Response of Eli Lilly and Company to the United States Sentencing Commission's Request for Written Public Comment Regarding the Proposed Amendments to the United States Sentencing Guidelines

Federal Register Notice of January 18, 2013

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I. INTRODUCTION AND BACKGROUND

Eli Lilly and Company ("Lilly") is a pharmaceutical company headquartered in Indianapolis, Indiana. Lilly has approximately 38,000 employees around the world[1] and currently manufactures over twenty drugs approved for human use.[2] These comments seek first and foremost to ensure public safety by addressing the need for strict punishment for and deterrence of offenses involving counterfeit and adulterated drugs. They also discuss the financial and other harms associated with the misappropriation of pharmaceutical manufacturers' intellectual property.

In light of these harms, Lilly recommends that the United States Sentencing Commission (the "Commission"):

(1) amend the United States Sentencing Guidelines Statutory Index to reference violations of 18 U.S.C. § 2320(a)(4) to the guideline at section 2N1.1 applicable to "Tampering or Attempting to Tamper Involving Risk of Death or Bodily Injury;"

(2) amend section 2N1.1 to include a cross-reference to the restitution guideline, section 5E1.1; and

(3) amend the Statutory Index to reference violations of 21 U.S.C. § 333(b)(7) to section 2N1.1.

A. The Health and Safety Threat Posed by Counterfeit and Adulterated Pharmaceuticals

Counterfeit drugs and drugs adulterated as described in 21 U.S.C. § 333(b)(7) (hereinafter referred to as "333(b)(7) adulterated") pose an inherent risk of death or serious bodily injury. The U.S. Food and Drug Administration (the "FDA") has established an extensive submission and approval process to ensure that drugs purchased by U.S. consumers are safe and effective.[3] Lilly subjects potential drugs to years of research and clinical trials before obtaining FDA approval and continues to assess the benefits and risks long after approval.[4] Lilly's manufacturing processes are tightly controlled in order to prevent inadvertent or knowing

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[1] *See* Eli Lilly and Company ("Lilly"), "Key Facts," http://www.lilly.com/about/key-facts/Pages/key-facts.aspx (last visited February 4, 2013).
[2] *See* Lilly, "Human," http://www.lilly.com/products/human/Pages/human.aspx (last visited February 4, 2013).
[3] *See* U.S. Food and Drug Administration, "The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective," http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm (last visited February 4, 2013).
[4] *See* Lilly, "Lilly's Role," http://www.lilly.com/products/patient-safety/lillys-role/Pages/lillys-role.aspx (last visited February 4, 2013).

adulteration of its drug products. Offenses involving counterfeit drugs or 333(b)(7) adulterated drugs circumvent these processes and pose a grave threat to public health and safety. Interpol reports "a significant increase in the manufacture, trade and distribution of counterfeit, stolen and illicit medicines and medical devices."[5] In China, for example, substandard or fake medications reportedly cause up to 300,000 deaths each year.[6]

The United States is not immune to this growing problem. Reports include a U.S. patient who fell into a coma after taking Xanax pills he had purchased online that contained quadruple the usual dosage that would be prescribed by a doctor[7] and another who died after taking counterfeit anti-depression drugs that he purchased from an online pharmacy.[8] Studies have found that counterfeit anti-HIV medications, cholesterol-lowering drugs, and anti-arthritis medications have been sold in the U.S. containing cement, gypsum, sawdust, industrial solvents, and yellow paint.[9] Nineteen medical practices in the United States were affected by counterfeit Avastin—a cancer treatment drug—that did not contain the active ingredient and likely resulted in cancer patients not receiving their prescribed therapy.[10] And in 2010, a counterfeit version of Tamiflu sold online was labeled as "generic" Tamiflu but actually contained an ingredient that could cause life-threatening reactions to those allergic to penicillin.[11]

In addition, there is a well-documented link between sales of counterfeits—including counterfeit drugs—and funding of terrorist activities. A recent Stimson Center report notes that "not only have groups such as the Russian mafia, Colombian drug cartels, Chinese triads, and Mexican drug gangs all become heavily involved in producing and trafficking counterfeit drugs over the past decade, but mounting evidence also points to the direct involvement of Hezbollah and al Qaeda."[12] As that report notes, increasing opportunities to make financial gains from the pharmaceutical counterfeit industry will lead nefarious actors to pay even more attention to it in the future.[13] Indeed, terrorists could use counterfeit pharmaceuticals both to finance terror-related activity and to harm Americans directly by selling harmful adulterated drugs to unsuspecting American consumers. FDA Commissioner Margaret Hamburg has recognized this

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[5] *See* Interpol, "Pharmaceutical Crime," http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-crime (last visited February 4, 2013).

[6] *See* Steve Boggan, "Headache pills made of rat poison and Viagra made of chalk: We reveal the chilling truth about Internet drugs," April 27, 2009, *MailOnline*, http://www.dailymail.co.uk/health/article-1173735/After-deacons-daughter-killed-medicine-bought-online--chilling-truth-Internet-black-marketprescription-drugs.html (last visited February 4, 2013).

[7] *See* Keith Epstein, "Online Extra: The Deadly Side Effects of Net Pharmacies," Dec. 18, 2006, *BusinessWeek*, available at http://www.businessweek.com/magazine/content/06_51/b4014070.htm (last visited February 4, 2013).

[8] *See* Angie Cannon, "Dicey Drugs from Abroad," June 18, 2001, *U.S. News & World Report.*

[9] *See* Henry I. Miller, "Imported Drugs: Hidden Disasters," April 8, 2008, *New York Post.*

[10] *See* U.S. Food and Drug Administration, "Counterfeit Version of Avastin in U.S. Distribution," http://www.fda.gov/Drugs/DrugSafety/ucm291960.htm (last visited February 4, 2013).

[11] U.S. Food and Drug Administration, "FDA Sounds Alarm on Phony Tamiflu," http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm216009.htm (last visited February 4, 2013).

[12] Brian D. Finlay, "Counterfeit Drugs and National Security," The Stimson Center, p. 1, November 2011, available at http://www.stimson.org/images/uploads/research-pdfs/Full_-_Counterfeit_Drugs_and_National_Security.pdf (last visited February 4, 2013).

[13] *Id.*

risk, stating, "we know that we are also vulnerable to potential attacks involving our food or drug supply by terrorists determined to do harm."[14]

B. Economic Threat Posed by Counterfeit Pharmaceuticals

Estimates of the total percentage of global pharmaceutical sales involving counterfeit drugs "range from as high as 50% to as low as 1%, with other estimates including 40%, 30%, 17%, 13%, and 10%."[15] The World Health Organization has estimated that "8% of the bulk drugs imported into the U.S. are counterfeit, unapproved, or substandard" and that "10% of global pharmaceutical commerce, or $21 billion, involves counterfeit drugs."[16] With the annual global pharmaceutical market reaching an estimated $880 billion as of 2011, counterfeit medications exact an ever-increasing toll on the U.S. economy and tax revenues.[17]

Counterfeit pharmaceuticals also exact a financial toll on the innovators developing new pharmaceuticals. It takes approximately ten to fifteen years to bring a new drug to market, and without intellectual property protection, pharmaceutical research companies would not be able to recoup the approximately $800 million to $1.3 billion that they invest, on average, to discover and develop each new drug.[18] Failure to enforce strong intellectual property rights would have a chilling effect on the industry's ability to bring new lifesaving drugs to patients around the world.

II. SPECIFIC ISSUES FOR COMMENT

Below, Lilly sets forth its comments with respect to select issues for comment included in Part 3 of the Request. Although Lilly offers comment on each relevant request in Part 3, it recommends that the Commission reference offenses under both 18 U.S.C. §§ 2320(a)(4) and 333(b)(7) to the guideline at section 2N1.1.

A. Offenses Under 18 U.S.C. § 2320 Involving Counterfeit Drugs (and Response to Directive)

(i) In addition, to assist the Commission in determining how best to respond to the directive, the Commission seeks comment on offenses under section 2320 involving counterfeit drugs. What actual and potential harms to the public do such offenses pose? What aggravating and mitigating circumstances may be involved in such offenses that are not already

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[14] Margaret Hamburg, Commissioner of Food and Drugs, remarks at Protecting Health: FDA's Global Challenge (January 28, 2010).

[15] World Health Organization, "Combating Counterfeit Drugs: A Concept Paper for Effective International Cooperation," January 27, 2006, available at http://www.who.int/medicines/events/FINALBACKPAPER.pdf (last visited February 4, 2013).

[16] Albert I. Wertheimer, et al, "Counterfeit Pharmaceuticals: Current Status and Future Projections," 43 J. Am. Pharm. Assoc. 710-8 (2003).

[17] *See* Press Release, Thomson Reuters, Thomson Reuters Annual Pharmaceutical Factbook Reveals Key Insights into Current Trends (June 26, 2012), available at http://thomsonreuters.com/content/press_room/science/688408 (last visited February 4, 2013).

[18] *See* Lilly, "Intellectual Property," http://www.lilly.com/about/key-issues/Pages/intellectual-property.aspx (last visited February 4, 2013); "Key Facts," *supra* note 1.

adequately addressed in the guidelines? For example, if death or serious bodily injury resulted from the offense, should that circumstance be addressed by a departure provision, by a specific offense characteristic, by a cross-reference to another guideline (e.g., a homicide guideline), or in some other manner?

As noted above in the Introduction and Background, offenses involving trafficking in counterfeit drugs pose grave risks to the public. The obvious risk is that counterfeit drugs, like legitimate prescription drugs, typically are ingested or injected into the body. But counterfeits have circumvented the FDA review process, are often poorly made, and often include either harmful substances or inaccurate amounts of active ingredients. For instance, the International Policy Network reports that counterfeit Heparin from China killed sixty-two people in the United States during early 2008.[19]

Counterfeit drug offenses harm the public in less obvious ways as well. Many counterfeit drugs lack the effective ingredient and leave those who take them without the therapy they need. In the developing world, fake antimalarial and tuberculosis medications result in an estimated 700,000 deaths each year.[20] The recent domestic distribution of a counterfeit version of the cancer treatment Avastin confirms that the risk posed by counterfeit drugs lacking effective ingredients is a very real one in the United States.[21] Further, many counterfeiters—especially those counting on repeat business—will include some of the active ingredient in their fake drugs but too little of it. This may contribute to the development of drug-resistant disease strains.[22] Indeed, extremely drug-resistant strains of tuberculosis are now found in forty-nine countries, malaria parasites in much of Africa and Asia are now resistant to most drugs, and resistance is becoming a serious problem for HIV medications.[23] In the words of the director of infectious diseases at Belgium's St. Pierre University Hospital, "we are creating a virological time bomb."[24]

To best account for the inherent risks posed by violations of 18 U.S.C. § 2320(a)(4)—the risk of death or bodily injury—the Commission should adopt Option Three and reference such offenses to the guideline applicable to "Tampering or Attempting to Tamper Involving Risk of Death or Serious Bodily Injury." This guideline, section 2N1.1, appropriately accounts for the risks inherent in all counterfeit drug offenses.[25] Moreover, Section 2N1.1 already accounts for

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[19] Julian Harris, et al., "Keeping it Real: Combating the spread of fake drugs in poor countries," May 2009, pp. 4, 11, available at http://www.policynetwork.net/sites/default/files/keeping_it_real_2009.pdf (last visited February 5, 2013).

[20] *Id.* at 4.

[21] *See* "Counterfeit Version of Avastin in U.S. Distribution," *supra* note 10.

[22] Harris, et al., *supra* note 19, at 4, 11-12.

[23] *Id.*

[24] *Id.* at 12.

[25] *See* Counterfeit Pharmaceutical Inter-Agency Working Group, "Report to the Vice President of the United States and to Congress," March 2011, p. 17, available at http://www.whitehouse.gov/sites/default/files/omb/IPEC/Pharma_Report_Final.pdf (last visited February 4, 2013) ("there are inherent risks associated with counterfeit drugs that are not accounted for under [section 2B5.3] and that warrant an enhanced sentence even where a defendant does not recklessly risk serious bodily injury"); UCL School of Pharmacy, "Falsified Medicines and the Global Public's Health," May 26, 2011, p. 1, available at http://www.ifpma.org/fileadmin/content/Publication/2012/UCL-Matrix_Insight-Falsified_Medicines_and_the_Global_Publics_Health.pdf (last visited February 4, 2013) ("Even if they contain the right ingredients, medicines which have been produced in unregulated circumstances are inherently hazardous.");

the primary aggravating and mitigating factors relating to counterfeit drug offenses. It includes a specific offense characteristic providing enhancements where the offense causes actual injury and the proper cross-references to murder and attempted murder for those offenses involving the requisite *mens rea*.[26] It also includes a special instruction—applicable to those instances in which an offender is charged with a single count involving the death or permanent, life-threatening, or serious bodily injury of multiple victims—that requires calculation of the offense level according to the multiple count guidelines in Chapter Three, Part D as if the offender had been convicted of a separate count for each victim.[27] Finally, although it is unclear how any violation of 18 U.S.C. § 2320(a)(4) would not pose the inherent risk of death or serious bodily injury, section 2N1.1 already accounts for such a mitigating circumstance.[28] These provisions, already codified in section 2N1.1, appear to address the primary aggravating and mitigating circumstances relevant to counterfeit drug offenses.

Thus, by implementing Option Three, the Commission can best respond to Congress's directive and account for the harms that violations of 18 U.S.C. § 2320(a)(4) cause.

> *(ii) Does the new specific offense characteristic in Option 1, or the revised specific offense characteristic in Option 2, adequately respond to the directive? If not, what changes, if any, should the Commission make to § 2B5.3 to better account for offenses under section 2320(a)(4) and the factors identified in the directive?*

An inter-agency executive working group recently reported to the Vice President and Congress that "there are inherent risks associated with counterfeit drugs that are not accounted for under [section 2B5.3] and that warrant an enhanced sentence even where a defendant does not recklessly risk serious bodily injury."[29] Yet, Options One and Two preserve the reference of offenses involving counterfeit drugs to section 2B5.3, the guideline applicable to "Criminal Infringement of Copyright or Trademark." Although counterfeit drug offenses are costly violations of intellectual property rights that threaten to stifle innovation and the advancement of pharmaceutical research and development, they are also much more than that. Each counterfeit drug has circumvented the FDA review and approval process designed to ensure safety and efficacy. **The bottom line is that every counterfeit drug carries with it the inherent risk of death or serious bodily injury**.[30]

Hence, Options One and Two do not sufficiently account for Congress's directive, especially the directive's emphasis on effective deterrent and punishment as well as appropriate accounting for potential and actual harm to the public.[31] Referencing counterfeit drug offenses

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World Health Organization International Medical Products Anti-Counterfeiting Taskforce, "Principles and Elements for National Legislation against Counterfeit Medical Products," December 12, 2007, p. 2, available at http://www.who.int/impact/events/FinalPrinciplesforLegislation.pdf (last visited February 4, 2013) ("educates stakeholders about the inherent dangers of counterfeit medical products").

[26] *See* U.S. Sentencing Guidelines Manual § 2N1.1(b)-(c).

[27] *See id.* § 2N1.1(d).

[28] *See id.* § 2N1.1 cmt. n.1 ("In the unusual case in which the offense did not cause a risk of death or serious bodily injury, and neither caused nor was intended to cause bodily injury, a downward departure may be warranted.").

[29] *See* "Report to the Vice President of the United States and to Congress," *supra* note 25.

[30] *See supra* note 25.

[31] *See* Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 717(b)(2) (July 9, 2012).

to a guideline designed to treat intellectual property violations as theft or fraud[32] would ignore the directive's instruction to assure reasonable consistency with other guidelines.[33] Infringing a trademark or copyright by making an unauthorized t-shirt or book undoubtedly causes pecuniary and reputational harm, but it is a crime different in both type and gravity than infringing intellectual property rights in pharmaceuticals, an offense that also foists grave risks onto the public and threatens to stifle innovation and advancement in pharmaceutical research. Because an offense involving counterfeit drugs is unlike the ordinary intellectual property offenses treated by section 2B5.3, it would be inconsistent to punish counterfeit drug offenses under that section.

Nevertheless, although Lilly strongly recommends adoption of Option Three, if the Commission were to adopt Option One or Option Two, it should revise those options in order to reflect the risks inherent in all 18 U.S.C. § 2320(a)(4) violations.[34] Specifically, the new specific offense characteristic in section 2B5.3 should result in an enhancement and minimum offense level at least as significant as that currently provided in section 2B5.3(b)(5) for offenses involving a conscious or reckless risk of death or serious bodily injury. This would result in at least a two-level enhancement and a minimum offense level of fourteen.[35] The Commission should also account for the aggravating circumstances already addressed in section 2N1.1 by including a specific offense characteristic for actual harm caused, cross-references to the murder and attempted murder guidelines, and a special instruction for convictions on single counts involving the death or serious injury of multiple victims.[36]

> *(iii) [D]oes Option 3 of the proposed amendment—referencing offenses involving counterfeit drugs to § 2N1.1—adequately respond to the directive? If not, what changes, if any, should the Commission make to § 2N1.1 to better account for offenses under section 2320(a)(4) and the factors identified in the directive?*
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> *Option 3 of the proposed amendment would reference offenses under section 2320 that involve counterfeit drugs (e.g., offenses described in section 2320(a)(4)) to § 2N1.1 (Tampering or Attempting to Tamper Involving Risk of Death or Serious Bodily Injury). If the Commission were to adopt Option 3, what changes, if any, should the Commission make to that guideline to better account for such offenses?*

As noted above, Lilly believes that Option Three best responds to the directive and presents the best of the three noticed alternatives.[37] Option Three references counterfeit drug offenses to section 2N1.1, a guideline for offenses where the risk of bodily harm or death is the norm and downward departures in the absence of such a risk is the rare exception.[38] Thus, it

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[32] *See* U.S. Sentencing Guidelines Manual § 5B3.1, cmt. background.
[33] *See* Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 717(b)(2)(C) (July 9, 2012).
[34] *See supra* pp. 1-4 and note 25.
[35] *See* U.S. Sentencing Guidelines Manual § 2B5.3(b)(5).
[36] *See id.* § 2N1.1(b)-(d).
[37] *See, e.g., supra* pp 3-5.
[38] *See id.* § 2N1.1 cmt. n.1 ("The base offense level reflects that this offense typically poses a risk of death or serious bodily injury to one or more victims . . . . In the unusual case in which the offense did not cause a risk of death or

responds to Congress's directive by reflecting the serious nature of offenses involving counterfeit drugs, effectively deterring and punishing those serious offenses in light of the grave harms to the public they pose, and differentiating these offenses from those intellectual property offenses treated in section 2B5.3 that do not pose the health and safety risks inherent to counterfeit drug offenses.[39] Option Three also accounts for relevant aggravating and mitigating factors[40] and assures that the Guidelines meet the statutory purposes of sentencing.[41]

Lilly does recommend, however, that the Commission consider including a new cross-reference in section 2N1.1 to better account for the harm caused to the trademark rights of the pharmaceutical manufacturers whose drugs are counterfeit. Specifically, the Commission should add a new cross-reference to existing section 2N1.1(c) referencing the restitution guideline at section 5E1.1. Violations of 18 U.S.C. § 2320 entitle victims to restitution for losses sustained as a result of the offender's criminal conduct pursuant to the Mandatory Victims' Restitution Act of 1996,[42] the Victim and Witness Protection Act of 1982,[43] and the Crime Victims Rights Act of 2004.[44] As a practical matter, no amount of restitution can fully restore a pharmaceutical manufacturer to the position it occupied prior to the counterfeiting of its drugs because it is impossible to place a value on the damage such conduct causes to the manufacturer's image and the brand names of its pharmaceutical products. Nevertheless, cross-referencing offenses involving counterfeit drugs to section 5E1.1 directs sentencing courts to make some effort to make the trademark holder whole.[45]

Thus, adopting Option Three and incorporating a cross-reference to section 5E1.1 best "reflect[s] the intent of Congress that the guidelines and policy statements reflect the serious nature of offenses under section 2320(a)(4) and the need for an effective deterrent and appropriate punishment to prevent such offenses."[46]

(iv) Option 1 of the proposed amendment would provide a new specific offense characteristic in § 2B5.3 for offenses involving counterfeit drugs. If the Commission were to adopt Option 1, how should this new specific offense characteristic interact with other specific offense characteristics in §

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serious bodily injury, and neither caused nor was intended to cause bodily injury, a downward departure may be warranted.").

[39] *Cf.* Food and Drug Administration Safety and Innovation Act, § 717(b)(2)(A)-(C); U.S. Sentencing Guidelines Manual § 2B5.3 cmt. background; *see also supra* pp. 1-4 and note 25.

[40] *Cf.* Food and Drug Administration Safety and Innovation Act, § 717(b)(2)(D); *see also supra* pp. 4-5.

[41] *Cf.* Food and Drug Administration Safety and Innovation Act, § 717(b)(2)(F); *see also* 18 U.S.C. § 3553(a)(2). Section 3553(a)(2) states that sentencing courts shall consider the need to (1) "reflect the seriousness of the offense, [] promote respect for the law, and [] provide just punishment for the offense;" (2) "afford adequate deterrence to criminal conduct;" (3) "protect the public from further crimes of the defendant;" and (4) "provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner."

[42] *See* 18 U.S.C. §§ 3663A(b)(1)(B) & 3663A(c)(1)(A)(ii).

[43] *See* 18 U.S.C. § 3663(a)(1)(A).

[44] *See* 18 U.S.C. § 3771(a)(6).

[45] Section 5E1.1 also instructs courts to apply payments from offenders toward satisfaction of any restitution judgment before applying it toward satisfaction of criminal fines. *See* U.S. Sentencing Guidelines Manual § 5E1.1 (c).

[46] *See* Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 717(b)(2)(A) (July 9, 2012).

2B5.3? In particular, how should it interact with the specific offense characteristic currently at § 2B5.3(b)(5), which provides a 2-level enhancement and a minimum offense level 14 if the offense involved a risk of death or serious bodily injury or possession of a dangerous weapon? Should the new specific offense characteristic be fully cumulative with the current one, or should they be less than fully cumulative in cases where both apply?

As discussed above, Option One fails to account sufficiently for the serious public harms inherent in violations of 18 U.S.C. § 2320(a)(4).[47] Therefore, Lilly recommends that the Commission adopt Option Three. While section 2B5.3 is designed to reflect "the nature and magnitude of the pecuniary harm" caused by counterfeiting offenses,[48] referencing such offenses to section 2N1.1 recognizes that such offenses also "typically pose[] a risk of death or serious bodily injury to one or more victims."[49] Moreover, referencing violations of section 2320(a)(4) to section 2N1.1 is also consistent with Congress's directive ordering the Commission to take into account the potential and actual harm not only to the party whose intellectual property rights have been violated, but also to the general public.[50]

Nevertheless, if the Commission adopts Option One, the new specific offense characteristic in section 2B5.3 should result in an enhancement and minimum offense level at least as significant as that currently provided in section 2B5.3(b)(5) for offenses involving a conscious or reckless risk of death or serious bodily injury.[51] As stated above, **every counterfeit drug carries with it the inherent risk of death or serious bodily injury**.[52] Therefore, at a minimum, the Option One specific offense characteristic should include a two-level enhancement and a minimum offense level of fourteen.[53] This specific offense characteristic should not be fully cumulative when both it and section 2B5.3 apply, as one accounts for the inherent risk involved in counterfeit drug offenses, while the other accounts for a culpable *mens rea* or the use of a weapon.[54]

Yet even a specific offense characteristic comparable to that currently found in section 2B5.3(b)(5) fails to account for the harm caused by offenses involving counterfeit drugs. The application notes accompanying section 2B5.3 contemplate an upward departure where the

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[47] *See supra* pp. 5-6.
[48] *See* U.S. Sentencing Guidelines Manual § 2B5.3 cmt. background.
[49] *See id.* § 2N1.1 cmt. n.1.
[50] *See* Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 717(b)(2)(B) (July 9, 2012).
[51] *See supra* p. 6.
[52] *See* Counterfeit Pharmaceutical Inter-Agency Working Group, *supra* note 25 ("there are inherent risks associated with counterfeit drugs that are not accounted for under [section 2B5.3] and that warrant an enhanced sentence even where a defendant does not recklessly risk serious bodily injury"); UCL School of Pharmacy, *supra* note 25 ("Even if they contain the right ingredients, medicines which have been produced in unregulated circumstances are inherently hazardous."); World Health Organization International Medical Products Anti-Counterfeiting Taskforce, *supra* note 25 ("educates stakeholders about the inherent dangers of counterfeit medical products").
[53] *Cf.* U.S. Sentencing Guidelines Manual § 2B5.3(b)(5).
[54] *See id.* Lilly believes that both enhancements should and will apply to nearly every violation of section 2320(a)(4). But it is possible that an offender could argue that some number of precautions negates the conscious or reckless *mens rea* required for application of the enhancement in section 2B5.3(b)(5), even though such precautions could never negate the dangers inherent to counterfeit drug offenses. *See supra* pp. 1-4 and note 25.

offense involves "substantial harm to the reputation of the copyright or trademark owner" or was committed "in connection with, or in furtherance of," a national, or international, organized crime enterprise.[55] It goes without saying that reports of a counterfeit branded pharmaceutical harming the public[56] likely will make patients wary of ingesting a medicine copied by criminals and substantially harm the image of the company holding the intellectual property rights to that drug. And legitimate drug producers' reputations are equally harmed where counterfeit drugs simply are ineffective, as patients and doctors alike, believing the counterfeit to be the real drug, will be led to believe the real drug is ineffective.[57] Further, there are growing concerns that counterfeit drug operations support organized crime and international terrorism.[58] Because these upward departure factors are inherent in offenses involving counterfeit drugs, Lilly recommends adopting Option Three and referencing those offenses to section 2N1.1, which more appropriately accounts for the seriousness of counterfeit drug offenses as the norm, rather than the exception.

B. Offenses Under 21 U.S.C. § 333(b)(7) Involving Intentionally Adulterated Drugs Resulting in a Reasonable Probability of Serious Adverse Health Consequences or Death

(i) Option 2 of the proposed amendment amends Appendix A (Statutory Index) to reference offenses under section 333(b)(7) to § 2N1.1 (Tampering or Attempting to Tamper Involving Risk of Death or Bodily Injury). Section 2N1.1 provides a base offense level of 25 and an enhancement of 2 to 4 levels if the victim sustained serious bodily injury, depending on whether the injury was permanent or life-threatening. Section 2N1.1 also contains cross-references to other guidelines and a special instruction for certain cases involving more than one victim. [¶] If the Commission were to reference offenses under section 333(b)(7) to § 2N1.1, as the proposed amendment provides, what changes, if any, should the Commission make to § 2N1.1 to better account for offenses under section 333(b)(7)?

Offenses involving adulterated drugs punished under 21 U.S.C. § 333(b)(7) present many of the same dangers to the public addressed above with respect to counterfeit drugs.[59] Approved pharmaceutical manufacturers are subject to FDA oversight and inspection of their manufacturing processes as well as strict packaging and labeling requirements.[60] Offenders who adulterate[61] drugs as described in section 333(b)(7) undermine this regulatory scheme and

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[55] *See* U.S. Sentencing Guidelines Manual § 2B5.3 cmt. n.4.
[56] *See, e.g.*, "FDA Sounds Alarm on Phony Tamiflu," *supra* note 11.
[57] *See, e.g.*, "Counterfeit Version of Avastin in U.S. Distribution," *supra* note 10.
[58] *See* Finlay, *supra* note 12; Interpol, *supra* note 5.
[59] *See supra* pp. 1-4 and note 25.
[60] *See* 21 C.F.R. §§ 211.1-211.208.
[61] Adulterated drugs generally fall into one of four categories: (1) those drugs, including their packaging, containing poisonous or insantitary ingredients or not manufactured in conformity with current good manufacturing practice, (2) those drugs with strength, quality, or purity differing from the standard set in an official compendium; (3) those drugs not recognized in an official compendium and misrepresenting their strength, quality, or purity; and (4) those drugs mixed with another substance so as to reduce their quality or strength or altogether substituted for another substance. *See* 21 U.S.C. § 351(a)-(d).

endanger the public. Indeed, the twenty-year maximum sentence and $1,000,000 maximum fine set forth in section 333(b)(7) only apply where a person knowingly and intentionally adulterates a drug such that there is "a reasonable probability of causing serious adverse health consequences or death to humans or animals."[62] Thus, the guideline selected to treat convictions under section 333(b)(7) should account for the fact that section 333(b)(7) explicitly applies to only those offenses that are likely to harm health or cause death.

Therefore, for many of the reasons set forth in the discussion of counterfeit drug offenses above,[63] Lilly recommends that the Commission adopt Option Two, which references offenses under 21 U.S.C. § 333(b)(7) to the guideline for "Tampering or Attempting to Tamper Involving Risk of Death or Bodily Injury." This guideline, section 2N1.1, accounts for the risks inherent in violations of section 333(b)(7).[64] It accounts for relevant aggravating factors through a specific offense characteristic providing enhancements if the offense causes actual injury and cross-referencing those offenses involving the requisite *mens rea* to murder and attempted murder guidelines.[65] Section 2N1.1 also includes a special instruction—applicable to those instances in which an offender is charged with a single count involving the death or permanent, life-threatening, or serious bodily injury of multiple victims—that requires calculation of the offense level according to the multiple count guidelines in Chapter Three, Part D as if the offender had been convicted of a separate count for each victim.[66] Finally, it accounts for the rare mitigating circumstance in which an offense referenced to section 2N1.1 does not cause a risk of death or serious bodily injury.[67]

(ii) Option 1 of the proposed amendment contemplates that offenses under section 333(b)(7) would be referenced to § 2N2.1. Section 2N2.1 provides a base offense level 6 and an enhancement for repeat offenders under 21 U.S.C. 331. It also provides a cross reference to § 2B1.1 (Theft, Property Destruction, and Fraud) if the offense involved fraud and a cross reference to any other offense guideline if the offense was committed in furtherance of, or to conceal, an offense covered by that other offense guideline. If offenses under section 333(b)(7) are to be sentenced under § 2N2.1, what changes, if any, should the Commission make to § 2N2.1? For example, should the Commission adopt Option 1, which would

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[62] 21 U.S.C. § 333(b)(7).

[63] *See* discussion of Option Three, *supra* pp. 4-7.

[64] *See* 21 U.S.C. § 333(b)(7); *see also supra* pp. 1-4 and note 25.

[65] *See* U.S. Sentencing Guidelines Manual § 2N1.1(b)-(c).

[66] *See id.* § 2N1.1(d).

[67] *See id.* § 2N1.1 cmt. n.1 ("In the unusual case in which the offense did not cause a risk of death or serious bodily injury, and neither caused nor was intended to cause bodily injury, a downward departure may be warranted."). The commission should consider a new application note applicable to cases consisting entirely of genuine pharmaceutical products legitimately and legally produced in accordance with the regulatory framework in a country outside of the United States. Such cases typically involve diverting authentic drugs (not counterfeits) from the foreign market where approved into the United States where unapproved, thus circumventing the FDA's regulatory framework. Because such offenses involve authentic drugs produced legally by legitimate pharmaceutical companies, albeit for foreign markets, the health and safety risk inherent in such offenses is lessened (although not eliminated, such as where patient information is in a foreign language) and may justify a downward departure of approximately 8 levels. However, if any counterfeit (rather than diverted authentic) drugs are involved in the case, such a downward departure should not apply.

provide an alternative base offense level of 14 if the defendant was convicted under section 333(b)(7)? Should the Commission provide a different alternative base offense level instead? Or should the Commission provide additional specific offense characteristics, additional cross references, or a combination of such provisions to better account for offenses under section 333(b)(7)? If so, what provisions should the Commission provide?

Option One, which references offenses under 21 U.S.C. § 333(b)(7) to the guideline for "Violations of Statutes and Regulations Dealing With Any Food, Drug, Biological Product, Device, Cosmetic, Agricultural Product, or Consumer Product," does not adequately account for the dangers posed by adulterated drugs.[68] First, this guideline, section 2N2.1, encompasses a broad range of dissimilar regulatory violations, including those involving cosmetics and other consumer products. Although the application notes cognize the possibility of upward departures where there is "substantial risk of bodily injury or death,"[69] section 2N2.1 fails to account for the fact that **adulterated drug offenses as described in section 333(b)(7) inherently involve such risks**.[70] As with counterfeit drug offenses, the risk of death or bodily injury presented by such adulterated drug offenses is the norm, not the exception.[71] Second, section 2N2.1 assumes "knowing or reckless conduct" constituting a regulatory offense,[72] while offenses under section 333(b)(7) require "knowing and intentional" adulteration of drugs.[73] Therefore, offenses under section 333(b)(7) should be referenced to a more appropriate guideline—like section 2N1.1—that better accounts for the inherent danger of the offense and section 333(b)(7)'s more culpable *mens rea*.

Nevertheless, if the Commission adopts Option One, it should amend section 2N2.1 to create a minimum offense level—not an alternative base level—of at least fourteen. This would make Option One commensurate with the intellectual property offenses involving conscious or reckless risk of death or serious bodily injury treated in section 2B5.3(b)(5). But even the minimum offense level of fourteen in section 2B5.3(b)(5) requires a less culpable *mens rea* than that specified in section 333(b)(7).[74] Therefore, even adopting a minimum offense level of fourteen fails to account for section 333(b)(7)'s more culpable *mens rea*. This underscores the propriety of adopting Option Two and referencing offenses under section 333(b)(7) to section 2N1.1.

Finally, if the Commission were to adopt Option One, it should apply the four-level enhancement in the current specific offense characteristic at section 2N2.1(b)(1) to violations of section 333(b)(7) committed by offenders with previous convictions under either 18 U.S.C. § 331 or 18 U.S.C. § 333.

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[68] *See supra* pp. 1-4 and note 25.
[69] U.S. Sentencing Guidelines Manual § 2N2.1 cmt. n.3(a).
[70] *See* 21 U.S.C. § 333(b)(7) (providing punishment for adulterating drugs "such that the drug . . . has a reasonable probability of causing serious adverse health consequences or death to humans or animals"); *see also supra* note 25.
[71] *See supra* pp. 7, 9.
[72] U.S. Sentencing Guidelines Manual § 2N2.1 cmt. n.1.
[73] 21 U.S.C. § 333(b)(7).
[74] *Compare* 21 U.S.C. § 333(b)(7) ("knowingly and intentionally"), *with* U.S. Sentencing Guidelines Manual § 2B5.3(b)(5) ("conscious or reckless").

(iii) Finally, the Commission seeks comment comparing and contrasting offenses involving intentionally adulterated drugs under section 333(b)(7) and offenses involving counterfeit drugs under section 2320(a)(4). How do these offenses compare to each other in terms of the conduct involved in the offense, the culpability of the offenders, the actual and potential harms posed by the offense, and other factors relevant to sentencing? Which offenses should be treated more seriously by the guidelines and which should be treated less seriously?

Lilly recommends that the Commission reference both counterfeit and section 333(b)(7) adulterated drug offenses to section 2N1.1. Both offenses require the most culpable *mens rea*: intent.[75] Both create an inherent risk of death or bodily injury.[76] Indeed, in many instances, counterfeit drug offenses will involve adulterated drugs that have been diluted or otherwise altered from their original state.[77] As such, both offenses should be treated with equal severity by reference to section 2N1.1.

Punishing both counterfeit and adulterated drug offenses under section 2N1.1 also furthers the purposes of sentencing. By accounting for the seriousness of such offenses, both of which are dangerous and economically harmful, section 2N1.1 would provide just punishment promoting respect for the law.[78] Referencing both offenses to section 2N1.1 would also achieve the dual goals of deterring others from committing these dangerous crimes and protecting the public from future crimes of the defendant.[79]

III. CONCLUSION

As emphasized herein, every counterfeit and section 333(b)(7) adulterated drug circumvents the FDA review and approval process and therefore carries with it the inherent risk of death or serious bodily injury. Not every counterfeit or adulterated drug does, in fact, cause death or serious injury. Nevertheless, trafficking in counterfeit or section 333(b)(7) adulterated drugs is like shooting a gun into a building. The bullet may, or may not, injure a person in the building. More care can be taken to aim the gun at a part of the building that is believed to be unoccupied. In any event, the act itself (whether trafficking in counterfeit or adulterated drugs or

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[75] *See* 18 U.S.C. § 2320(a); 21 U.S.C. § 333(b)(7).

[76] *See supra* pp. 1-4 and note 25.

[77] *See* Allan Coukell, Director, Pew Prescription Project, comments of May 1, 2009, transcript available at http://www.fda.gov/downloads/NewsEvents/MeetingsConferencesWorkshops/UCM163646.pdf (last visited February 5, 2013) ("Economically motivated adulteration also manifests as deliberate counterfeiting of finished products (as distinct from compromised manufacture).").

[78] *Cf.* 18 U.S.C. § 3553(a)(2)(A); *see also supra*, pp. 1-4 and note 25.

[79] *Cf.* 18 U.S.C. § 3553(a)(2)(B)-(C); *see also* Federal Register Notice of Proposed 2013 Amendments to Federal Sentencing Guidelines and Request for Public Comment, 78 Fed. Reg. 4197, 4202-03 (Jan. 18, 2013) (discussing various proposed options with minimum offense levels of 12 or 14 or an alternative base level of 14, all of which are likely to result in lesser sentences than the options referencing to section 2N1.1, which applies a base offense level of 25).

shooting into a building) carries inherent risks and thus should be strongly deterred and punished, whether or not a person is actually harmed.[80]

In sum, Lilly recommends that the Commission:

(1) amend the United States Sentencing Guidelines Statutory Index to reference violations of 18 U.S.C. § 2320(a)(4) to the guideline at section 2N1.1 applicable to "Tampering or Attempting to Tamper Involving Risk of Death or Bodily Injury;"

(2) amend section 2N1.1 to include a cross-reference to the restitution guideline, section 5E1.1; and

(3) amend the Statutory Index to reference violations of 21 U.S.C. § 333(b)(7) to section 2N1.1.

* * *

We thank the Commission for allowing Lilly this opportunity to provide comments on the proposed amendments to the Guidelines. Counterfeit and adulterated drugs pose serious economic, health, and public safety threats, and Lilly looks forward to working with the Commission to ensure appropriate levels of punishment, deterrence, and restitution are applied to offenses involving counterfeit and adulterated drugs.

[80] We note also that evidence of harm to patients from counterfeit drugs may be more difficult to identify than harm to people from shooting a gun into a building. A cancer patient may die after receiving treatment from a counterfeit cancer drug, but the cause of death may be attributed entirely to the cancer and not to the drug which appeared genuine but was not.