Written Statement of Denise C. Barrett

On Behalf of the Federal Public and Community Defenders

Before the United States Sentencing Commission

Public Hearing on Pre-Retail Medical Products

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

The SAFE Doses Act, Pub. L. 112-186, creates new criminal penalties for theft and fraudulent conduct involving "pre-retail medical products." Although Congress passed the Act with large-scale organized cargo thefts in mind,[1] the statutory language sweeps so broadly as to include within its reach a wide variety of conduct:

- stealing a box of infant formula from a pharmacy wholesaler;
- creating fake shipping documents and other "drug pedigrees"[2] as part of a scheme to hide a theft or to further a gray market scheme;
- stealing a parked tractor trailer loaded with latex gloves, bed pans, urinals, and ice bags;
- fencing stolen pre-retail medical products;
- stealing a warehouse full of pharmaceuticals;
- reselling millions of dollars' worth of prescription drugs obtained from cargo thieves that were not stored properly and caused physical injury to the end user.

Consequently, the guidelines regarding these offenses must permit consideration of a wide-range of aggravating and mitigating circumstances. Because §2B1.1, to which the new offense and many of the related offenses covered under the SAFE Doses Act, should be referred, is already unduly complicated and undergoing a multi-year review, we believe that the prudent course of action is to simply cross-reference 18 U.S.C. § 670 to §2B1.1 and do nothing more. It seems especially cumbersome to add yet another series of specific offense characteristics (SOCs)

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[1] Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012, H. Rep. No. 112-459, at 4 (2012). *See also DIA and FDA Host Conference on Cargo and Warehouse Theft of Medical Products*, http://www.prweb.com/releases/2011/4/prweb8307568.htm.

[2] "A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them." FDA, *CPG Sec. 160.900 Prescription Drug Marketing Act – Pedigree Requirements under 21 C.F.R. Part 203*, http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073857.htm.

to §2B1.1, grapple with how they interact with existing SOCs, and adequately consider mitigating factors in an effort to account for offenses that are prosecuted infrequently.

I. Overview of the Reach of the SAFE Doses Act

A. The SAFE Doses Act Sweeps Broadly, Covering a Wide-Variety of Products Whose Theft Poses No Harm to Public Safety and at a Time when the Incidence of Cargo Theft of Medical Products Has Declined.

Before addressing the proposed amendments and issues for comment, we think it helpful to set forth the scope of the definition of pre-retail medical products to dispel the notion that the theft of all such products presents a risk to public safety, or that harsh sentences as opposed to effective loss prevention efforts are necessary to deter such crimes.

1. The Definition of Pre-retail Medical Product Is Extraordinarily Broad.

The definition of "medical product"[3] is so broad as to include ice bags,[4] hot/cold water bottles,[5] tongue depressors,[6] dental floss,[7] toothbrushes,[8] bedpans,[9] elastic bandages,[10] adhesive tape,[11] gloves,[12] arm slings,[13] heating pads,[14] examination gowns,[15] anti-bacterial hand soap,[16]

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[3] The Act defines "medical product" as "drug, biological product, device, medical food, or infant formula," which in turned are defined by reference to the Federal Food, Drug and Cosmetic Act, the Public Health Services Act, and the Orphan Drug Act. 18 U.S.C. § 670 (e).

[4] 21 C.F.R. § 880.6050.

[5] 21 C.F.R. § 880.6085.

[6] 21 C.F.R. § 880.6230.

[7] 21 C.F.R. § 872.6390.

[8] 21 C.F.R. § 872.6855.

[9] 21 C.F.R. § 880.6800.

[10] 21 C.F.R. § 880.5075.

[11] 21 C.F.R. § 880.5240.

[12] 21 C.F.R. § 800.20.

[13] 21 C.F.R. § 890.3640.

[14] 21 C.F.R. § 890.5740.

[15] 21 C.F.R. § 880.6256.

antiperspirants,[17] sunscreen,[18] hearing aids,[19]wheelchairs,[20] hospital beds,[21]mobile medical apps,[22] programmable pacemakers,[23] prescription drugs,[24] and laser surgical devices.[25]

2. Not All Thefts of Pre-retail Medical Products Pose a Threat to Public Safety and of Those that Do, the Severity of the Threat Varies Widely.

Because the definition of "medical product" covers so many different kinds of products, it cannot be assumed that the theft and distribution of a medical product poses a threat to public safety. The U.S. Food and Drug Administration's (FDA) notification procedures for stolen medical products demonstrate this point. For some stolen products, like dental floss, hand cream, first aid kits, and sunscreen, the FDA may issue no consumer warning whatsoever.[26] For others, like infant formula, the FDA may simply provide notice of the product stolen and warn consumers to look for signs of tampering. Significantly, it does not warn consumers to discard

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[16] *See* 21 U.S.C. § 321(g)(1) (B) ("drug" means "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals"); *see also* ISSA's *Guide to the Regulation of Antibacterial Hand Soaps*, http://www.issa.com/data/files/articles/88/soap.pdf.

[17] 21 C.F.R. § 350.3.

[18] 21 C.F.R. § 352.3.

[19] 21 C.F.R. § 874.3300.

[20] 21 C.F.R. § 890.3850.

[21] 21 C.F.R § 880.5120.

[22] 21 C.F.R. § 880.6310.

[23] 21 C.F.R. § 870.1750.

[24] 21 U.S.C. § 321(g)(1).

[25] 21 C.F.R. § 878.4810.

[26] FDA, *Notification of Stolen Johnson & Johnson Group of Consumer Complaints Products* (Clayton, Indiana), http://www.fda.gov/ICECI/CriminalInvestigations/ucm271551.htm . *See also* FDA, *Notification Regarding Stolen Proctor and Gamble Non-Prescription Healthcare Products, Cosmetics, Dental Floss, Toothbrushes, and Feminine Hygiene Products*, http://www.fda.gov/ICECI/CriminalInvestigations/ucm241181.htm.

the product or not to use it.[27] In contrast, when certain medications are stolen, the notice may warn those in possession of the stolen product to discontinue its use and discard it.[28]

The regulatory framework governing medical devices also demonstrates the point that not all stolen medical products pose a danger to public safety if they work their way into the supply chain. The FDA regulations set forth three categories of regulatory control for medical devices. Class I devices are subject to limited general controls, which are deemed "sufficient to provide reasonable assurance of the safety and effectiveness of the device."[29] Class I devices "present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices."[30] Class I includes such items as rubber tips for canes, ice bags, and elastic bandages. "[Forty-seven percent] of medical devices fall under this category and 95% of these are exempt from the regulatory process."[31] Class II devices are subject to special controls to assure safety and effectiveness. These controls may include performance standards, post market surveillance, patient registries, and guidance documents. Examples of class II devices include powered wheelchairs, infusion pumps, and surgical drapes.[32] "[Forty-three percent] of medical devices fall under this category."[33] Class III devices require premarket approval and include life-sustaining or life-supporting devices, or devices meant "for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential

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[27] FDA, *Notification of Stolen Mead Johnson Infant Formula Products*, http://www.fda.gov/ICECI/CriminalInvestigations/ucm191658.htm. *See also* Information Notice on Stolen Consumer Health Products from GlaxoSmithKline (2011) (theft of shipment of Tums and Os-Cal), http://www.fda.gov/ICECI/CriminalInvestigations/ucm240206.htm.

[28] FDA, *FDA Warns Consumers, Pharmacists, and Wholesalers Not to Use Stolen Advair Diskus Inhalers* (2010), http://www.fda.gov/ICECI/CriminalInvestigations/ucm219418.htm.

[29] 21 C.F.R. § 860.3(c)(1). Thus even though a medical product may be subject to FDA general controls, it may be exempt from many good manufacturing practices, including regulations governing production, packing, handling, and distribution. *See generally* 21 C.F.R. § 820 et. seq. Examples of devices free of such regulations include elastic bandages, 21 C.F.R. § 880.5075(b), stand-on patient scales, 21 C.F.R. § 880.2700, skin pressure protectors, 21 C.F.R. § 880.6450, and irrigating syringes not labeled or represented as sterile. 21 C.F.R. § 880.6960.

[30] FDA, *Medical Devices: General and Special Controls*, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm (hereinafter *General and Special Controls*).

[31] FDA, *Medical Devices: Learn if a Medical Device Has Been Cleared by FDA for Marketing*, http://www.fda.gov/medicaldevices/resourcesforyou/consumers/ucm142523.htm (hereinafter *Learn if a Medical Device Has Been Cleared*).

[32] *General and Special Controls*, *supra* note 30.

[33] *Learn if a Medical Device Has Been Cleared*, *supra* note 31.

unreasonable risk of illness or injury."[34] Examples of Class III devices are replacement heart valves, breast implants, and pacemakers. "[Ten percent] of medical devices fall under this category."[35]

3. The Theft of Pre-Retail Medical Products has Taken a Downward Turn as a Result of Industry Safeguards.

According to FreightWatch International's *2012 U.S. Cargo Theft Report*, pharmaceutical cargo theft has taken a dramatic turn downward as a result of protections the industry has put in place. In 2012, the industry saw 30 reported cargo thefts, with an average loss of $168,219, down from the $585,000 average loss in 2011, and the $3.7 million loss in 2010.[36]

Recent thefts have been unsuccessful because of swift and effective responses by law enforcement and the use of covert tracking. For example, on January 23, 2013, a tractor trailer load of pharmaceuticals was stolen from a rest stop in Jackson, Georgia. The load contained an embedded GPS tracking device, which enabled police to track the trailer and recover it abandoned, "likely due to the thieves monitoring of police frequencies alerting them to swift law enforcement engagement."[37] Similarly, on Feb 1, 2013, a load of pharmaceuticals stolen from a truck stop in Michigan was found eight miles away as a result of the use of covert tracking devices.[38]

II. Proposed Amendment

At least until the Commission finishes its multi-year review of §2B1.1 and collects more data on the prosecutions of pre-retail medical products under these new statutory provisions, we think it better to allow existing guideline provisions to account for the wide-range of conduct that may occur in these cases.

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[34] 21 C.F.R. § 860.3(c)(3).

[35] *Learn if a Medical Device Has Been Cleared, supra* note 31.

[36] Eric Palmer, *Cargo Theft Down in Year of Key Arrests* (Jan. 22, 2013), http://www.fiercepharmamanufacturing.com/story/cargo-theft-down-year-key-arrests/2013-01-22.

[37] FreightWatch International, *Pharmaceutical Theft and Recovery, Georgia*, http://www.freightwatchintl.com/intelligencecenter/securitynews/pharmaceutical-theft-and-recovery-georgia.

[38] FreightWatch International, *Pharmaceutical Theft and Recovery, Michigan* http://www.freightwatchintl.com/intelligencecenter/securitynews/pharmaceutical-theft-and-recovery-michigan.

The guidelines already provide for significant terms of imprisonment for persons engaged in the theft, receipt, and resale of medical products. Three case examples demonstrate this point. William Rodriquez, a Florida man involved in a scheme to resell drugs he obtained from cargo thieves received a ten-year term of imprisonment and was ordered to forfeit $55 million.[39] His guideline range under §2B1.1 was 262-327 months.[40] In another case, a customer service distribution manager for a medical supply company, convicted of conspiracy to transport stolen property in connection with a scheme to steal and sell ultrasound probes received a below-guideline sentence of 24 months imprisonment, which was just 3 months below the government's recommended sentence under the 1998 guidelines, and was ordered to pay $368,000 in restitution.[41] Finally, two brothers who ran a wholesale grocery business were sentenced to a below-guideline range of 22 months imprisonment for buying stolen infant formula on the secondary market.[42]

Loss amounts alone can quickly drive up sentences in these cases because of the high volume of products involved, the value of the products, or both. Moreover, because the bulk of these offenses are cargo thefts,[43] the November 1, 2007 amendment for cargo theft already provides for a 2-level increase and a minimum offense level of 14. In addition to those increases, many other specific offense characteristics exist to cover the aggravating factors set forth in the statute and that may otherwise be present in offenses involving pre-retail medical products. These include:

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[39] He received a thirty month sentence of imprisonment for conspiracy to commit fraud under 18 U.SC. § 371 and ninety months consecutive for money laundering. *United States v. William Rodriguez*, 12-202160-CR-Gragam (S.D. Fla. 2012).

[40] The parties agreed to the following guidelines for the conspiracy under 18 U.S.C. § 371: §2B1.1 base offense level of 6; 24 levels for loss; 2 levels for 10 or more victims; 2 levels for sophisticated means; 2 levels because the goods were part of a cargo shipment; 2 levels for conscious risk of death or serious bodily injury; 4 levels for aggravated role in the offense. The final offense level for the money laundering offense was 36. The two offenses grouped for a combined offense level of 42, with a final offense level of 39 after a 3-level reduction for acceptance of responsibility.

[41] *United States v. Sess Merke*, No. CR05-270L (W.D. Wash. 2006). Had he been sentenced under the 2012 guidelines, his guideline range would have been 30-37 months because both the base offense level and the loss amounts under §2B1.1 have increased.

[42] *United States v. Ishaq and Rasseem Kaloti*, 2:11-cr-00215-JPS-1 (E.D. Wis. 2012).

[43] FDA, *Inspections, Compliance, Enforcement, and Criminal Investigations: Cargo Thefts*, http://www.fda.gov/ICECI/CriminalInvestigations/ucm182888.htm (reporting on thefts of cargo from tractor-trailers and warehouses).

- A 2-level increase "if the offense involved receiving stolen property and the defendant was a person in the business of receiving and selling stolen property." §2B1.1(b)(4).

- A 2-level increase and minimum offense level of 14 "if the offense involved (A) the conscious or reckless risk of death or serious bodily injury; or (B) possession of a dangerous weapon (including a firearm) in connection with the offense." §2B1.1(c)(14).

- A cross-reference to the drug guideline at §2D1.1 if the theft involved a controlled substance. §2B1.1(c).

- A 2-level increase "if the defendant abused a position of public or private trust," *e.g.*, by using one's employment in the supply chain to carry out the offense. §3B1.3.[44]

- An upward departure provision at §5K2.1 for death.

- An upward departure provision at §5K2.6 for the use or possession of a weapon or dangerous instrumentalities.

Should the Commission not be satisfied that existing provisions can account for the wide variety of conduct involved in the theft of pre-retail medical products and proceed to tinker with §2B1.1 by adding more SOCs, those SOCs should be carefully crafted. Specifically, the proposed SOCs should (1) apply only to the "aggravated offenses "defined at 18 U.S.C. § 670(b); (2) be limited to a 2-level, not a 4-level, increase; and (3) not cumulate with similar specific offense characteristics. First, the commentary should make clear that for any of the proposed SOCs to apply, the defendant must be convicted of the corresponding aggravated offense set forth in 18 U.S.C. § 670(b). The government should not be able to avoid proving the elements of one of the aggravated offenses, but then be able to enhance the defendant's sentence based upon the same conduct proven only by preponderance of the evidence and without the same evidentiary safeguards available in a trial. Congress chose to define aggravated offenses, not a single offense with aggravating sentencing factors. The Commission should not undo that choice.

Second, the proposed increases should be limited to two-levels to maintain some semblance of proportionality with similar SOCs and to prevent factor creep – a continuing

[44] To cover those cases that may arise where §3B1.3 does not expressly apply under its current terms, the Commission could either add an application note to §3B1.3 or an application note to §2B1.1 to encourage an adjustment, similar to what it did in 2011 when it amended §2D1.1, n. 22 to cover persons convicted of drug offenses in the waste disposal chain. *See* Discussion *infra*.

problem with §2B1.1 discussed later in these comments. The proposed amendment provides for a [2][4] level increase if "*the offense involved* the use of . . . violence or force." (emphasis added). Section 2D1.1(b)(2), the drug guideline, calls for a 2-level increase if the "*defendant used* violence, made a credible threat to use violence, or directed the use of violence." (emphasis added). There is no reason why a defendant convicted of the theft of pre-retail medical products, but who did not personally use violence or force and may be subject to the enhancement only because of the relevant conduct of others, should receive a greater increase in offense level than a defendant convicted of a drug trafficking offense who personally used or directed violence.

The proposed amendment also provides for a [2][4] level increase if the offense involved the use of a deadly weapon. The guidelines maintain no consistency in how they treat the use of a deadly weapon, *see* §2A2.4(b)(1) (3-level increase for possession or threatened use of dangerous weapon); §2A4.1(b)(3) (2-level increase "if a dangerous weapon was used"); §2A6.2(b)(1)(C) (2-level increase for "possession, or threatened use, of a dangerous weapon"); §2B1.5(b)(6) (2-level increase for brandishing or threatening use of dangerous weapon); §2B3.1(b)(2) (setting forth six different levels of increase for various conduct, including four levels for use of a dangerous weapon). A 2-level increase, however, is more common and thus a 2-level increase under proposed §2B1.1(b)(14) would maintain some level of proportionality with other guideline provisions. Moreover, should a theft of a pre-retail medical product involve the use of violence, force, a threat of violence or force, or a deadly weapon, and the government wants to seek a higher guideline range, then it can always prosecute the offense as a robbery rather than a theft.

Defenders also believe that nothing more than a 2-level increase is called for in cases where the "offense resulted in serious bodily injury or death, including serious bodily injury or death resulting from the use of the medical product involved." As drafted, this adjustment requires no personal culpability on the part of the defendant. It is a strict liability enhancement that does not require conscious, reckless, or deliberate risk of serious bodily injury or death. It, like the other proposed enhancements, also holds the defendant accountable for the conduct of others involved in the offense, not just his or her own conduct. Under those circumstances, if there is to be any enhancement, it should be limited to two levels.

III. Issues for Comment

A. Section 670(b)(2)(C) May be Referenced to §2A1.4. The Other Sections of 18 U.S.C. § 670 Should be Referenced to §2B1.1 and No Other Guideline. The References to the Other Offenses Covered in the Safe Doses Act Should Remain the Same.

The Commission seeks comment on whether 18 U.S.C. § 670 should be referenced to a guideline other than §2B1.1, including §2A1.4. In particular, the Commission asks whether

§ 670 should be referenced to §2B5.3 (Criminal Infringement of Copyright or Trademark), §2N1.1 (Tampering or Attempting to Tamper [With Consumer Products] Involving Risk of Death or Bodily Injury), §2N2.1 (Violations of Statutes and Regulations Dealing with Any Food, Drug, Biological Product, Device, Cosmetic, Agricultural Product, or Consumer Product), and §2A1.4 (Involuntary Manslaughter). It also asks whether it should reference any of the other offenses covered by the directive to guidelines other than those to which they are currently referenced.

We have no objection to referring 18 U.S.C. § 670(b)(2(C) – an aggravated form of a section 670 offense – to §2A1.4, the guideline for involuntary manslaughter. That guideline may be appropriate in cases where the offense or use of the medical product involved in the offense resulted in death.

Section 670 should not be referenced to §§2B5.3, 2N1.1, or 2N2.1. A reference to §2B5.3 (Criminal Infringement of Copyright or Trademark) is not appropriate because a section 670 (a)(2) counterfeit label or documentation offense is unlike the true counterfeiting offenses covered under §2B5.3. While section 670(a)(2) includes counterfeiting the labeling or documentation of a pre-retail medical product, the offense is only superficially similar to 18 U.S.C. § 2320 and the other counterfeiting offenses referenced to §2B5.3. Section 2B5.3 is targeted at counterfeit retail products, where the offense conduct typically involves trafficking in fake goods that infringe on the rights of a copyright or trademark holder. In such cases, calculation of the "infringement amount" drives the offense level. Calculation of the infringement amount depends upon a complicated series of rules and may include the retail value of the infringed item or the retail value of the infringing item. None of those rules have relevance to a section 670 offense, which may involve counterfeit labels or documentation, but where the pre-retail medical products are not themselves counterfeit, and thus have no "infringement amount."

A cross-reference to §2N1.1 (Tampering or Attempting to Tamper Involving Risk of Death or Bodily Injury) also is inappropriate, because unlike offenses referenced to §2N1.1, the theft of a pre-retail medical product does not typically pose a risk of death or serious bodily injury much less with the mens rea required for tampering. The only offenses referenced to §2N1.1 are 18 U.S.C. §§ 1365(a) and (e), which expressly require that the tampering with a consumer product be done with "reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting an extreme indifference to such risk." None of the offenses set forth in 18 U.S.C. § 670 require such a mens rea. And as discussed above, thefts of pre-retail medical products include so many different kinds of products that not all thefts pose a risk of death or serious bodily injury. Should the conduct of a defendant in a particular case fall within 18 U.S.C. § 1365, the government can charge and prove that offense so the defendant may be sentenced under §2N1.1.

A cross-reference to §2N2.1 also is not necessary. Section 2N2.1 covers a variety of offenses related to violations of statutes and regulations dealing with FDA and consumer products. Section 2N2.1 has two cross-references: (1) a cross-reference to §2B1.1 if the offense involved fraud; and (2) a cross-reference to any other offense guideline if "the offense was committed in furtherance of, or to conceal, an offense covered by another offense guideline." If section 670 were to be referenced to §2N2.1, these cross-references would ensure that the §2B1.1 guideline would apply in virtually every case. It would therefore be redundant to reference section 670 to §2N2.1.

We also do not think the Commission should reference any of the other seven offenses covered by the directive to guidelines other than those to which they are currently referenced. Congress amended these statutes to ensure that they would carry the same penalty as section 670 unless the penalty provided under the specific statutory provision is greater. As applied to the theft of pre-retail medical products, the guidelines already permit these offenses to be punished the same as a section 670 offense or greater. Four of the offenses, §§ 659, 2118(b), 2314, 2315 are already referenced to §2B1.1 – the guideline for section 670.

The section 1952 offense (interstate and foreign travel or transportation in aid of racketeering enterprises) is referenced to §2E1.2, which in turn contains a reference to the offense level for the "unlawful activity in respect to which the travel or transportation was undertaken." Hence, if a person were convicted of interstate or foreign travel or transportation in aid of racketeering with respect to the theft of pre-retail medical products, then §2B1.1 would apply.

The section 1957 offense (engaging in monetary transactions in property derived from specified unlawful activity) is referenced to §2S1.1, which uses the offense level for the underlying offense from which the laundered moneys were derived if the defendant committed the underlying offense. Hence, if the defendant committed a section 670 offense and laundered those funds, he would be sentenced under §2B1.1 and receive any number of additional enhancements. If he did not commit the underlying offense of theft of pre-retail medical products, his base offense level would start at 8 under §2S1.1(a)(2), which is higher than the base offense level under §2B1.1 and his offense level would be increased by the value of the laundered funds and other specific offense characteristics, including a 1-level increase for a conviction under 1957.

The section 2117 offense (burglary) is referenced to §2B2.1, which carries a significantly higher base offense level of 12 for burglary of a non-residential structure such as a warehouse, as compared to the base offense level of 6 or 7 set forth in §2B1.1. That guideline also contains enhancements for more than minimal planning, amount of loss, possession of a dangerous weapon, and the taking of, among other things, a controlled substance. It therefore is likely that a person convicted of a burglary involving the theft of a pre-retail medical product would receive

a higher offense level under §2B2.1 than under §2B1.1. Because the statute contemplates that the sentence for a burglary involving the theft of a pre-retail medical product might be higher than the section 670 offense, it makes little sense to further complicate the guideline by providing additional cross-references.

The remaining section 2118 offenses are referenced to guidelines (§§2B3.1, 2A2.1, 2A2.2, and 2A1.1) that account for aggravating factors like physical injury, weapons, violence, and death. All of them contain substantially higher base offense levels than §2B1.1.

B. If the Commission were to Adopt the Proposed Amendment to §2B1.1, Its Cumulative Effect Should be Limited. The Guidelines Should Provide For a Departure Where the Theft Involves Class I FDA Medical Devices That Are Subject to Minimal Regulation or Products That Would Not Require a Consumer Warning to Discard the Product.

The Commission seeks comment on several issues related to the proposed amendment to §2B1.1 should the Commission choose to adopt it, including how it might interact with other enhancements and whether it adequately responds to other directives in the Act.

1. Interaction of Proposed Amendment with Other Specific Offense Characteristics in §2B1.1

The Commission asks how the proposed amendment should interact with (a) the current 2-level enhancement and minimum offense level of 14 for cargo theft; and (b) the current 2-level enhancement and minimum offense level of 14 if the offense involved a risk of death or serious bodily injury or possession of a dangerous weapon. Defenders submit that if the proposed amendment to §2B1.1 applies, then the enhancements for cargo theft and risk of death or serious bodily injury or possession of a dangerous weapon should not apply. We also believe that the Commission should limit the cumulative effect of the cargo theft enhancement and the §2B1.1(b)(4) enhancement for being in the business of receiving stolen property.

The ever-present concerns about the cumulative effect of specific offense characteristics and how they result in disproportionate punishment increases at various offense levels are a reason why the Commission should not adopt the proposed amendment, but should instead wait until it finishes its multi-year review of §2B1.1. Factor creep, a problem acknowledged by the Commission in its *Fifteen Year Report*,[45] and addressed in our most recent priorities letter,[46] has long been a problem with certain guidelines, including §2B1.1.

[45] U.S. Sentencing Comm'n, *Fifteen Years of Guidelines Sentencing: An Assessment of How Well the Federal Criminal Justice System is Achieving the Goals of Sentencing Reform* 137 (2004).

With "factor creep," the cumulative effect of enhancements does not properly track offense seriousness. The resulting sentence increase from a single 2-level enhancement can vary dramatically and disproportionately. For example, a defendant whose offense level increases from 6 to 8 experiences no additional increase in the advisory guideline range; the defendant whose offense level increases from 11 to 13 is exposed to four additional months at the low-end of the guideline range; the defendant whose offense level increases from 20 to 22 is exposed to eight additional months; and the defendant whose offense level increases from 32 to 34 is exposed to thirty additional months. Such disparate increases based on the same conduct do not promote respect for the law or provide for fair and proportionate sentences. Indeed, long ago, the Second Circuit acknowledged how the cumulative effect of enhancements skews the guideline ranges dramatically as the offense level increases. *United States v. Lauersen*, 362 F.3d 160, 163 (2d Cir. 2004) (cumulative impact of enhancements permitted consideration of downward departure), *vacated on other grounds*, 543 U.S. 1097 (2005).

A related problem with specific offense characteristics is that they often double or triple count the same essential harms. With §2B1.1, that is especially true because a defendant will typically receive an enhancement for the magnitude of the loss and then get one or more enhancements for how the loss was caused. While the harms may be superficially different, the manner and means of committing the offense are often inextricably linked to the magnitude of the loss and thus often overstate the seriousness of the offense. For example, an organized scheme to steal cargo is likely to result in a greater loss, but the loss amount and the cargo theft each receive an enhancement under the guidelines.

Additionally, the specific offense characteristics in the proposed amendment overlap with other enhancements, and thus should be limited. For example, the enhancement for "use of force" is potentially so broad that it might apply in many cases involving the theft of pre-retail products from distribution centers and tractor-trailers. The term "force" in the proposed amendment is not limited by reference to "physical force." *Cf.* 18 U.S.C. § 16 (crime of violence defined by reference to "physical force"). Nor is it limited to force against a person. If it includes "force" against property, it may apply in any case involving the breaking and entering into a warehouse, burglary, and theft of a tractor-trailer. At the same time, the theft of pre-retail medical products from a tractor-trailer or warehouse will usually result in an enhancement for "cargo theft." The same essential conduct – using force to steal cargo – would result in double-counting.

Similarly, the proposed amendment and the enhancement and minimum offense level currently at §2B1.1(b)(14) for "the conscious or reckless risk of death or serious bodily injury"

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[46] Letter from Marjorie Meyers, Chair, Federal Defender Guideline Committee, to the Honorable Patti B. Saris, Chair, U.S. Sentencing Comm'n, at 8-9 (July 23, 2012) (hereinafter "Meyers Letter").

or "possession of a dangerous weapon" target the same harm. Any offense that "resulted in serious bodily injury or death, including serious bodily injury or death resulting from the use of the medical product involved" is likely to involve the "conscious or reckless risk of death or serious bodily injury." Any offense that involved the "use of a deadly weapon" will necessarily involve the "possession of a dangerous weapon." In fact, under both scenarios, one enhancement could be considered a "lesser included" enhancement of the other. To apply both would result in a disproportionate increase in sentence length. In short, enhancements aimed at the same essential conduct and harm should not apply cumulatively.

Aside from the concerns delineated in the issues for comment, the Commission should also limit the cumulative effect of the cargo theft enhancement at §2B1.1(b)(13) and the enhancement for being in the business of receiving and selling stolen property at §2B1.1(4). Section 2B1.1(b)(13) provides a 2-level enhancement and minimum offense level of 14 if the offense involved an organized scheme to steal or *receive* stolen goods or chattels that are part of a cargo shipment. If the defendant received stolen good from a cargo theft, he is also likely to receive another 2-level adjustment for being in the business of receiving and selling stolen property. *See* §2B1.1(b)(4) and cmt. (n. 5) (value and size of inventory of stolen property is factor to consider in applying enhancement). Such double counting of the harm resulting from the same conduct – receipt of a high volume of stolen goods – should be limited.

Applying multiple specific offense characteristics is not necessary to arrive at an appropriate sentencing range. Even without SOCs, a guideline range based on the loss amount alone can overstate offense seriousness and produce sentences greater than necessary. A recent case involving stolen infant formula demonstrates the point. The defendant and his brother operated a grocery wholesale business. They purchased infant formula from secondary market suppliers without confirming that it was obtained from legitimate sources. Both were convicted of, inter alia, receiving stolen infant formula. Under §2B1.1, the guideline range was 37-46 months, based on an offense level 21(base offense level of 6, 18 for amount of loss, and minus 3 for acceptance of responsibility), and criminal history category I. The parties stipulated that the 2-level adjustment for being in the business of stolen property did not apply. The government also agreed to a below-guideline sentence of thirty months. The court imposed a sentence of twenty-two months.[47]

2. The Guidelines Already Provide for a Minimum Offense Level in Cases Involving the Theft of Pre-retail Medical Products.

The Commission asks if the "proposed amendment adequately responds to requirement (2) of the directive that the Commission consider establishing a minimum offense level for

[47] *See United States v. Rassem Kaloti and Ishaq Kaloti*, Case No. 11-cr-215 (E.D. Wis. 2011).

offenses covered by the Act." As a threshold matter, we note that the directive requires only that the Commission *consider* establishing a minimum offense level. Nothing in the directive requires it do so. More significantly, we believe that the guidelines currently ensure a minimum base offense level for a sizable percentage of these cases. The focus of FDA efforts is on cargo thefts of FDA products that have been "stolen from warehouses or tractor-trailers."[48] Hence, many of these cases will be subject to the cargo theft enhancement at §2B1.1(b)(13), which carries a minimum base offense level of 14. Aside from that, every section 670 offense will have a minimum base offense level of 6.

3. The Commission's Proposal Does Not Adequately Consider Mitigating Circumstances.

The Commission requests comment on whether the proposed amendment adequately responds to the directive that the Commission account for aggravating and mitigating circumstances. The proposed amendment only responds to the aggravating factors that Congress set forth in the Act. It does not account for any mitigating circumstances. While there have been too few prosecutions involving pre-retail medical products for us to provide comprehensive comments on the mitigating factors present in these cases, several are of obvious concern. First, as is often the case, persons involved in the theft of pre-retail medical products play many different roles in the offense. Just as in a drug case, there will be defendants whose role in the offense was limited to being nothing more than a carrier of products from point A to point B. These are easily replaced participants, whose role may be critical to the ultimate success of the theft and eventual distribution of the products, but who are substantially less culpable than persons directly responsible for the theft or those who received sizable profits from the offense. To account for this lesser culpability, the Commission should direct the courts to consider applying §3B1.2 in cases where the defendant had limited knowledge of the scope of the scheme and received little personal gain relative to the loss amount. This would be similar to the provision the Commission made for nominee owners in health care fraud schemes. *See* USSG §3B1.2, cmt. (n. 3(A)).

Second, the Commission should provide for a [2][4] level decrease in offense level if the offense involved the theft of Class I FDA medical devices or the theft of a product that would not require a consumer warning to discard the product. One of the factors the Commission shall consider in promulgating guidelines and policy statements is "the nature and degree of the harm

[48] FDA, *Inspections, Compliance, Enforcement, and Criminal Investigations, Cargo Thefts*, http://www.fda.gov/ICECI/CriminalInvestigations/ucm182888.htm. *See also* FDA *Cargo/Warehouse Letter to Stakeholders* (2010), http://www.fda.gov/ICECI/CriminalInvestigations/ucm209979.htm; FDA Staff Manual Guides, Vol IV-Agency Program Directives, General or Multidiscipline, FDA's Response to Cargo Thefts (March 2012), http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM297208.pdf.

caused by the offense" as well as aggravating and mitigating circumstances. It is apparent that offenses involving pre-retail medical products do not all present the same potential harm to public safety. Product theft that results in a FDA warning for consumers to discard the project presents a greater harm than theft that does not warrant such a warning.

4. The Proposed Amendment Does Not Adequately Balance out the Competing Considerations in the Directive and the Commission's Duties under 28 U.S.C. § 994.

Sections (1), (4), (5), and (6) of the Act's directive require the Commission to consider a variety of factors, including the "need for an effective deterrent and appropriate punishment to prevent such offenses," and to "ensure that the Federal sentencing guidelines and policy statements adequately meet the purposes of sentencing set forth in section 3553(a)(2) of title 18, United States Code." Because we believe that §2B1.1 is fundamentally broken, and the proposed amendment merely adds to its problems, we do not believe the proposal complies with the directives. Section 2B1.1 too often produces sentences that are greater than necessary and this proposed amendment will only exacerbate that problem.[49]

And, as we have discussed in past submissions to the Commission, the empirical evidence has soundly debunked the myth of general deterrence. Harsher sentences do not deter. The increased chance of being apprehended for a crime, *i.e.*, certainty, is more likely to produce a deterrent benefit than the severity of punishment.[50] The reasons are simple: (1) human beings are not typically "rational actors who consider the consequences of their behavior before deciding to commit a crime," (2) would-be offenders are rarely aware of the penalties they face or whether penalties have increased; and (3) even if they were rational actors who knew the penalties, "enhancing the severity of punishment will have little impact on people who do not believe they will be apprehended for their actions."[51] Notwithstanding the overwhelming evidence against the notion that lengthier prison sentences deter, the executive and legislative branches rarely acknowledge the evidence, choosing instead to ratchet up penalties to appear "tough on crime" or to give prosecutors incentives to pursue cases. It is up to this Commission, as an independent expert body, to reject the myth of general deterrence and carry out the duties specified in 28 U.S.C. § 994.

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[49] *See* Meyers Letter, *supra* note 46, at 7-10; Statement of Kathryn N. Nester Before the U.S. Sentencing Comm'n, Washington, D.C. at 1-6 (March 14, 2012);

[50] *See generally* Valerie Wright, *Deterrence in Criminal Justice: Evaluating Certainty vs. Severity of Punishment* 1 (2010), http://www.sentencingproject.org/doc/deterrence%20briefing%20.pdf.

[51] *Id*. at 2-3.

One of the duties, delineated in section 994(c), is to consider whether a number of specified factors, "among others, have any relevance to the nature, extent, place of service, or other incidents of an appropriate sentence, and shall take them into account only to the extent that they do have relevance." One of the factors that the Commission shall take into account "*only* to the extent" it has relevance is "the deterrent effect a particular sentence may have on the commission of the offense by others." 28 U.S.C. § 944(c)(6) (emphasis added). If the empirical evidence shows that sentence length has no deterrent effect on the commission of the offense by others, then the Commission should give little to no weight to general deterrence when fashioning the guidelines and policy statements.

5. The Term "Pre-retail Medical Product" Should Be Defined by Reference to Its Statutory Definition.

The Commission seeks comment on whether it should define "pre-retail" by reference to the statutory definition, whether the definition is adequately clear, and if not, what guidance it should provide, if any, to address situations where it lacks clarity. It also asks whether the definition of "supply chain" informs the determination of whether the medical product has been made available for retail purchase by a consumer.

As to the definition of "pre-retail medical product," as used in any new guideline, we agree that it should be defined by reference to 18 U.S.C. § 670(e), *i.e.*, "a medical product that has not yet been made available for retail purchase by a consumer." While the exact parameters of this definition are unclear, particularly as it applies to medical products that are never intended for retail purchase by a consumer or that are taken from the retailer but not available for purchase, we think it better to allow the courts to construe the statutory language in determining the elements of the offense. As the courts interpret the statute, the definition will become more precise.

Defenders do not believe that the definition of the term "supply chain" should inform the determination of whether the "medical product has not yet been made available for retail purchase by a consumer." Under 18 U.S.C. § 670(e), the term "supply chain" includes "manufacturer, wholesaler, repacker, own-labeled distributor, private-label distributor, jobber, broker, drug trader, transportation company, hospital, pharmacy, or security company." The reference to "hospital" and "pharmacy" is particularly confusing here. Hospitals and pharmacies can operate as retail and wholesale distributors. *See* 21 C.F.R. § 201.5(g)(3) (defining "wholesale distributor" as, among other entities, "retail pharmacies that conduct wholesale distributions").[52] In the case of a retail hospital or pharmacy conducting wholesale distributions,

[52] *See also* Florida Dep't of Business and Professional Regulations, *Retail Pharmacy Drug Wholesale Distributor*, http://www.myfloridalicense.com/dbpr/ddc/RetailPharmacyDrugWholesaleDistributor.html; National Alliance for Model State Drug Laws, *Drug Pedigree Requirements for Pharmacies and Wholesalers: State Statutes* 114 (2011) (referencing hospital pharmacies that conduct wholesale

the medical products would likely be considered "pre-retail" and covered under 18 U.S.C. § 670.[53] In contrast, if that same hospital or pharmacy makes the product available for retail purchase by a consumer, then the product would fall outside the definition of "pre-retail." Similarly, a chain pharmacy may operate a warehouse, which is responsible for intracompany sales or transfers to local pharmacies where the product is made available for retail purchase by a consumer.[54] In such a case, products taken from the warehouse would be "pre-retail," whereas products taken from the local pharmacy likely would not fall within that definition. For these reasons, the term "supply chain" does not inform the definition of pre-retail.

6. No Additional SOC is Necessary to Account for Situations Where the Defendant is An Employee or Agent of an Organization in the Supply Chain for a Pre-retail Medical Product.

The guidelines provide several ways for a court to account for the defendant's status as an employee or agent of an organization in the supply chain for a pre-retail medical product. In some cases, §3B1.3 will apply. In others, where the defendant did not occupy a position of trust, the court can consider the defendant's status as an employee or agent in determining where within the range to sentence the defendant. To cover those cases, the Commission could add an application note to §2B1.1 along the following lines:

> *In determining the sentence within the applicable guideline range, the court may consider whether the defendant was employed by, or was an agent of, an organization in the supply chain for the pre-retail medical product. Where such factors are present in an extreme form, a departure*

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distributions), http://www.namsdl.org/documents/StateStatutoryCompilationJuly2011.pdf; United States Congress Staff Report: *Shining Light on the "Gray Market": An Examination of Why Hospitals are Forced to Pay Exorbitant Prices for Prescription Drugs Facing Critical Shortages* 17 (2012) (discussing how some states allow pharmacies to re-sell their inventories to other pharmacies or wholesalers), http://democrats.oversight.house.gov/images/stories/7.25.12%20Staff%20Report%20Shining%20Light%20on%20the%20Gray%20Market.pdf.

[53] Retail-level pharmacies are allowed to sell a portion of their inventory to distributors. This occurs most often in cases when the drugs will expire within ninety days and the pharmacy does not believe it can dispense them in that timeframe. To put the drug back into the supply chain and prevent it from going to waste, the pharmacy may sell it to a distributor or large wholesaler. *See Short-supply Prescription Drugs: Shining a Light on the Gray Market*, Hearing before the Subcommittee on Commerce, Science, and Transportation, United States Senate, 112th Cong. (July 25, 2012) (statement of Patricia Earl, Industry Analyst, National Coalition of Pharmaceutical Distributors), http://commerce.senate.gov/public/?a=Files.Serve&File_id=8ca3cabd-477c-4f3c-985f-c351067912b4.

[54] *See, e.g.*, National Alliance for Model State Drug Laws, *Drug Pedigree Requirements for Pharmacies and Wholesalers: State Statutes* 2, 30, 42 (2011), http://www.namsdl.org/documents/StateStatutoryCompilationJuly2011.pdf.

> *from the guidelines may be warranted. See Chapter Five, Part K (Departures).*

Such an application note, while not common in the guidelines, is not without precedent. Section 2M5.2 cmt. (n. 2) advises the court that "[i]n determining the sentence within the applicable guideline range, the court may consider the degree to which the violation threatened a security interest of the United States, the volume of commerce involved, the extent of planning or sophistication, and whether there were multiple occurrences. Where such factors are present in an extreme form, a departure from the guidelines may be warranted."

7. The Commission Need Not Amend the Guidelines for the Other Offenses Amended by the Safe Doses Act.

The directive to the Commission provides that the Commission shall review and if appropriate amend the guidelines for 18 U.S.C. § 2118 and other offenses amended by the Safe Doses Act. As we discussed above, many of these other offenses are already referenced to §2B1.1 or to guidelines that cross-reference §2B1.1. Thus, if the Commission were to promulgate the proposed amendment to §2B1.1, that amendment would apply to those offenses. As to the other offenses, they start at higher base offense levels than §2B1.1 and will generally result in a substantial guideline range.