Written Statement of Denise C. Barrett

On Behalf of the Federal Public and Community Defenders

Before the United States Sentencing Commission

Public Hearing on Counterfeit and Adulterated Drugs

March 13, 2013

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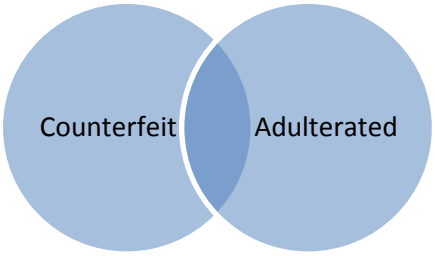
My name is Denise C. Barrett and I am National Sentencing Resource Counsel with the Federal Public and Community Defenders. I would like to thank the Commission for holding this hearing and giving me the opportunity to testify on behalf of the Federal Public and Community Defenders regarding counterfeit and adulterated drugs.

I. Counterfeit Drug Offenses and the Offense of Intentionally Adulterating Drugs under 21 U.S.C. § 333(b)(7)

Before discussing the details of the Commission's proposed amendments, we respond to the Commission's request for comment comparing and contrasting the offense of trafficking in counterfeit drugs, 18 U.S.C. § 2320(a)(4), and the offense of intentionally adulterating drugs such that they have a reasonable probability of causing serious adverse health consequences or death. 21 U.S.C. § 333(b)(7). These two offenses involve two distinct primary harms. The gravamen of the counterfeiting offense at 18 U.S.C. § 2320(a)(4) – a subsection of the general counterfeiting statute – is an infringement of the intellectual property rights of drug companies. The gravamen of the adulterated drug offense is the permanent physical harm[1] or death caused by intentionally and knowingly adulterating drugs in specified ways. Because section 333(b)(7) is an offense that by definition jeopardizes public safety, and targets those who adulterate drugs, it should be deemed more serious than an offense that chiefly threatens a property right, and in only some instances poses any real threat of bodily harm.

This is not to say that some conduct cannot involve both offenses. As illustrated below, the two offenses can sometimes overlap, but not always.



To be considered counterfeit for purposes of section 2320(a)(4), the drug need not be adulterated. Nor must the drug be an inferior product.[2] To be counterfeit, a drug need only bear

[1] The term "serious adverse health consequence" has a distinct meaning under FDA law. It is a permanent, not temporary or medically reversible condition. *See* Discussion, *infra*.

[2] The FDA's website uses the term "counterfeit" medicine" quite "expansively," equating it with adulterated drugs, but the legal difference between adulterated and counterfeit is quite clear. *Compare* 21

the "the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug." 21 U.S.C. § 321(g)(2). Nor is an adulterated drug necessarily counterfeit.[3] Indeed, one of the worst cases of adulterated drugs in recent times – an adulterated steroid that caused meningitis – was not counterfeit.[4] In some instances, a drug may be both counterfeit and adulterated, *e.g.*, because it bears a trademark of a manufacturer other than the one who made it and lacks an active ingredient. In such a case, the party who adulterated it and trafficked in it would be subject to prosecution under both 21 U.S.C. § 333(b)(7) and 18 U.S.C. § 2320(a)(4) or any of the other provisions prohibiting adulteration, *see* 21 U.S.C. § 331(a)(b), 331(i)(3), and counterfeit drugs, 21 U.S.C. § 331(i)(3).[5]

Prosecutions under the Counterfeit Statutes. Before the enactment of 18 U.S.C. § 2320(a)(4), two statutes covered counterfeit drugs: (1) 18 U.S.C. § 2320(a)(1), which prohibits trafficking in counterfeit goods and services; and (2) 21 U.S.C. § 331(i), which prohibits the "doing of any act which causes a drug to be counterfeit, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug." Section 2320(a)(1) is a felony punishable by not more than ten years imprisonment. Section 331(i) is either a misdemeanor punishable by not more than one year imprisonment or a felony punishable by up to three years imprisonment if the offense was also committed with the intent to defraud or mislead. 21 U.S.C. § 333(a)(1) and (2). Prosecutors use both statutes in counterfeit drug cases, with charging decisions varying from district-to-district and case-to-case.

U.S.C. § 321 (g)(2) (defining counterfeit) *with* 21 U.S.C. § 351 (setting forth circumstances when a drug shall be deemed to be "adulterated").

[3] In other contexts, Congress has recognized a distinction between counterfeit and adulterated drugs. *See* 21 U.S.C. § 331(b) (prohibiting "adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce); 21 U.S.C. § 331(i)(3) (prohibiting "any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug); 21 U.S.C. § 355(e) (directing FDA to develop standards and technologies of "securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs").

[4] FDA, *Multistate Outbreak of Fungal Meningitis and other Infections*, http://www.fda.gov/Drugs/DrugSafety/FungalMeningitis/default.htm; *see also* CNN Health, *Feds Open Criminal Inquiry Into Firm Linked To Deadly Meningitis Outbreak*, http://www.cnn.com/2012/10/23/health/massachusetts-outbreak-criminal-investigation.

[5] *See, e.g.*, *United States v. George*, 233 Fed. Appx. 402 (5th Cir. 2007) (defendant sentenced to 24 months following convictions for multiple counts of trafficking in counterfeit erectile dysfunction drugs, 18 U.S.C. § 2320(a); causing the counterfeiting of trademarks on drugs, 21 U.S.C. § 331(i), and causing the introduction of adulterated or misbranded drugs with the intent to defraud or mislead, 21 U.S.C. § 331(a)); *United States v. Mark Hughes*, 4:0-cr-00401-HEA-1 (E.D. Mo. 2012) (defendant sentenced to 46 months imprisonment for trafficking in counterfeit erectile dysfunction drugs in violation of 18 U.S.C. § 2320, and concurrent term of 36 months for adulteration/misbranding under 21 U.S.C. § 33).

Our review of counterfeit drug prosecutions shows that a sizable number involve counterfeit erectile dysfunction drugs, including counterfeit Viagra®, Cialis®, and Levitra®. Other counterfeit drugs, such as weight loss drugs, anti-anxiety medications, and anti-depressants, are prosecuted much less frequently. Here are some examples of cases where the court imposed significant terms of imprisonment under the currently applicable guidelines:

- In Texas, a defendant convicted of conspiracy to traffick in counterfeit drugs, misbranding, and counterfeiting of trademarks was sentenced to 78 months imprisonment and ordered to pay $1,286,060 in restitution to Eli Lilly Corporation and Pfizer Pharmaceuticals.[6]

- In a Houston case prosecuted under both 18 U.S.C. § 2320 and 21 U.S.C. § 331, the 32-year-old owner of a small business received a sentence of 33 months imprisonment following his conviction for conspiring with others in the People's Republic of China to traffic in counterfeit goods and trafficking in counterfeit and misbranded pharmaceuticals. The case arose out of the discovery at a mail facility in California of two packages containing about 6,500 loose counterfeit Viagra® pills.[7]

- In the Western District of North Carolina, a 56-year-old man was recently sentenced to 24 months imprisonment for selling counterfeit Viagra® and Cialis® at a convenience store in Charlotte, North Carolina. The court also ordered him to pay a $10,000 fine. The pills had some of the active ingredients of the drugs, but the strength was unknown. He was convicted of conspiracy to violate § 2320(a) and § 331(i) as well as several substantive counts of 18 U.S.C. § 2320(a) and 21 U.S.C. § 331(i).[8]

- In Los Angeles, a 36-year-old "drop shipper" who packaged and shipped more than 160,000 counterfeit drugs, including Viagra®, Cialis®, Valium®, Xanax®, and Lipitor® for a Chinese national living in New Zealand received a sentence of 24 months imprisonment following his conviction for conspiracy to traffic in counterfeit goods, in violation of 18 U.S.C. § 2320. He was also ordered to pay $324,530 in restitution to the pharmaceutical companies that manufactured the brand name products.[9]

- In Colorado, the government recommended, and the court imposed, a top-of-the-guideline range sentence of 87 months on the defendant who was convicted of trafficking

[6] *United States v. Kevin Xu*, 4:07-cr-00362-1 (S.D. Tex. 2009).

[7] *United States v. En Wang*, 4:10-cr-00087-1 (S.D. Tex. 2011).

[8] *United States v. Awni Shauaib Zayyad*, 3:10-cr-00243-RJC-DCK-1 (W.D.N.C. 2013).

[9] *United States v. Francis Ortiz Gonzalez*, No. CR-10-136-GW (C.D. Cal. 2013).

in a counterfeit version of the weight loss drug, Alli®. He was also ordered to pay $507,567.94 in restitution, including $417,396.39 to Eli Lilly.[10]

In other cases, defendants have received shorter below guidelines sentences for similar felony offenses,[11] or the government has allowed them to plead to a misdemeanor counterfeit offense under 21 U.S.C. §§ 331, 333.[12]

Intentional Adulteration Likely to Cause Permanent Injury or Death. Because 21 U.S.C. § 333(b)(7) is a new criminal statute, it is too soon to tell what these offenses will entail. Nonetheless, an examination of the elements of the adulteration offense under subsection 333(b)(7), FDA recall practices, and FDA warning letters regarding adulterated drugs give some context to this new offense.

To be convicted of an offense under section 333(b)(7), the defendant must knowingly and intentionally adulterate a drug in a specified way and such that it "has a reasonable probability of causing serious adverse health consequences or death to humans or animals." For purposes of section 333(b)(7), a drug is adulterated if

- if contains "any filthy, putrid, or decomposed substance";
- "its strength differs from, or its quality or purity falls below, the standard set forth in an [official] compendium";
- "its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess";

[10] *United States v. Shengyang Zhou*, 1:10-cr-00226-PAB-1 (D. Colo. 2011).

[11] *See, e.g.*, *United States v. Gregory Bochter*, No. 6:12-cr-60-orl-18KRS (M.D. Fla. 2012) (8 month sentence of imprisonment imposed on drop shipper for trafficking in about 6000 counterfeit erectile dysfunction drugs from China, in violation of 18 U.S.C. § 2320); *United States v. Sarah Knott*, No. 8:11-cr-001100-JFM-1 (D. Md. 2012) (2 years probation for trafficking in over 45, 0000 counterfeit Viagra® tablets, in violation of 18 U.S.C. § 2320); *United States v. Curtis Henry*, No. 6:11-cr-06165-CJS-1 (W.D.N.Y. 2012) (3 years probation for trafficking in 740 counterfeit erectile dysfunction drugs from China); *United States v. Frank Fu Jen Huang*, 2:04-cr-01298-R-1 (C.D. Cal. 2006) (departure/variance from 78-97 months range of imprisonment to six months of home detention, 2,500 hours of community service, and 5 years probation).

[12] *See, e.g.*, *United States v. Ali Jones*, 2:08-cr-00887-JWJ-1 (C.D. Cal. 2008) (2 years probation for sale of counterfeit erectile dysfunction drugs advertised on craigslist; government agreed not to charge the defendant with a felony count under 18 U.S.C. § 2320); *United States v. Jun Huang*, 2:09-cr-01028-CT-1 (C.D. Cal. 2010) (1 year probation for sale of counterfeit drugs in violation of 21 U.S.C. § 331); *United States v. David Srulevitch*, No. 2:04-cr-01559-R-1 (C.D. Cal. 2005) (5 years probation for making about 700,000 counterfeit Viagra®).

- "any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."

21 U.S.C. § 351(a)(1), (b), and (c).

In addition to being adulterated in one of these specific ways, the adulterated drug must have a "reasonable probability of causing serious adverse health consequences or death to humans or animals." 21 U.S.C. § 333(b)(7). The language "serious adverse health consequences or death" is regulatory language the FDA uses to describe a Class I recall.[13] While the term "serious adverse health consequence" is not defined by statute or regulation, it is essentially a permanent or medically irreversible health consequence.[14] Class I recalls based upon concerns that an adulterated drug may cause serious adverse health consequences are typically voluntary recalls from the manufacturing firm. For example, in December 2012, Qualitest – a generic pharmaceutical manufacturer – recalled 101 lots of hydrocodone bitartrate and acetaminophen tablets 10mg/500mg[15] because of the potential for the tablets to have a higher dosage of acetaminophen than indicated.[16] In another case, vials of a blood thinner – argatroban – were recalled because one vial was reported to have crystalline and fiber particulates.[17] In a much more high profile case that resulted in a criminal investigation, a Class I recall issued for several

[13] 21 C.F.R. § 7.3(m). FDA has a three-tiered recall classification system, which indicates the "relative degree of health hazard presented by the product being recalled." *Id.* Class I is discussed in the text. Class II recalls involve a situation where "use of or exposure to the [drug] may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." A Class III recall involves a situation "in which use of or exposure to a [drug] is not likely to cause adverse health consequences." *Id. See also* FDA, *Safety: Background and Definitions*, http://www.fda.gov/Safety/Recalls/ucm165546.htm.

[14] *Cf*. 21 C.F.R. § 7.3 (m)(2) (defining a Class II recall as one where use or exposure to the product may "cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote").

[15] This is the generic equivalent of the brand name Lortab®.

[16] FDA, *Enforcement Report – Week of February 6, 2013*, http://www.accessdata.fda.gov/scripts/enforcement/enforce_rpt-Product Tabs.cfm?action=select&recall_number=D-138-2013&w=02062013&lang=eng; Qualitest, News Release, http://www.qualitestrx.com.

[17] FDA, *Enforcement Report – Week of August 8, 2012*, http://www.accessdata.fda.gov/scripts/enforcement/enforce_rpt-Product-Tabs.cfm?action=select&recall_number=D-1429-2012&w=08082012&lang=eng.

different solutions distributed by the New England Compounding Center. The contaminated drugs have been linked to an outbreak of fungal meningitis.[18]

In addition to working with manufacturers to recall a drug, the FDA may issue warning letters to pharmaceutical manufacturing and compounding facilities alleging that drugs are adulterated under the provisions of 21 U.S.C. § 351(a)(1), (b), (c), or (d) – the provisions at issue in 21 U.S.C. § 333(b)(7).[19] These warning letters typically set forth violations discovered during FDA inspections, measures that must be taken to correct the violations within a specified time, and consequences for failing to do so.

To our knowledge, most of the problems with adulterated drugs subject to Class I recalls or warning letters are handled through the regulatory process, not criminal prosecutions. The relatively small number of prosecutions for adulteration under 21 U.S.C. § 331(a) and (b) suggest that there will be fewer prosecutions for the more serious offense of intentional adulteration likely to result in permanent physical harm or death. Prior to the enactment of 21 U.S.C. § 333(b)(7), two statutory provisions expressly addressed adulterated drugs. Section 331(a) prohibited "[t]he introduction or delivery for introduction in to interstate commerce of any. . . drug. . . that is adulterated or misbranded." Section 331(b) prohibited "[t]he adulteration or misbranding of any. . . drug. . . in interstate commerce." Violations of these provisions are misdemeanor offenses, punishable by a term of imprisonment for not more than one year,[20] or felonies, punishable for not more than three years, if the violations were committed with the intent to defraud or mislead or the person had a prior conviction under 21 U.S.C. § 331. *See* 21

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[18] FDA, *Multistate Outbreak of Fungal Meningitis and other Infections*, http://www.fda.gov/Drugs/DrugSafety/FungalMeningitis/default.htm; *see also* CNN Health, *Feds Open Criminal Inquiry Into Firm Linked To Deadly Meningitis Outbreak*, http://www.cnn.com/2012/10/23/health/massachusetts-outbreak-criminal-investigation.

[19] *See, e.g.*, Letter from Emma Singleton, Dir., Public Health Service, Food and Drug Administration, Florida District, to Paul Franck, President and Chief Executive Officer, Franck's Lab, Inc. (July 9, 2012) (charging adulteration of injection drug product under 21 U.S.C. §351(a)(1) and (c) because of presence of microorganisms and because strength, purity, and quality were different from what it is represented to possess); Letter from Emma Singleton, Dir., Public Health Service, Food and Drug Administration, Florida District, to Dr. Michael Rizo, Infupharma, LLC (July 30, 2012) (alleging that vials of Avastin® – an injectable cancer drug, which contained microorganisms, consisted of "filthy, putrid or decomposed substance"); Letter from Michael M. Levy, Dir. Division of New Drugs and Labeling Compliance, Center for Drug Evaluation and Research, to Eugene Tagazzo, Hopewell Pharmacy and Compounding Center (Sept. 28, 2009) (alleging that injectable STS were not "recognized in official compendium and their strengths differ from, or their quality or purity fall below that which they purport or are represented to possess" and that they "contain a substance [DEGMEE], mixed therewith so as to reduce their quality or strength").

[20] Even though a single count of conviction carries a maximum of one year imprisonment, prosecutors may pursue multiple counts that yield consecutive sentences.

U.S.C. §§ 331(b) & 333(a). Both of these offenses are referred to USSG §2N2.1, which carries a base offense level of 6, a 4-level enhancement for sustaining a prior conviction under 21 U.S.C. § 331, and a cross-reference to §2B1.1 if the offense involved fraud. In FY 2011, §2N2.1 applied in only 34 cases. It is not clear how many of those cases involved adulterated drugs because subsections 331(a) and (b) cover misbranding, as well as adulteration of non-drug products, including food, tobacco, and cosmetics.[21]

One of the more serious cases of an adulterated drug prosecution under 21 U.S.C. § 331 arose in connection with the distribution of adulterated cancer drugs from foreign countries. [22] Some of the drugs, shipped in cold packs, were wet and disintegrated upon receipt. These drugs were adulterated because "the methods of their storage and shipment were not appropriate and did not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of these prescription drugs."[23] The defendant pled guilty to conspiracy to cause the introduction of adulterated prescription drugs into interstate commerce, in violation of 18 U.S.C. § 371 and 21 U.S.C. § 331. His final offense level under §2N1.2 was 20, criminal history category I, with a range of 33 to 41 months. At sentencing, the government sought a 41 month sentence. After careful consideration of all of the 3553(a) factors, the court imposed a below guideline sentence of 24 months imprisonment.[24]

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[21] Of the 21 U.S.C. §§ 331(a) and (b) prosecutions we were able to discover involving drugs, the charges were often predicated on misbranding, not adulteration. *See, e.g., United Sates v. Isablle Martire*, No 8:11-cr-00373 (D. Md. 2011) (oncologist pled guilty to introducing misbranded drugs into market place when she purchased drugs that had been approved for use in the United Kingdom and Europe but not by the FDA, and then treated her patients with them)*; United States v. Nicholas Lundsten*, No. 2009-cr-00283 (D. Minn. 2010) (26 year old charged with misdemeanor misbranding and sentenced to 9 months for selling counterfeit erectile dysfunction drugs; government elected not to pursue a felony count); *United States v. Patrick Barron*, No. 2009-cr-00283 (D. Minn. 2010) (defendant sentenced to nine months imprisonment following misdemeanor conviction for introducing misbranded Xanax and Phentermine from China; the government dropped a felony count to spare the defendant the collateral consequences of a felony conviction).

[22] Another high profile case involving adulterated drugs occurred in 2008 when serious injuries and 81 deaths were linked to contaminated heparin manufactured by Baxter HealthCare Corporation, which had obtained the active ingredient from China. The FDA believed that the contamination was deliberate and economically motivated. *See* U.S. Gov't Accountability Office, *GAO-11-95, FDA Response to Heparin Contamination* 1 (2010). Numerous civil suits were filed against Baxter, but we are unaware of any criminal prosecutions.

[23] FDA, U.S. Dep't of Justice Press Release, August 23, 2012: *California Man Sentenced for Importing Adulterated Cancer Drugs; Forfeits $1.4 million & Land Rover Automobile*, http://www.fda.gov/ICECI/CriminalInvestigations/ucm316986.htm.

[24] *United Sates v. James Newcomb*, No. 4:12-CR-9 RWS (E.D. Mo. 2012) (sentencing transcript). Another defendant in the same case, who helped Newcomb run his business, and who cooperated, received a probationary sentence of five years. *Id.* A doctor who was convicted of misbranding in

In summary, given the nature of adulteration offenses brought under existing law and their relative infrequency, it is difficult to project what kinds of cases will be prosecuted under the provisions of 21 U.S.C. § 333(b)(7), which compared with §§ 331(a) and (b) has a more heightened mens rea requirement, a specific actus reus requirement that the defendant adulterate the drug, a more narrow definition of adulteration, and an additional element that the adulteration have a reasonable probability of causing serious adverse health consequences or death to humans or animals.

II. Proposed Amendments for Counterfeit Drugs

The Commission proposes three options to respond to section 717 of the Food and Drug Administration Safety and Innovation Act (FDASIA), Pub.L. 112-144 (July 9, 2012), which amended section 2320 to add a new subsection (a)(4) that prohibits trafficking in a counterfeit drug, and which carries a twenty year maximum term of imprisonment. The FDASIA also contained a directive to the Commission to, inter alia, "review and amend, *if appropriate*" the guidelines and policy statements "in order to reflect the intent of Congress that such penalties be increased in comparison to those currently provided by the guidelines and policy statements." (emphasis added).

Given the range of sentences imposed in counterfeit drug cases, as discussed above, and the ability of the current guidelines to capture aggravating factors that may be associated with 18 U.S.C. § 2320(a)(4) offenses, we encourage the Commission to forego making any amendments to the guidelines other than cross-referencing 18 U.S.C. § 2320(a)(4) to §2B5.3.

If the Commission nonetheless believes that further amendment is necessary, we would encourage it to adopt a variant of Option 2 with a 2-level enhancement and minimum base offense level of 12 if the offense involved a counterfeit drug. We do not believe that the current 2-level, minimum base offense level of 14, enhancement for the "conscious or reckless risk of death or serious bodily injury" should be changed to a 4-level enhancement, as proposed in Option 2.

Offenses under section 2320 are currently referenced to §2B5.3, which has a base offense level of 8 and multiple specific offense characteristics (SOCS), including the following that are especially relevant to counterfeit drug cases:

- multiple level adjustments for the infringement amount, §2B5.3(b)(1);
- a 2-level increase with minimum offense level of 12 for importation, §2B5.3(b)(3);

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connection with his receipt of the drugs received two years probation. *United State v. Abid Nisar*, No. 4:12-cr-00009-RSW-3 (E.D. Mo. 2012).

- a 2-level increase for conscious or reckless risk of death or serious bodily injury with a minimum offense level of 14, §2B5.3(b)(5).

The application note also includes a general departure provision for cases where the offense level "substantially understates of overstates the seriousness of the offense." USSG §2B5.3, comment. (n.4).

As discussed earlier, defendants convicted of larger-scale trafficking in counterfeit drugs have received significant sentences of imprisonment under these provisions while those engaged in smaller-scale trafficking have received lower sentences, often with the government's agreement.

While the congressional directive expresses the intent of Congress that penalties for offenses involving counterfeit drugs "be increased in comparison to those currently provided by the guidelines and policy statements," Pub. L. 112-144, § 717(b), the legislative history of the FDASIA is not clear on whether Congress had an accurate understanding of the penalties imposed in *counterfeit drug* cases as opposed to counterfeit goods cases. The Honorable F. James Sensenbrenner, Jr., cited the following data: "According to the Sentencing Commission, between FY06 and FY10, there were 385 federal prosecutions for counterfeit goods. The median sentence was 17 months. The mean sentence was only 10 months."[25] It does not appear that Congress had before it information regarding the actual penalties imposed *in counterfeit drug cases* prosecuted under the felony provisions of 18 U.S.C. § 2320. Nor does it appear that the data accounted for the number of cases where the government may have moved for a downward departure for cooperation or otherwise agreed to a sentence less than the applicable guideline range.

Defenders do not have access to the data necessary to determine the average penalties imposed in counterfeit drug prosecutions under 18 U.S.C. § 2320, but a review of available cases, discussed above, suggests that the average guideline range could well be over ten months. In those cases where the sentence was less than ten months, the government often agreed to the disposition. Instead of rushing to amend the guidelines, we think the more prudent course of action is to collect the empirical evidence about drug counterfeiting cases prosecuted under 18 U.S.C. §2320 to develop a full picture of the actual sentences imposed and the reasons for the sentences.

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[25] *Safe Doses Act, The Counterfeit Drug Penalty Enhancement Act of 2011, and the Foreign Counterfeit Prevention Act: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Security of the Committee on the Judiciary, House of Representatives*, 112th Cong. 2 (March 28, 2012) (statement of Honorable F. James Sensenbrenner, Jr.), http://judiciary.house.gov/hearings/printers/112th/112-132_73542.PDF.

With respect to Congress's suggestion that a ten month sentence is too low for a counterfeit drug offense, the current guideline contains numerous enhancements that will increase the guidelines beyond the 10-16 month range in the typical case. Infringement amount alone can greatly increase a sentence. Indeed, our review of counterfeit drug cases shows infringement amounts leading to increases as high as 8, 10, and 14-levels.

The guidelines also provide for a 2-level enhancement, and a minimum offense level of 12, if the offense involved importation. USSG §2B5.3(b)(3). Because most counterfeit drugs are imported from other countries, that enhancement and minimum offense level already provide for the minimum offense level of 12 that federal agencies are seeking for counterfeit drug offenses.[26]

A. Comments on Options 1 and 2 of the Proposed Amendment

Option 1 of the proposed amendment would add a [2][4]-level increase if the offense involved a counterfeit drug, with a minimum offense level of 14. Option 2 would add a 2-level increase with a minimum offense level of 12; and increase from 2-levels to 4 the current adjustment for "conscious or reckless risk of death or serious bodily injury" while keeping the minimum offense level of 14. Option 2 would also minimize the cumulative effect of multiple SOCs by limiting their application to the one that results in the "greatest" increase.

Option 2 appears to be based upon recommendations of the Counterfeit Pharmaceutical, Inter-Agency Working Group, which includes the Office of the Intellectual Property Enforcement Coordinator, the Food and Drug Administration, U.S. Customs and Border Protection, U.S. Immigration and Customs Enforcement, the Departments of Justice, State, and Commerce, and the Agency for International Development.[27] Those same recommendations are set forth in the Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations.[28]

While we believe the current guidelines are adequate for counterfeit drug offenses, if the Commission nonetheless wants to proceed with an amendment, we believe the 2-level, minimum offense level of 12, for counterfeit drugs in Option 2 has a better chance of capturing offense

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[26] *See* Executive Office of the President of the United States, *Counterfeit Pharmaceutical Inter-Agency Working Group Report to the President of the United States and to Congress* 3, 6-8, 11-14, 17 (March 2011) (discussing problems of importation of counterfeit drugs and recommending minimum offense level of 12 for the sale of counterfeit drugs); *Executive Office of the President of the United States Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations* 8 (March 2011).

[27] *Counterfeit Pharmaceutical Interagency Working Group, supra* note 26.

[28] *Administration's White Paper on Intellectual Property Enforcement, supra* note 26.

seriousness than Option 1. We do not, however, believe that the existing 2- level enhancement for conscious of reckless risk of death or serious bodily injury should be increased to 4 levels. A 4-level enhancement would result in disproportionality for a similar offense characteristic across the guidelines. It would also dramatically increase sentences.

1. Minimum Offense Level

A minimum offense level of 12, rather than 14, better captures the range of offense conduct that falls under this guideline. The minimum offense level of 14 in Option 1 significantly overstates the seriousness of the offense. Indeed, the multiple executive branch agencies charged with enforcing the laws against counterfeit drugs have expressed the view that a minimum offense level of 12 is adequate.[29]

Setting the minimum offense level at 14 would result in disproportionate sentences because it would treat counterfeit drugs like crimes such as aggravated assault, §2A2.2, and criminal sexual abuse of a ward, §2A3.3, which have a base offense level of 14.[30] Surely, an offense that at its core involves the theft of intellectual property rights, and that may present a risk to public safety in some, but not all instances, is not as serious as one that actually results in bodily injury to another person.

2. Adjustment for "conscious or reckless risk of death or serious bodily injury"

A 2-level enhancement for "conscious or reckless risk of death or serious bodily injury," is sufficient, and a 4-level increase is unnecessary and inappropriate. Option 2's proposed 4-level enhancement is a prime example of how the guidelines have slowly risen over the years, resulting in sentences greater than necessary under 18 U.S.C. § 3553(a). In 2000, the Commission, with urging from the Department of Justice,[31] amended §2B5.3 to provide for a 2-level enhancement and minimum offense level of 13 if the offense involved the conscious risk of

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[29] *Administration's White Paper on Intellectual Property Enforcement, supra* note 26, at 8*; Counterfeit Pharmaceutical Interagency Working Group, supra* note 26, at 17. Even industry representatives, who in the past have advocated for a "significant" increase in sentences for counterfeit drugs, have only proposed a 2-level increase with a minimum offense level of 13, not 14. Letter from Kendra Martello and Jeffrey Francer, Pharmaceutical Research and Manufacturers of America, to the U.S. Sentencing Comm'n, at 4-5 (March 28, 2008).

[30] A minimum offense level of 12 also raises concerns about proportionality because it treats trafficking in counterfeit drugs the same as involuntary manslaughter involving criminally negligent conduct, §2A1.4, and as more serious than assault resulting in bodily injury, which carries an offense level of 11. U.S.S.G. §2A2.3.

[31] Statement of James K. Robinson, Ass't Attorney General, Criminal Division, Before the U.S. Sentencing Comm'n, Washington D.C., at 4 (March 23, 2000).

serious bodily injury or possession of a dangerous weapon in connection with the offense. In its reason for amendment, the Commission cited to testimony it had received, which indicated "that the conscious risk or reckless risk of serious bodily injury may occur in some cases involving counterfeit consumer products."[32] The testimony presented to the Commission included counterfeit pharmaceuticals[33] and the staff report envisioned that this enhancement would apply to pharmaceuticals.[34] To increase that enhancement again is unnecessary and unwarranted.

A 4-level increase for the "conscious risk of death or serious bodily injury" would also undo the proportionality between USSG §§2B1.1 and 2B5.3 that the Commission has worked to accomplish. Just four years ago, the Commission raised the minimum offense level for §2B5.3(b)(5) from 13 to 14 and added "risk of death" because it believed that "paralleling the fraud guideline would promote proportionality." USSG App. C, Amend. 735 (Nov. 1, 2009). For the Commission to now provide for a 4-level enhancement for the conscious or reckless risk of death or serious bodily injury would create disproportionality with regard to the exact same SOC at §2B1.1(b)(14), which provides for a 2-level enhancement.[35] A 4-level increase also would treat *risk* of harm the same as actual harm. *See*, *e.g.*, §2A2.2(b)(1) ("permanent or life-threatening bodily injury"); §2A2.2(b)(2) (use of a dangerous weapon in aggravated assault when there is actual serious bodily injury); §2A2.(3) (moderate level of bodily injury); §2A2.3 ("substantial bodily injury to a minor under the age of sixteen years").

3. Limit Cumulative Effect of SOCs

Whether the Commission adopts Option 1, Option 2, or some variant thereof, we encourage the Commission to limit the cumulative effect of multiple specific offense characteristics. As the Commission has observed, and we have discussed repeatedly, factor creep is a problem that plagues certain guidelines.[36] The cumulative effect of multiple SOCs results in disproportionate and unduly severe sentences. Here, we are particularly concerned

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[32] USSG, App. C, Amend. 590 (May 1, 2000).

[33] Statement of David Quam, General Counsel to the International Anti-Counterfeiting Coalition, Inc., before the U.S. Sentencing Comm'n, Washington, D.C., at 2 (March 23, 2000).

[34] Staff Report, U.S. Sentencing Comm'n, *No Electronic Theft Act* 36 (1999).

[35] If the Commission were to proceed with a 4-level increase, the Department or other stakeholders interested in raising penalties in the future undoubtedly will call upon it to make §2B1.1(b)(14) proportional to §2B5.3 just as happened in 2009 when the Commission decided to make §2B5.3 proportional to §2B1.1.

[36] U.S. Sentencing Comm'n, *Fifteen Years of Guidelines Sentencing: An Assessment of How Well the Federal Criminal Justice System is Achieving the Goals of Sentencing Reform* 137 (2004); Letter from Marjorie Meyers, Chair, Federal Defender Guideline Committee, to the Honorable Patti B. Saris, Chair, U.S. Sentencing Comm'n, at 8-9 (July 23, 2012).

about the cumulative effect of an increase in offense level because the offense involved a counterfeit drug and the increase for importation under §2B5.3(b)(3)(A).[37] Importation occurs in a majority of counterfeit drug case because the drugs are made overseas, mainly in China. So, in all likelihood, a defendant convicted of trafficking in counterfeit drugs would automatically receive multiple enhancements for essentially the same conduct. To further avoid factor creep, if the Commission adopts Option 1, the cumulative effect of the current 2-level adjustment for "conscious or reckless risk of death or serious bodily injury" or "possession of a dangerous weapon" with an adjustment for counterfeit drug offenses should be limited. An application note that the court should not apply both §2B5.3(b)(5) and (b)(6) together should suffice to prevent disproportionate increases that result from the cumulative effect of SOCs.

4. Aggravating and Mitigating Circumstances

The Commission requests comment on what aggravating and mitigating circumstances may be involved in counterfeiting drug offenses that are not already adequately addressed in the guidelines. Defenders have concerns about persons who play low level roles in counterfeit drug cases who are easily replaced and not directly responsible for selling or marketing the drugs to consumers. An example of someone in such a role would be a drop shipper who does nothing more than receive the drugs from overseas and then mail it out to another party in the United States. Such persons, like drug couriers, should typically receive a minor role adjustment. To ensure that courts consider such an adjustment, it would be helpful to add an application note to §2B5.3 stating that §3B1.2 (Mitigating Role) may be relevant in determining the seriousness of the defendant's offense. As to those rare cases prosecuted under 18 U.S.C. § 2320(a)(4) where the offense resulted in serious bodily injury or death, the application note could reference Chapter Five, Part K (Departures), §5K2.1 (death) and §5K2.2 (physical injury).

B. Comments on Option 3

Option 3 references counterfeit drug offenses under 18 U.S.C. §2320(a)(4) to §2N1.1 (Tampering or Attempting to Tamper Involving Risk of Death or Bodily Injury), which has a base offense level of 25, with 2- to 4- level SOCs for bodily injury, and cross-references to murder and extortion. This option should be rejected. As discussed previously, the gravamen of trafficking in counterfeit drugs is the theft of intellectual property. Congress treated it as such by placing the new offense in the general counterfeiting statute at 18 U.S.C. § 2320. The

[37] Section 2B5.3(b)(3)(A) provides for a 2-level increase and minimum offense level of 12 in 3 specified circumstances – manufacture, importation, or uploading of infringing items. In FY 2011, 56.7% of §2B5.3 cases received a 2-level enhancement. USSC, *Guideline Application Frequencies for Fiscal Year 2011* (2012). Because the offense characteristics are lumped together, however, it is impossible to tell how many cases sentenced under §2B.5. 3 involved importation much less how many involved counterfeit drugs and importation.

Administration's Joint Strategic Plan on Intellectual Property Enforcement treats it the same way.[38] The Commission itself has historically treated trafficking in counterfeit pharmaceuticals as an offense involving the criminal infringement of trademark, using the potential dangers associated with counterfeit drugs as justification for the 2-level enhancement at §2B5.3(b)(5)(A) for "conscious risk of death or serious bodily injury."

To treat counterfeit drug offenses the same as tampering with consumer products under §2N1.1 drastically overstates the seriousness of a counterfeit drug offense. The base offense level of 25 in §2N1.1, "reflects that this offense *typically* poses a risk of death or serious bodily injury to one or more victims; or causes, or is intended to cause bodily injury." USSG § 2N1.1, cmt. (n. 1) (emphasis added). Counterfeit drugs do not typically pose such a risk. Nor do the perpetrators of such crimes typically intend to cause bodily injury. Indeed, of the prosecutions we examined for counterfeit drugs under §2B5.3, very few included an enhancement for conscious risk of death or serious bodily injury.[39] Hence, the empirical evidence regarding counterfeit drug prosecutions lends no support to this proposal. The absence of upward departures in counterfeit drug cases is also evidence that referencing 18 U.S.C. § 2320(a)(4) to §2N1.1 is unwarranted.

III. Proposed Amendments for Certain Adulterated Drugs under 21 U.S.C. § 333(b)(7)

The Commission has proposed two options to respond to section 716 of the Food and Drug Administration Safety and Innovation Act, which added a new penalty provision to 21 U.S.C.§ 333(b)(7). Subsection (b)(7) applies to any person who "knowingly and intentionally adulterates a drug" such that the drug is adulterated under subsection (a)(1), (b), (c), or (d) of 21 U.S.C. § 351 and "has a reasonable probability of causing serious adverse health consequences or death to humans or animals." Option 1 would establish a new alternative base offense level of 14 in §2N2.1. Option 2 would amend Appendix A to reference offenses under 21 U.S.C. § 333(b)(7) to §2N1.1, which has a base offense level of 25.

As we noted earlier, it is difficult to project what kinds of cases will be prosecuted under the provisions of 21 U.S.C. § 333(b)(7). Problems with adulterated drugs are typically handled through the regulatory process of recalls and warning letters. Whether section 333(b)(7) becomes a new tool in FDA's arsenal that supplements the regulatory process remains to be seen. Given the relatively few prosecutions under 21 U.S.C. § 331(b), it is difficult to imagine that section 333(b)(7) will be used very often.

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[38] *See supra* note 26.

[39] From FY2008 to FY2011, §2B5.3 applied in 783 cases. Only two of those cases received an enhancement for the conscious risk of death in serious bodily injury. USSG, *Guideline Application Frequencies for FY2008, FY 2009, FY 2010, FY2011*.

Defenders believe that instead of choosing between two significantly different base offense levels for these offenses, or attempting to ascertain what specific offense characteristic or cross-references might apply, the Commission should reference this statute to §2X5.1.[40] By declining to set a base offense level or specific offense characteristics for this new offense for which the Commission has no data, the prudent course would be to let the district courts determine the most analogous guideline under §2X5.1. After a sufficient number of cases have been prosecuted and sentenced, the Commission would then have more data available from which to make decisions regarding the appropriate guidelines for the offense.

If the Commission were to amend the guidelines, Defenders believe that the more prudent course of action would be to set the base offense level at 14 as in Option 1. If the cases turn out to be more serious, courts may always depart upwardly and in doing so provide feedback to the Commission for future use. We object to setting the base offense level at 25 because we believe it is likely to be too high for some, if not all, of the cases prosecuted under this new provision, and the history of the guidelines reflects that it is typically easier to raise a guideline than lower it.

[40] Congress gave no directive to the Commission regarding this offense.