APPENDIX

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874 F.3d 1037
United States Court of Appeals,
Ninth Circuit.

UNITED STATES of America, Plaintiff-Appellee,
v.
Micah Joel Ahkeem Iverson KELLY, AKA Iverson Kelly Micah Johel Ahkeem, Defendant-Appellant.

No. 16-10460
|
Argued and Submitted September 15, 2017 San Francisco, California
|
Filed October 30, 2017

Synopsis

Background: Defendant entered a plea of guilty to possession with the intent to sell over 446 grams of ethylone, a form of Ecstasy, after his motion to dismiss the indictment was denied by the United States District Court for the District of Nevada, Gloria M. Navarro, Chief Judge, 2016 WL 3769339, on the recommendation of the United States District Court for the District of Nevada, Nancy J. Koppe, United States Magistrate Judge, 2016 WL 8732182. Defendant appealed.

Holdings: The United States Court of Appeals, Richard C. Tallman, Circuit Judge, held that:

[1] Drug Enforcement Agency (DEA) did not violate the non-delegation doctrine in temporarily scheduling the isomers of butylone;

[2] defendant had constructive public notice that distributing Ecstasy in the form of ethylone could result in criminal sanctions;

[3] rule of lenity did not apply to defendant; and

[4] DEA's interpretation of the Controlled Substances Act was properly accorded *Chevron* deference.

Affirmed in part, dismissed in part.

***1041** Appeal from the United States District Court for the District of Nevada, Gloria M. Navarro, Chief District Judge, Presiding, D.C. No. 2:15-cr-00041-GMN-NJK-1

Attorneys and Law Firms

Erica J. Choi (argued), Assistant Federal Public Defender; Rene L. Vallardes, Federal Public Defender; Office of the Federal Public Defender, Las Vegas, Nevada; for Defendant-Appellant.

Nancy M. Olson (argued), Assistant United States Attorney; Elizabeth O. White, Appellate Chief; Steven W. Myhre, Acting United States Attorney; United States Attorney's Office, Las Vegas, Nevada; for Plaintiff-Appellee.

Before: Ronald M. Gould, Richard C. Tallman, and Paul J. Watford, Circuit Judges.

OPINION

TALLMAN, Circuit Judge:

Defendant-Appellant Micah Joel Ahkeem Iverson Kelly ("Kelly") challenges the district court's denial of his motion to dismiss the indictment charging him with distributing so-called "designer drugs." Kelly entered a conditional plea of guilty to selling and possessing with the intent to sell over 446 grams of ethylone under the street name "Ecstasy." On appeal, Kelly argues he preserved the following issues: (1) the Drug Enforcement Administration ("DEA") violated the non-delegation doctrine by failing to comply with the Controlled Substances Act, as codified at 21 U.S.C. §§ 811(h) and 812(b) in temporarily scheduling ethylone; (2) DEA violated due process by failing to provide adequate notice that ethylone was a controlled substance; ***1042** (3) the rule of lenity applies because § 811(h) is ambiguous as to whether DEA may temporarily schedule unnamed isomers; (4) DEA's temporary scheduling of ethylone is not entitled to deference under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984); and (5) the district court erred in finding that his criminal history category was V, instead of IV, in violation of the Sentencing Guidelines. We have jurisdiction under 28 U.S.C. § 1291 and we affirm as to the first four issues and dismiss as to the last, which we find barred by his partial appellate waiver.

I

[1] [2]Congress enacted the Controlled Substances Act ("CSA") as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970 to restrict the illegal trafficking of various substances found to pose a danger to the health and general welfare of the nation. Pub. L. No. 91-513, § 101(2), 84 Stat. 1242 (codified at 21 U.S.C. § 801(2)).[1] The CSA makes it unlawful to knowingly manufacture, distribute, or possess any controlled substance except in a manner authorized by the CSA. §§ 841(a)(1), 844(a). The CSA categorizes all controlled substances into five schedules. § 812.[2] The initial schedules established by Congress are found at 21 U.S.C. § 812(c), and the current schedules are published in 21 C.F.R. Part 1308. "Violations involving schedule I substances carry the most severe penalties, as these substances are believed to pose the most serious threat to public safety." *Touby v. United States*, 500 U.S. 160, 162, 111 S.Ct. 1752, 114 L.Ed.2d 219 (1991).

1 All further statutory and regulatory citations are to Title 21 of the United States Code and Title 21 of the Code of Federal Regulations, unless otherwise noted.

2 A controlled substance is "a drug or other substance" that is included in Schedule I, II, III, IV, or V. § 802(6). "Control" is a term of art in the CSA, meaning "to add a drug or other substance ... to a schedule." § 802(5).

[3] [4]The CSA authorizes the Attorney General to add, remove, or transfer substances to, from, or between schedules. § 811. The Attorney General has delegated this authority to the Administrator of the DEA, who in turn has delegated it to the Deputy Administrator. 28 C.F.R. § 0.100(b). "When adding a substance to a schedule, the [DEA] must follow specified procedures." *Touby*, 500 U.S. at 162, 111 S.Ct. 1752. The DEA may add a drug to a schedule in one of two ways: permanently or temporarily.

A

To permanently schedule a drug, the DEA first must obtain a scientific and medical evaluation of the drug and a recommendation as to whether it should be controlled from the Secretary of Health and Human Services ("HHS"). § 811(b). The DEA may not schedule the drug if the Secretary recommends against it. *Id.* Second, the DEA must consider eight statutory factors, including the drug's actual or relative potential for abuse, scientific evidence of its pharmacological effect, the state of current scientific knowledge regarding the drug, the drug's psychic or physiological dependence liability, and whether it is an immediate precursor of a drug that is already controlled. § 811(c).

If the DEA wants to place the drug into Schedule I, it must also find that the drug has a high potential for abuse, no currently accepted medical use in treatment, and no accepted safe use under medical supervision. ***1043** § 812(b)(1).[3] The DEA must then comply with the formal rulemaking provisions of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 556–57. § 811(a). Lastly, it must issue a final rule adding the drug to 21 C.F.R. § 1308.11, which contains the current list of Schedule I substances. *Id.* This final rule, which concludes the permanent scheduling process, is subject to judicial review. § 877.

3 These three factors, in varying gradations, are used to categorize drugs into the other four schedules. For example, Schedule II drugs have a high potential for abuse, but they have a currently accepted medical use. § 812(b)(2).

Because of these procedural requirements, it often takes six to twelve months for the DEA to permanently schedule a new drug after the DEA identifies it. *Touby*, 500 U.S. at 163, 111 S.Ct. 1752. This delay produced predictable results. "Drug traffickers were able to take advantage of this time gap by designing drugs that were similar in pharmacological effect to scheduled substances but differed slightly in chemical composition, so that existing schedules did not apply to them." *Id.* "These 'designer drugs' were developed and widely marketed long before the Government was able to schedule them and initiate prosecutions." *Id.*

B

[5]To combat the designer drug problem and reduce the inherent regulatory delay, Congress amended the CSA in 1984 to create an expedited procedure by which the DEA can temporarily schedule a new drug 30 days after identifying it if doing so is "necessary to avoid an imminent hazard to the public safety." § 811(h)(1); *see Touby*, 500 U.S. at 163, 111 S.Ct. 1752. A temporarily scheduled drug may only be placed into Schedule I, and only if the Secretary has not approved it for sale or

exempted it for research under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355. *Id.* Temporary scheduling under § 811(h) allows the DEA "to bypass, for a limited time, several of the requirements for permanent scheduling." *Touby*, 500 U.S. at 163, 111 S.Ct. 1752.

To find that a drug poses an imminent hazard to public safety justifying temporary scheduling, the DEA must consider only three of the eight factors required for permanent scheduling: (1) the drug's history and current pattern of abuse; (2) the scope, duration, and significance of the abuse; and (3) what, if any, risk it poses to the public health. § 811(c)(4)–(6), (h)(3). In considering these factors, the DEA must consider the drug's "actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution." § 811(h)(3). In addition, the DEA must find that it has a high potential for abuse, no currently accepted medical use in treatment, and no accepted safe use under medical supervision. § 812(b)(1).

[6]Rather than comply with the APA formal rulemaking provisions attending permanent scheduling, the DEA must provide only 30-days' notice of the proposed temporary scheduling in the Federal Register. § 811(h)(1)(A). The DEA must also transmit to the Secretary a 30-days' notice of its intent to temporarily schedule the drug, and it must consider any comments the Secretary submits in response. § 811(h)(1)(B), (h)(4). However, unlike permanent scheduling, the Secretary's prior approval of the temporary scheduling is not required. *Touby*, 500 U.S. at 163, 111 S.Ct. 1752. Lastly, the DEA must issue a final order adding the drug to 21 C.F.R. § 1308.11(h). § 811(h)(1). The temporary scheduling order remains valid for two years, during which time the DEA presumably will initiate permanent scheduling ***1044** proceedings, in which case the order may be extended for an additional year. § 811(h)(2). A temporary scheduling order is not subject to judicial review, except (as here) when challenged by a criminal defendant in defense to prosecution. § 811(h)(6); *Touby*, 500 U.S. at 168, 111 S.Ct. 1752.

If the drug is later permanently scheduled, it is removed from § 1308.11(h) and added to § 1308.11(b)–(g), depending on whether it is designated as an opiate, opium derivative, hallucinogenic substance, depressant, stimulant, or cannabimimetic agent. *See* § 811(h)(5).

C

On November 7, 2013, the DEA notified the Secretary by letter of its intent to temporarily schedule ten synthetic cathinones, including butylone, because doing so was necessary to avoid an imminent hazard to the public safety. Synthetic cathinones are recreational drugs popular with some youth and young adults in the United States. They produce pharmacological effects substantially similar to MDMA, cathinone, methcathinone, amphetamine, and methamphetamine. Synthetic cathinones are commonly marketed on the street as "Ecstasy" or "bath salts," sold in the form of tablets and powders, and ingested by swallowing or snorting.

The DEA's letter to the Secretary did not mention the ten synthetic cathinones' isomers[4] or salts. On December 4, 2013, the Secretary advised the DEA that there were no investigational or approved new drug applications for the ten synthetic cathinones and that HHS had no objection to their temporary placement in Schedule I. On January 28, 2014, the DEA published in the Federal Register a Notice of its intent to temporarily schedule the ten synthetic cathinones, along with their "optical, positional, and geometric isomers, salts and salts of isomers." On March 7, 2014, the DEA issued a final Order temporarily adding the ten synthetic cathinones to Schedule I at § 1308.11(h)(19)–(28). As relevant here, the Order temporarily added "[b]utylone, its optical, positional, and geometric isomers, salts and salts of isomers" to Schedule I at § 1308.11(h)(22).[5]

4 An isomer is "any of two or more chemical compounds having the same constituent elements in the same proportion by weight but differing in physical or chemical properties because of differences in the structures of their molecules." *Isomer*, Webster's New College Dictionary (2009).

5 Three years later, after the events in this case, the DEA issued a final Rule permanently scheduling the ten synthetic cathinones. *See* 82 Fed. Reg. 12171 (Mar. 1, 2017) (codified at 21 C.F.R. § 1308.11(d)(59)–(68)). Currently, butylone and its optical, positional, and geometric isomers, salts, and salts of isomers are designated as Schedule I(c) hallucinogenic substances listed in the regulations at § 1308.11(d)(62).

II

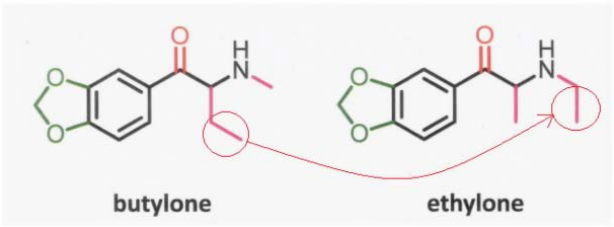
APP 3

A

In January 2015, a Nevada drug task force learned that Kelly was selling large quantities of MDMA[6], or "Ecstasy," in the Las Vegas area. An undercover officer arranged to purchase the MDMA from Kelly, and Kelly sold approximately 140 grams of powder to the officer in two separate transactions. During the third transaction, Kelly was arrested possessing another 306 grams. Forensic analysis later revealed that the powder was ethylone, not MDMA. A grand jury indicted Kelly on ***1045** three counts of distributing and possessing with intent to distribute "Ethylone, a Schedule I controlled substance," in violation of 21 U.S.C. § 841(a)(1) and (b)(1)(C).

6 "*3, 4-methylenedioxy-methamphetamine* (MDMA) is a synthetic drug that alters mood and perception." National Institute on Drug Abuse, *What is MDMA?*, https://www.drugabuse.gov/publications/drugfacts/mdma-ecstasymolly (last visited Oct. 6, 2017).

It is undisputed here that ethylone is a positional isomer of butylone. An isomer is a molecule with the same chemical formula as another molecule, but its atoms are arranged in a different sequence. For example, butylone and ethylone share the chemical formula $C_{12}H_{15}NO_3$, but they differ in the location of a functional group:



Based on how the atoms are arranged, isomers can be classified as chain, functional, positional, conformational, optical, or geometric. *See A Brief Guide to Types of Isomerism in Organic Chemistry*, http://www.compoundchem.com/2014/05/22/typesofisomerism/ (last visited July 24, 2017). Not all isomers of a scheduled drug are illegal, however. Thus, Schedule I categorically controls all permanently scheduled drugs' *optical* isomers only. An exception exists if the permanently scheduled drug is a hallucinogenic substance listed in § 1308.11(d), in which case Schedule I categorically controls its *optical*, *positional*, and *geometric* isomers. *See* §§ 802(14), 812(c)(I); 21 C.F.R. § 1300.01(b). Permanently scheduled hallucinogenic substances are called "Schedule I(c)" drugs, which refers to the initial statutory schedule in which they are placed. § 812(c)(I)(C).

B

On the morning that his trial was set to begin, Kelly moved to dismiss the indictment on the ground that ethylone was not a Schedule I controlled substance. He did not contest for purposes of his motion, and does not contest on appeal, that ethylone is a positional isomer of butylone. He argued, however, that ethylone was not properly scheduled because (1) the DEA failed to comply with §§ 811(h) and 812(b)'s procedural requirements; (2) the DEA did not provide adequate notice that ethylone was a controlled substance; (3) § 811(h) was ambiguous as to whether the DEA was authorized to temporarily schedule unnamed isomers without identifying or making the requisite findings for them, and the rule of lenity required the court to resolve that ambiguity in Kelly's favor; and (4) the DEA's temporary scheduling of ethylone was arbitrary and capricious.

A magistrate judge issued a report and recommendation denying Kelly's motion, which the district court adopted in full. The district court found that § 811(h) unambiguously authorized the DEA to schedule unnamed isomers. It declined to apply the rule of lenity because the DEA's Order was not a criminal statute, but rather an administrative regulation that was entitled to *Chevron* deference. Applying *Chevron*, the court upheld the DEA's Order because (1) § 811(h) was unambiguous that the DEA could schedule ethylone as an unnamed positional isomer of butylone; and (2) the DEA's action was not arbitrary or ***1046** capricious. Lastly, the court found that Kelly had adequate notice that ethylone was a controlled substance because the DEA's Notice and Order expressly included butylone's "optical, positional, and geometric isomers."[7]

7 The district court also denied Kelly's request for an evidentiary hearing to present expert testimony that "a substance's isomer does not necessarily have the same effects and properties as the substance itself." The court held that such a hearing was not necessary because it was sufficient, for purposes of the motion to dismiss, that Kelly agreed ethylone was a positional isomer of butylone.

C

After his motion to dismiss was denied, Kelly pleaded guilty to all three counts in the indictment under a conditional plea agreement that reserved his right to bring this appeal of the district court's denial of his motion to dismiss. In support of his guilty plea, Kelly admitted to selling and possessing with the intent to sell over 446 grams of ethylone. He also agreed that the district court would determine his criminal history category under the Sentencing Guidelines. He stipulated to a recommended sentence of 57 months "so long as the Criminal History Category [was] IV or less." If the "Criminal History Category [was] V or greater," he stipulated that his recommended sentence would be at the "low-end of the Sentencing Guidelines range determined by the Court." In addition, Kelly expressly waived his "right to appeal any sentence imposed within or below the applicable Sentencing Guideline range as determined by the Court," as well as "the manner in which the Court determined that sentence."

At sentencing, the district court adopted the Presentence Report, found a criminal history category of V, and sentenced Kelly to 70 months' imprisonment at the low end of his applicable Guidelines range. After judgment was entered, Kelly timely appealed the denial of his motion to dismiss the indictment and his sentence.

III

[7] [8] [9] [10]We have jurisdiction under 28 U.S.C. § 1291. "We review the sufficiency of an indictment de novo." *United States v. Kaplan*, 836 F.3d 1199, 1216 (9th Cir. 2016). "We review de novo a district court's decision whether to dismiss a charge in an indictment based on its interpretation of a federal statute." *United States v. Olander*, 572 F.3d 764, 766 (9th Cir. 2009). We review de novo both an "agency's interpretation or application of a statute," *Snoqualmie Indian Tribe v. FERC*, 545 F.3d 1207, 1212 (9th Cir. 2008), and the constitutionality of an agency's regulation, *see Gonzalez v. Metro. Transp. Auth.*, 174 F.3d 1016, 1018 (9th Cir. 1999). And we review de novo whether a defendant has waived his appeal rights pursuant to a plea agreement. *United States v. Lightfoot*, 626 F.3d 1092, 1094 (9th Cir. 2010).

IV

[11] [12]Federal Rule of Criminal Procedure 12(b) allows a defendant to file a pretrial motion to dismiss an indictment for failure to state an offense if the motion "can be determined without a trial on the merits." Fed. R. Crim. P. 12(b)(3)(B)(v). "A motion to dismiss is generally capable of determination before trial if it involves questions of law rather than fact." *United States v. Nukida*, 8 F.3d 665, 669 (9th Cir. 1993) (quotations omitted). Because Kelly's challenges to the indictment are based on legal issues and he does not dispute that ethylone is a positional isomer of butylone, we may resolve the issues here without intruding upon the "province of the ultimate ***1047** finder of fact." *Id.* (quotation omitted); *see United States v. Covington*, 395 U.S. 57, 60, 89 S.Ct. 1559, 23 L.Ed.2d 94 (1969). In determining whether an indictment charges a cognizable offense, we are bound by the four corners of the indictment, must accept the truth of the allegations in the indictment, and cannot consider evidence that does not appear on the face of the indictment. *United States v. Lyle*, 742 F.3d 434, 436 (9th Cir. 2014); *United States v. Jensen*, 93 F.3d 667, 669 (9th Cir. 1996).

A

[13]Kelly argues that the DEA did not place ethylone into Schedule I as a matter of law because §§ 811(h) and 812(b) require that the DEA name and make findings for each individual isomer it intends to temporarily schedule. He contends that the DEA's failure to do so violated the Constitution's non-delegation doctrine. Kelly's argument is a misreading of the CSA. The plain language of the statute permits the DEA to make findings for a parent substance as a basis to temporarily schedule that substance and its isomers. The DEA properly made findings for butylone and provided notice covering butylone and its isomers as required by §§ 811(h) and 812(b). In following the congressional mandate, we hold the DEA did not violate the non-delegation doctrine.

[14] [15]The Constitution states that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." U.S. Const., art. I, § 1. The non-delegation doctrine provides that "Congress may not constitutionally delegate its legislative power to another branch of Government." *Touby*, 500 U.S. at 165, 111 S.Ct. 1752. "It is clear that in [§ 811(h)] and [§ 812(b)] Congress has placed multiple specific restrictions on the [DEA]'s discretion to define criminal conduct." *Id.* at 167, 111 S.Ct. 1752. "These restrictions satisfy the constitutional requirements of the nondelegation doctrine." *Id.*

Section 812(b) prohibits any substance from being placed into Schedule I unless the DEA finds that it has (1) a high

potential for abuse, (2) no currently accepted medical use in treatment, and (3) no accepted safe use under medical supervision. § 812(b)(1). Section 811(h) requires that, to temporarily schedule a drug, the DEA must consider (4) the history and current pattern of the drug's abuse, (5) the scope, duration, and significance of the abuse, and (6) what risk, if any, the drug poses to the public health. § 811(c)(4)–(6), (h)(3). In doing so, the DEA "shall be required to consider" the drug's "actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution." § 811(h)(3).

The DEA must consider these factors "with respect to each drug or other substance proposed to be controlled." § 811(c). The effect of scheduling a substance in Schedule I(c) includes:

> Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the [parent] hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation[.]

21 U.S.C. § 812, Schedule I(c). Under this section, if the required findings are made for a parent hallucinogenic substance, then the scheduling also includes its isomers. 21 U.S.C. § 812, Schedule I(c); 21 C.F.R. § 1308.11(d). Substances are temporarily scheduled under Schedule I. § 811(h)(1). As it did for butylone, if the DEA makes findings for the parent hallucinogenic substance, ***1048** that substance's isomers may be included in the emergency scheduling. Once the findings have been made, the DEA may not issue an order temporarily scheduling a drug without publishing in the Federal Register a 30-day notice of its intent "to issue such [an] order and the *grounds* upon which such order is to be issued." § 811(h)(1)(A) (emphasis added).

The DEA did not violate the non-delegation doctrine when it temporarily scheduled ethylone. The agency made specific findings as to the parent drug, butylone. For example, the Notice and Order found that the ten synthetic cathinones "can cause acute health problems leading to emergency department admissions, violent behaviors causing harm to self or others, or death." The DEA also found that "the possibility of death for individuals abusing [the ten synthetic cathinones] indicates that these substances are serious public health threats," and it provided examples of two individuals who died after ingesting butylone or a mixture containing butylone and another controlled substance. Although Kelly contends otherwise, the DEA was not required to make specific findings for every isomer of butylone. The findings for butylone are sufficient to satisfy the requirements for temporary listing under § 811(h) because under Schedule I findings regarding the parent substance are sufficient to justify the scheduling of its isomers.

Thus, by complying with §§ 811(h) and 812(b)'s "specific restrictions on [its] discretion to define criminal conduct," the DEA's temporary scheduling of ethylone did not amount to an exercise of legislative power in violation of the non-delegation doctrine. *Touby*, 500 U.S. at 167, 111 S.Ct. 1752; *see also Gonzales v. Oregon*, 546 U.S. 243, 259–60, 126 S.Ct. 904, 163 L.Ed.2d 748 (2006) (recognizing that the CSA gives the DEA "limited powers, to be exercised in specific ways," that "[t]o exercise [its] scheduling power, the [DEA] must follow a detailed set of procedures," and that the CSA is "specific as to the manner in which the [DEA] must exercise this authority"); *Chrysler Corp. v. Brown*, 441 U.S. 281, 303, 99 S.Ct. 1705, 60 L.Ed.2d 208 (1979) ("[A]gency discretion is limited not only by substantive, statutory grants of authority, but also by the procedural requirements which assure fairness and mature consideration of rules of general application." (quotation omitted)). The DEA properly exercised its limited powers as defined by Congress to temporarily list butylone and its isomers, including ethylone.

B

[16] [17] [18]When the DEA filed the Notice and Order in the Federal Register, Kelly received fair notice that ethylone was a controlled substance. The Fifth Amendment provides that "[n]o person shall ... be deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V. "It is a basic principle of due process" that the law must provide a "person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly." *Grayned v. City of Rockford*, 408 U.S. 104, 108, 92 S.Ct. 2294, 33 L.Ed.2d 222 (1972). Due process "mandate[s] that no individual be forced to speculate, at peril of indictment, whether his conduct is prohibited." *Dunn v. United States*, 442 U.S. 100, 112, 99 S.Ct. 2190, 60 L.Ed.2d 743 (1979); *see also Lanzetta v. State of New Jersey*, 306 U.S. 451, 453, 59 S.Ct. 618, 83 L.Ed. 888 (1939) ("All are entitled to be informed as to what the State commands or

forbids."). To that end, "the terms of a penal statute creating a new offense must be sufficiently explicit to inform those who are subject to it what conduct on their part will render them liable to its penalties." *Lanzetta*, 306 U.S. at 453, 59 S.Ct. 618 (quotation omitted). ***1049** "Congress has provided that proper publication in the Federal Register shall act as constructive notice to all of those affected by the regulation in question." *United States v. Wilhoit*, 920 F.2d 9, 10 (9th Cir. 1990) (citing 44 U.S.C. § 1507).

[19]Kelly had notice through the DEA's temporary scheduling of butylone and its isomers that his drug-selling conduct was forbidden. The agency fully complied with its statutory authority granted by Congress to address this emergency prompted by synthetic compounds like Ecstasy, which endanger the public. Here, the DEA's Order stated that "[a]s a result of this order, the ... criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities, and possess) ... [the ten] synthetic cathinones." Further, under the heading "Criminal Liability," it warned that "[a]ny activity involving [the ten synthetic cathinones] not authorized by, or in violation of the CSA, occurring as of March 7, 2014, is unlawful, and may subject the person to ... criminal sanctions." More specifically, the Order advised that "[b]utylone, its optical, positional, and geometric isomers, salts and salts of isomers," were temporarily scheduled under Schedule I. The DEA's Notice contained substantially similar language.

Through the Federal Register, Kelly had public notice that distributing Ecstasy in the form of ethylone could result in criminal sanctions. *See Wilhoit*, 920 F.2d at 10.

C

[20] [21]The rule of lenity does not apply to Kelly's case. "The rule of lenity requires ambiguous criminal laws to be interpreted in favor of the defendants subjected to them." *United States v. Santos*, 553 U.S. 507, 514, 128 S.Ct. 2020, 170 L.Ed.2d 912 (2008) (plurality opinion). It derives from the fundamental principle that "no man shall be held criminally responsible for conduct which he could not reasonably understand to be proscribed." *United States v. Harriss*, 347 U.S. 612, 617, 74 S.Ct. 808, 98 L.Ed. 989 (1954).

[22] [23]The rule of lenity "only applies if, after considering text, structure, history, and purpose, there remains a grievous ambiguity or uncertainty in the statute such that the Court must simply guess as to what Congress intended." *Barber v. Thomas*, 560 U.S. 474, 488, 130 S.Ct. 2499, 177 L.Ed.2d 1 (2010) (citation and quotations omitted). "In these circumstances—where text, structure, and history fail to establish that the Government's position is *unambiguously* correct—we apply the rule of lenity and resolve the ambiguity in [the defendant's] favor." *United States v. Granderson*, 511 U.S. 39, 54, 114 S.Ct. 1259, 127 L.Ed.2d 611 (1994); *People v. Materne*, 72 F.3d 103, 106 (9th Cir. 1995) ("Only where the defendant's interpretation is unreasonable does the rule of lenity not apply.").

[24]The text, history and purpose of the CSA paint a clear picture that Congress intended to empower the DEA to temporarily schedule isomers. The plain language of §§ 811 and 812 discusses isomers and their scheduling in conjunction with the parent substances. The CSA defines an isomer for Schedule I(c) under § 802(14). The regulations further clarify what an isomer is under 21 C.F.R. § 1300.01(b). These definitions refer to Schedule I generally and do not purport to limit isomers to the DEA's permanent scheduling authority. In addition, when the DEA schedules a parent substance under Schedule I(c), unless otherwise prohibited, that scheduling also includes its isomers. § 812 Schedule I(c). The plain language of ***1050** the CSA clearly contemplates the scheduling of isomers under both the temporary and permanent scheduling authority.

History also demonstrates that isomers can be temporarily listed. In 2000 Congress ordered the DEA to temporarily list the performance enhancing drug "GHB" "together with its ... isomers" in the same way that the DEA always does under § 811(h), confirming its approval of the DEA's actions. *See* Pub. L. No. 106-172, § 3(a), 114 Stat. 7, 8 (Feb. 18, 2000). Dozens of drugs have been temporarily listed with their isomers since 1984, and 16 are listed now. 21 C.F.R. § 1308.11(h).

[25]Finally, the purpose of the DEA's temporary scheduling power is to stop dangerous designer drugs as they are developed. The 1984 amendments giving the DEA the temporary scheduling power clarified the definition of "isomer" to avoid the "isomer defense"—when clever drug designers switch an isomer in an effort to avoid prosecution. S. Rep. No. 98-225, at 263 (1983). Congress sought to avoid "clandestine manufacturers [attempting] to circumvent the law by manufacturing positional and geometric isomers of hallucinogens in schedule I." *Id.* Congress unambiguously granted the temporary scheduling authority to prohibit conduct, like Kelly's, of distributing dangerous

substances that have yet to be permanently listed. If the DEA could not temporarily schedule isomers of parent substances, the entire emergency scheduling scheme would collapse. The DEA would be in a never-ending inquiry to temporarily schedule every single isomer and make findings on every chemical variation of a dangerous drug. It is highly unlikely the agency could keep up with the pace of clandestine drug manufacturers.

The plain language, history, and purpose of temporary scheduling authority make congressional intent clear. The rule of lenity only applies to "ambiguous criminal laws." *Santos*, 553 U.S. at 514, 128 S.Ct. 2020. There is no ambiguity here.[8]

[8] Kelly argues the rule of lenity trumps the deference we give to the agency under *Chevron*. *Mujahid v. Daniels*, 413 F.3d 991, 999 (9th Cir. 2005) (the Supreme Court has not "address[ed] when the rule of lenity takes priority over *Chevron* deference."). As we find that the rule of lenity does not apply, we do not address this argument.

D

The DEA's decision to temporarily schedule ethylone was authorized pursuant to its temporary scheduling power and a clear directive from Congress. The district court properly found the DEA's temporary scheduling authorized at *Chevron* step one.

[26] [27] [28]*Chevron* sets forth a two-step test for reviewing an agency's interpretation of a federal statute. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–44, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). Under *Chevron* step one, the court must determine "whether Congress has directly spoken to the precise question at issue." *Id.* at 842, 104 S.Ct. 2778. "If the intent of Congress is clear, that is the end of the matter," and the court "must give effect to the unambiguously expressed intent of Congress." *Id.* at 842–43, 104 S.Ct. 2778. However, "if the statute is silent or ambiguous with respect to the specific issue," the court must proceed to the second *Chevron* step. *Id.* at 843, 104 S.Ct. 2778. Under *Chevron* step two, the court must uphold the agency's interpretation unless it is "arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 844, 104 S.Ct. 2778.

[29]The plain language of the CSA evinces Congress' intent to permit the DEA to temporarily schedule a parent ***1051** substance and its isomers, such as butylone and ethylone. First, under the permanent scheduling authority, if the drug is in a subcategory of Schedule I (*a* through *c*) then the DEA is only required to make findings regarding the "parent" substance and then permits the scheduling of the isomers of that parent. § 812 Schedule I(c). In conjunction with this authority, the statute defines isomers: "[a]s used in schedule I(c), the term 'isomer' means any optical, positional, or geometric isomer." 21 U.S.C. § 802(14). In defining and discussing isomers the CSA does not confine them to permanent scheduling, rather this applies to the DEA's overall scheduling authority, permanent and temporary. Congress was contemplating the scheduling of isomers throughout the CSA, not only in their permanent scheduling.

The temporary scheduling authority is broader and more efficient than permanent scheduling. The temporary authority is intended to permit the DEA to react quickly to new drugs on the market that present a threat to human health. S. Rep. No. 98-225, at 263–64 (1983). In order to properly address this threat, Congress gave the DEA the power to schedule threatening substances more efficiently, but only for a two-year period. § 811(h)(2). The agency need only make three findings in order to temporarily schedule a substance, which makes it less burdensome to quickly schedule dangerous substances. § 811(h)(3). Congress granted this broad authority to schedule drugs and their isomers to expedite the scheduling process to avoid limiting law enforcement actions against traffickers and creating a "serious health problem." S. Rep. No. 98-225, at 264 (1983).

The intent of Congress is clear that the DEA has authority to temporarily schedule a parent substance and its isomers. Our inquiry ends at the first step of *Chevron*, 467 U.S. at 842, 104 S.Ct. 2778. The district court properly accorded *Chevron* deference to the agency interpretation.

E

[30] [31]Kelly's plea agreement clearly and unambiguously waived his right to appeal the very sentencing issue he raises here. Kelly does not contend that his waiver of this right was unknowing or involuntary. *See United States v. Speelman*, 431 F.3d 1226, 1229 (9th Cir. 2005); *see also United States v. Arzate-Nunez*, 18 F.3d 730, 737 (9th Cir. 1994) ("A defendant who enters a conditional guilty plea ... must state in writing any issues he wishes to reserve for appeal and may lose the right to appeal issues not so expressly reserved.").[9] As Kelly fails to argue that his unambiguous waiver of his right to appeal was

involuntary, the plea agreement controls on this issue and we hold his sentencing challenge was waived.

[9] Kelly also argues, for the first time in his reply brief, that he is released from his appeal waiver because the Government breached the plea agreement. We decline to consider this argument because Kelly waived it by failing to raise it in his opening brief. *See United States v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1020 (9th Cir. 1999).

V

We affirm the district court's denial of Kelly's motion to dismiss the indictment; affirm Kelly's conviction; and dismiss Kelly's challenge to the district court's criminal history category calculation and resulting 70-month sentence.

AFFIRMED in part, DISMISSED in part.

All Citations

874 F.3d 1037, 17 Cal. Daily Op. Serv. 10,445, 2017 Daily Journal D.A.R. 10,373

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UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, Plaintiff-Appellee, v. MICAH JOEL AHKEEM IVERSON KELLY, AKA Iverson Kelly Micah Johel Ahkeem, Defendant-Appellant.	No. 16-10460 D.C. No. 2:15-cr-00041-GMN-NJK-1 District of Nevada, Las Vegas ORDER

Before: GOULD, TALLMAN, and WATFORD, Circuit Judges.

The panel has voted to deny the petition for rehearing en banc.

The full court has been advised of the petition for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for rehearing en banc is DENIED.

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

UNITED STATES OF AMERICA, Plaintiff, vs. MICAH JOEL AHKEEM IVERSON KELLY, Defendant.	Case No.: 2:15-cr-0041-GMN-NJK **ORDER**

Pending before the Court is the Report and Recommendation (the "R&R") (ECF No. 84) entered by Magistrate Judge Nancy J. Koppe on April 15, 2016, denying Defendant Micah Joel Ahkeem Iverson Kelly's ("Defendant's") Motion to Dismiss (ECF No. 65). Defendant timely filed his Objection. (ECF No. 89). The Government filed a Response agreeing with the R&R without any additional argument and "rel[ying] upon its previously filed pleadings, responses and replies." (ECF No. 92).

I. BACKGROUND

On February 24, 2015, an Indictment was entered charging Defendant with two counts of Distribution of a Controlled Substance – Ethylone, in violation of 21 U.S.C. §§ 841(a)(1) and (b)(1)(C), and one count of Possession of a Controlled Substance with Intent to Distribute – Ethylone, in violation of 21 U.S.C. §§ 841(a)(1) and (b)(1)(C). (ECF No. 10). Ethylone is defined in the Indictment as "a Schedule I controlled substance." (*Id.*).

Judge Koppe's R&R thoroughly explains the arguments provided by each party regarding Defendant's Motion to Dismiss, and the Court incorporates that explanation by reference here. (*See* R&R 4:9–8:14, ECF No. 84). Essentially, in his Motion to Dismiss, Defendant seeks to dismiss the Indictment with prejudice because the Drug Enforcement

APP 11

Administration (the "DEA") failed to "follow statutorily mandated procedures when it attempted to schedule ethylone as a Schedule I controlled substance." (Mot. to Dismiss 1:17–20, ECF No. 65). Defendant argues that the DEA did not consider or make the necessary findings regarding "the statutory factors required to permit ethylone's scheduling." (*Id.* 3:7–8). Further, he asserts that the DEA failed to provide proper notice to the Department of Health and Human Services, and the DEA's "notice and order in the Federal Register were insufficient to schedule ethylone." (*Id.* 3:8–12). Defendant also contends that the DEA acted in an arbitrary and capricious manner by doing "absolutely nothing to research or analyze any of the required factors to temporarily schedule ethylone." (*Id.* 21:21–23).

Moreover, in his Reply,[1] Defendant responds to the Government's application of *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984). First, Defendant argues that *Chevron* does not apply to this case because "*Chevron* deference only extends to agency interpretations of regulatory statutes, not to criminal statutes administered by courts." (Reply 2:8–9, ECF No. 78). If *Chevron* applies, however, Defendant urges the Court to find the Controlled Substances Act (the "CSA") to be "ambiguous as to which subsection of schedule I butylone belongs and which isomers of butylone are scheduled." (*Id.* 18:4–5). Defendant then argues that the Court should apply the rule of lenity to resolve that ambiguity in his favor. (*Id.* 5:5–9:26).

In the R&R, Judge Koppe rejected these arguments and recommended denial of the Motion. (R&R 5:12–28). More specifically, Judge Koppe found that *Chevron* applies here, and "the intent of Congress is clear . . . [t]he CSA clearly includes isomers." (*Id.* 10:3, 10:25–26). Judge Koppe then determined that the DEA properly temporarily scheduled ethylone, and "the

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[1] District courts may disregard arguments first raised in a reply brief because the timing of the argument deprives the opposing party of the opportunity to respond. *See, e.g.*, *Provenz v. Miller,* 102 F.3d 1478, 1483 (9th Cir. 1996). Here, however, because the Parties stipulated to a Sur-Reply and Final Reply, any new issues are fully briefed.

rule of lenity does not apply." (*Id.* 11:6–15). Finally, Judge Koppe found that Defendant failed to meet the "heavy burden" of demonstrating that "the DEA acted in an arbitrary and capricious manner in temporarily scheduling ethylone." (*Id.* 11:16–26).

II. LEGAL STANDARD

A party may file specific written objections to the findings and recommendations of a United States Magistrate Judge made pursuant to Local Rule IB 1–4. 28 U.S.C. § 636(b)(1)(B); D. Nev. R. IB 3–2. Upon the filing of such objections, the Court must make a *de novo* determination of those portions of the Report to which objections are made. *Id.* The Court may accept, reject, or modify, in whole or in part, the findings or recommendations of the Magistrate Judge. 28 U.S.C. § 636(b)(1); D. Nev. IB 3–2(b).

III. DISCUSSION

Defendant asserts five objections to Judge Koppe's R&R denying his Motion to Dismiss. (Obj., ECF No. 89). First, Defendant argues that Judge Koppe erred in denying Defendant's Motion to Dismiss without holding an evidentiary hearing. (*Id.* 5:23–6:15). Second, Defendant contends that the R&R improperly applied *Chevron* deference rather than the rule of lenity. (*Id.* 6:16–8:25). Third, Defendant argues that the R&R "erroneously expand[ed] Congress's narrow definition of 'isomer.'" (*Id.* 9:1–10:2). Fourth, Defendant argues that the R&R "misapplie[d] the *Chevron* framework." (*Id.* 10:3–18). Lastly, Defendant asserts that Judge Koppe erred in not finding the DEA to have acted in an arbitrary and capricious manner. (*Id.* 10:19–11:26). All of these objections, however, amount to little more than the reassertion of the same arguments presented in Defendant's Motion to Dismiss, Reply, and Final Reply. (ECF Nos. 65, 78, 82).

Having reviewed the record in this case, the Court agrees with the analysis and findings of Judge Koppe in the R&R (ECF No. 84) denying Defendant's Motion to Dismiss and incorporates them by reference in this Order. Specifically, regarding the first objection, the

Court finds that no evidentiary hearing is proper here. (R&R 9:7–20). The legal question at issue is the "constitutionality of the scheduling of ethylone as a controlled substance." (*See* Order 1:14–15, ECF No. 57). As Defendant explained in his Motion to Dismiss, his reason for an evidentiary hearing would be to present evidence that ethylone and buytlone are not the same substance "through the testimony of experts in the fields of chemistry and toxicology." (Mot. to Dismiss 8:11–13). However, for the purposes of this Motion, it is sufficient that ethylone is an isomer of butylone, which Defendant does not dispute. (*Id.* 7:2). Accordingly, no evidentiary hearing is necessary, and Defendant's objection is overruled.

Next, the Court finds that Judge Koppe properly applied *Chevron* deference to the DEA's temporary scheduling of ethylone. *Chevron* applies to determine if a regulation is legitimate, as opposed to the rule of lenity, which applies to the application of a legitimate, although ambiguous law. *See Crandon v. United States,* 494 U.S. 152, 158 (1990) (the rule of lenity "serves to ensure both that there is fair warning of the boundaries of criminal conduct and that legislatures, not courts, define criminal liability."). Defendant is arguing against the legitimacy of the temporary scheduling of ethylone; therefore, *Chevron* properly applies.

Regarding Defendant's remaining objections, the Court finds the factual findings in the notice and order regarding butylone are sufficient findings for butylone *as temporarily scheduled*, which expressly includes butylone's isomers: "(22) Butylone, its optical, positional, and geometric isomers, salts and salts of isomers." (Final Order 22, Ex. C to Mot. to Dismiss, ECF No. 65-1). Defendant argues that there is ambiguity as to which subsection (a, b, c, or d) of schedule I that butylone falls under (Obj. 9:14–16), which matters because only subsection c includes all three types of isomers (optical, positional, and geometric). Because the regulation states, "butylone, its optical, positional, and geometric isomers," the Court finds that butylone was specifically scheduled to include all three types of isomers, rendering irrelevant any question of alleged subsection ambiguity. *See* 28 C.F.R. 1308.11(h)(11). Further, under

21 U.S.C. § 812, each subsection of schedule I begins by specifically including the controlled substance type's isomers "[u]nless specifically excepted or unless listed in another schedule." 21 U.S.C. § 812(c) (Schedule I(a)–(d)). This statutory inclusion of isomers under each of schedule I's four sections further negates any indication of ambiguity. Finally, because the DEA notified the Secretary of Health and Human Services about butylone, and the DEA's notice and order provided sufficient findings regarding ethylone as an isomer of butylone, the Court finds that Defendant's objection that the DEA acted in an arbitrary and capricious manner is without merit. *See* 21 U.S.C. § 811(h).

IV. CONCLUSION

IT IS HEREBY ORDERED that Report and Recommendation (ECF No. 84) is **ACCEPTED and ADOPTED in full**.

IT IS FURTHER ORDERED that Defendant's Motion to Dismiss (ECF No. 65) is **DENIED**.

DATED this 14 day of July, 2016.

Gloria M. Navarro, Chief Judge
United States District Judge

APP 15

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

* * *

UNITED STATES OF AMERICA, Plaintiff, vs. MICAH IVERSON KELLY, Defendant.	Case No. 2:15-cr-00041-GMN-NJK REPORT & RECOMMENDATION (Docket No. 65)

This matter was referred to the undersigned Magistrate Judge on Defendant's Motion to Dismiss Indictment. Docket No. 65. The Court has considered Defendant's motion, the United States' response, Defendant's reply, the United States' surreply, and Defendant's final reply. Docket Nos. 65, 73, 78, 81, 82.

I. BACKGROUND

In 1970, Congress enacted the Controlled Substance Act ("CSA"), 84 Stat. 1242, as amended, 21 U.S.C. §§ 801 *et seq*, which places restrictions on the possession and distribution of various substances found to pose a danger to the health and general welfare of the nation. *Touby v. United States*, 560 U.S. 160, 162 (1991). The CSA "establishes five categories or 'schedules' of controlled substances, the manufacture, possession, and distribution of which the [CSA] regulates or prohibits." *Id*. Schedule I substances are those that are believed to pose the most serious threat to public safety and, therefore, carry the most severe penalties when they are involved in violations. *Id*. Section 201(a) of the CSA authorizes the Attorney General to add or remove substances, or to

move a substance from one schedule to another. 21 U.S.C. § 811(a).

When permanently adding a substance to a schedule, the Attorney General must follow specified procedures, which will generally take approximately six to twelve months from the time law enforcement officials identify a dangerous new substance.[1] *Touby*, 550 U.S. at 162-163 (omitting internal quotes). In the past, "[d]rug traffickers were able to take advantage of this time gap by designing drugs that were similar in pharmacological effect to scheduled substances but differed slightly in chemical composition, so that existing schedules did not apply to them. These 'designer drugs' were developed and widely marketed long before the Government was able to schedule them and initiate prosecutions. *Id*. at 163.

In an effort to address this issue, Congress amended the CSA in 1984 to create an expedited procedure by which the Attorney General can schedule a substance on a temporary basis so long as there was an "imminent hazard to the public safety." 21 U.S.C. § 811(h). To temporarily schedule a drug under section 811(h), the Attorney General must consider only three of the eight factors required for permanent scheduling. 21 U.S.C. § 811(h)(3). Specifically, the Attorney General "must consider the substance's 'history and current pattern of abuse,' the 'scope, duration, and significance of abuse,' and the 'risk [...] to the public health.'" *United States v. Anderson*, 2014 WL 2742810, *2 (D.Nev. June 16, 2014) (citing 21 U.S.C. § 811(c)(4)-(6)). The Attorney General should also consider actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. § 811(h)(3). Then, the Attorney General must provide a 30-day notice of the proposed scheduling in the Federal Register. 21 U.S.C. § 811(h)(1).[2] After the thirty days

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[1]The Attorney General must first request a scientific and medical evaluation from the Secretary of Health and Human Services, along with a recommendation as to whether the substance should be controlled (if the Secretary recommends against it, a substance cannot be scheduled). 21 U.S.C. § 811(b). The Attorney General must then consider eight factors with respect to the substance, including its potential for abuse, scientific evidence of its pharmacological effect, its psychic or physiological dependence liability, and whether the substance is an immediate precursor of a substance already controlled. 21 U.S.C. § 811(c). Next, the Attorney General must comply with the notice-and-hearing provisions of the Administrative Procedure Act, 5 U.S.C. §§ 551-559, which permit comment by interested parties. 21 U.S.C. § 811(a). Further, the CSA permits any aggrieved person to challenge the scheduling of a substance by the Attorney General in a court of appeals. 21 U.S.C. § 877.

[2]Notice also must be transmitted to the Secretary of Health and Human Services ("HHS"), but the Secretary's prior approval of a proposed scheduling order is not required. *See* 21 U.S.C. §

have elapsed, the substance becomes a Schedule I controlled substance for two years, although the Attorney General may, during the pendency of proceedings to permanently schedule the substance, extend the temporary scheduling for a period of up to one year. 21 U.S.C. § 811(h)(2). An order to temporarily schedule a substance "is not subject to judicial review," 21 U.S.C. § 811(h)(6), except by a defendant charged with a criminal act involving a substance that has been temporarily scheduled. *Touby*, 500 U.S. at 168.

The Attorney General has promulgated regulations delegating to the DEA his powers under the CSA, including the power to schedule controlled substances on a temporary basis.[3] *See* 28 CFR § 0.100(b) (1990). Pursuant to that delegation, on November 7, 2013, the DEA Administrator sent a letter notifying the Secretary of HHS of his intention to publish an order in the Federal Register temporarily scheduling ten synthetic cathinone substances. Docket No. 65-1 at 1-2. One of those substances was butylone. *Id*. at 1. On January 28, 2014, the DEA published in the Federal Register a notice of intent to temporarily schedule the same ten synthetic cathinone substances, including butylone. *Id*. at 5-12. Specifically, the notice stated the DEA's intent to temporarily schedule "butylone, its optical, positional[4], and geometric isomers, salts and salts of isomers..." *Id*. at 11. The notice discussed the history and current pattern of abuse, the scope, duration and significance of abuse, and the risk to public health caused by the substances, as required by 21 U.S.C. § 811(h)(3). *Id.* at 7-9.

On March 7, 2014, the DEA published in the Federal Register its final order temporarily scheduling these substances. *Id*. at 14-22. The final order listed "[b]utylone, its optical, positional, and geometric isomers, salts and salts of isomers" among the temporarily scheduled substances. *Id*. at 22. Further, like the notice of intent, the final order considered the history and current pattern of

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811(h)(4).

[3]Both Congress' power to delegate legislative power to the Attorney General and the Attorney General's power to delegate his temporary scheduling power to the DEA have been upheld as constitutional delegations. *See Touby*, 500 U.S. at 169. Defendant does not challenge these delegations in the instant motion. *See* Docket No. 65.

[4]On December 7, 2007, the DEA published in the Federal Register a specific definition of positional isomer for use in determining which isomers of Schedule I substances would be subject to Schedule I control. *Id*. at 24-26.

abuse, the scope, duration and significance of abuse, and the risk to public health caused by the substances, as required by 21 U.S.C. § 811(h)(3). *Id.* at 16-19.

On February 24, 2015, a federal grand jury sitting in Las Vegas, Nevada issued an indictment charging Defendant Micah Kelly with two counts of Distribution of a Controlled Substance - Ethylone, in violation of Title 21, United States Code, Sections 841(a)(1) and (b)(1)(C), and one count of Possession of a Controlled Substance with Intent to Distribute - Ethylone, in violation of Title 21, United States Code, Sections 841(a)(1) and (b)(1)(C). Docket No. 10. Defendant now seeks a dismissal of the indictment, with prejudice. Docket No. 65.

In support of his request, Defendant submits that the Drug Enforcement Agency ("DEA") failed to follow the procedure set forth in 21 U.S.C. § 811(h) to temporarily schedule ethylone. Docket No. 65 at 2-3, 5-6. Defendant contends that, when the DEA attempted to temporarily schedule ethylone, it did so with ten specifically named substances (and ethylone was not one of the named substances), "plus all of each substance's optical, positional, and geometric isomers, salts, and salts of isomers." *Id*. at 3. Defendant submits that the DEA failed in three separate ways. "First, the DEA neither considered nor made any findings with regard to the statutory factors required to permit ethylone's scheduling. Second, the DEA did not provide notice of its intent to schedule ethylone" to the Department of Health and Human Services, "naming only the ten substances, but not naming ethylone or any other isomers. Third, the DEA's notice and order in the Federal Register were insufficient to schedule ethylone, as they made none of the required findings as to ethylone." *Id*. at 6, 8-20. Defendant submits that ethylone is an isomer of butylone, but that ethylone is not butylone and, therefore, ethylone has not been scheduled. *Id*. at 6-8.

Additionally, Defendant submits that the DEA acted in an arbitrary and capricious manner in its attempt to schedule ethylone, because Congress unsuccessfully attempted to pass legislation permanently scheduling ethylone between 2011 and 2013 and the DEA therefore attempted to bypass the law by temporarily scheduling ethylone as one of butylone's isomers. *Id*. at 3, 21-23. As a result, Defendant submits that ethylone is not a controlled substance and, thus, he cannot be guilty of the crimes charged in the indictment. *Id.* at 3. Therefore, Defendant asks the Court to dismiss the indictment against him with prejudice. *Id*. at 3, 23.

In response, the United States responds that "a substance's salts, isomers, and salts of isomers are categorically controlled under Schedule I, unless specifically excepted, and do not require their own separate factor analysis."[5] Docket No. 73 at 2, 4-9. The United States submits that the DEA did not except any of butylone's isomers when it temporarily scheduled it; to the contrary, the DEA explicitly included butylone's optical, geometric, and positional isomers, as well as its salts and salts of isomers, in its notice of intent and final temporary scheduling order. *Id.* at 2. Further, the United States contends that the DEA followed the procedure required by statute, and that the statute clearly controls the isomers of Schedule I controlled substances. *Id*. at 2-3. The United States contends that Defendant's motion is a challenge to the DEA's statutory interpretation of its scheduling authority, and argues that Congress' intent was clear, and the DEA's interpretation of the statute at issue is based on a permissible construction of that statute. *Id*. at 3. The United States further contends that the Court should apply *Chevron USA, Inc. V. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), in determining whether DEA's statutory interpretation of its scheduling authority is permissible, and that Defendant incorrectly framed the issue as to whether the DEA acted in an arbitrary and capricious manner. Docket No. 73 at 3-4, 18-20. The United States therefore asks the Court to deny Defendant's motion to dismiss the indictment. *Id*. at 20.

In reply, Defendant argues that *Chevron* does not apply to federal criminal law and, therefore, does not apply in the instant case. Docket No. 78 at 2, 4-5. Even if *Chevron* does apply, however, Defendant argues that the statute at issue is ambiguous as to which isomers of temporarily scheduled drugs are themselves scheduled. *Id.* at 2, 5-9. Defendant submits that, as the United States contends that ethylone is a positional isomer of butylone, it is only subject to Schedule I controls if butylone is scheduled in Schedule I(c). *Id*. Defendant submits that the United States' position that all isomers of butylone are categorically scheduled is incorrect, and that the Rule of Lenity requires the Court to resolve the ambiguities of the CSAin his favor. *Id*. at 3, 9. Further, Defendant submits that Congress never intended the DEA to schedule "unknown, un-vetted substances by simply adding

[5]The parties agree that ethylone is an isomer of butylone. Docket No. 65 at 3; Docket No. 73 at 2. The United States submits that, more specifically, ethylone is a positional isomer of butylone and butylone is a positional isomer of ethylone. Docket No. 73 at 2, n. 1.

'and isomers' to its temporary scheduling orders." *Id*. at 10-13. Finally, Defendant contends that the DEA's procedures did not provide fair warning that ethylone is a controlled substance. *Id*. at 3, 13-15. As a result, Defendant asks the Court to dismiss his indictment with prejudice, as it fails to allege a crime. *Id*. at 15-17.

After Defendant filed his reply, the parties filed a stipulation with the Court in which they represented that the United States wanted to address and clarify some points that Defendant had raised in his reply. Docket No. 79 at 1. As counsel for the United States needed to consult with the DEA and was sechduled to begin a jury trial, the parties asked for a little over two weeks for the United States to file a sur-reply. *Id*. at 1-2. The parties further asked that Defendant have a week to file a reply to the United States' sur-reply. *Id*. at 2. The Court allowed the parties the requested amount of time to file the requested documents. Docket No. 80 at 3.

In sur-reply, the United States submits that Defendant raised two new arguments in his reply: "(1) the [CSA] is ambiguous; and (2) DEA did not specify which schedule I subcategory butylone belonged to." Docket No. 81 at 1. The United States submits that the "DEA clearly, and in compliance with the statutory procedures required by Title 21, Secion 811(h) temporarily scheduled butylone, along with its optical geometric, and positional isomers." *Id*. at 2. The United States contends that the "notice of intent to schedule and the final order temporarily scheduling butylone, along with its optical, geometric, and positional isomers, in conjunction with the CFR definition of positional isomer, is the legal basis." *Id*. Futher, the United States says it will provide expert testimony to prove that ethylone is a positional isomer of butylone and is therefore a controlled substance. *Id*. Therefore, the United States contends, the indictment properly alleges a crime. *Id*.

Additionally, the United States submits that Defendant's contention that Section 811(h)'s silence on subcategories is ambiguous is flawed. *Id*. at 3. The United States notes that Defendant is charged with violating criminal statutes, and not Section 811(h), and the criminalization of distributing a Schedule I controlled substance is not ambiguous. *Id*. Further, the United States submits that the final temporary scheduling order, which explicitly includes positional isomers of butylone, serves to provide the public with notice. *Id*. Finally, the United States notes that the statute does not require notice of subcategorization within Schedule I. *Id*.

The United States contends that *Chevron* applies because 811(h) is an enabling statute, and not a criminal statute. *Id*. at 3-5. The United States further submits that the Rule of Lenity does not trump *Chevron* deference, and notes that Defendant failed to provide any authority to support his contention to the contrary. *Id*. at 5, n. 5. The United States contends that Congress enacted the temporary scheduling authority "to protect the public in direct response to the designer drug crisis." *Id*. at 6. Congress, therefore, "intentionally prioritzed the need to protect the public safety." *Id*. Further, Congress "understood that 'isomers of dangerous drugs often elicit similar harmful pharmacological effects, and that clandestine manufacturers attempt to circumvent the law by manufacturing positional and geometric isomers of hallucinogens.'" *Id*. (internal citation omitted). Congress therefore "codified a definition of isomer 'to assure that those isomers requiring control under the CSA are covered by the statute.'" *Id*. (internal citation omitted). The United States submits that, under this framework, the "DEA's interpretation of Section 811(h) as including a substance's isomers, effectuates Congress' intent to protect the public safety and control the isomers covered by schedule I of the CSA." *Id*. Finally, the United States contends that Defendant's reliance on recent Congressional inaction in relation to the scheduling of ethylone and butylone is misplaced, as the parties can only speculate as to the reason for the inaction. *Id*. at 7-9. In any event, the United States submits that Congress' action or lack thereof in regard to scheduling specific substances "has no bearing on the issue of whether a previous Congress intended to control specific isomers of schedule I substances." *Id*. at 7-8. Finally, the United States directs the Court's attention to the Report and Recommendation ("R&R") on two cases involving issues regarding ethylone scheduling written by a Magistrate Judge in Alaska. *See* Docket No. 81-1 (*United States v. Riley-Jennings*, Docket No. 59, 15-cr-0040-SLG-DMS; *United States v. West, III, et al.*, Docket No. 89,14-cr-118-TMB-DMS).

In his final reply, Defendant denies the suggestion that he introduced new arguments in his reply brief. Docket No. 82 at 2. Defendant contends that ethylone is not a controlled substance because the DEA did not schedule it, and because the CSA is ambiguous about isomers. *Id*. As ethylone is not a controlled substance, Defendant submits, the indictment fails to establish an essential element of the crime charged and, therefore, must be dismissed. *Id*. at 2-3. Further, Defendant contends that the United States has "flip-flopped" its position regarding how the Court

must read the CSA, and that *Chevron* is not appropriate for interpreting criminal statutes. *Id*. at 4-7, 9-10. Additionally, Defendant states that the Court must apply the Rule of Lenity in interpreting the statute. *Id*. at 7-8.

Finally, Defendant asks the Court to disregard the Alaska R&R submitted by the United States. *Id*. at 12. Defendant states that the Alaska R&R is premised on an entirely different legal and procedural posture as the Alaska Court determined that the question of whether butylone and ethylone are in fact positional isomers is ultimately a jury question; while in this case, Chief United States District Judge Gloria M. Navarro determined that it is a legal question. *Id*. Second, Defendant contends that he has not raised a constitutional challenge to the DEA's definition of positional isomer, and has instead questioned the DEA's failure to follow the proper procedure to temporarily schedule ethylone. *Id*. Third, Defendant points out that he has requested a hearing on this motion and is prepared to present expert testimony; therefore, the expert testimony presented in the Alaska cases is extraneous and possibly prejudicial. *Id*. at 12-13. Finally, Defendant states that the R&R has no precedential authority. *Id*. at 13.

II. ANALYSIS

Federal Rule of Criminal Procedure 12(b)(2) provides that "a party may raise by pertrial motion any defense, objection, or request that the court can determine without a trial of the general issue." A pre-trial motion to dismiss an indictment cannot be brought to challenge the merits of the case, and cannot be used as a device for a summary trial of the evidence. *United States v. Jensen*, 93 F.3d 667, 669 (9th Cir. 1996)

In determining a motion to dismiss an indictment, "a court is limited to the face of the indictment and must accept the facts alleged in that indictment as true." *United States v. Ruiz-Castro*, 125 F. Supp. 2d 411, 413 (D. Haw. 2000) (*citing Winslow v. United States*, 216 F.2d 912, 913 (9th Cir. 1954), *cert. denied*, 349 U.S. 922 (1955)). *See also United States v. Boren*, 278 F.3d 911, 914 (9th Cir. 2002) ("In ruling on a pre-trial motion to dismiss an indictment for failure to state an offense, the district court is bound by the four corners of the indictment"). "[T]he court must accept the truth of the allegations in the indictment in analyzing whether a cognizable offense has been charged. The indictment either states an offense or it does not. There is no reason to conduct

an evidentiary hearing." *Id*. *See also United States v. Sampson*, 371 U.S. 75, 78-79(1962) ("Of course, none of these charges have been established by evidence, but at this stage of the proceedings the indictment must be tested by its sufficiency to charge an offense"). The "unavailability of Rule 12 in determination of general issues of guilt or innocence ... helps ensure that the respective provinces of the judge and jury are respected...." *United States v. Nukida*, 8 F.3d 665, 670 (9th Cir. 1993).

Defendant requests an evidentiary hearing to present expert evidence. However, an evidentiary hearing is inappropriate at this time. The question of whether ethylone is an isomer of butylone - specifically, a positional isomer - is a question for the jury. *See, e.g., United States v. Johnson*, 2014 WL 7330935, *5 (D.Nev. July 31, 2014); *United States v. Long*, 2014 WL 1661497, *2 (D.S.D. April 25, 2014) ("a district court errs procedurally when it takes up a sufficiency of the evidence challenge prior to trial"); *United States v. Reece*, 2013 WL 5234227, at *4 (W.D.La. Sept. 13, 2013) ("Whether AM-2201 actually is a controlled substance analogue is a question of fact that must be assumed as true for purposes of this motion and left to the jury to determine at trial on the merits").

In any event, both parties agree - at least for the purpose of this motion - that ethylone is an isomer of butylone. *See* Docket No. 65 at 7 ("Ethylone is an isomer of butylone"); Docket No. 73 at 2 ("As the defendant admitted in his motion, ethylone is an isomer of butylone"). Therefore, an evidentiary hearing on whether ethylone is an isomer of butylone would be frivolous. Accordingly, the Court denies Defendant's request for an evidentiary hearing.

Defendant submits that the Court may not apply *Chevron* in determining whether the DEA's interpretation of the CSA was reasonable because the statute implicated is a criminal statute. The United States contends, to the contrary, that the statute implicated is an enabling statute. Courts have generally applied *Chevron* deference to an executive agency's interpretation of a law that contemplates both criminal and administrative enforcement. *See Babbitt v. Sweet Home Chapter, Communities for Great Ore.*, 515 U.S. 687 (1995) (deferring to agency's interpretation of law that carried criminal penalties). *See also United States v. Royer*, 549 F.3d 886, 899 (2d Cir. 2008); *United States v. Flores*, 404 F.3d 320, 326-327 (5th Cir. 2005); *Hemp Industries Ass'n v. Drug*

Enforcement Admin., 357 F.3d 1012, 1015 (9th Cir. 2004); *United States v. Atandi*, 376 F.3d 1186, 1189 (10th Cir. 2004); *In re Sealed Case*, 223 F.3d 775, 779 (D.C. Cir. 2000); *United States v. Kanchanalak*, 192 F.3d 1037, 1047 (D.C. Cir. 1999). The Court therefore applies *Chevron*.

"When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions." *Chevron*, 467 U.S. at 842. First, applying the ordinary tools of statutory construction, the court must determine "whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id*. at 842–843. However, "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id*. at 843. *See also Hemp Industries Ass'n.*, 357 F.3d at 1015.

Chevron "is rooted in a background presumption of congressional intent: namely, 'that Congress, when it left ambiguity in a statute' administered by an agency, 'understood that the ambiguity would be resolved, first and foremost, by the agency, and desired the agency (rather than the courts) to possess whatever degree of discretion the ambiguity allows.'" *City of Arlington, Tex. V. F.C.C.*, _____ U.S. _____, 133 S.Ct. 1863, 1868 (2013) (citing *Smiley v. Citibank (South Dakota), N. A.*, 517 U.S. 735, 740–741 (1996)). *Chevron* "thus provides a stable background rule against which Congress can legislate: Statutory ambiguities will be resolved, within the bounds of reasonable interpretation, not by the courts but by the administering agency." *City of Arlington, Tex.*, 133 S.Ct. At 1868. "Congress knows to speak in plain terms when it wishes to circumscribe, and in capacious terms when it wishes to enlarge, agency discretion." *Id*. Therefore, an agency's properly promulgated regulation is entitled to great deference and courts must give considerable weight to an agency's construction of a statute that it has been aassigned to enforce. *Chevron*, 467 U.S. at 844.

In the instant case, the Court finds that the intent of Congress is clear. The CSA clearly includes isomers. 21 U.S.C. § 802(14) defines the term isomer. In its definition, it states that, "[a]s used in schedule I(c), the term 'isomer' means any optical, positional, or geometric isomer." 21 U.S.C. §802(14). Further, the CSA clearly states that, for Schedule I(c) drugs,

> Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation[.]

21 U.S.C. 812, Schedule I(c). Therefore, the Court finds that Congress clearly intended to include isomers, unless specifically exempted or listed in another schedule, when scheduling substances. As the Court finds that the intent of Congress is clear and that the DEA exercised its properly delegated authority in defining positional isomer and issuing the scheduling order at issue, the Court's inquiry ends. *Chevron*, 467 U.S. at 842-843. Therefore, the Court gives deference to the DEA's statutory interpretation of the CSA, and finds that ethylone was properly temporarily scheduled.[6]

The Court further finds that the rule of lenity does not apply. "We have never suggested that the rule of lenity should provide the standard for reviewing facial challenges to administrative regulations whenever the governing statute authorizes criminal enforcement." *Babbitt*, 515 U.S. at 704, n. 18. *See also Staples v. United States*, 511 U.S. 619 n. 17 (1994) (rule of lenity requires that "ambiguous criminal statute[s] ... be construed in favor of the accused").

Finally, Defendant argues that the DEA acted in an arbitrary and capricious manner in temporarily scheduling ethylone. Courts "may not set aside agency action unless that action is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1244 (9th Cir. 2013) (internal citation omitted). This standard is met only where the party challenging the agency's decision meets the "heavy burden" of showing that "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The Court finds that Defendant has failed to meet that burden here.

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[6]The Court declines to speculate as to why Congress did not enact prior bills that included language scheduling ethylone.

III. CONCLUSION

Accordingly,

Based on the foregoing and good cause appearing therefore,

IT IS RECOMMENDED that Defendant's Motion to Dismiss Indictment (Docket No. 65) be **DENIED**.

NOTICE

Pursuant to Local Rule IB 3-2 **any objection to this Report and Recommendation must be in writing and filed with the Clerk of the Court within 14 days of service of this document.** The Supreme Court has held that the courts of appeal may determine that an appeal has been waived due to the failure to file objections within the specified time. *Thomas v. Arn*, 474 U.S. 140, 142 (1985). This Circuit has also held that (1) failure to file objections within the specified time and (2) failure to properly address and brief the objectionable issues waives the right to appeal the District Court's order and/or appeal factual issues from the order of the District Court. *Martinez v. Ylst*, 951 F.2d 1153, 1157 (9th Cir. 1991); *Britt v. Simi Valley United Sch. Dist.*, 708 F.2d 452, 454 (9th Cir. 1983).

DATED this 15th day of April, 2016.

NANCY J. KOPPE
United States Magistrate Judge

United States Code Annotated
Title 21. Food and Drugs (Refs & Annos)
Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)
Subchapter I. Control and Enforcement
Part A. Introductory Provisions (Refs & Annos)

21 U.S.C.A. § 802

§ 802. Definitions

Effective: July 22, 2016

Currentness

As used in this subchapter:

(1) The term "addict" means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

(2) The term "administer" refers to the direct application of a controlled substance to the body of a patient or research subject by--

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner,

whether such application be by injection, inhalation, ingestion, or any other means.

(3) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(4) The term "Drug Enforcement Administration" means the Drug Enforcement Administration in the Department of Justice.

(5) The term "control" means to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise.

(6) The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

(7) The term "counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

(8) The terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.

(9) The term "depressant or stimulant substance" means--

(A) a drug which contains any quantity of barbituric acid or any of the salts of barbituric acid; or

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.

(12) The term "drug" has the meaning given that term by section 321(g)(1) of this title.

(13) The term "felony" means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term "isomer" means the optical isomer, except as used in schedule I(c) and schedule II(a)(4). As used in schedule I(c), the term "isomer" means any optical, positional, or geometric isomer. As used in schedule II(a)(4), the term "isomer" means any optical or geometric isomer.

(15) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.

(16) The term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

(17) The term "narcotic drug" means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(B) Poppy straw and concentrate of poppy straw.

(C) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed.

(D) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (A) through (E).

(18) The term "opiate" or "opioid" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(19) The term "opium poppy" means the plant of the species Papaver somniferum L., except the seed thereof.

(20) The term "poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(22) The term "production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(23) The term "immediate precursor" means a substance--

(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.

(24) The term "Secretary", unless the context otherwise indicates, means the Secretary of Health and Human Services.

(25) The term "serious bodily injury" means bodily injury which involves--

(A) a substantial risk of death;

(B) protracted and obvious disfigurement; or

(C) protracted loss or impairment of the function of a bodily member, organ, or mental faculty.

(26) The term "State" means a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.

(27) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

(28) The term "United States", when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.

(29) The term "maintenance treatment" means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

(30) The term "detoxification treatment" means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

(31) The term "Convention on Psychotropic Substances" means the Convention on Psychotropic Substances signed at Vienna, Austria, on February 21, 1971; and the term "Single Convention on Narcotic Drugs" means the Single Convention on Narcotic Drugs signed at New York, New York, on March 30, 1961.

(32)(A) Except as provided in subparagraph (C), the term "controlled substance analogue" means a substance--

(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;

(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; or

(iii) with respect to a particular person, which such person represents or intends to have 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.

(B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue.

(C) Such term does not include--

(i) a controlled substance;

(ii) any substance for which there is an approved new drug application;

(iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 355 of this title to the extent conduct with respect to such substance is pursuant to such exemption; or

(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

(33) The term "listed chemical" means any list I chemical or any list II chemical.

(34) The term "list I chemical" means a chemical specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this subchapter and is important to the manufacture of the controlled substances, and such term includes (until otherwise specified by regulation of the Attorney General, as

considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following:

(A) Anthranilic acid, its esters, and its salts.

(B) Benzyl cyanide.

(C) Ephedrine, its salts, optical isomers, and salts of optical isomers.

(D) Ergonovine and its salts.

(E) Ergotamine and its salts.

(F) N-Acetylanthranilic acid, its esters, and its salts.

(G) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.

(H) Phenylacetic acid, its esters, and its salts.

(I) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.

(J) Piperidine and its salts.

(K) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.

(L) 3,4-Methylenedioxyphenyl-2-propanone.

(M) Methylamine.

(N) Ethylamine.

(O) Propionic anhydride.

(P) Isosafrole.

(Q) Safrole.

(R) Piperonal.

(S) N-Methylephedrine.

(T) N-methylpseudoephedrine.

(U) Hydriodic acid.

(V) Benzaldehyde.

(W) Nitroethane.

(X) Gamma butyrolactone.

(Y) Any salt, optical isomer, or salt of an optical isomer of the chemicals listed in subparagraphs (M) through (U) of this paragraph.

(35) The term "list II chemical" means a chemical (other than a list I chemical) specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this subchapter, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following chemicals:

(A) Acetic anhydride.

(B) Acetone.

(C) Benzyl chloride.

(D) Ethyl ether.

(E) Repealed. Pub.L. 101-647, Title XXIII, § 2301(b), Nov. 29, 1990, 104 Stat. 4858.

(F) Potassium permanganate.

(G) 2-Butanone (or Methyl Ethyl Ketone).

(H) Toluene.

(I) Iodine.

(J) Hydrochloric gas.

(36) The term "regular customer" means, with respect to a regulated person, a customer with whom the regulated person has an established business relationship that is reported to the Attorney General.

(37) The term "regular importer" means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Attorney General.

(38) The term "regulated person" means a person who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(39) The term "regulated transaction" means--

(A) a distribution, receipt, sale, importation, or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions (as determined by the Attorney General, in consultation with the chemical industry and taking into consideration the quantities normally used for lawful purposes), of a listed chemical, except that such term does not include--

(i) a domestic lawful distribution in the usual course of business between agents or employees of a single regulated person;

(ii) a delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this clause does not relieve a distributor, importer, or exporter from compliance with section 830 of this title;

(iii) any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this subchapter or subchapter II of this chapter;

(iv) any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act, subject to clause (v), unless--

(I) the Attorney General has determined under section 814 of this title that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(II) the quantity of the listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General;

(v) any transaction in a scheduled listed chemical product that is a sale at retail by a regulated seller or a distributor required to submit reports under section 830(b)(3) of this title; or

(vi) any transaction in a chemical mixture which the Attorney General has by regulation designated as exempt from the application of this subchapter and subchapter II of this chapter based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered; and

(B) a distribution, importation, or exportation of a tableting machine or encapsulating machine.

(40) The term "chemical mixture" means a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.

(41)(A) The term "anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes

(i) androstanediol--

(I) 3β,17β-dihydroxy-5α- androstane; and

(II) 3α,17β-dihydroxy-5α- androstane;

(ii) androstanedione (5α-androstan-3,17-dione);

(iii) androstenediol--

(I) 1-androstenediol (3β,17β-dihydroxy-5α-androst-1-ene);

(II) 1-androstenediol (3α,17β-dihydroxy-5α-androst-1-ene);

(III) 4-androstenediol (3β,17β-dihydroxy-androst-4-ene); and

(IV) 5-androstenediol (3β,17β-dihydroxy-androst-5-ene);

(iv) androstenedione--

(I) 1-androstenedione ([5α]-androst-1-en-3,17-dione);

(II) 4-androstenedione (androst-4-en-3,17-dione); and

(III) 5-androstenedione (androst-5-en-3,17-dione);

(v) bolasterone (7α,17α- dimethyl-17β-hydroxyandrost-4-en-3-one);

(vi) boldenone (17β-hydroxyandrost-1,4,-diene-3-one);

(vii) calusterone (7β, 17α-dimethyl-17β-hydroxyandrost-4-en-3-one);

(viii) clostebol (4-chloro-17β-hydroxyandrost-4-en-3-one);

(ix) dehydrochloromethyltestosterone (4-chloro-17β-hydroxy-17α-methyl-androst-1, 4-dien-3-one);

(x) Δ 1-dihydrotestosterone (a.k.a. "1-testosterone") (17β-hydroxy-5α-androst-1-en-3-one);

(xi) 4-dihydrotestosterone (17β-hydroxy-androstan-3-one);

(xii) drostanolone (17β-hydroxy-2α- methyl-5α-androstan-3-one);

(xiii) ethylestrenol (17α-ethyl-17β-hydroxyestr-4-ene);

(xiv) fluoxymesterone (9-fluoro-17α-methyl-11β, 17β-dihydroxyandrost-4-en-3-one);

(xv) formebolone (2-formyl-17α-methyl-11α, 17β-dihydroxyandrost-1,4-dien-3-one);

(xvi) furazabol (17α-methyl-17β-hydroxyandrostano[2,3-c]-furazan);

(xvii) 13β-ethyl-17β-hydroxygon-4-en-3-one;

(xviii) 4-hydroxytestosterone (4,17β-dihydroxy-androst-4-en-3-one);

(xix) 4-hydroxy-19-nortestosterone (4,17β-dihydroxy-estr-4-en-3-one);

(xx) mestanolone (17α-methyl- 17β-hydroxy-5α-androstan-3-one);

(xxi) mesterolone (1α-methyl-17β-hydroxy-[5α] -androstan-3-one);

(xxii) methandienone (17α-methyl-17β-hydroxyandrost-1,4-dien-3-one);

(xxiii) methandriol (17α-methyl- 3β,17β-dihydroxyandrost-5-ene);

(xxiv) methenolone (1-methyl-17β-hydroxy-5α-androst-1-en-3-one);

(xxv) 17α-methyl-3β, 17β-dihydroxy-5α-androstane;

(xxvi) 17α-methyl-3α, 17β-dihydroxy-5α-androstane;

(xxvii) 17α-methyl-3β, 17β-dihydroxyandrost-4-ene.

(xxviii) 17α-methyl-4-hydroxynandrolone (17α-methyl-4-hydroxy-17β-hydroxyestr-4-en-3-one);

(xxix) methyldienolone (17α-methyl-17β-hydroxyestra-4,9(10)-dien-3-one);

(xxx) methyltrienolone (17α-methyl-17β-hydroxyestra-4,9-11-trien-3-one);

(xxxi) methyltestosterone (17α-methyl-17β-hydroxyandrost-4-en-3-one);

(xxxii) mibolerone (7α, 17α-dimethyl-17β-hydroxyestr-4-en-3-one);

(xxxiii) 17α-methyl-Δ 1-dihydrotestosterone (17β-hydroxy-17α-methyl-5α- androst-1-en-3-one) (a.k.a. "17-α-methyl-1-testosterone");

(xxxiv) nandrolone (17β-hydroxyestr-4-en-3-one);

(xxxv) norandrostenediol--

(I) 19-nor-4-androstenediol (3β, 17β-dihydroxyestr-4-ene);

(II) 19-nor-4-androstenediol (3α, 17β-dihydroxyestr-4-ene);

(III) 19-nor-5-androstenediol (3β, 17β-dihydroxyestr-5-ene); and

(IV) 19-nor-5-androstenediol (3α, 17β-dihydroxyestr-5-ene);

(xxxvi) norandrostenedione--

(I) 19-nor-4-androstenedione (estr-4-en-3,17-dione); and

(II) 19-nor-5-androstenedione (estr-5-en-3,17-dione;

(xxxvii) norbolethone (13β, 17α-diethyl-17β-hydroxygon-4-en-3-one);

(xxxviii) norclostebol (4-chloro-17β-hydroxyestr-4-en-3-one);

(xxxix) norethandrolone (17α-ethyl-17β-hydroxyestr-4-en-3-one);

(xl) normethandrolone (17α-methyl-17β-hydroxyestr-4-en-3-one);

(xli) oxandrolone (17α-methyl-17β-hydroxy-2-oxa-[5α]- androstan-3-one);

(xlii) oxymesterone (17α-methyl-4,17β-dihydroxyandrost-4-en-3-one);

(xliii) oxymetholone (17α-methyl-2-hydroxymethylene-17β-hydroxy- [5α]-androstan-3-one);

(xliv) stanozolol (17α-methyl- 17β-hydroxy-[5α]-androst-2-eno[3,2-c]-pyrazole);

(xlv) stenbolone (17β-hydroxy-2-methyl-[5α] -androst-1-en-3-one);

(xlvi) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);

(xlvii) testosterone (17β-hydroxyandrost-4-en-3-one);

(xlviii) tetrahydrogestrinone (13β,17α-diethyl-17β-hydroxygon-4,9, 11-trien-3-one);

(xlix) trenbolone (17β-hydroxyestr-4,9,11-trien-3-one);

(l) 5α-Androstan-3,6,17-trione;

(li) 6-bromo-androstan-3,17-dione;

(lii) 6-bromo-androsta-1,4-diene-3,17-dione;

(liii) 4-chloro-17α-methyl-androsta-1,4-diene-3,17β-diol;

(liv) 4-chloro-17α-methyl-androst-4-ene-3β,17β-diol;

(lv) 4-chloro-17α-methyl-17β-hydroxy-androst-4-en-3-one;

(lvi) 4-chloro-17α-methyl-17β-hydroxy-androst-4-ene-3,11-dione;

(lvii) 4-chloro-17α-methyl-androsta-1,4-diene-3,17β-diol;

(lviii) 2α,17α-dimethyl-17β-hydroxy-5α-androstan-3-one;

(lix) 2α,17α-dimethyl-17β-hydroxy-5β-androstan-3-one;

(lx) 2α,3α-epithio-17α-methyl-5α-androstan-17β-ol;

(lxi) [3,2-c]-furazan-5α-androstan-17β-ol;

(lxii) 3β-hydroxy-estra-4,9,11-trien-17-one;

(lxiii) 17α-methyl-androst-2-ene-3,17β-diol;

(lxiv) 17α-methyl-androsta-1,4-diene-3,17β-diol;

(lxv) Estra-4,9,11-triene-3,17-dione;

(lxvi) 18a-Homo-3-hydroxy-estra-2,5(10)-dien-17-one;

(lxvii) 6α-Methyl-androst-4-ene-3,17-dione;

(lxviii) 17α-Methyl-androstan-3-hydroxyimine-17β-ol;

(lxix) 17α-Methyl-5α-androstan-17β-ol;

(lxx) 17β-Hydroxy-androstano[2,3-d]isoxazole;

(lxxi) 17β-Hydroxy-androstano[3,2-c]isoxazole;

(lxxii) 4-Hydroxy-androst-4-ene-3,17-dione[3,2-c]pyrazole-5α-androstan-17β-ol;

(lxxiii) [3,2-c]pyrazole-androst-4-en-17β-ol;

(lxxiv) [3,2-c]pyrazole-5α-androstan-17β-ol; and

(lxxv) any salt, ester, or ether of a drug or substance described in this paragraph.

The substances excluded under this subparagraph may at any time be scheduled by the Attorney General in accordance with the authority and requirements of subsections (a) through (c) of section 811 of this title.

(B)(i) Except as provided in clause (ii), such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration.

(ii) If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of subparagraph (A).

(C)(i) Subject to clause (ii), a drug or hormonal substance (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that is not listed in subparagraph (A) and is derived from, or has a chemical structure substantially similar to, 1 or more anabolic steroids listed in subparagraph (A) shall be considered to be an anabolic steroid for purposes of this chapter if--

(I) the drug or substance has been created or manufactured with the intent of producing a drug or other substance that either--

(aa) promotes muscle growth; or

(bb) otherwise causes a pharmacological effect similar to that of testosterone; or

(II) the drug or substance has been, or is intended to be, marketed or otherwise promoted in any manner suggesting that consuming it will promote muscle growth or any other pharmacological effect similar to that of testosterone.

(ii) A substance shall not be considered to be a drug or hormonal substance for purposes of this subparagraph if it--

(I) is--

(aa) an herb or other botanical;

(bb) a concentrate, metabolite, or extract of, or a constituent isolated directly from, an herb or other botanical; or

(cc) a combination of 2 or more substances described in item (aa) or (bb);

(II) is a dietary ingredient for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(III) is not anabolic or androgenic.

(iii) In accordance with section 885(a) of this title, any person claiming the benefit of an exemption or exception under clause (ii) shall bear the burden of going forward with the evidence with respect to such exemption or exception.

(42) The term "international transaction" means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

(43) The terms "broker" and "trader" mean a person that assists in arranging an international transaction in a listed chemical by--

(A) negotiating contracts;

(B) serving as an agent or intermediary; or

(C) bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.

(44) The term "felony drug offense" means an offense that is punishable by imprisonment for more than one year under any law of the United States or of a State or foreign country that prohibits or restricts conduct relating to narcotic drugs, marihuana, anabolic steroids, or depressant or stimulant substances.

(45)(A) The term "scheduled listed chemical product" means, subject to subparagraph (B), a product that--

(i) contains ephedrine, pseudoephedrine, or phenylpropanolamine; and

(ii) may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act as a nonprescription drug.

Each reference in clause (i) to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical.

(B) Such term does not include a product described in subparagraph (A) if the product contains a chemical specified in such subparagraph that the Attorney General has under section 811(a) of this title added to any of the schedules under section 812(c) of this title. In the absence of such scheduling by the Attorney General, a chemical specified in such subparagraph may not be considered to be a controlled substance.

(46) The term "regulated seller" means a retail distributor (including a pharmacy or a mobile retail vendor), except that such term does not include an employee or agent of such distributor.

(47) The term "mobile retail vendor" means a person or entity that makes sales at retail from a stand that is intended to be temporary, or is capable of being moved from one location to another, whether the stand is located within or on the premises of a fixed facility (such as a kiosk at a shopping center or an airport) or whether the stand is located on unimproved real estate (such as a lot or field leased for retail purposes).

(48) The term "at retail", with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively.

(49)(A) The term "retail distributor" means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to ephedrine, pseudoephedrine, or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

(B) For purposes of this paragraph, entities are defined by reference to the Standard Industrial Classification (SIC) code, as follows:

(i) A grocery store is an entity within SIC code 5411.

(ii) A general merchandise store is an entity within SIC codes 5300 through 5399 and 5499.

(iii) A drug store is an entity within SIC code 5912.

(50) The term "Internet" means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.

(51) The term "deliver, distribute, or dispense by means of the Internet" refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet.

(52) The term "online pharmacy"--

(A) means a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet; and

(B) does not include--

(i) manufacturers or distributors registered under subsection (a), (b), (d), or (e) of section 823 of this title who do not dispense controlled substances to an unregistered individual or entity;

(ii) nonpharmacy practitioners who are registered under section 823(f) of this title and whose activities are authorized by that registration;

(iii) any hospital or other medical facility that is operated by an agency of the United States (including the Armed Forces), provided such hospital or other facility is registered under section 823(f) of this title;

(iv) a health care facility owned or operated by an Indian tribe or tribal organization, only to the extent such facility is carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act;

(v) any agent or employee of any hospital or facility referred to in clause (iii) or (iv), provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of health care facilities specified in clause (iv), only to the extent such individuals are furnishing services pursuant to the contracts or compacts described in such clause;

(vi) mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;

(vii) a person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States;

(viii) a pharmacy registered under section 823(f) of this title whose dispensing of controlled substances via the Internet consists solely of--

(I) refilling prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (55); or

(II) filling new prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (56); or

(ix) any other persons for whom the Attorney General and the Secretary have jointly, by regulation, found it to be consistent with effective controls against diversion and otherwise consistent with the public health and safety to exempt from the definition of an "online pharmacy".

(53) The term "homepage" means the opening or main page or screen of the website of an online pharmacy that is viewable on the Internet.

(54) The term "practice of telemedicine" means, for purposes of this subchapter, the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1395m(m) of Title 42, which practice--

(A) is being conducted--

(i) while the patient is being treated by, and physically located in, a hospital or clinic registered under section 823(f) of this title; and

(ii) by a practitioner--

(I) acting in the usual course of professional practice;

(II) acting in accordance with applicable State law; and

(III) registered under section 823(f) of this title in the State in which the patient is located, unless the practitioner--

(aa) is exempted from such registration in all States under section 822(d) of this title; or

(bb) is--

(AA) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

(BB) registered under section 823(f) of this title in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 823(f) of this title;

(B) is being conducted while the patient is being treated by, and in the physical presence of, a practitioner--

(i) acting in the usual course of professional practice;

(ii) acting in accordance with applicable State law; and

(iii) registered under section 823(f) of this title in the State in which the patient is located, unless the practitioner--

(I) is exempted from such registration in all States under section 822(d) of this title; or

(II) is--

(aa) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

(bb) registered under section 823(f) of this title in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 823(f) of this title;

(C) is being conducted by a practitioner--

(i) who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act;

(ii) acting within the scope of the employment, contract, or compact described in clause (i); and

(iii) who is designated as an Internet Eligible Controlled Substances Provider by the Secretary under section 831(g)(2) of this title;

(D)(i) is being conducted during a public health emergency declared by the Secretary under section 247d of Title 42; and

(ii) involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates, provided that such designation shall not be subject to the procedures prescribed by subchapter II of chapter 5 of Title 5;

(E) is being conducted by a practitioner who has obtained from the Attorney General a special registration under section 831(h) of this title;

(F) is being conducted--

(i) in a medical emergency situation--

(I) that prevents the patient from being in the physical presence of a practitioner registered under section 823(f) of this title who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;

(II) that prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 823(f) of this title;

(III) during which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and

(IV) that requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and

(ii) by a practitioner that--

(I) is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;

(II) is registered under section 823(f) of this title in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 823(f) of this title; and

(III) issues a controlled substance prescription in this emergency context that is limited to a maximum of a 5-day supply which may not be extended or refilled; or

(G) is being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

(55) The term "refilling prescriptions for controlled substances in schedule III, IV, or V"--

(A) means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of subsections (b) and (c) of section 829 of this title, as appropriate; and

(B) does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

(56) The term "filling new prescriptions for controlled substances in schedule III, IV, or V" means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if--

(A) the pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of subsections (b) and (c) of section 829 of this title (in this paragraph referred to as the "original prescription");

(B) the pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in subparagraph (A); and

(C) the practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

CREDIT(S)

(Pub.L. 91-513, Title II, § 102, Oct. 27, 1970, 84 Stat. 1242; Pub.L. 93-281, § 2, May 14, 1974, 88 Stat. 124; Pub.L. 95-633, Title I, § 102(b), Nov. 10, 1978, 92 Stat. 3772; Pub.L. 96-88, Title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub.L. 96-132, § 16(a), Nov. 30, 1979, 93 Stat. 1049; Pub.L. 98-473, Title II, § 507(a), (b), Oct. 12, 1984, 98 Stat. 2071; Pub.L. 98-509, Title III, § 301(a), Oct. 19, 1984, 98 Stat. 2364; Pub.L. 99-514, § 2, Oct. 22, 1986, 100 Stat. 2095; Pub.L. 99-570, Title I, §§ 1003(b), 1203, 1870, Oct. 27, 1986, 100 Stat. 3207-6, 3207-13, 3207-56; Pub.L. 99-646, § 83, Nov. 10, 1986, 100 Stat. 3619; Pub.L. 100-690, Title VI, § 6054, Nov. 18, 1988, 102 Stat. 4316; Pub.L. 101-647, Title XIX, § 1902(b), Title XXIII, § 2301, Title XXXV, § 3599I, Nov. 29, 1990, 104 Stat. 4852, 4858, 4932; Pub.L. 103-200, §§ 2(a), 7 to 9(a), Dec. 17, 1993, 107 Stat. 2333, 2340; Pub.L. 103-322, Title IX, § 90105(d), Title XXXIII, § 330024(a), (b), (d)(1), Sept. 13, 1994, 108 Stat. 1988, 2150; Pub.L. 104-237, Title II, §§ 204(a), 209, Title IV, § 401(a), (b), Oct. 3, 1996, 110 Stat. 3102, 3104, 3106, 3107; Pub.L. 104-294, Title VI, §§ 604(b)(4), 607(j), Oct. 11, 1996, 110 Stat. 3506, 3512; Pub.L. 105-115, Title I, § 126(c)(3), Nov. 21, 1997, 111 Stat. 2328; Pub.L. 106-172, §§ 3(c), 5(a), Feb. 18, 2000, 114 Stat. 9, 10; Pub.L. 106-310, Div. B, Title XXXVI, § 3622(a), Oct. 17, 2000, 114 Stat. 1231; Pub.L. 107-273, Div. B, Title IV, § 4002(c)(1), Nov. 2, 2002, 116 Stat. 1808; Pub.L. 108-358, § 2(a), Oct. 22, 2004, 118 Stat. 1661; Pub.L. 109-162, Title XI, § 1180, Jan. 5, 2006, 119 Stat. 3126; Pub.L. 109-177, Title VII, §§ 711(a)(1), (2)(A), 712(a)(1), Mar. 9, 2006, 120 Stat. 256, 257, 263; Pub.L. 110-425, § 3(a), Oct. 15, 2008, 122 Stat. 4821; Pub.L. 113-260, § 2(a), Dec. 18, 2014, 128 Stat. 2929; Pub.L. 114-198, Title III, § 303(a)(2), July 22, 2016, 130 Stat. 722.)

Notes of Decisions (136)

21 U.S.C.A. § 802, 21 USCA § 802
Current through P.L. 115-140.

End of Document

United States Code Annotated
Title 21. Food and Drugs (Refs & Annos)
Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)
Subchapter I. Control and Enforcement
Part B. Authority to Control; Standards and Schedules

21 U.S.C.A. § 811

§ 811. Authority and criteria for classification of substances

Effective: November 25, 2015

Currentness

(a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule--

(1) add to such a schedule or transfer between such schedules any drug or other substance if he--

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

(c) Factors determinative of control or removal from schedules

In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

(d) International treaties, conventions, and protocols requiring control; procedures respecting changes in drug schedules of Convention on Psychotropic Substances

(1) If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section.

(2)(A) Whenever the Secretary of State receives notification from the Secretary-General of the United Nations that information has been transmitted by or to the World Health Organization, pursuant to article 2 of the Convention on Psychotropic Substances, which may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State shall immediately transmit the notice to the Secretary of Health and Human Services who shall publish it in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the scientific and medical evaluations which he is to prepare respecting such drug or substance. The Secretary of Health and Human Services shall prepare for transmission through the Secretary of State to the World Health Organization such medical and scientific evaluations as may be appropriate regarding the possible action that could be proposed by the World Health Organization respecting the drug or substance with respect to which a notice was transmitted under this subparagraph.

(B) Whenever the Secretary of State receives information that the Commission on Narcotic Drugs of the United Nations proposes to decide whether to add a drug or other substance to one of the schedules of the Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State shall transmit timely notice to the Secretary of Health and Human Services of such information who shall publish a summary of such information in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the recommendation which he is to furnish, pursuant to this subparagraph, respecting such proposal. The Secretary of Health and Human Services shall evaluate the proposal and furnish a recommendation to the Secretary of State which shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

(3) When the United States receives notification of a scheduling decision pursuant to article 2 of the Convention on Psychotropic Substances that a drug or other substance has been added or transferred to a schedule specified in the notification or receives notification (referred to in this subsection as a "schedule notice") that existing legal controls applicable under this subchapter to a drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act do not meet the requirements of the schedule of the Convention in which such drug or substance has been placed, the Secretary of Health and Human Services after consultation with the Attorney General, shall first determine whether existing legal controls under this subchapter applicable to the drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act, meet the requirements of the schedule specified in the notification or schedule notice and shall take the following action:

(A) If such requirements are met by such existing controls but the Secretary of Health and Human Services nonetheless believes that more stringent controls should be applied to the drug or substance, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance, pursuant to subsections (a) and (b) of this section, to apply to such controls.

(B) If such requirements are not met by such existing controls and the Secretary of Health and Human Services concurs in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance under the appropriate schedule pursuant to subsections (a) and (b) of this section.

(C) If such requirements are not met by such existing controls and the Secretary of Health and Human Services does not concur in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall--

(i) if he deems that additional controls are necessary to protect the public health and safety, recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to subsections (a) and (b) of this section, to apply such additional controls;

(ii) request the Secretary of State to transmit a notice of qualified acceptance, within the period specified in the Convention, pursuant to paragraph 7 of article 2 of the Convention, to the Secretary-General of the United Nations;

(iii) request the Secretary of State to transmit a notice of qualified acceptance as prescribed in clause (ii) and request the Secretary of State to ask for a review by the Economic and Social Council of the United Nations, in accordance with paragraph 8 of article 2 of the Convention, of the scheduling decision; or

(iv) in the case of a schedule notice, request the Secretary of State to take appropriate action under the Convention to initiate proceedings to remove the drug or substance from the schedules under the Convention or to transfer the drug or substance to a schedule under the Convention different from the one specified in the schedule notice.

(4)(A) If the Attorney General determines, after consultation with the Secretary of Health and Human Services, that proceedings initiated under recommendations made under paragraph[1] (B) or (C)(i) of paragraph (3) will not be completed within the time period required by paragraph 7 of article 2 of the Convention, the Attorney General, after consultation with the Secretary and after providing interested persons opportunity to submit comments respecting the requirements of the temporary order to be issued under this sentence, shall issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. In the case of proceedings initiated under subparagraph (B) of paragraph (3), the Attorney General, concurrently with the issuance of such order, shall request the Secretary of State to transmit a notice of qualified acceptance to the Secretary-General of the United Nations pursuant to paragraph 7 of article 2 of the Convention. A temporary order issued under this subparagraph controlling a drug or other substance subject to proceedings initiated under subsections (a) and (b) of this section shall expire upon the effective date of the application to the drug or substance of the controls resulting from such proceedings.

(B) After a notice of qualified acceptance of a scheduling decision with respect to a drug or other substance is transmitted to the Secretary-General of the United Nations in accordance with clause (ii) or (iii) of paragraph (3)(C) or after a request has been made under clause (iv) of such paragraph with respect to a drug or substance described in a schedule notice, the Attorney General, after consultation with the Secretary of Health and Human Services and after providing interested persons opportunity to submit comments respecting the requirements of the order to be issued under this sentence, shall issue an order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention in the case of a drug or substance for which a notice of qualified acceptance was transmitted or whichever the Attorney General determines is appropriate in the case of a drug or substance described in a schedule notice. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. If, as a result of a review under paragraph 8 of article 2 of the Convention of the scheduling decision with respect to which a notice of qualified acceptance was transmitted in accordance with clause (ii) or (iii) of paragraph (3)(C)--

(i) the decision is reversed, and

(ii) the drug or substance subject to such decision is not required to be controlled under schedule IV or V to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention,

the order issued under this subparagraph with respect to such drug or substance shall expire upon receipt by the United States of the review decision. If, as a result of action taken pursuant to action initiated under a request transmitted under clause (iv) of paragraph (3)(C), the drug or substance with respect to which such action was taken is not required to be controlled under schedule IV or V, the order issued under this paragraph with respect to such drug or substance shall expire upon receipt by the United States of a notice of the action taken with respect to such drug or substance under the Convention.

(C) An order issued under subparagraph (A) or (B) may be issued without regard to the findings required by subsection (a) of this section or by section 812(b) of this title and without regard to the procedures prescribed by subsection (a) or (b) of this section.

(5) Nothing in the amendments made by the Psychotropic Substances Act of 1978 or the regulations or orders promulgated thereunder shall be construed to preclude requests by the Secretary of Health and Human Services or the Attorney General through the Secretary of State, pursuant to article 2 or other applicable provisions of the Convention, for review of scheduling decisions under such Convention, based on new or additional information.

(e) Immediate precursors

The Attorney General may, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it in a schedule, other substances shall not be placed in a schedule solely because they are its precursors.

(f) Abuse potential

If, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

(g) Exclusion of non-narcotic substances sold over the counter without a prescription; dextromethorphan; exemption of substances lacking abuse potential

(1) The Attorney General shall by regulation exclude any non-narcotic drug which contains a controlled substance from the application of this subchapter and subchapter II of this chapter if such drug may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this subchapter unless controlled after October 27, 1970 pursuant to the foregoing provisions of this section.

(3) The Attorney General may, by regulation, exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this subchapter if he finds such compound, mixture, or preparation meets the requirements of one of the following categories:

(A) A mixture, or preparation containing a nonnarcotic controlled substance, which mixture or preparation is approved for prescription use, and which contains one or more other active ingredients which are not listed in any schedule and which are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

(B) A compound, mixture, or preparation which contains any controlled substance, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.

(C) Upon the recommendation of the Secretary of Health and Human Services, a compound, mixture, or preparation which contains any anabolic steroid, which is intended for administration to a human being or an animal, and which, because of its concentration, preparation, formulation or delivery system, does not present any significant potential for abuse.

(h) Temporary scheduling to avoid imminent hazards to public safety

(1) If the Attorney General finds that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, he may, by order and without regard to the requirements of subsection (b) of this section relating to the Secretary of Health and Human Services, schedule such substance in schedule I if the substance is not

listed in any other schedule in section 812 of this title or if no exemption or approval is in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act. Such an order may not be issued before the expiration of thirty days from--

(A) the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and

(B) the date the Attorney General has transmitted the notice required by paragraph (4).

(2) The scheduling of a substance under this subsection shall expire at the end of 2 years from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings under subsection (a)(1) of this section with respect to the substance, extend the temporary scheduling for up to 1 year.

(3) When issuing an order under paragraph (1), the Attorney General shall be required to consider, with respect to the finding of an imminent hazard to the public safety, only those factors set forth in paragraphs (4), (5), and (6) of subsection (c) of this section, including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(4) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(5) An order issued under paragraph (1) with respect to a substance shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under subsection (a) of this section with respect to such substance.

(6) An order issued under paragraph (1) is not subject to judicial review.

(i) Temporary and permanent scheduling of recently emerged anabolic steroids

(1) The Attorney General may issue a temporary order adding a drug or other substance to the definition of anabolic steroids if the Attorney General finds that--

(A) the drug or other substance satisfies the criteria for being considered an anabolic steroid under section 802(41) of this title but is not listed in that section or by regulation of the Attorney General as being an anabolic steroid; and

(B) adding such drug or other substance to the definition of anabolic steroids will assist in preventing abuse or misuse of the drug or other substance.

(2) An order issued under paragraph (1) shall not take effect until 30 days after the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued. The order shall expire not later than 24 months after the date it becomes effective, except that the Attorney General may, during the pendency of proceedings under paragraph (6), extend the temporary scheduling order for up to 6 months.

(3) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(4) A temporary scheduling order issued under paragraph (1) shall be vacated upon the issuance of a permanent scheduling order under paragraph (6).

(5) An order issued under paragraph (1) is not subject to judicial review.

(6) The Attorney General may, by rule, issue a permanent order adding a drug or other substance to the definition of anabolic steroids if such drug or other substance satisfies the criteria for being considered an anabolic steroid under section 802(41) of this title. Such rulemaking may be commenced simultaneously with the issuance of the temporary order issued under paragraph (1).

(j) Interim final rule; date of issuance; procedure for final rule

(1) With respect to a drug referred to in subsection (f), if the Secretary of Health and Human Services recommends that the Attorney General control the drug in schedule II, III, IV, or V pursuant to subsections (a) and (b), the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule controlling the drug in accordance with such subsections and section 812(b) of this title using the procedures described in paragraph (3).

(2) The date described in this paragraph shall be the later of--

(A) the date on which the Attorney General receives the scientific and medical evaluation and the scheduling recommendation from the Secretary of Health and Human Services in accordance with subsection (b); or

(B) the date on which the Attorney General receives notification from the Secretary of Health and Human Services that the Secretary has approved an application under section 505(c), 512, or 571 of the Federal Food, Drug, and Cosmetic Act or

section 262(a) of Title 42, or indexed a drug under section 572 of the Federal Food, Drug, and Cosmetic Act, with respect to the drug described in paragraph (1).

(3) A rule issued by the Attorney General under paragraph (1) shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor. The interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, the Attorney General shall issue a final rule in accordance with the scheduling criteria of subsections (b), (c), and (d) of this section and section 812(b) of this title.

CREDIT(S)

(Pub.L. 91-513, Title II, § 201, Oct. 27, 1970, 84 Stat. 1245; Pub.L. 95-633, Title I, § 102(a), Nov. 10, 1978, 92 Stat. 3769; Pub.L. 96-88, Title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub.L. 98-473, Title II, §§ 508, 509(a), Oct. 12, 1984, 98 Stat. 2071, 2072; Pub.L. 108-358, § 2(b), Oct. 22, 2004, 118 Stat. 1663; Pub.L. 112-144, Title XI, § 1153, July 9, 2012, 126 Stat. 1132; Pub.L. 113-260, § 2(b), Dec. 18, 2014, 128 Stat. 2930; Pub.L. 114-89, § 2(b), Nov. 25, 2015, 129 Stat. 700.)

Notes of Decisions (74)

Footnotes

[1] So in original. Probably should be “subparagraph”.

21 U.S.C.A. § 811, 21 USCA § 811
Current through P.L. 115-140.

End of Document

United States Code Annotated
Title 21. Food and Drugs (Refs & Annos)
Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)
Subchapter I. Control and Enforcement
Part B. Authority to Control; Standards and Schedules

21 U.S.C.A. § 812

§ 812. Schedules of controlled substances

Effective: July 9, 2012

Currentness

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) Schedule I--

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) Schedule II--

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) Schedule III--

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV--

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) Schedule V--

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Initial schedules of controlled substances

Schedules I, II, III, IV, and V shall, unless and until amended[1] pursuant to section 811 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

Schedule I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.

(2) Allylprodine.

(3) Alphacetylmathadol.[2]

(4) Alphameprodine.

(5) Alphamethadol.

(6) Benzethidine.

(7) Betacetylmethadol.

(8) Betameprodine.

(9) Betamethadol.

(10) Betaprodine.

(11) Clonitazene.

(12) Dextromoramide.

(13) Dextrorphan.

(14) Diampromide.

(15) Diethylthiambutene.

(16) Dimenoxadol.

(17) Dimepheptanol.

(18) Dimethylthiambutene.

(19) Dioxaphetyl butyrate.

(20) Dipipanone.

(21) Ethylmethylthiambutene.

(22) Etonitazene.

(23) Etoxeridine.

(24) Furethidine.

(25) Hydroxypethidine.

(26) Ketobemidone.

(27) Levomoramide.

(28) Levophenacylmorphan.

(29) Morpheridine.

(30) Noracymethadol.

(31) Norlevorphanol.

(32) Normethadone.

(33) Norpipanone.

(34) Phenadoxone.

(35) Phenampromide.

(36) Phenomorphan.

(37) Phenoperidine.

(38) Piritramide.

(39) Proheptazine.

(40) Properidine.

(41) Racemoramide.

(42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine.

(2) Acetyldihydrocodeine.

(3) Benzylmorphine.

(4) Codeine methylbromide.

(5) Codeine-N-Oxide.

(6) Cyprenorphine.

(7) Desomorphine.

(8) Dihydromorphine.

(9) Etorphine.

(10) Heroin.

(11) Hydromorphinol.

(12) Methyldesorphine.

(13) Methylhydromorphine.

(14) Morphine methylbromide.

(15) Morphine methylsulfonate.

(16) Morphine-N-Oxide.

(17) Myrophine.

(18) Nicocodeine.

(19) Nicomorphine.

(20) Normorphine.

(21) Pholcodine.

(22) Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine.

(2) 5-methoxy-3,4-methylenedioxy amphetamine.

(3) 3,4,5-trimethoxy amphetamine.

(4) Bufotenine.

(5) Diethyltryptamine.

(6) Dimethyltryptamine.

(7) 4-methyl-2,5-dimethoxyamphetamine.

(8) Ibogaine.

(9) Lysergic acid diethylamide.

(10) Marihuana.

(11) Mescaline.

(12) Peyote.

(13) N-ethyl-3-piperidyl benzilate.

(14) N-methyl-3-piperidyl benzilate.

(15) Psilocybin.

(16) Psilocyn.

(17) Tetrahydrocannabinols.

(18) 4-methylmethcathinone (Mephedrone).

(19) 3,4-methylenedioxypyrovalerone (MDPV).

(20) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E).

(21) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D).

(22) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C).

(23) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I).

(24) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2).

(25) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4).

(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H).

(27) 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N).

(28) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P).

(d)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

(2) In paragraph (1):

(A) The term "cannabimimetic agents" means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

(ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

(B) Such term includes--

(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497);

(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog);

(iii) 1-pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678);

(iv) 1-butyl-3-(1-naphthoyl)indole (JWH-073);

(v) 1-hexyl-3-(1-naphthoyl)indole (JWH-019);

(vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);

(vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);

(viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081);

(ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);

(x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);

(xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);

(xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);

(xiii) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19 and RCS-4);

(xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8); and

(xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203).

Schedule II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) coca[3] leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine.

(2) Anileridine.

(3) Bezitramide.

(4) Dihydrocodeine.

(5) Diphenoxylate.

(6) Fentanyl.

(7) Isomethadone.

(8) Levomethorphan.

(9) Levorphanol.

(10) Metazocine.

(11) Methadone.

(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.

(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.

(14) Pethidine.

(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.

(18) Phenazocine.

(19) Piminodine.

(20) Racemethorphan.

(21) Racemorphan.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

Schedule III

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Phenmetrazine and its salts.

(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

(4) Methylphenidate.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.

(2) Chorhexadol.

(3) Glutethimide.

(4) Lysergic acid.

(5) Lysergic acid amide.

(6) Methyprylon.

(7) Phencyclidine.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

(c) Nalorphine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit,

with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(e) Anabolic steroids.

Schedule IV

(1) Barbital.

(2) Chloral betaine.

(3) Chloral hydrate.

(4) Ethchlorvynol.

(5) Ethinamate.

(6) Methohexital.

(7) Meprobamate.

(8) Methylphenobarbital.

(9) Paraldehyde.

(10) Petrichloral.

(11) Phenobarbital.

Schedule V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

CREDIT(S)

(Pub.L. 91-513, Title II, § 202, Oct. 27, 1970, 84 Stat. 1247; Pub.L. 95-633, Title I, § 103, Nov. 10, 1978, 92 Stat. 3772;

Pub.L. 98-473, Title II, §§ 507(c), 509(b), Oct. 12, 1984, 98 Stat. 2071, 2072; Pub.L. 99-570, Title I, § 1867, Oct. 27, 1986, 100 Stat. 3207-55; Pub.L. 99-646, § 84, Nov. 10, 1986, 100 Stat. 3619; Pub.L. 101-647, Title XIX, § 1902(a), Nov. 29, 1990, 104 Stat. 4851; Pub.L. 112-144, Title XI, § 1152, July 9, 2012, 126 Stat. 1130.)

Notes of Decisions (138)

Footnotes

1 Revised schedules are published in the Code of Federal Regulations, Part 1308 of Title 21, Food and Drugs.

2 So in original. Probably should be “Alphacetylmethadol”.

3 So in original. Probably should be capitalized.

21 U.S.C.A. § 812, 21 USCA § 812
Current through P.L. 115-140.