some circuits espousing the denial of the acceptance of responsibility reduction when a defendant merely challenges relevant conduct, the potential for injustice becomes ever more prevalent.

The Commission's proposed definitions set vague standards. More empirical data and information is necessary before an adequate definition may be crafted, which should include relative effects and comparative harms.

## **2. The Class-Based Approach Is Not Appropriate and The Commission Should Consider Alternatives.**

The Commission requests comment on whether fentanyl and fentanyl analogues are sufficiently similar to one another in chemical structure, pharmacological effect, potential for addiction and abuse, patterns of trafficking and abuse, and/or associated harms to support the class-based approach for sentencing purposes. Defenders answer no. In light of the lack of empirical data and research to show that they are sufficiently similar, the Commission should not assume that they are. Such an assumption could lead to grossly disproportionate sentences. The Commission should not feign to understand enough about these substances to apply a class-based approach at this time.

The Commission asks whether it should establish different penalties or a different equivalency applicable to such substances. Defenders answer yes. Treating fentanyl and its analogues the same under one class-based approach is inappropriate in light of what we know about the vastly differing potencies, purities, effects, and harms. The class-based approach is both over-inclusive and under-inclusive for this reason. Defenders urge the Commission to instead consider either departure provisions or a standardized dose system, based on empirical data that includes consideration for the less potent and less dangerous substances. If the Commission undertakes this endeavor it may want to consider amending §2D1.1, comment. (n.1), to encourage a downward departure whenever the weight of the mixture or substance containing a detectable amount of a drug exceeds the weight of the active ingredient; and (2) encourage a downward or upward departure whenever the potency of a fentanyl analogue is greater or lesser than Alpha-Methylfentanyl or 3-Methylfentanyl.<sup>108</sup> Together with the invited upward departures already included in §2D1.1, comment. (n.27), based upon unusually high drug quantity and purity, this proposal would better account for the major traffickers and those closest to clandestine labs, as well as those smaller level and less culpable actors, including those who never knew they had encountered a fentanyl-related drug.

The Commission could also reconsider how quantity is determined as it did with LSD, and using empirical evidence, arrive at a creative dosage-based system that accounts for differences in potency and comparative harms.

The Commission also requests comment on whether Alpha-Methylfentanyl and 3-Methylfentanyl are sufficiently similar to be included in the class-based approach. Defenders do not have enough empirical evidence to offer comment on this issue.

**C. An Enhancement for Offenses Involving Fentanyl and Fentanyl Analogues Misrepresented or Marketed as Another Substance Unnecessarily Complicates the Guidelines and Will Result in Unwarranted Disparity.**

The Commission proposes adding a specific offense characteristic to §2D1.1 for cases involving fentanyl misrepresented or marketed as another substance. For the reasons discussed above, changes to the guidelines regarding fentanyl and its analogues are not necessary or appropriate. If the Commission, however, opts to add yet another specific offense characteristic to §2D1.1, it should add no more than

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<sup>108</sup> Letter from Marjorie Meyers, Nov. 13, 2017, at 9.

two levels, and at least require that the defendant “knowingly misrepresented or knowingly marketed that mixture or substance as another substance,” as proposed in the Commission’s second option.<sup>109</sup>

The first of the Commission’s proposed options for a new specific offense characteristic simply focuses on the offense rather than the defendant’s knowledge.<sup>110</sup> This proposed enhancement will disproportionately penalize individuals who were not aware the substance they possessed or distributed contained fentanyl. Such individuals are certainly less culpable than their willful counterparts. This concept has been recognized by some states in their drug laws.<sup>111</sup> By purposely misrepresenting the substance, certain more culpable individuals, are intentionally disregarding the harm that could come to the end user. The unwitting individual convicted of fentanyl or fentanyl analogue trafficking is far more common. Commission data shows these unwitting individuals comprise a significant portion of the federal cases.<sup>112</sup> Increased penalties in such cases are inconsistent with the purposes of sentencing set forth in 18 U.S.C. § 3553(a).<sup>113</sup> Further, because unwitting individuals comprise a large number of cases, and those who knowingly misrepresent the nature of the substance are such a small portion, the risk of disparity is even greater and far-reaching.

The Commission’s first option would penalize a person more harshly for what may be completely accidental behavior. Take for example the case of Caleb Smith from the Middle District of Pennsylvania, which tragically resulted in two deaths.<sup>114</sup> Mr. Smith had no criminal history, a master’s degree, and was studying for medical

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<sup>109</sup> 83 Fed. Reg. at 3875.

<sup>110</sup> *Id.* (if the offense involved a mixture or substance containing a detectable amount of fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide) or a fentanyl analogue that was misrepresented or marketed as another substance”).

<sup>111</sup> *See, e.g.*, Fla. Stat. Ann. § 893.101 (2002) (establishing that lack of knowledge as to the illicit nature of a substance is an affirmative defense to prosecution for the jury to consider).

<sup>112</sup> USSC, *Public Data Presentation for Synthetic Cathinones, Synthetic Cannabinoids, and Fentanyl and Fentanyl Analogues Amendments* (Jan. 2018)

<sup>113</sup> *See supra* pp 23-25.

<sup>114</sup> *United States v. Smith*, No. 3:16-CR-223 (M.D. Pa. Oct. 24, 2016) (dismissed by prosecutors after defendant’s death).



school entrance exams.<sup>115</sup> He bought what he thought was Adderall from an online retailer and when he took some with his girlfriend, they both overdosed.<sup>116</sup> He survived.<sup>117</sup> Prosecutors indicted him for distributing fentanyl resulting in death and, fraught with grief and stress of the prosecution, he committed suicide one day after being released on bond.<sup>118</sup> Prosecutors charged the man responsible for marketing the misbranded pills online with the same offense, subject to the same twenty-year mandatory minimum penalty and ultimately, subject to the same guideline range if also found to be a criminal history category I.<sup>119</sup> Caleb's story provides a real-world example of a person who accidentally distributed a drug being disproportionately treated the same as the far more culpable major trafficker, and also highlights the necessity of a knowledge requirement to the proposed enhancement.

Alternative one also ignores valuable insight from the Supreme Court. In *McFadden v. United States*, the Court held that the government must prove that a defendant knew the substance at issue was, in fact, a controlled substance.<sup>120</sup> Defenders realize that the likelihood of an individual believing the substance to be a completely innocuous one is slim, however, the premise still stands. A defendant should only be criminally punished when the *mens rea* element of the Controlled Substance Act is met. Similarly, a defendant should only be subject to enhanced penalties by the same standard. Arguably, the knowledge requirement should apply to the whole of §2D1.1—the government should have to prove that a defendant knew the substance they are being held responsible for under the guidelines was, in fact, that substance.

In addition, a two-level, rather than a four-level, increase sufficiently addresses the Commission's concerns about the additional culpability of individuals who

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<sup>115</sup> Zachary A. Siegel, *Death by Prosecution: Was there a Bigger Player in Drug Case Involving Man who killed Himself after Federal Indictment*, In Justice Today (2018), <https://injusticetoday.com/murder-by-prosecution-was-there-a-bigger-player-in-drug-case-involving-man-who-killed-himself-724c2ad3e4f6>.

<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> See *United States v. Broussard*, 0:16-MJ-909 (D. Minn. Dec. 8, 2016) (Motion at 1).

<sup>120</sup> *McFadden v. United States*, 135 S. Ct. 2298, 2305 (2015).

knowingly misrepresent a substance. It significantly raises the guideline range for those individuals. An individual whose total offense level is 29 without the enhancement (at 151 to 188 months) would be elevated to level 31 (at 188 to 235 months). Thus, a two-level enhancement provides a twenty-percent increase in the sentence for cases in which the defendant knowingly misrepresented fentanyl as another substance.

**D. No Changes Are Necessary to Account for Substantial Threats to Public Health or Safety.**

The Commission seeks comment on whether the guidelines should be amended to “provide appropriate penalties for cases in which fentanyl or a fentanyl analogue may create a substantial threat to the public health or safety (including the health or safety of law enforcement and emergency personnel).” Expert evidence and the enhancements currently available under the guidelines indicate no changes are necessary.

As research progresses and accurate information emerges, the consensus from the medical industry is that there is little risk of overdose from inhalation or absorption from incidental or casual contact. In a joint position statement issued by the American College of Medical Toxicology (ACMT) and the American Academy of Clinical Toxicology (AACT), “after a review of the issue and scientific literature” researchers concluded that “the risk of clinically significant exposure to emergency responders is extremely low.”<sup>121</sup> Experts concluded that “[i]ncidental dermal absorption is unlikely to cause opioid toxicity” and “[f]or routine handling of the drug, nitrile gloves provide sufficient dermal protection.”<sup>122</sup>

Other medical experts have voiced similar skepticism of the dangers from incidental exposure. Two professors at Harvard Medical School, both practicing physicians, recently dubbed concerns for a threat to safety by incidental exposure as “unfounded hysteria about synthetic opioids that behave within the predictable confines of their chemical nature . . . [w]hen touched by human hands in powder or

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<sup>121</sup> ACMT and AACT, *ACMT and AACT Position Statement; Preventing Occupational Fentanyl and Fentanyl Analog Exposure to Emergency Responders* (2017), [https://www.acmt.net/\\_Library/Fentanyl\\_Position/Fentanyl\\_PPE\\_Emergency\\_Responders\\_.pdf](https://www.acmt.net/_Library/Fentanyl_Position/Fentanyl_PPE_Emergency_Responders_.pdf).

<sup>122</sup> *Id.*

liquid form, nothing happens.”<sup>123</sup> They attribute the hysteria to unsubstantiated, but widely disseminated, media reports, noting the similarity to when irrational fears affected physicians treating patients with H.I.V./AIDS.<sup>124</sup> The Northern New England Poison Center (NNEPC) also weighed in on the issue announcing that “[t]he risk of significant opioid exposure is minimal for first responders who encounter fentanyl, carfentanil or other fentanyl analogs in the field.”<sup>125</sup>

If, however, the ACMT and AACT, among others, are wrong, and fentanyl and its analogues do pose a threat to law enforcement and emergency personnel, then it is very likely fentanyl and its analogues would qualify as “hazardous waste” under the Resource Conservation and Recovery Act, 42 U.S.C. § 6928(d). This would mean that both the two-level enhancement at §2D1.1(b)(13)(A) applies, and, if the two-level enhancement was deemed insufficient, an upward departure may be warranted.<sup>126</sup>

Under these circumstances there is no need to further complicate the guidelines with an additional enhancement.

The Defenders appreciate the Commission’s consideration of this statement and for providing the opportunity to testify today.

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<sup>123</sup> Jeremy Samuel Faust & Edward W. Boyer, *Opioid Hysteria Comes to Massachusetts Courts*, *The New York Times* (Jan. 23, 2018) (criticizing the state’s decision to ban fentanyl from being brought into courthouses as exhibits out of concern for danger. The doctors explain that “[t]he policy is based in part on the idea that even miniscule amounts of skin exposure to these drugs can be life-threatening. This is patently false—and we fear that it will worsen what is already a public health crisis.”).

<sup>124</sup> *Id.*

<sup>125</sup> NNEPC, *Fentanyl and Carfentanil Exposures in First Responders* (Sept. 6, 2017) (citing the ACMT and AACT Position Statement), <https://www.nnepc.org/substance-abuse/fentanyl-and-carfentanil-exposures-in-first-responders>.

<sup>126</sup> §2D1.1(b)(13)(A) & comment. (n.18(A)).

# APPENDIX

**Expert Report of Anthony P. DeCaprio, Ph.D**  
**Prepared for: James E. Felman, Esq.; Kynes Markman and Felman, Tampa, FL**  
**December 19, 2013**

In this report I provide my opinions on two issues related to the DEA “analogue based scheduling” process as applied to emerging drugs of abuse including the synthetic cathinones and stimulant drugs of the phenethylamine and tryptamine class.

I first provide my general opinions on the scientific validity of “Prong 2” of the relevant statute, which defines a compound as a controlled substance analogue under Title 21 U.S.C. §802(32)(A) as a substance: *(ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II.* This Prong is generally referred to as the “pharmacological similarity” criterion.

I then provide my specific opinions regarding the likelihood that an individual would have been able to make an informed judgment as to whether any of the specific group of compounds listed below would have fulfilled the pharmacological similarity criterion based on relevant information publically available prior to August, 2012. The specific compounds at issue include the synthetic cannabinoids known as AM-2201, JWH-081, JWH-122, JWH-203, JWH-210, and RCS-4, the phenethylamine derivative 4-fluoroamphetamine (4-FA), and the synthetic tryptamines 5-MeO-DALT and 5-MeO-DIPT. It is assumed that this informed judgment would have been based on peer-reviewed scientific publications, patents, government reports, and other types of relevant data as available to the public prior to August, 2012.

**I. General Opinions Regarding DEA Drug Analogue Scheduling Based on  
“Pharmacological Similarity” (Prong 2):**

The psychotropic effects of drugs of abuse almost always involve binding and activation (or inhibition) of specific receptors for neurotransmitter or other neuroactive molecules in the CNS.

In order to assess the ability of prototypical drugs to produce these effects, initial studies often employ measurement of binding affinity with isolated receptors. These experiments are performed *in vitro*, *i.e.*, in an artificial “test tube” system outside of a whole animal or human being.

One measure of the ability of a drug to bind to a specific receptor or transporter molecule is the  $K_i$ , or “equilibrium dissociation constant”. This parameter is defined as the concentration of the drug needed to occupy one-half (50%) of the specific binding sites at equilibrium. The smaller the value of  $K_i$ , the higher the affinity of the drug for the receptor. A general rule among pharmacologists is that  $K_i$  values of 10 nM or less are considered to reflect “high” receptor affinity, while  $K_i$  values of 100 nM or more reflect “low” affinity.  $K_i$  values are often employed in drug development and other biomedical studies to provide some indication of how effectively a drug will (or will not) activate a particular receptor. This may (or may not) be correlated with a specific biologic, pharmacologic, or toxicologic effect.

*In vitro* metrics of biological activity or potency include the EC<sub>50</sub>, or “half-maximal effective concentration” and the IC<sub>50</sub>, or “half-maximal inhibitory concentration”. These are respectively used to express the concentration of a drug required to increase a specific biological activity (*e.g.*, neurotransmitter release) from baseline to 50% of maximum (for drugs acting as “agonists”), and the concentration required to decrease the activity to 50% of baseline (for drugs acting as “antagonists”). As with  $K_i$ , the smaller the value of the EC<sub>50</sub> or IC<sub>50</sub>, the higher the potency of the drug.

There are significant problems with attempting to extrapolate *in vitro* binding or activity data determined for one drug to another untested, but chemically related compound. This is because small structural differences in drug molecules can lead to large changes in transporter or receptor binding affinity, thus potentially leading to major pharmacological differences. Consequently, the appropriate use of such assays is only to indicate which compounds may be considered for further testing.

As it is impossible to predict with confidence how *in vitro* data will translate into

pharmacological effects in living systems, the objective and accurate prediction of drug activity in humans based on *in vitro* data alone is unreliable. Thus, at the very least, a sound and reliable analogue drug scheduling approach should involve assessment of stimulant, depressant, or hallucinogenic effects in animal models, in addition to corroboration from human data. Prong 2 of the statute does, after all, specify that these effects be demonstrated “.... *on the central nervous system...*”, a requirement that cannot be achieved by *in vitro* testing or structure-activity considerations alone.

Animal models have also been employed to help predict possible psychoactive effects of drugs in humans. Such models assess behavioral pharmacology endpoints such as locomotor activity, catalepsy, and drug discrimination responses, in addition to physiological measurements such as body temperature and level of pain sensation. While offering additional data on the potential CNS activity of candidate drugs, these models all suffer from shortcomings when used to predict similar effects in humans, and therefore are best considered suggestive, but not selective, tools.

Pharmacological effects in humans are by their nature nuanced, graded, and variable. A “stimulatory” effect produced by two drugs that, on the surface, appears “similar”, may in fact be due to radically different pharmacological mechanisms. The phrases “pharmacological activity” and “pharmacological effect” are ambiguous and could refer to one of an almost unlimited variety of pharmacological properties. Examples of such properties include binding affinity of drugs to membrane and cytoplasmic receptors, enzymes, transporter molecules, DNA, RNA, or other molecular targets in addition to specific drug effects on liver, renal, CNS, lung, or any of a myriad of specialized cells. Such properties can also refer to functional effects on cognition, physiological parameters such as blood pressure and heart rate, sexual function, appetite, behavior, memory, locomotion, etc.

The bottom line is that Prong 2 of the statute is seriously flawed, in that it sets a standard that cannot be satisfied in the absence of actual human data. *In vitro* and animal models alone are insufficient to predict potential CNS stimulant, depressant, or hallucinogenic effects of novel compounds in humans with a high level of confidence.

## II. Specific Opinions Regarding the Availability of Relevant Scientific Data for Selected Compounds Prior to August, 2012:

**UR-144:** 1-(Pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone; CAS 1199943-44-6. Reported to have  $K_i$  values of 150 and 1.8 nM for CB-1 and CB-2, respectively (Frost, 2010), compared to values for JWH-018 of 9.0 and 2.9 nM for CB-1 and CB-2, respectively (Aung, 2000). **The limited *in vitro* data available for UR-144 are consistent with low potency for CB-1 activation. Therefore, in my opinion they would not have been sufficient to support a conclusion with reasonable certainty that the Prong 2 criteria were satisfied for this compound.**

**XLR-11:** 1-(5-Fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone; CAS 1364933-54-9. No *in vitro*, animal model, or human data available prior to August, 2012. **Therefore, there are no data to support a conclusion with reasonable certainty that the Prong 2 criteria were satisfied for this compound.**

**AM-2201:** 1-(5-Fluoropentyl)-3-(1-naphthoyl)indole; CAS 335161-24-5. Reported to have  $K_i$  values of 1.0 and 2.6 nM for CB-1 and CB-2, respectively (Makryannis, 2001), compared to values for JWH-018 of 9.0 and 2.9 nM for CB-1 and CB-2, respectively (Aung, 2000). EC50 value for stimulation of [<sup>35</sup>S]GTP $\gamma$ S binding to rat brain cortical membranes (a measure of CB-1 receptor activation) of 24.4 nM, compared to 36.0 nM for JWH-018 (Nakajima, 2011). No additional *in vitro*, animal model, or human data available prior to August, 2012. **While the data available for AM-2201 at that time are suggestive, in my opinion they would not have been sufficient to support a conclusion with reasonable certainty that the Prong 2 criteria were satisfied for this compound.**

**JWH-081:** (4-Methoxy-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone; CAS 210179-46-7. Reported to have  $K_i$  values of 1.2 and 12.4 nM for CB-1 and CB-2, respectively, compared to values for JWH-018 of 9.0 and 2.9 nM for CB-1 and CB-2, respectively (Aung 2000). No additional *in vitro*, animal model, or human data available prior to August, 2012. **While the data available for JWH-081 at that time are suggestive, in my opinion they would not have**



**been sufficient to support a conclusion with reasonable certainty that the Prong 2 criteria were satisfied for this compound.**

**JWH-122:** (4-Methyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone; CAS 619294-47-2. Reported to have  $K_i$  values of 0.69 and 1.2 nM for CB-1 and CB-2, respectively (Huffman, 2003), compared to values for JWH-018 of 9.0 and 2.9 nM for CB-1 and CB-2, respectively (Aung, 2000). EC<sub>50</sub> values for stimulation of [<sup>35</sup>S]GTPγS binding to rat brain cortical membranes of 32.9 nM, compared to 36.0 nM for JWH-018 (Nakajima, 2011). No additional *in vitro*, animal model, or human data available prior to August, 2012. **While the data available for JWH-122 at that time are suggestive, in my opinion they would not have been sufficient to support a conclusion with reasonable certainty that the Prong 2 criteria were satisfied for this compound.**

**JWH-203:** 2-(2-Chlorophenyl)-1-(1-pentyl-1H-indol-3-yl)-ethanone; CAS 864445-54-5. Reported to have  $K_i$  values of 8.0 and 7.0 nM for CB-1 and CB-2, respectively (Huffman, 2005b), compared to values for JWH-018 of 9.0 and 2.9 nM for CB-1 and CB-2, respectively (Aung, 2000). ED<sub>50</sub> values of 0.1, 0.3, and 6 nM for decreased spontaneous activity, % maximum possible antinociceptive effect, and decreased rectal temperature in mice (considered to be physiological endpoints associated with CB-1 activation), compared to 0.3, 0.09, and 1.8 for JWH-018 (Wiley, 2012). No additional *in vitro*, animal model, or human data available prior to August, 2012. **The data available for JWH-203 at that time with regard to receptor binding and physiological effect are conflicting. Therefore, in my opinion they would not have been sufficient to support a conclusion with reasonable certainty that the Prong 2 criteria were satisfied for this compound.**

**JWH-210:** (4-Ethyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone; CAS 824959-81-1. Reported to have  $K_i$  values of 0.46 and 0.69 nM for CB-1 and CB-2, respectively (Huffman, 2005b), compared to values for JWH-018 of 9.0 and 2.9 nM for CB-1 and CB-2, respectively (Aung, 2000). EC<sub>50</sub> value for [<sup>35</sup>S]GTPγS binding to rat brain cortical membranes of 20.4 nM, compared to 36.0 nM for JWH-018 (Nakajima, 2011). No additional *in vitro*, animal model, or human data available prior to August, 2012. **While the data available for JWH-122 at that**

time are suggestive, in my opinion they would not have been sufficient to support a conclusion with reasonable certainty that the Prong 2 criteria were satisfied for this compound.

**RCS-4:** (4-Methoxyphenyl)(1-pentyl-1H-indol-3-yl)methanone; CAS 1345966-78-0. EC50 value for stimulation of [<sup>35</sup>S]GTPγS binding to rat brain cortical membranes of 199 nM, compared to 36.0 nM for JWH-018 (Nakajima, 2011). No additional *in vitro*, animal model, or human data available prior to August, 2012. **The limited *in vitro* data available for JWH-203 are consistent with low potency for CB-1 activation. Therefore, in my opinion they would not have been sufficient to support a conclusion with reasonable certainty that the Prong 2 criteria were satisfied for this compound.**

**4-Fluoroamphetamine (4-FA):** 1-(4-Fluorophenyl)propan-2-amine; CAS 459-02-9. Numerous literature reports prior to August, 2012. Reuptake IC50 values of 270, 356, and 2352 nM for dopamine (DA), norepinephrine (NE), and serotonin (5-HT), respectively, compared to 172, 148, and 3769 nM for amphetamine (Marona, 1995). EC50 value for neurotransmitter release of 51.5, 28.0, and 939 nM for DA, NE, 5-HT, respectively, compared to 8.0, 7.2, and 1756 nM for amphetamine (Wee, 2005). Synaptosome release EC50 values of 200, 730, and 370 nM for DA, NE, 5-HT, respectively, compared to 28, 790, and 11 nM for methamphetamine. Reuptake IC50 values for DA, NE, 5-HT, respectively, of 770, 6800, and 420 nM, compared to 370, 4000, and 200 nM for methamphetamine (Nagai, 2007). **The data available for 4-FA at that time with regard to *in vitro* endpoints are conflicting. Therefore, in my opinion they would not have been sufficient to support a conclusion with reasonable certainty that the Prong 2 criteria were satisfied for this compound.**

**5-MeO-DALT:** N-Allyl-N-[2-(5-methoxy-1H-indol-3-yl)ethyl]prop-2-en-1-amine; CAS 928822-98-4). EC50 value of 660 nM for stimulation of [<sup>35</sup>S]GTPγS binding to brain cortical membranes, compared to 49 nM for serotonin (Nonaka, 2007). No additional *in vitro*, animal model, or human data available prior to August, 2012. **The limited *in vitro* data available for 5-MeO-DALT are consistent with low potency for monoamine receptor activation. Therefore, in my opinion they would not have been sufficient to support a conclusion with**

reasonable certainty that the Prong 2 criteria were satisfied for this compound.

**5-MeO-DiPT (“Foxy”):** 3-[2-(Diisopropylamino)ethyl]-5-methoxyindole; CAS 4021-34-5.  
DEA Schedule I since 2004.

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