



**U.S. Department of Justice**

Criminal Division

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*Office of Policy and Legislation*

*Washington, D.C. 20530*

March 8, 2013

The Honorable Patti B. Saris, Chair  
United States Sentencing Commission  
One Columbus Circle, NE  
Suite 2-500, South Lobby  
Washington, DC 20002-8002

Dear Judge Saris:

On behalf of the U.S. Department of Justice, we submit the following comments regarding the proposed amendments to the federal sentencing guidelines and issues for comment published in the Federal Register on January 18, 2013. We thank the members and staff of the Commission for being responsive to many of the Department's sentencing policy priorities this amendment year and for working hard to address all of the guideline issues under consideration. We look forward to continuing our work with the Commission during the remainder of the amendment year on all of the published amendment proposals.

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**U.S. DEPARTMENT OF JUSTICE VIEWS ON THE PROPOSED AMENDMENTS TO  
THE FEDERAL SENTENCING GUIDELINES AND THE ISSUES FOR COMMENT  
PUBLISHED BY THE U.S. SENTENCING COMMISSION IN THE FEDERAL  
REGISTER ON JANUARY 18, 2013.**

**1. Pre-Retail Medical Products; SAFE DOSES Act (Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act)**

The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012<sup>1</sup>, or SAFE DOSES Act, created a new criminal offense for the theft of “pre-retail medical products.”<sup>2</sup> The non-aggravated offense carries a maximum penalty of three years imprisonment. However, if— (1) the defendant is employed by or an agent of an organization in the medical products supply chain; (2) the offense involves the use of violence, force, or threat of violence or force; (3) the offense involves the use of a deadly weapon; or (4) the offense is a second or subsequent conviction under the statute, the maximum term of imprisonment is five years. If the offense involves medical products valued at \$5,000 or greater, the maximum term of imprisonment is 15 years; or 20 years if one of the other aggravating factors has also occurred. And if the offense results in serious bodily injury or death, the maximum sentence jumps to 30 years imprisonment. The SAFE DOSES Act also applies these enhanced maximum penalties to certain existing offenses, such as 18 U.S.C. § 2314 (transportation of stolen goods), when the offense involves pre-retail medical products.

The SAFE DOSES Act defines “medical product” to include drugs, biological products, devices, medical foods, and infant formula. These products are closely regulated by the U.S. Food and Drug Administration (“FDA”), because their misuse, as well as their theft and reintroduction into the supply chain, pose a genuine threat to public health. When medical products are diverted from lawful distribution channels, they may not be stored or handled properly, for example, and improper storage and handling can cause contamination, weaken efficacy, or otherwise damage the product. Offenders may delay resale of the stolen medical products to evade detection, or the medical products may simply expire or have diminished safety or efficacy by the time they are reintroduced into commerce. The SAFE DOSES Act recognizes the risk that thefts of medical products pose to the public health and was intended to increase the sentences of offenders who knowingly steal or traffic in pre-retail medical products.

The SAFE DOSES Act was enacted in response to recent incidents of medical product theft, some of which illustrate the risk, and some which illustrate the actual harm, to the public health resulting from such thefts. In 2009, a truck carrying 129,000 vials of Levemir, a long-acting insulin manufactured by Novo-Nordisk, was hijacked in North Carolina. Levemir generally becomes less effective if it is unrefrigerated or exposed to heat or direct light for significant periods of time. Several months after the thefts, vials of the stolen insulin began

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<sup>1</sup> Pub. L. No. 112-186 , 126 Stat. 1427 (Oct. 5, 2012).

<sup>2</sup> Codified at 18 U.S.C. § 670.

appearing in pharmacies and medical facilities, and were dispensed to patients. FDA subsequently received multiple reports of patients suffering adverse events after using Levemir from the stolen shipments. In connection with this theft, in the Southern District of Florida, William D. Rodriguez was convicted and sentenced to 120 months in prison for conspiracy to engage in interstate transportation of stolen property and related charges.<sup>3</sup>

The FDA reports on cargo thefts involving medical products on its website,<sup>4</sup> and the Commission can get a sense from this inventory of just how widespread this problem has become. Through the inventory, pharmacies, retainers, distributors, as well as consumers, can learn whether FDA regulated products they might be working with have been compromised.

#### The Commission's Proposal and Issues for Comment

The Commission proposes amending the sentencing guidelines to refer violations of the new offense to §2B1.1 (Theft, Property Destruction, and Fraud) with a possible additional reference to §2A1.4 (Involuntary Manslaughter). The Commission further proposes adding a new specific offense characteristic to §2B1.1 to provide an enhancement of two or four levels, and a minimum offense level of 14, for pre-retail medical product offenses that involve certain aggravating conduct, such as the use of violence or force or a deadly weapon, or conduct that results in serious bodily injury or death.

Both the FDA and the Department of Justice generally support this approach, and we believe treating violations of the new offense under §2B1.1 is appropriate. As explained in more detail below, we recommend that the proposed specific offense characteristic be amended so that if violence is used in the offense or if serious bodily injury or death results from it, the enhancement would be cumulative to the existing specific offense characteristics in §2B1.1 or any other new enhancement. We also recommend that the Commission consider increasing the enhancement for conduct involving a conscious or reckless risk of death or serious bodily injury to four levels from the current two levels and, where the resulting offense level is less than 16, increase to level 16. Finally, we believe the new enhancements should apply to all offenses involving stolen or diverted medical products, as that term is defined in 18 U.S.C. § 670(e), and not just to offenses involving “pre-retail medical products.”

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<sup>3</sup> *United States v. Rodriguez*, No. 12-cr-20216-DLG (S.D. Fla. 2012). Other examples of medical product theft include a January 2010 armed hijacking of a delivery truck in Puerto Rico that contained numerous prescription and over-the-counter drugs. The stolen drugs included Havrix, a Hepatitis A vaccine that must be stored between 36 and 46 degrees Fahrenheit to avoid degradation. More recently, in May 2011, Boston Scientific Corporation reported the theft of endoscopic and urologic devices that were labeled “sterile.” The devices were not in fact sterile; they were stolen en route to Boston Scientific Corporation’s sterilization facility. Thus, despite the “sterile” label, the devices, if reintroduced into the supply chain and later used, could pose a significant risk of infection to patients.

<sup>4</sup> See *Cargo Thefts*, FDA, <http://www.fda.gov/ICECI/CriminalInvestigations/ucm182888.htm>, (last visited Mar. 1, 2013).

The Commission's proposed specific offense characteristic would provide for a total enhancement of two or four levels if an offense involved any of statutory aggravating factors. We do not believe this approach is fully consistent with the statutory sentencing scheme as amended by the SAFE DOSES Act. The statutory maximum prison sentence increases from three to five years if the defendant is employed by, or is an agent of, an organization in the supply chain, if the offense involved the use of violence, force, or threat of violence of force, or if the offense involved the use of a deadly weapon. However, the maximum prison sentence increases to 30 years if the offense actually results in serious bodily injury or death.<sup>5</sup>

Despite the significant difference in the statutory maximum penalty for offenses that result in serious bodily injury, the proposal treats all the aggravating factors equally and provides for a total enhancement of only two or four levels if any or all of these aggravating factors are present. The statutory scheme – and congressional intent – countenance providing an enhancement, above and beyond those currently in the guidelines, when violence occurs or if serious bodily injury results. If an offender is employed by an organization in the supply chain for the medical product involved in the offense, and the offender also fires a deadly weapon in the commission of the offense, that defendant should be subject to a separate, cumulative enhancement for the distinct and important aggravating factor of engaging in violence. Providing for a cumulative enhancement for this factor would reflect the greater culpability of such offenders and the risks and harms involved in the offense.

We strongly recommend that offenses resulting in serious bodily injury or death be subject to a separate, 4-level enhancement and a minimum offense level of 18. Pre-retail medical theft that results in serious bodily injury or death is subject a maximum 30 years in prison, regardless of whether any of the other aggravating factors is present. Including an injury enhancement within a specific offense characteristic that encompasses other aggravating factors without cumulative effect would not provide just and proportional punishment or adequate deterrence. Anyone who steals medical products and causes serious bodily injury or death by reintroducing them recklessly into the stream of commerce, should go to prison for a significant term. We also believe the Commission should consider increasing the enhancement for conduct involving a conscious or reckless risk of death or serious bodily injury to four levels from the current two levels and, where the resulting offense level is less than 16, increase to level 16.<sup>6</sup>

The Commission requests comment on how the new specific offense characteristic, if promulgated, should interact with existing specific offense characteristics in §2B1.1. We recommend that the proposed new specific offense characteristics for use of violence and injury be cumulative with the existing specific offense characteristics in §2B1.1, including §2B1.1(b)(14), which provides for a 2-level enhancement and a minimum offense level of 14 for offenses that involve a conscious or reckless risk of death or serious bodily injury or possession

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<sup>5</sup> There are two other statutory aggravating factors: (1) a prior conviction under 18 U.S.C. § 670, and (2) a value of \$5,000 or more for the medical product involved in the offense. We believe these aggravating factors are adequately addressed by existing provision in the guidelines.

<sup>6</sup> If the Commission makes this change and also provides that the enhancement be cumulative to any enhancement for injury, then the injury enhancement should only be two levels rather than four.

of a dangerous weapon. We believe it is appropriate to distinguish between offenses involving a risk of harm and offenses involving actual harm; there is difference – recognized in the law – between offenders who possess a dangerous weapon during an offense and those who use a deadly weapon in the commission of the offense.

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The Commission proposes adopting the statutory definition of “pre-retail medical product” for use in §2B1.1 and requests comment as to whether this definition is adequately clear. The statute defines the term “pre-retail medical product” to mean one that “has not yet been made available for retail purchase by a consumer.” 18 U.S.C. § 670(e). We are concerned that the application of this definition in the context of §2B1.1 may be less than optimal. We have prosecuted thefts of medical devices from hospital supply rooms, and, although these devices have not yet reached the end consumer, there is ambiguity over whether such devices have “been made available for retail purchase.”

More importantly, we believe limiting the application of the new specific offense characteristic to “pre-retail medical products” will lead to disparate and inconsistent treatment of similar conduct. The Department has prosecuted numerous cases involving the reintroduction of previously dispensed medications into the supply chain. In such cases, defendants often purchase dispensed prescription drugs from patients, repackage the drugs or use solvents to clean the packaging to remove evidence of the prior dispensing, and resell the drugs to wholesale distributors or pharmacies that then dispense the drugs to unwary consumers. *See United States v. Segredo*, No. 1:07-cr-20766-ASG-1 (S.D. Fla. 2010) and *United States v. Handy, et al.*, Criminal No. 06-226-PB (D. NH). Recently, three individuals were indicted in the Middle District of Tennessee for allegedly obtaining over \$58 million dollars worth of drugs from “street collectors” in New York and Miami and selling the repackaged drugs to independent pharmacies as if the drugs were purchased from legitimate wholesale distributors. *United States v. Edwards et al.*, No. 3:13-cr-00012 (M.D. Tenn. 2013). These diversion cases – where prescription drugs previously dispensed by retail pharmacies are returned to the supply chain after being stored, handled improperly or repackaged under questionable conditions – present the same or greater public health concerns as cargo thefts that motivated the passage of the SAFE DOSES Act. In some cases, FDA testing has confirmed that solvents used to clean the packaging of diverted drugs have leached into the drugs themselves. The FDA has also found blood residue on a repackaged tablet.

Similarly, the Department has prosecuted cases involving organized theft rings that purchase large quantities of infant formula stolen from retail stores and reintroduce the stolen infant formula into the supply chain. *See, e.g., United States v. Tavares et al.*, 1:10-cr-00342 (N.D. Ga.). In many cases, the infant formula may not be stored properly and in some cases may be expired by the time it is resold. Although this infant formula stolen from retail outlets may not meet the definition of “pre-retail medical product,” its theft and diversion pose the same or even greater risk to the public health than infant formula that is stolen directly from the manufacturer’s warehouse.

Many of these cases have been charged – and may continue to be charged – as mail fraud, wire fraud, or interstate transportation of stolen property, and are typically sentenced under §2B1.1. We recommend the Commission revise its proposed specific offense characteristic in §2B1.1 to apply to all offenses involving stolen, diverted, or unlawfully imported medical products. Such an amendment would better effectuate the public health goals of the SAFE DOSES Act (and the Food and Drug Administration Safety and Innovation Act, *see infra*) and also ensure that similarly culpable conduct receive similar treatment under the guidelines. The risk to the public health is similar, whether the medical products are stolen while in transit from the manufacturer or wholesaler to a hospital, stolen directly from a hospital or pharmacy itself, illegally returned to the supply chain after previous sale or dispensing, or illegally introduced into the supply chain from foreign sources. In all of these situations, the medical products may be subject to harmful conditions and their reintroduction into the supply chain poses a risk of harm to consumers.

The Commission also requests comment on whether to account for the increased statutory maximum penalty for defendants who are employed by, or an agent of, an organization in the supply chain through Chapter Two or Three of the guidelines. The SAFE DOSES Act defines the “supply chain” to include manufacturers, wholesalers, repackers, own-labeled distributors, private-label distributors, jobbers, brokers, drug traders, transportation companies, hospitals, pharmacies, and security companies. We do not believe the existing adjustment in §3B1.3 adequately addresses the aggravating factor of defendants who are employed by, or an agent of, an organization in the supply chain. Many mid- and lower-level employees of organizations in the supply chain will lack the substantial education or training, or professional or managerial discretion, needed to qualify for an adjustment under §3B1.3. Nevertheless, these employees will be subject to enhanced statutory penalties under 18 U.S.C. § 670, and we believe should therefore be subject to a guideline enhancement. We support the Commission’s proposal to include a new specific offense characteristic in §2B1.1 that would provide an enhancement for supply chain employees or agents. In cases where the employee also uses a special skill or occupies a position of trust, the additional adjustment provided for in §3B1.3 may be warranted and could apply cumulatively to the §2B1.1 enhancement.

Finally, as the Commission notes, in addition to creating a new offense under 18 U.S.C. § 670, the SAFE DOSES Act enhanced penalties for certain existing offenses if the offense involves pre-retail medical products. Many of these existing offenses are referred to guidelines other than §2B1.1. In order to ensure that the higher penalties are reflected in these guidelines, and to promote consistency, we support providing a similar specific offense characteristic to the one proposed for §2B1.1 in the other referenced guidelines.

## **2. Trade Secrets; Foreign and Economic Espionage Penalty Enhancement Act**

The Commission seeks comment on what changes, if any, should be made to the guidelines to respond to the directive contained in the Foreign and Economic Espionage Penalty

Enhancement Act of 2012, and more specifically, comment on a set of six questions related to the application of the guidelines to trade secret offenses.

The Department, including the Federal Bureau of Investigation, the National Security Division, and the Computer Crime and Intellectual Property Section of the Criminal Division, strongly supports amending §2B1.1 to include enhancements for the simple theft of a trade secret and for transmitting or attempting to transmit a stolen trade secret outside the United States, and an increased enhancement for theft of a trade secret to benefit a foreign government or instrumentality. As described in more detail below, adding an enhancement for the simple theft of trade secrets will bring the sentencing guideline applicable to trade secrets in line with the guidelines applicable to other forms of intellectual property crime and better reflect the seriousness of the trade secret offenses. Likewise, increasing enhancements for trade secret theft involving a foreign nexus recognizes the serious and growing threat of such violations to our economic and national security interests.

### The Threat of Economic Espionage and Trade Secret Theft

Efforts by foreign and domestic competitors who deliberately target economic intelligence and company trade secrets in leading U.S. industries and technologies cost the U.S. economy billions of dollars and can undermine national security. The Federal Bureau of Investigation has seen an overall increase in economic espionage cases, doubling the number of arrests associated with trade secret theft over the past four years.<sup>7</sup> The FBI has identified a number of factors that have contributed to the increased threat of trade secret theft, and while some of these factors are temporary effects of the global financial crisis, other factors such as the increasing global reach of business and trade, and the ever-increasing use of digital networks and storage, suggest the problem of trade secret theft will continue to grow. *Id.*

U.S. companies are often targeted by foreign competitors seeking to gain an economic or other advantage. For example, foreign competitors aggressively target and recruit employees at U.S. companies and research institutions. Foreign competitors operating illegally also seek to gain economic intelligence through bribery, cyber intrusions, theft, wiretapping, and by establishing and misusing seemingly innocent business relationships between foreign companies and U.S. industries for the purpose of gathering economic intelligence.<sup>8</sup>

All cases prosecuted under 18 U.S.C § 1831, by definition, involve a foreign nexus, specifically, an intent to benefit a foreign government, instrumentality or agent. Many cases involving trade secret theft prosecuted under 18 U.S.C. § 1832 also involve a foreign nexus. *See, e.g., United States v. Qin*, No. 10-20454 (E.D. Mich. 2010) (two defendants, one a former General Motors engineer, were convicted by a federal jury in Detroit for conspiring to steal hybrid technology trade secrets from GM with the intent to use them in a joint venture with an

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<sup>7</sup> *See Testimony*, FBI, <http://www.fbi.gov/news/testimony/economic-espionage-a-foreign-intelligence-threat-to-americans-jobs-and-homeland-security>, (last visited Mar. 1, 2013).

<sup>8</sup> *See Economic Espionage*, FBI, <http://www.fbi.gov/about-us/investigate/counterintelligence/economic-espionage>, (last visited Mar. 1, 2013).

automotive competitor in China. Based on preliminary calculations, GM estimates that the value of the stolen GM documents at more than \$40 million);<sup>9</sup> *United States v. Kolon Industries, Inc.*, No. 3:12-CR-137 (E.D.Va. 2012) (Seoul-based company and five of its executives and employees were indicted for engaging in a multi-year campaign to steal trade secrets related to para-aramid fiber, including DuPont's Kevlar. According to the indictment, Kolon targeted current and former employees at DuPont, and a competitor, Teijin, hired them to serve as consultants and then asked them to reveal valuable trade secret information. The indictment alleged payments of more than \$300,000 made to former DuPont employees in exchange for trade secret information.);<sup>10</sup> *United States v. Liu*, No. 3:05-cr-00085 (M.D. La. 2011) (former Dow Chemical Co. research scientist sentenced to 60 months in prison for conspiring with current and former Dow employees to steal trade secrets from Dow and sell them to companies in China);<sup>11</sup> *United States v. Yu*, No. 09-CR-20304 (E.D. Mich. 2009) (former Ford Motor Co. employee and Chinese national, was sentenced to 70 months in federal prison on two counts of trade secret theft. After accepting a position with a Chinese competitor and before telling Ford of his new job, defendant electronically copied thousands of Ford documents, including sensitive Ford design documents, and took them to his new employer in China).<sup>12</sup>

#### Summary of Department Recommendations

As discussed in further detail below, the Department recommends the following:

- A 2-level enhancement in §2B1.1 for offenses involving theft of a trade secret;
- An additional 2-level enhancement, and a minimum offense level of 14, if the defendant transmits or attempts to transmit a stolen trade secret outside the United States; and
- An additional 2-level enhancement (cumulative with the enhancements above), and a minimum offense level of 14, for economic espionage offenses.

#### Commission Requests for Comment

*What offenses, if any, other than sections 1831 and 1832 should the Commission consider in responding to the directive? What guidelines, if any, other than §2B1.1 should the Commission consider amending in response to the directive?*

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<sup>9</sup> See Press Release, U.S. Attorney's Office, E. Dist. of Md., Two Convicted in Conspiracy to Steal GM Secrets (Nov. 30, 2012), [http://www.justice.gov/usao/mie/news/2012/2012\\_11\\_30\\_sdu.html](http://www.justice.gov/usao/mie/news/2012/2012_11_30_sdu.html).

<sup>10</sup> See Press Release, U.S. Attorney's Office, E. Dist. of Va., Top Executives at Kolon Industries Indicted for Stealing DuPont's Kevlar Trade Secrets (Oct. 18, 2012), <http://www.justice.gov/usao/vae/news/2012/10/20121018kolonnr.html>.

<sup>11</sup> See Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Former Dow Research Scientist Sentenced to 60 Months in Prison for Stealing Trade Secrets and Perjury (Jan. 13, 2012), <http://www.justice.gov/opa/pr/2012/January/12-crm-051.html>.

<sup>12</sup> See Press Release, U.S. Attorney's Office, E. Dist. of Mich., Chinese National Sentenced Today for Stealing Ford Trade Secrets (Apr. 12, 2011), <http://www.justice.gov/criminal/cybercrime/press-releases/2011/ysent2.pdf>.

The Department recommends that in responding to the directive, the Commission consider other offenses and guidelines applicable to other forms of intellectual property, as well as offenses and guidelines that relate to conduct frequently connected to trade secret offenses under §§ 1831 and 1832. Like copyrights and trademarks, trade secrets are a form of intellectual property. However, most intellectual property offenses are referenced to §2B5.3 (Counterfeiting and Infringement of Copyright or Trademark), which provides a higher base offenses level (8) than §2B1.1 (6), as well as an enhancement for offense conduct that causes infringing items to enter the stream of commerce in the United States, either through manufacturing or importing of infringing articles, or uploading of infringing items to the Internet.

The Department regards criminal offenses involving trade secrets to be no less serious than other forms of intellectual property crime and, in fact, has made the investigation and prosecution of trade secret theft and economic espionage a top priority. *See, e.g.*, U.S. Dept. of Justice, PRO IP Act Annual Report FY2012 at 14 (Dec. 2012); FBI, PRO IP Act Annual Report 2012 at 1 (2012). The Department, therefore, urges the Commission to consider bringing the offense level applicable to trade secret theft offenses under §2B1.1 into parity with offenses referenced to §2B5.3.

*What should the Commission consider in reviewing the seriousness of the offenses described in the directive, the potential and actual harm caused by these offenses, and the need to provide adequate deterrence against such offenses?*

In addition to bringing the applicable guideline into parity with other intellectual property guidelines, the Department recommends that the Commission consider the serious economic and national security impact of trade secret misappropriation, as well as the increasing and evolving threat. The United States' leading role in technological innovation makes U.S. companies attractive targets for economic espionage. In addition to putting an individual victim at a competitive disadvantage, economic espionage for the benefit of a foreign entity affects the economic competitiveness of the United States as a whole, and in cases involving sensitive or critical technologies, may pose a risk to national security. Although the existing guidelines provide a 2-level enhancement for economic espionage offenses under § 1831, the Department recommends that the guidelines provide a more significant enhancement for economic espionage offenses to reflect the seriousness of the harm they inflict. Because prosecutions under § 1831 require proof that the defendant knew or intended the trade secret theft offense to benefit a foreign entity, investigation and prosecution of such offenses can present particular challenges in acquiring evidence and testimony of witnesses, or effecting service of process on parties located abroad. *See, e.g., United States v. Pangang Group Co., Ltd.*, 879 F.Supp.2d 1052 (N.D. Cal. 2012) (granting motion to quash service on foreign corporation of indictment charging § 1831). A more significant enhancement is thus further justified by the need to deter foreign entities engaged in trade secret theft from exploiting such investigative difficulties to their advantage.

Even in trade secret theft cases under 18 U.S.C. § 1932, in which it cannot be established that a defendant knew or intended for the theft to benefit a foreign government or

instrumentality, the transmission of stolen trade secret information outside the United States presents an aggravating factor that warrants an additional enhancement. Transmitting trade secrets outside the country substantially increases the risk that the information will be exploited by a foreign competitor and, as outlined above, transmittal outside the U.S. also creates additional obstacles to effective investigation and prosecution. An additional enhancement is thus further justified by the need to deter such conduct.

*Do the guidelines appropriately account for the simple misappropriation of a trade secret? Is the existing enhancement at §2B1.1(b)(5), which provides a 2-level enhancement "if the offense involved misappropriation of a trade secret and the defendant knew or intended that the offense would benefit a foreign government, foreign instrumentality, or foreign agent," sufficient to address the seriousness of the conduct involved in the offenses described in the directive?*

The Department respectfully submits that the existing guidelines as they relate to the simple theft of a trade secret and to trade secret theft committed with knowledge or intention to benefit a foreign government, instrumentality or agent, are not sufficient to appropriately account for the seriousness of the offenses. As noted above, §2B1.1 provides a base offense level of six for trade secret theft under 18 U.S.C. § 1831, and thus the offense level for simple trade secret theft is less than the base offense level for other intellectual property crimes such as criminal copyright infringement, both of which have a base offense level of eight under §2B5.3. *See* 18 U.S.C. §§ 2319 (copyright), 2320 (trademark counterfeiting). As the Administration noted in its March 2011 White Paper on Intellectual Property Enforcement Legislative Recommendations (p. 5), a 2-level enhancement for simple trade secret theft (even without other aggravating factors) would bring the effective offense level in line with other intellectual property offenses, and more appropriately reflect the seriousness of trade secret theft offenses.

Economic espionage for the benefit of a foreign government, instrumentality or agent presents a more significant and multi-faceted risk of harm than does simple trade secret theft under § 1832. It can not only bankrupt individual trade secret owners, but can also undermine the overall competitiveness of the United States, and even threaten national security. *See United States v. Chung*, 659 F.3d 815 (9<sup>th</sup> Cir. 2011) (former Rockwell and Boeing engineer sentenced to 188 months in prison for committing economic espionage, acting as an agent of China for more than three decades while employed by Rockwell and Boeing, and making false statements to the FBI. Chung, who had held a "secret" security clearance when he worked at Rockwell and Boeing, misappropriated trade secrets to benefit China, including information related to the Space Shuttle program and the Delta IV rocket.) In this regard, such offenses warrant a significantly higher offense level.

*Should the Commission provide one or more additional enhancements to account for (A) the transmission or attempted transmission of a stolen trade secret outside of the United States; and (B) the transmission or attempted transmission of a stolen trade secret outside of the United States that is committed or attempted to be committed for the benefit of a foreign government,*

*foreign instrumentality, or foreign agent? If so, under what circumstances should such an enhancement apply, and what level of enhancement should apply?*

The Department supports an additional 2-level enhancement for trade secret offenses involving the transmission or attempted transmission of stolen trade secrets outside the United States in both the circumstances described above. All trade secret theft offenses inflict harm on the owners of trade secrets, but the transmission of stolen trade secrets outside the United States presents an additional aggravating factor, due to the threat such conduct poses to the U.S. economy and the competitiveness of our leading companies, to our nation's national security, as well as difficulties in investigating, prosecuting, and otherwise holding trade secret thieves accountable once trade secret data has been transmitted abroad. This 2-level enhancement should apply in addition to the previously discussed 2-level enhancement for "simple" theft of trade secrets, as well as the additional enhancement for economic espionage offenses committed for the benefit of a foreign entity. The net effect would be to give simple trade secret theft a 2-level enhancement, transmission of trade secrets outside the U.S. a 4-level enhancement, and virtually all economic espionage offenses a 6-level enhancement, which would more appropriately reflect the seriousness of these offenses. Virtually all economic espionage offenses will involve the transmission or attempted transmission of stolen trade secrets outside the U.S., although it is possible that in rare cases, an economic espionage offense could be committed where the stolen trade secret data is intended to remain in the U.S., in which case the combined enhancements would total four levels rather than six.

*Should the Commission restructure the existing 2-level enhancement in subsection (b)(5) into a tiered enhancement that directs the court to apply the greatest of the following: (A) an enhancement of 2 levels if the offense involved the simple misappropriation of a trade secret; (B) an enhancement of 4 levels if the defendant transmitted or attempted to transmit the stolen trade secret outside of the United States; and (C) an enhancement of [5][6] levels if the defendant committed economic espionage, i.e., the defendant knew or intended that the offense would benefit a foreign government, foreign instrumentality, or foreign agent?*

The Department strongly supports the restructuring described above, which would yield the same offense levels (in virtually all cases) as the series of cumulative individual 2-level enhancements discussed previously, but would be simpler to apply. The Department believes that economic espionage for the benefit of a foreign entity presents a significantly higher threat of harm than simple trade secret theft, and thus an enhancement of six levels above the base offense level of six is warranted (even in rare economic espionage cases in which transmission or attempted transmission of a trade secret outside the United States cannot be shown).

*Should the Commission provide a minimum offense level of [14][16] if the defendant transmitted or attempted to transmit stolen trade secrets outside of the United States or committed economic espionage?*

The Department supports a minimum offense level of 14 for trade secret theft offenses in both of the circumstances described above. As noted in the Administration's March 2011 White

Paper, a minimum offense level for these offenses will more appropriately account for the aggravated risk of harm posed by these offenses, even where a significant pecuniary loss cannot be demonstrated.

### **3. Counterfeit and Adulterated Drugs; Food and Drug Administration Safety and Innovation Act**

#### Counterfeit Drug Offenses

The Food and Drug Administration Safety and Innovation Act (“FDASIA”),<sup>13</sup> amended 18 U.S.C. § 2320 to add a new subsection (a)(4) prohibiting trafficking in a “counterfeit drug.” The amendment defined the term “counterfeit drug” for purposes of § 2320 as a drug (as defined in the Federal Food, Drug, and Cosmetic Act) “that uses a counterfeit mark on or in connection with the drug.” § 2320(f)(6). The FDASIA raised the statutory maximum penalties for violations of this new provision up to 20 years imprisonment for a first offense, as compared to 10 years for trafficking in other types of counterfeit goods. This change brings the statutory maximum penalties for counterfeit drugs in line with those applicable to counterfeiting offenses that result in serious bodily injury. The FDASIA also included a directive to the Sentencing Commission to review the guidelines applicable to § 2320 offenses involving counterfeit drugs and to consider amending them to address such offenses.

The manufacture and sale of counterfeit drugs represents an alarming and growing problem that can not only undermine consumer confidence, but can also pose serious and life-threatening health and safety risks. More sophisticated methods of manufacturing, packaging and distribution facilitated by worldwide Internet access have created unprecedented opportunities for criminals to traffic in dangerous fake drugs. These drugs may look real but often contain little or none of the active ingredients of genuine drugs, different active ingredients, or harmful ingredients, at the expense of the health and safety of consumers. Indeed, there have been instances of significant physical harm and even death to consumers as a result of drug counterfeiters’ actions.

The problem is compounded by a variety of factors. Production costs for drugs are low; facsimiles of genuine drugs are inexpensive to manufacture, as are high-quality counterfeit labels and packaging. Counterfeit drugs are hard to detect; the small physical size of pharmaceuticals makes them easy to ship and import through express consignments, making interdiction difficult. Moreover, without sophisticated chemical analysis, some counterfeits are indistinguishable from the real thing and may be undetected for long periods of time. Profit margins are high; many genuine name-brand drugs are expensive – particularly certain physician-administered and orphan drugs,<sup>14</sup> which can cost hundreds of dollars per dose – which provides significant room

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<sup>13</sup> Pub. L. 112-144, 126 Stat. 993 (July 9, 2012).

<sup>14</sup> “Orphan drugs” are drugs intended to treat a rare disease or condition such that they affect fewer than 200,000 persons in the United States, or they are not expected to be profitable within seven years of FDA approval. See 21 U.S.C. § 360bb(a)(2).

for counterfeiters to offer fakes well below the cost of genuine drugs while still making a hefty profit. Some potential purchasers of counterfeit drugs are often vulnerable or more susceptible to offers of drugs through nontraditional or untrusted sources – particularly through the burgeoning Internet pharmacy industry through which fake drugs can be easily sold. Consumers in need of critical, expensive pharmaceuticals for health maintenance may seek out discounted drugs for financial reasons, especially if they lack insurance coverage. And while some consumers may understand that there is a risk associated with obtaining drugs outside of approved or reputable sources, many are easily duped by professional-looking websites and the high-quality packaging and appearance of the counterfeit drugs. While the federal government is attempting an ongoing campaign to educate consumers of the dangers of Internet “pharmacies,” much work needs to be done, and in the meantime, purveyors of fakes – often located overseas – are able to prey on the unwary.

Traffickers in fake drugs may be prosecuted criminally under several statutes. Title 18 U.S.C. § 2320 (trafficking in counterfeit goods) applies where a counterfeit mark is used on or in connection with trafficking in the drugs, such as where a counterfeit trademark is reflected in a pill through a logo or a pill’s shape and color, or the trademark appears on packaging for the drugs. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 *et seq.*) also provides criminal penalties for a wider variety of conduct related to the manufacture and distribution of counterfeit drugs, including sales of adulterated, misbranded, mislabeled, or counterfeit drugs. The term “counterfeit” in the FDCA is broader than in § 2320 in that it is not limited to the use of counterfeit trademarks in association with a drug.

Drug counterfeiting offenses under the newly-created offense at 18 U.S.C. § 2320(a)(4), like other trademark counterfeiting crimes, involve multiple victims. Not only may trademark owners suffer harm, in the form of lost sales or diminution of the reputation associated with their brands, but more importantly, unsuspecting consumers who purchase fake drugs are defrauded, and face risk to their health from ineffective, dangerous, and even lethal substances. Government health care programs also lose money in connection with drug counterfeiting, when unscrupulous physicians purchase drugs outside the normal supply chain, receive counterfeit drugs, and bill programs such as Medicare for the cost of genuine drugs. In these situations, patients are duped into believing drugs, such as infused cancer drugs provided directly to them in doctor’s offices, are safe, effective, and genuine.

#### Summary of Food and Drug Administration and Department of Justice Recommendations

As discussed in further detail below, the FDA and the Department of Justice recommend the following:

- Adoption of Option 1 of the Commission proposals;
- A 4-level enhancement, with a minimum offense level of 16, for § 2320 offenses involving a counterfeit drug; and

- An additional 4-level enhancement (cumulative with the above), with a minimum offense level of 16, for § 2320 offenses, including counterfeit drug offenses, that involve a conscious or reckless risk of serious bodily injury or death.

### The Commission Proposals

The Commission proposes three options to address the amendments to § 2320 in the FDASIA. Option 1 would add a new specific offense characteristic to §2B5.3 that would provide an enhancement of two or four levels, and a minimum offense level of 14, for § 2320 offenses that involve a “counterfeit drug.” Option 2 would amend the existing specific offense characteristic at §2B5.3(b)(5), which currently provides a 2-level enhancement and a minimum offense level of 14 for offenses involving the conscious or reckless risk of serious bodily injury or death (or possession of a dangerous weapon in connection with the offense). Under Option 2, there would be a 2-level enhancement with a minimum offense level of 12 for § 2320 offenses involving a counterfeit drug, and a 4-level enhancement and a minimum offense level of 14 for offenses involving conscious or reckless risk of injury or death. Option 2 would also amend the relevant commentary to invite an upward departure if death or serious bodily injury resulted from the offense. Option 3 would change the reference for § 2320(a)(4) “counterfeit drug” offenses from §2B5.3 to §2N1.1 (Tampering or Attempting to Tamper Involving Risk of Death or Bodily Injury).

Of the three options the Commission proposes, the FDA and the Department of Justice recommend the approach of Options 1 and 2 that would maintain the existing reference to §2B5.3. Section 2320(a)(4) is a trademark counterfeiting offense that, like other § 2320 offenses, is driven primarily by a profit motive, and impacts trademark owners as well as purchasers and end-users. In this regard, maintaining a reference to §2B5.3 would provide consistency with other § 2320 offenses, avoid sharply disparate sentencing levels between counterfeit drugs and other counterfeit products that may pose similar dangers to health or safety, such as counterfeit automobile airbags, electrical components, and safety or medical equipment, and would allow for greater proportionality in addressing the varying levels of culpable conduct. However, because trafficking in counterfeit drugs poses dangers to public health and safety that are similar in many respects to those posed by §1365 drug tampering offenses, we further recommend modifying the Commission’s proposals to provide for higher enhancements and related minimum offense levels as outlined below.

Both Options 1 and 2 would add a specific offense characteristic related to counterfeit drugs that would result in a 2- or 4-level enhancement for § 2320 offenses involving counterfeit drugs. We support a 4-level enhancement to appropriately reflect the inherent dangers posed where a defendant traffics in drugs knowing that they are counterfeit, even absent other specific evidence of the defendant’s consciousness of, or recklessness with regard to, the risk of injury. Cases involving a demonstrated conscious or reckless risk of serious injury or death present an additional significant aggravating factor warranting a higher penalty. Therefore, we recommend that the Commission consider increasing the enhancement for such conduct to four levels from the current two levels and, where the resulting offense level is less than 16, increase to level 16.

As between Options 1 and 2, we favor the approach of Option 1, provided that the separate enhancements proposed in Option 1 could be applied cumulatively.

Issues for Comment:

*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 §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?*

If the Commission chooses Option 1, we would recommend additional language to clarify that the enhancements for counterfeit drugs and conscious or reckless risk of death or serious bodily injury are to be fully cumulative given the distinct purpose of each enhancement. Although drugs are not the only counterfeit items that can pose a risk to health or safety, because drugs are intended to be ingested and to address a medical condition, the mere involvement of counterfeit drugs presents an inherent risk that creates a significant aggravating factor in § 2320(a)(4) offenses, as compared to other types of § 2320 offenses involving products with less potential for injury. Moreover, that counterfeit drugs of any type present at least some risk of injury is, or should be, obvious to a defendant, even absent any additional specific indications that the counterfeit drugs in question pose a health risk. In cases where additional indications of risk do exist, such as where a defendant is aware or has reason to believe that a counterfeit drug contains harmful ingredients, or lacks an effective dosage of an active ingredient and is intended for treatment of a serious condition, or would be marketed to particularly vulnerable victims such as seniors or children, application of an additional enhancement for conscious or reckless risk would be warranted.

If the Commission chooses the approach of Option 2, which specifies the choice of the highest of three enhancements that may apply, we recommend offenses involving either counterfeit drugs or a conscious or reckless risk of injury or death receive at least 4-level enhancements and, if the resulting offense level is less than level 16, increase to level 16.

*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?*

Option 3 is less preferable than the other options. The degree of risk or harm associated with a particular counterfeit drug offense under § 2320(a)(4) may warrant an offense level of 25

or higher (similar to §2N1.1) if the offense involved, for example, counterfeit drugs lacking necessary active ingredients to address life-threatening illnesses, drugs containing harmful ingredients, or significant quantities of counterfeit drugs. But an offense level of 25 or more may not be appropriate for every counterfeit drug offense under § 2320(a)(4). Section 2B5.3 allows for a graduated offense level that is more closely tailored to the magnitude of the offense. It takes into account the value and volume of counterfeit items involved in the offenses by referencing the §2B1.1 loss table and it also provides enhancements based on the risk of injury and actual injury. However, should the Commission choose Option 3, the Department would recommend that the Commission consider incorporating additional specific offense characteristics to address large-scale offenses, and consider additional language clarifying that a departure may be warranted in certain circumstances involving offenses posing less of a threat to the public health or less culpable conduct.

*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 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?*

Counterfeiting involves fraudulently misrepresenting the origin of a product. Not only does counterfeiting adversely affect the legitimate owner of a trademark through lost sales or harm to its reputation, but just as importantly, it harms consumers by violating and exploiting the trust they have placed in a particular brand or manufacturer. The misrepresentation of origin that is the crux of trademark counterfeiting is usually accompanied by misrepresentations about the ingredients, methods of manufacture, quality, or other aspects of the product; counterfeits are almost always of inferior quality. In the case of counterfeit medicines, substandard quality can be dangerous because it results in a consumer (who may be in a compromised medical condition) failing to receive appropriate treatment, and may result in the consumer receiving affirmatively harmful substances as well. Even in those rare cases in which a counterfeit product happens to be made to the same specifications as the genuine product, the consumer has no assurance that the rigorous standards regarding manufacture, shipping and storage – each of which can affect the safety and efficacy of a drug – have been met. As described previously, the actual and potential dangers to consumers are all the more serious when the counterfeit product in question is a drug intended to be ingested or injected into the human body. The type and degree of harm that can be caused by a counterfeit drug varies widely depending on the type and intended use of a drug, the presence of harmful ingredients or lack of active ingredients, and the volume of distribution.

Recent cases in the U.S. involving counterfeit drugs illustrate some of the risks and actual harms caused by these products. In *United States v. Zhou*, No. 1:10-cr-00226-PAB (D. Colo. 2010), two defendants were charged criminally for manufacturing and importing counterfeit Alli

and other weight-loss medications containing harmful ingredients such as Sibutramine (a controlled substance), antidepressants, potent diuretics available only by prescription, and drugs not approved in the United States.<sup>15</sup> In February 2012, the FDA issued an advisory to health care providers regarding counterfeit versions of an injectable cancer drug Avastin being distributed in the U.S. The counterfeit version did not contain the active ingredient in Avastin, bevacizumab, and so patients receiving the counterfeit version were not being effectively treated.<sup>16</sup> The FDA issued similar notices in April 2012 and again on February 5, 2013, regarding counterfeit Altuzan, an unapproved version of Avastin that also was distributed directly to U.S. physicians.<sup>17</sup>

Many counterfeit pharmaceuticals originate in China and elsewhere in Asia, and incidents there illustrate other types of harm posed by counterfeits. In 2009, Chinese authorities reported seizing thousands of bottles of counterfeit brand-name diabetes medications that contained six times the recommended dosage of the active ingredient glyburide, used to lower blood sugar. This counterfeit drug was linked to multiple hospitalizations for hypoglycemia, and two deaths.<sup>18</sup> The dangers of widespread counterfeiting were also illustrated in 1995 during a meningitis epidemic in Niger. Some 50,000 people were inoculated with counterfeit vaccines resulting in the deaths of 2,500 people.<sup>19</sup>

Counterfeit malaria drugs have caused widespread harm in Southeast Asia and other parts of the world afflicted with malaria: although the harm is difficult to quantify, the World Health Organization has estimated that up to 20% of the approximately one million deaths caused by malaria each year worldwide were attributable to counterfeit malaria drugs.<sup>20</sup> Counterfeit malaria drugs either contain no active ingredients, thus prolonging the period of infectiousness

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<sup>15</sup> See Press Release, U.S. Attorney's Office, Dist. of Colo., Two Arrested for Illegally Trafficking Counterfeit Weight Loss Medication (Mar. 25, 2010), <http://www.fda.gov/iceci/criminalinvestigations/ucm206314.htm>.

<sup>16</sup> See Safety Alert, FDA, Avastin (bevacizumab): Counterfeit Product (Feb. 14, 2012), <http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm291968.htm>.

<sup>17</sup> See Safety Alert, FDA, Altuzan (bevacizumab): Counterfeit Product (Apr. 3, 2012), <http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm298583.htm>; Health Care Provide Alert, FDA, Another Counterfeit Cancer Medicine Found in United States (Feb. 5, 2013), <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/counterfeitmedicine/ucm338283.htm>.

<sup>18</sup> See *Deadly diabetes drug found in Sichuan*, Shanghai Daily, Feb. 5, 2009, available at <http://mobile.shanghaidaily.com/article/?id=389938>.

<sup>19</sup> *Counterfeit Medicines*, World Health Organization, Fact Sheet (revised Nov. 14, 2006), available at [http://www.who.int/medicines/services/counterfeit/impact/ImpactF\\_S/en/](http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/) (last visited Mar. 1, 2013).

<sup>20</sup> Andrew Marshall, *The Fatal Consequences of Counterfeit Drugs*, Smithsonian Magazine, Oct. 2009, available at <http://www.smithsonianmag.com/people-places/Prescription-for-Murder.html>. The National Institutes of Health reports that 20% and 35% of anti malaria drugs tested in Sub-Saharan Africa and Southeast Asia are falsified. National Institutes of Health, Fogarty International Center, *Fogarty Study Shows Poor Quality Malaria Drugs Pose Threat*, Global Health Matters, May/June 2012, at 4, available at <http://www.fic.nih.gov/News/GlobalHealthMatters/Documents/ghmmay-jun2012.pdf>. See also *Battling Malaria Drug Resistance Along the Thai-Cambodian Border*, World Health Organization, [http://www.who.int/malaria/diagnosis\\_treatment/arcp/background/en/index.html](http://www.who.int/malaria/diagnosis_treatment/arcp/background/en/index.html) (last visited Mar. 1, 2013) ("Fake drugs with inadequate amounts of active ingredient may kill off some more susceptible parasites, but leave stronger ones – those more likely to develop tolerance - to multiply. Use of these drugs also extends the period of infectiousness, and can lead to the patient's death.").

and increasing the likelihood of death, or, more insidiously, they contain insufficient amounts of active ingredients, failing to destroy the stronger parasites and leaving them more tolerant and likely to multiply, thus increasing the spread of the disease.<sup>21</sup> There have been reports of a dramatic increase in counterfeit malaria drugs in Thailand and Myanmar (Burma), beginning around 2004-2005, that were indistinguishable from the genuine drug.<sup>22</sup> According to Oxford University epidemiologist Paul Newton, “shoddy and counterfeit medications have been a major problem for at least 10 years, and they’re responsible for reducing the efficacy of malaria drugs throughout Southeast Asia.”<sup>23</sup>

While the FDA assesses the drug supply in the U.S. to be far safer than that in many other countries, constant vigilance and deterrence of this activity through meaningful penalties and other steps are the only ways to ensure that the significant level of counterfeit medicines found in other countries does not make its way here.

We support changes to the guidelines that would take into account actual harm resulting from counterfeiting offenses. The current §2B5.3(b)(5) enhancement applies where there is a *risk* of serious bodily injury or death, but the existing guidelines do not adequately address counterfeiting offenses in which such risks are borne out, and an offense actually results in significant injury or death. We also support amending the guidelines applicable to counterfeiting offenses to take actual injury into account, either through additional specific offense characteristics providing for significant enhancements, or through the inclusion of additional commentary regarding an upward departure in cases where serious bodily injury or death results from an offense.

*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?*

As described above, we recommend that the Commission consider 4-level cumulative enhancements for counterfeit drugs and conscious or reckless risk of injury, respectively. We further recommend that if the resulting offense level is less than level 16, the level should be increased to level 16.

### Intentional Adulteration of Drugs

FDASIA also amended the Federal Food, Drug, and Cosmetic Act (FDCA) to significantly enhance penalties for intentionally adulterating drugs. Under the new provision,

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<sup>21</sup> *Battling Malaria Drug Resistance Along the Thai-Cambodian Border*, World Health Organization, [http://www.who.int/malaria/diagnosis\\_treatment/arcp/background/en/index.html](http://www.who.int/malaria/diagnosis_treatment/arcp/background/en/index.html) (last visited Mar. 1, 2013).

<sup>22</sup> “The malaria drugs for sale in eastern Myanmar became almost indistinguishable from the authentic ones. The packets even had hologram stickers that were nearly identical to the stickers from the factory.” Jason Beaubien, *Fake Malaria Drugs Fuel Rise Of Drug-Resistant Disease*, NPR (Dec. 19, 2012), <http://m.npr.org/story/167282184>.

<sup>23</sup> *Id.*

knowingly and intentionally adulterating a drug such that there is a reasonable probability of causing serious adverse health consequences or death carries a maximum penalty of 20 years in prison. Previously, the maximum penalty for such offenses was one year in prison or, if the offense was a second FDCA offense or committed with intent to defraud or mislead, three years in prison. *See* 21 U.S.C. § 333(a).

This provision was enacted in response to serious incidents involving contamination. For example, in early 2008, heparin, a commonly-used anticoagulant derived from the pig tissue and imported from China, was linked to an increase in deaths in the United States. An investigation by the FDA found that the heparin was intentionally adulterated with a substitute ingredient after a disease outbreak decimated the pig population in China. Other similar incidents around the world further highlight the risks of intentional adulteration. For example, cough syrup and teething products contaminated with diethylene glycol, a highly toxic solvent, recently caused the deaths of adults and children in Panama, Haiti, and Nigeria.

These incidents highlight the harm that can result from drug adulteration during the manufacturing process. Approximately 40 percent of the finished drug products used in the United States are manufactured elsewhere. About 80 percent of the active pharmaceutical ingredients used in the drugs that are manufactured in the United States come from more than 150 countries around the world. Those who intentionally adulterate drugs often do so from foreign locations, increasing the challenges of investigation and prosecution, and emphasizing the need for a strong deterrent in the form of significant penalties.

Drug adulteration can also occur when finished drug products are intentionally diluted. In 2004, a Rhode Island physician, Wallace Gonsalves, was convicted of drug adulteration, tampering with a consumer product, and other related violations after he diluted vaccines for varicella and measles, mumps, and rubella and administered the diluted vaccines to his immigrant patients. *United States v. Gonsalves*, No. 1:03-cr-00063-L (D. R.I. 2004). In 2002, a pharmacist, Robert Courtney, was convicted of drug adulteration and tampering for diluting various drugs, including chemotherapy drugs, before dispensing the drugs to customers in his pharmacy. *United States v. Courtney*, No. 4:01-cr-00253 (W.D. Mo. 2002). The investigation indicated that some of the drugs were diluted to less than ten percent of their original strength and that over 4,000 patients may have received the diluted drugs.

A drug may also become adulterated if it is stored or handled improperly. In 2012, James Newcomb was sentenced to 24 months in prison for conspiring to distribute adulterated drugs. Newcomb purchased foreign prescription drugs and sold them to U.S. doctors at significantly lower prices than typically charged for legitimate FDA-approved drugs. *United States v. Newcomb*, No. 4:12 CR 00009 RWS (E.D. Mo. 2012). Among the drugs that Newcomb sold were “cold chain” cancer medications that require storage at constant cold temperatures but were received by customers in compromised condition.

Rarely can drug adulteration be detected by the naked eye. In many cases, sophisticated analysis is required to detect and identify the nature of the adulteration. When the drug is

intended for the treatment of seriously, chronically, or terminally ill patients, adverse consequences or diminished effectiveness caused by adulteration may be incorrectly attributed to the underlying illness itself and go unreported for months or may never be reported at all. The difficulty in detecting adulteration and the significant harm that can result when adulterated drugs are distributed to an unsuspecting and vulnerable population are additional factors that support the need for strong penalties.

### The Commission Proposal

The Commission proposes two options to address the enhanced statutory penalties for intentional adulteration of drugs. Option 1 would apply §2N2.1, the guideline applicable to other FDCA violations, and would amend §2N2.1 to establish a base offense level of 14 for convictions subject to the enhanced penalties for intentional drug adulteration. Option 2 would refer offenses under 21 U.S.C. § 333(b)(7) to §2N1.1 (Tampering or Attempting to Tamper Involving Risk of Death or Bodily Injury), which provides for a base offense level of 25.

The Department strongly supports Option 2 due to the similarities between the tampering offenses covered by §2N1.1 and intentional adulteration. The relevant tampering provision, 18 U.S.C. § 1365(a), prohibits tampering with a consumer product with “reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk.” Many of the cases that have been charged under this tampering provision could also have been charged as intentional adulteration, had the offense existed at the time.

There have been numerous prosecutions under the tampering statute involving medical professionals diluting and/or substituting other ingredients for prescription drugs. *See, e.g., United States v. Moyer*, 182 F.3d 1018, 1020 (8th Cir. 1999) (doctor removed morphine from patients IV bags and replaced it with saline). In 2010, a surgery technician was convicted of five counts of tampering with a consumer product after she injected herself with syringes filled with Fentanyl and replaced the missing pain reliever with saline. As a result of her conduct, patients did not receive needed pain relief and over 30 of her patients contracted hepatitis C from the contaminated syringes. In these and similar cases, the defendants could now be charged with the enhanced FDASIA penalties under 21 U.S.C. § 333(b)(7) when the conduct is intentional, causes the drug to be adulterated, and creates a serious risk of harm to the patient. Both the *Gonsalves* and *Courtney* cases described above were charged as both tampering and adulteration. Referring these similar offenses to the same guideline would promote consistency and minimize unwarranted disparity based on charging decisions.

Strong penalties are appropriate as part of an overarching strategy to protect the integrity of the U.S. drug supply from intentional threats, both domestic and foreign. We note that the enhanced penalties under 21 U.S.C. § 333(b)(7) will apply only when the government has proven *both* that the defendant acted knowingly and intentionally *and* that the offense caused a reasonable probability of serious adverse health consequences or death. Thus, only conduct that poses a genuine threat to the safety of the U.S. drug supply will be covered by this offense.

Violations posing no significant risk of harm, or those where the adulteration is the result of accident or negligence, are not covered.

We believe Option 1 is inappropriate for these offenses. Congress enacted higher penalties for intentional adulteration to protect the public health, not to address economic harm. Option 1 relies on §2N1.1, which ties penalties to the monetary loss suffered by victims. Where the gravamen of the offense of conviction is intentional tampering causing a genuine risk to the health and safety of the American public, economic loss is not the appropriate measure of culpability.

The Commission requests comment comparing and contrasting offenses involving intentional adulteration of drugs under 21 U.S.C. § 333(b)(7) with those involving drug counterfeiting under 18 U.S.C. § 2320. Although there is some overlap between counterfeiting and intentional adulteration, we believe intentional adulteration – and the elements of the crime required to be proven for the offense – are more closely related to tampering. Counterfeiting under 18 U.S.C. § 2320 is a trademark offense as well as a public health offense, and addressing the offense by reference to §2B5.3, the guideline for other trademark counterfeiting offenses, promotes consistency and allows for a graduated approach for different levels of harm, both economic and physical. Intentional adulteration under 21 U.S.C. § 333(b)(7), on the other hand, has no trademark component and is limited to those cases that necessarily involve an elevated risk of harm. For these reasons, Option 2 of the published proposals is the appropriate one.

#### **4. Counterfeit Goods or Services to the Armed Forces; National Defense Authorization Act for Fiscal Year 2012**

The National Defense Authorization Act for Fiscal Year 2012 (“NDAA”) amended the Trademark Counterfeiting Act of 1984, 18 U.S.C. § 2320, to define a new specific class of counterfeit items, “counterfeit military goods and services,” consisting of counterfeit items that are either “falsely identified or labeled as meeting military specifications,” or “intended for use in a military or national security application.” 18 U.S.C. § 2320(f)(4). The NDAA also created a new subsection at § 2320(a)(3) prohibiting trafficking in counterfeit military goods and services where the “use, malfunction, or failure of [such items] is likely to cause serious bodily injury or death, the disclosure of classified information, impairment of combat operations, or other significant harm to a combat operation, a member of the Armed Forces, or national security.” Violations of § 2320(a)(3) are subject to a higher statutory maximum penalty and fine than § 2320 offenses generally. Under the new military subsection, a violation is subject to a maximum penalty of 20 years in prison and a \$5 million fine for a first offense, whereas a violation of § 2320(a)(1) is subject to a maximum penalty of 10 years in prison and a \$2 million fine. *See* 18 U.S.C. §§ 2320(b)(1), (b)(3).

#### **Summary of Department Recommendations**

As discussed in further detail below, the Department recommends the following:

- Adoption of Option 1 of the Commission proposals; and
- If the Commission chooses Option 3, then modification of the proposed language to limit application of the enhancement to offenses in which the use or failure of counterfeit products would pose a likelihood of harm to critical infrastructure, national defense, national security, or law enforcement.

### The Commission Proposals

The Commission proposes four options to address the NDAA amendments to § 2320: the first three would add new specific offense characteristics to §2B5.3 for offenses involving counterfeit military items and/or risks of harm similar to those identified in the NDAA amendments to § 2320. The fourth option would replace the existing reference of § 2320(a)(3) offenses to §2B5.3 of the guidelines with a reference to §2M2.3 (Destruction of, or Production of Defective, National Defense Material, Premises, or Utilities) with the possibility of an additional reference to §2M2.1 (Destruction of, or Production of Defective, War Materials, Premises, or Utilities).

The Department supports an amendment to provide enhanced penalties for § 2320 offenses involving military counterfeits that pose a heightened risk to members of the Armed Forces, military readiness, national security, or other vital national interests. The Department has prosecuted a number of cases under § 2320 involving products sold to the military for sensitive applications that would likely fit the definition contained in the NDAA amendments. *See, e.g., United States v. McCloskey*, No. 10-CR-245 (D. D.C. 2010) (defendant sentenced to 38 months selling hundreds of thousands of counterfeit integrated circuits imported from China and Hong Kong to the U.S. Navy, defense contractors imported and others, marketing some of these products as “military-grade”);<sup>24</sup> *United States v. Ashoor*, No. 10-20354, 2011 WL 1659780 (5<sup>th</sup> Cir. Apr. 29, 2011) (defendant sentenced to 51 months for attempting to sell counterfeit network hardware to the Department of Defense for use by Marine Corps to transmit troop movements, relay intelligence and maintain security for a military base west of Fallujah, Iraq).<sup>25</sup> As with other types of trademark counterfeiting, trafficking in counterfeit military goods and services can impose harm not only on the legitimate trademark owners whose marks have been counterfeited, but also on the buyers of such products, particularly where the counterfeit products are substandard, defective, or unsafe, and where the consumer is unaware of the counterfeit nature of the product. Those concerns are particularly heightened in the military context, where the goods or services involved may be deployed in sensitive applications, and the lives of military personnel may literally depend on the integrity and reliability of a product. At the same time, the enormity of the defense supply chain can attract unscrupulous suppliers seeking to profit from

<sup>24</sup> See Press Release, U.S. Attorney’s Office, DC, Administrator of VisionTech Components, LLC Sentenced (Oct. 25, 2011), <http://www.justice.gov/usao/dc/news/2011/oct/11-472.html>.

<sup>25</sup> See Press Release, U.S. Dep’t of Justice, Office of Pub. Affairs, Departments of Justice and Homeland Security Announce 30 Convictions (May 6, 2010), <http://www.justice.gov/opa/pr/2010/May/10-crm-534.html>.

high volume sales of counterfeits, while the complexity of that supply chain can make it difficult to hold traffickers in counterfeits accountable. Both these factors weigh in favor of the need for increased deterrence against military counterfeits.

Of the options proposed by the Commission, the Department strongly favors the approach in Options 1, 2, and 3 that would maintain the reference to §2B5.3, rather than Option 4, which would instead reference § 2320(a)(3) offenses to §§2M2.3 or 2M2.1 of the guidelines. Sections 2M2.3 and 2M2.1 impose significant base offense levels (26 and 32, respectively) with no specific offense characteristics to differentiate among offenses based either on the volume, profitability, or longevity of the offense, or on the severity of the harm or risk of harm imposed on victims. Although the Department recognizes that trafficking in military counterfeits can pose significant risks to important interests or groups, and in many cases may warrant offense levels of 26 or higher, maintaining the reference to §2B5.3, with the addition of specific offense characteristics relevant to military counterfeits, would result in sentencing ranges more appropriately tailored to the severity of a particular military counterfeiting offense.

Of Options 1-3, the Department favors Option 1 because it would result in enhanced penalties for trafficking in military counterfeits while appropriately limiting application of the enhancement to offenses that pose the types of heightened risk to important interests specifically identified in the NDAA amendments. These amendments to § 2320 were drafted in response to increased awareness of the potential dangers posed by counterfeit goods entering into the military supply chain. *See, e.g.*, S. Rpt. No. 112-167 (2012); U.S. Gov't Accountability Office, GAO-12-375, DOD Supply Chain: Suspect Counterfeit Electronic Parts Can Be Found on Internet Purchasing Platforms (2012). It is also consistent with the Administration's strategy and recommended approach to addressing these types of offenses. *See* Office of the Intellectual Property Coordinator, *Administration's White Paper on Intellectual Property Legislative Recommendations* (Mar. 2011), at 6-7 (recommended sentencing enhancements for counterfeit products knowingly sold for defense, military, law enforcement and other critical uses). However, the language of the NDAA amendment reflects a recognition that not every sale of counterfeit goods or services to the military will necessarily pose the degree of heightened risk warranting the significantly enhanced penalties provided for in § 2320(b)(3). The NDAA amendments define "counterfeit military goods and services" broadly, to include any item bearing a counterfeit mark that is also either falsely identified as meeting "military specifications," or which is "intended for use in a military or national security application." This definition is broad enough to encompass not only items such as counterfeit integrated circuits intended for use in hostile combat environments that have been falsely identified as meeting military specifications for heat- or vibration-tolerance, but also commercial off-the-shelf items incidentally sold to the military, such as counterfeit printer toner for use in a JAG office, or cleaning products for use in barracks. Although counterfeiting of such general-purpose items is a serious offense, their use or malfunction generally will not present the types of heightened dangers § 2320(a)(3) was drafted to address, *i.e.*, likelihood of seriously bodily injury, disclosure of classified information, impairment of combat operations, or other significant harms. By limiting application of the enhancement to violations of § 2320(a)(3), Option 1 excludes counterfeit offenses with a merely incidental connection to the military.

Although the offense language in § 2320(a)(3) appropriately limits the enhanced statutory penalties of § 2320(b)(3) to cases in which counterfeit items are likely to cause specific types of significant harm, the harms enumerated in § 2320(a)(3) are not the only types of harm connected to the military or other national security interests for which an enhancement may be appropriate. The Department could also support the approach of Option 3, which uses language similar to the existing enhancement in §2B1.1(b)(17) for the Computer Fraud and Abuse Act, 18 U.S.C. § 1030, offenses involving computers integral to critical infrastructure or used in national security or law enforcement applications. This approach would be consistent with the government's approach to target counterfeits entering the supply chains of the Department of Defense and other U.S. government agencies.<sup>26</sup>

For the reasons outlined above, however, we would recommend that if the Commission chooses the Option 3 approach, the proposed language be further amended to limit application of the enhancement to offenses with more than an incidental connection to critical infrastructure of national security, *i.e.*, in which the defendant not only knew the counterfeit items were intended to be used in critical infrastructure or similar applications, but that the use or failure of such products would pose a likelihood of harm to critical infrastructure, national defense, national security, or law enforcement.

#### **5. Tax Circuit Conflict: Unclaimed Deductions and Tax Loss**

The Department of Justice, together with the Internal Revenue Service, will submit comments addressing this circuit conflict under separate cover.

#### **6. Acceptance Of Responsibility**

The Commission has proposed an amendment and posed two issues for comment relating to the guideline for acceptance of responsibility, §3E1.1 (Acceptance of Responsibility). The proposed amendment and issues for comment arise from two circuit conflicts involving the circumstances under which a defendant is eligible for a third level of reduction under subsection (b) of §3E1.1. Subsection (b) provides for an additional reduction where (1) the defendant qualifies for a two-level decrease under subsection (a) of §3E1.1; (2) the offense level determined prior to the operation of subsection (a) is level 16 or greater; and (3) the government has moved for the reduction, stating that the defendant has assisted authorities in the investigation or prosecution of his own misconduct by timely notifying authorities of his intention to enter a plea of guilty, thereby permitting the government to avoid preparing for trial and permitting the government and the court to allocate their resources efficiently.

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<sup>26</sup> See Press Release, U.S. Immigration and Customs Enforcement, Federal agencies launch "Operation Chain Reaction" (June 14, 2011), <http://www.ice.gov/news/releases/1106/110614washingtondc.htm>.

*Whether the sentencing court has discretion to deny the third level of reduction when the government has filed a motion under subsection (b) and the defendant is otherwise eligible.*

The first circuit conflict is over whether the sentencing court has discretion to deny the third level of reduction when the government has filed a motion under subsection (b) and the defendant is otherwise eligible. Compare *United States v. Mount*, 675 F.3d 1052, 1054-59 (7th Cir. 2012) (additional one-level reduction is mandatory once the government determines that the criteria in §3E1.1(b) are satisfied and it makes the necessary motion), with *United States v. Williamson*, 598 F.3d 227, 230 (5th Cir. 2010) (district court retains the ability to decide whether the §3E1.1(b) criteria have been met). The Commission has proposed an amendment that would recognize that it is within the court's discretion to grant or deny the government's motion. Specifically, the amendment would amend Application Note 6 to §3E1.1 by adding the following statement: "The court may grant the motion if the court determines that the defendant has assisted authorities in the investigation or prosecution of his own misconduct by timely notifying authorities of his intention to enter a plea of guilty, thereby permitting the government to avoid preparing for trial and permitting the government and the court to allocate their resources efficiently. In such a case, the 1-level decrease under subsection (b) applies." The Commission has also requested comment on whether the Commission should instead resolve this issue in a different manner.

The Department supports the proposed amendment, which generally adopts the approach followed by the Fifth Circuit. Ultimately, the decision whether to grant the additional level of reduction is the sentencing court's, not the government's. A government motion under §3E1.1(b) is a prerequisite to a third level reduction, but the sentencing court retains independent authority to determine whether the section's requirements have been satisfied. See USSG §3E1.1 cmt. n.6 ("an adjustment under subsection (b) *may* only be *granted* upon a formal motion by the Government at the time of sentencing") (emphasis added). By stating that the court "may" grant the government's motion after making its own determination, the amendment will clarify the Commission's intent and eliminate the circuit split.

*Whether the government has discretion to withhold making a motion under subsection (b) when there is no evidence that the government was required to prepare for trial.*

The second circuit conflict is over whether the government has discretion to withhold making a motion under subsection (b) when there is no evidence that the government was required to prepare for trial. Compare, e.g., *United States v. Newson*, 515 F.3d 374, 378 (5th Cir. 2008) (government may decline to file motion based on defendant's refusal to agree to appeal waiver in plea agreement), with, e.g., *United States v. Divens*, 650 F.3d 343, 345-48 (4th Cir. 2011) (if government determines that defendant's assistance relieved it of preparing for trial, defendant is entitled to the reduction). The Commission has called for comment on whether it should resolve this circuit conflict and, if so, how.

The Department believes that the Commission should resolve the circuit conflict and provide clarity on the scope of the government's discretion in filing motions under §3E1.1(b), so that this provision of the guidelines is fairly and evenly applied in the federal courts. The Department recommends resolving the conflict in the direction of the majority of the circuits, through an amendment clarifying, in an application note, that the government may decline to file a motion under subsection (b) even if it was not required to prepare for trial. Specifically, Application Note 6 to §3E1.1 should be amended to include the following italicized language: "Because the Government is in the best position to determine whether the defendant has assisted authorities in a manner that avoids preparing for trial, an adjustment under subsection (b) may only be granted upon a formal motion by the Government at the time of sentencing. *See* section 401(g)(2)(B) of Public Law 108-21. *The Government may decline to file such a motion even if it was not required to prepare for trial, if, in the government's determination, it was otherwise unable to allocate its resources efficiently.*"

The requirement that the government file a motion before a defendant may receive the third-point reduction was inserted by Congress in 2003, when it amended §3E1.1 as part of the Prosecutorial Remedies and Other Tools to end the Exploitation of Children Today Act of 2003 (PROTECT Act)<sup>27</sup> (also amending the Sentencing Guidelines application notes and background commentary). Before the amendment, a defendant with an offense level of 16 or greater was entitled to receive the additional one-level reduction if he had "assisted authorities in the investigation or prosecution of his own misconduct by taking one or more of the following steps":

(1) timely providing complete information to the government concerning his own involvement in the offense; or

(2) timely notifying authorities of his intention to enter a plea of guilty, thereby permitting the government to avoid preparing for trial and permitting the court to allocate its resources efficiently.

USSG §3E1.1(b) (2002).

The PROTECT Act, however, "altered that rule by amending the subsection and adding the further element of a prosecutor's motion, thereby making qualification for an additional reduction under subsection (b) more difficult." *United States v. Sloley*, 464 F.3d 355, 360 (2d Cir. 2006). The application notes to §3E1.1 now make clear that a government motion is a prerequisite to the grant of the additional point, stating: "Because the Government is in the best position to determine whether the defendant has assisted authorities in a manner that avoids preparing for trial, an adjustment under subsection (b) may *only* be granted upon a formal motion by the Government at the time of sentencing." USSG §3E1.1, cmt. n.6 (emphasis added).

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<sup>27</sup> Pub. L. No. 108-21, § 401(g), 117 Stat. 650, 671-672 (2003).

Section 3E1.1(b) states the necessary criteria that a defendant must meet to be eligible for the government to file a motion in support of the one-level reduction. It does not, however, state that if those minimum requirements are met, the government *must* file the motion. See *United States v. Moreno-Trevino*, 432 F.3d 1181, 1186 (10th Cir. 2005) (entering a timely guilty plea is a necessary but not sufficient condition for obtaining third-point reduction).

That interpretation of §3E1.1(b) follows from *Wade v. United States*, 504 U.S. 181 (1992), in which the Supreme Court held that the government may refuse to move for a downward departure for substantial assistance under 18 U.S.C. § 3553(e) or USSG §5K1.1 even if the defendant has provided substantial assistance. The Court stated that “although a showing of assistance is a necessary condition for relief, it is not a sufficient one” because the government validly may base its decision not to move “on its rational assessment of the cost and benefit that would flow from moving.” *Id.* at 187. As a result, mere evidence that the defendant had provided substantial assistance to the government would not be sufficient to trigger further inquiry by the court into the government’s decision not to file a motion. *Id.* at 186. Rather, a defendant is not “entitled to relief” unless “the prosecutor’s refusal to move was not rationally related to any legitimate Government end,” for instance, if it was “based on an unconstitutional motive” such as “the defendant’s race or religion.” *Id.* at 185-186.

When Congress amended §3E1.1(b) in the PROTECT Act after *Wade* was decided, it inserted language that is identical to that used in Section 5K1.1, the substantial assistance provision at issue in *Wade*: “upon motion of the government stating that the defendant has assisted authorities,” the defendant is entitled to a third-point reduction. USSG §3E1.1(b); *Wade*, 504 U.S. at 182; Margareth Etienne, *Acceptance of Responsibility and Plea Bargaining Under the Feeney Amendment*, 16 Fed. Sent’g Rep. 109, 112 (2003) (in amending §3E1.1(b), Congress “mimic[ked] the language found” in §5K1.1). Congress is therefore presumed to have intended the Supreme Court’s interpretation of §5K1.1 in *Wade* to apply to the identical language that it inserted into §3E1.1(b) in the PROTECT Act. See *Global Crossing Telecomm., Inc. v. Metrophones Telecomm., Inc.*, 550 U.S. 45, 75 (2007) (Thomas, J., dissenting) (discussing Congress’s presumption in the context of the Communications Act). As a result, §3E1.1(b) confers a “power, not a duty, to file a motion,” *Wade*, 504 U.S. at 185, in support of a sentencing reduction. Although meeting the criteria specified in §3E1.1(b) is necessary to receive the third-point reduction, it is not sufficient. *Moreno-Trevino*, 432 F.3d at 1186. The government is entitled to refuse to file a motion as long as its refusal is rationally related to a legitimate government end.

The government’s refusal to file a motion can be rationally related to a legitimate government end even if the government was not required to prepare for trial. Before Congress enacted the PROTECT Act, §3E1.1(b) provided that a defendant would qualify for a third-point reduction if he “timely notif[ied] authorities of his intention to enter a plea of guilty, thereby permitting the government to avoid preparing for trial and permitting the court to allocate its resources efficiently.” USSG §3E1.1(b)(2) (2002). In the PROTECT Act, Congress amended §3E1.1(b) to provide that a defendant qualifies for a third-point reduction only if his timely notice of his intent to plead guilty permits “the government to avoid preparing for trial” and

permits *both* “the government and the court to allocate their resources efficiently.” PROTECT Act, Pub. L. No. 108-21, § 401(g)(1)(B), 117 Stat. 650, 671 (2003) (emphasis added). The amended version of §3E1.1(b) does not include the term “trial resources”; instead, it explicitly identifies a broader government interest in allocating its resources efficiently that is distinct from the government interest in avoiding trial preparation.

## **7. *Setser v. United States***

The Commission has proposed amending §5G1.3 (Imposition of a Sentence on a Defendant Subject to an Undischarged Term of Imprisonment) in response to the Supreme Court’s holding in *Setser v. United States*, 132 S.Ct. 1463 (2012). The proposed amendment clarifies that §5G1.3, which provides guidance to courts regarding whether sentences are to run consecutively to, or concurrently with an undischarged term of imprisonment, applies to cases in which a term of imprisonment has not yet been imposed, but is anticipated.

The Department of Justice supports the proposed amendment. We hope this change will encourage sentencing courts to include a statement indicating how any imposed imprisonment term will run with a yet-to-be imposed, but anticipated, state term of imprisonment. Currently, when a sentencing court is silent regarding a yet-to-be imposed term, the Bureau of Prisons contacts the sentencing court and inquires as to the court’s intent. Often, this results in delay, and on occasion, the court simply indicates that it is not opposed to whatever determination the BOP makes, whether for a designation of state incarceration for service of the federal term or not.

Although the Bureau has the authority to designate that a federal sentence be served in a state institution, pursuant to 18 U.S.C. § 3621, this is not always an easy determination and it is preferable for the sentencing court to identify its intention. We also recommend a statement in the commentary encouraging sentencing courts to indicate their intent on the judgment and commitment order as to whether any future sentence, if the parties are aware of the possibility of a future sentence, is to be served concurrently or consecutively.

Statutory amendments may also be necessary to deal with the implications of *Setser*, and we look forward to working with the Commission to develop such legislation.

## **8. *Miscellaneous and Technical, Part A1: Federal Aviation Administration Modernization and Reform Act (Aiming a Laser Pointer At An Aircraft)***

The Commission proposes amending §2A5.2 to address 18 U.S.C. § 39A, a new statute created by the Federal Aviation Administration Modernization and Reform Act of 2012.<sup>28</sup> Section 39A prohibits knowingly aiming the beam of a laser pointer at an aircraft in the special aircraft jurisdiction of the United States, or at the flight path of such an aircraft. The Sentencing

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<sup>28</sup> Pub. L. No. 112-95, 126 Stat. 11 (Feb. 14, 2012).

Commission has proposed amending Appendix A (Statutory Index) to reference the new statutes at §2A5.2 (Interference with Flight Crew or Flight Attendant).

The Federal Aviation Administration and the Department of Justice support this amendment. In addition, we suggest that the following aggravating factors be mentioned in the commentary to §2A5.2 as considerations for sentencing courts in determining where in the guideline range to sentence the defendant or whether a departure from the applicable guideline range may be appropriate.

- The type, power, and class of the laser. Different lasers present different levels of danger to aviation. Green class 4 lasers present the greatest threat to aviation. Even low powered green Class 3A lasers can cause retina damage in 60 seconds,<sup>29</sup> and Class 4 lasers, in any color, due to their intensity, can burn the skin or cause devastating and permanent eye damage as a result of direct, diffuse, or indirect beam viewing.<sup>30</sup> Other lasers may be less dangerous.
- The presence of multiple bursts of laser illumination or a laser beam that tracks the movement of the aircraft. Multiple laser bursts indicate an intent to endanger the safety of the aircraft or at the very least show reckless endangerment. The FAA has experienced many cases with multiple bursts and has documented their increased danger. In some of these cases, after commercial airlines have reported laser strikes, law enforcement helicopters investigating the attacks were themselves hit repeatedly by laser strikes from the same perpetrator. In addition, a laser beam that tracks the movement of an aircraft prolongs the crewmembers' exposure to the beam and may prevent or inhibit the aircraft from escaping the laser beam, thus increasing the danger of the laser strike.
- Proximity to an airport and altitude. Laser strikes on aircraft that are in the process of taking off or landing, or simply at altitudes at or below 5,000 feet above ground level, create greater risk of harm.

The problem of laser strikes on aircraft has been growing. There has been a thirteen fold increase in laser incidents between 2005 and 2011.<sup>31</sup> There were 3,591 such incidents documented in 2011,<sup>32</sup> and approximately the same number in 2012.<sup>33</sup> We appreciate the

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<sup>29</sup> See Final Report - A Review of Recent Laser Illumination Events in the Aviation Environment, DOT/FAA/AM-06/23 at 1, (Oct. 2006).

<sup>30</sup> June 2010 Alert: Dangerous Class 4 Lasers Now Being Sold, LaserPointerSafety.com, <http://www.laserpointersafety.com/class4lasers/class4lasers/june2010alert.html> (last visited Mar. 1, 2013).

<sup>31</sup> Laser Safety Initiative, Fed. Aviation Admin., <http://www.faa.gov/about/initiatives/lasers/> (last visited Mar. 1, 2013).

<sup>32</sup> See Press Release, W. Dist. of Pa., Laser Attacks On Aircraft A New Federal Crime (Feb. 27, 2012), [http://www.justice.gov/usao/paw/news/2012/2012\\_february/2012\\_02\\_27\\_01.html](http://www.justice.gov/usao/paw/news/2012/2012_february/2012_02_27_01.html).

<sup>33</sup> Jim Avila & Serena Marshall, *Laser Strikes on Aircraft on Record Pace*, ABC News, Feb. 15, 2013, available at <http://abcnews.go.com/us/laser-strikes-record-pace-san-francisco-news-copter/story?id=18414315>.

Commission addressing this issue and we are prepared to provide any additional information related to this.

**9. Miscellaneous and Technical, Part A3: 18 U.S.C. § 1752; The Federal Restricted Buildings And Grounds Improvement Act**

Last year, 18 U.S.C. § 1752 (involving trespass on restricted buildings and grounds) was amended in the Federal Restricted Buildings and Grounds Improvement Act to add the White House complex and the Vice President's residence to the list of restricted locations where the United States Secret Service can make a federal arrest of those individuals who knowingly defeat or circumvent security measures to access those sites.<sup>34</sup>

The Commission has proposed adding 18 U.S.C. § 1752 to Appendix A and referencing it to §2A2.4 (Obstructing or Impeding Officers) and §2B2.3 (Trespass). We support this amendment. In addition, we recommend amending §2B2.3 (which currently has a base offense level of four) such that there is a minimum offense level of 14 for defendants who have trespassed with a gun in the highly sensitive sites covered under § 1752(c).

In the past, individuals who trespassed at the White House complex or the Vice President's residence have been charged with a D.C. violation, § 22-3102 (Unlawful Entry), which carries a six-month maximum imprisonment penalty. Violations of § 1752 carry a one-year statutory maximum, unless a deadly or dangerous weapon is used or carried, or significant bodily injury results, in which case the penalty is increased to a statutory ten-year maximum.

The recent addition of the White House complex and the Vice President's residence to § 1752 gives the United States Attorney's Office the opportunity to proceed in federal court for significant security breaches at some of the most important and sensitive secured federal property in our nation. Under the Commission's proposed approach – referencing the amended 18 U.S.C. § 1752 to §2B2.3 – an individual convicted under § 1752(a)(1) for scaling and jumping over a fence into the grounds of the White House, and running towards the house with a loaded gun, if a first time offender, would receive an offense level of 8 (Base Offense Level of four, plus two levels for a secure government facility, plus another two levels for a dangerous weapon), resulting in a sentence recommendation of 0-6 months. We do not believe that such a sentence would be commensurate with the seriousness of the conduct and risk of harm, which is aimed at our nation's top leadership. We believe that the sentence recommendation resulting from such circumstances should presume a prison sentence.

We propose adding a specific offense characteristic to §2B2.3 that appropriately recognizes that defeating security measures at the White House complex, the Vice President's residence, a location where a person protected by the Secret Service is temporarily visiting, or a site that is restricted in conjunction with an event of "national significance" (as set out in

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<sup>34</sup> Pub. L. No. 112-98, 126 Stat. 263 (Mar. 8, 2012).

§ 1752(c)), merits a more significant punishment than similar conduct at other locations. We propose the addition of the following language:

If the trespass occurred at restricted buildings or grounds as defined in 18 U.S.C. § 1752(c), increase by 6 levels.

We also propose increasing the dangerous weapon enhancement at (b)(2) from two to four levels for trespasses occurring at the sensitive sites covered by § 1752(c). These two amendments would yield an offense level of 10 for an unarmed trespasser and an offense level of 14 for an armed individual.

Distinguishing these very sensitive venues from other government locations acknowledges not only the very different potential consequences of an intruder at these locations but also the resources required to address the intrusion. The effect of the offense conduct identified in § 1752(a)(1) at the White House complex involves hundreds of personnel, the activation of specialized teams, and a comprehensive series of security protocols. The protocols have an effect upon law abiding citizens, who are peacefully and lawfully visiting protected grounds. Recognizing the gravity of the conduct prohibited in § 1752(a)(1) and the burden such conduct imposes upon the Secret Service is the appropriate step for the Commission.

#### **10. Miscellaneous and Technical, Part A4: Ultralight Aircraft Smuggling Prevention Act (19 U.S.C. § 1590)**

The Ultralight Aircraft Smuggling Prevention Act of 2012<sup>35</sup> amended 19 U.S.C. § 1950 (Aviation Smuggling) to close a legal loophole that had previously excluded ultralight aircraft. Between 2009 and 2011, more than 300 suspected ultralight aircraft were detected crossing the U.S. – Mexico border. These ultralights generally carry narcotics (usually less than 300 pounds). Often traffickers drop the drugs in the United States and fly immediately back to Mexico, while other times, they land, unload the drugs and occasionally abandon the aircraft. Under the revised statute, ultralight aircraft used to smuggle narcotics are treated in the same manner as larger aircraft, and the penalties under the Tariff Act of 1930 – up to a \$250,000.00 fine and up to 20 years in prison – apply. The Commission’s has proposed an amendment to Appendix A (Statutory Index) to reference 19 US.C. § 1590 offenses to §2T3.1 (Evading Import Duties or Restrictions (Smuggling); Receiving or Trafficking in Smuggled Property). We support the amendment.

#### **11. Miscellaneous and Technical, Part C: Appendix A (Statutory Index) References for Offenses Under 18 U.S.C. § 554**

As noted by the Commission, the Department requested in its 2012 annual letter that the Commission amend the statutory index (Appendix A) so that 18 U.S.C. § 554 offenses

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<sup>35</sup> Pub. L. No. 112–93, 126 Stat. 8 (Feb. 10, 2012).

(Smuggling goods from the United States) are referenced to USSG §2M5.1 (Evasion of Export Controls) in addition to §2M5.2 (Exportation of Arms, Munitions, or Military Equipment or Services Without Required Validated Export License). We thank the Commission for considering this amendment.

Currently, § 554 is referenced in Appendix A only to §2M5.2 (Exportation of Arms, Munitions, or Military Equipment or Services Without Required Validated Export License). As we have suggested previously, §2M5.1 is the more appropriate guideline when an offense under 18 U.S.C. § 554 is based upon a violation of economic sanctions or export control regulations relating to strategic dual-use goods rather than munitions. A typical example is the illegal export of a dual-use item, such as a specialty metal, a machine tool, or integrated circuits. This situation may become more common as some defense articles are moved from licensing under the Arms Export Control Act and the International Traffic in Arms Regulations by the U.S. Department of State to licensing under the International Emergency Economic Powers Act and the Export Administration Regulations by the U.S. Department of Commerce.

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We appreciate the opportunity to provide the Commission with our views, comments, and suggestions. We look forward to working further with you and the other Commissioners to refine the sentencing guidelines and to develop effective, efficient, and fair sentencing policy.

Sincerely,



Jonathan J. Wroblewski  
Director, Office of Policy and Legislation

cc: Commissioners  
Judy Sheon, Staff Director  
Ken Cohen, General Counsel