

COMMENT

on

PROPOSED AMENDMENT: PRE-RETAIL MEDICAL PRODUCTS

to the

UNITED STATES SENTENCING COMMISSION

by the

COALITION FOR PATIENT SAFETY AND MEDICINE INTEGRITY

March 19, 2013

The Coalition for Patient Safety and Medicine Integrity ("Coalition")¹ respectfully submits this comment on the United States Sentencing Commission's ("Commission") proposed amendment in response to the Safe Doses Act ("Act"), Pub. L. 112–86 (October 5, 2012), which created a new criminal offense and enhanced statutory penalties at 18 U.S.C. § 670 for crimes related to pre-retail medical products. Specifically, the Act "combats large-scale theft of pre-retail medical cargo," a phenomenon that "poses significant health risks to patients who are unaware that their medicines have been stolen and improperly cared for before being sold back into the supply chain."² The Coalition is dedicated to protecting the public health by ensuring that medical products retain safety and effectiveness through the supply chain. The Coalition supports the Commission's decision to amend the Guidelines Manual in order to carry out Congressional intent "that penalties for such offenses be sufficient to deter and punish such offenses, and appropriately account for the actual harm to the public from these offenses."³

The magnitude of risk of harm to the public resulting from crimes under the Act should not be understated. Criminals who steal pre-retail medical products and sell them back into the supply chain put patients—some of whom are being treated for serious diseases such as cancer, heart disease and neurological disorders—at risk by failing to properly care for the medication they steal, rendering the medication ineffective or even harmful.⁴ The United States House Of

¹ The Coalition includes: Abbott Laboratories, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Novartis, Novo Nordisk, Sanofi, the Pharmaceutical Research and Manufacturers of America (PhRMA), and the Healthcare Distribution Management Association (HDMA). The coalition's efforts are supported by Pharmaceutical Security Institute (PSI) and the National Insurance Crime Bureau (NICB).

² H.R. REP. NO. 112-549, at 4 (2012).

³ Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012, Pub. L. No. 112-86, § 7(a), 126 Stat. 1427, 1427–1431 (2012) ("SAFE DOSES Act").

⁴ H.R. REP. NO. 112-549, at 4; S. REP. NO. 112-204, at 2 (2012).

Representatives Report to Accompany H.R. 4223 ("House Report") specifically discussed the need for preventing further patient risk of serious injury and death.⁵ Likewise, the United States Senate Report to Accompany S. 1002 ("Senate Report") found that "[t]hese thefts put patients at risk that is posed by stolen medical products that are then mishandled, stored improperly, and reintroduced into the supply chain."⁶

The House Report cited numerous examples of the types and scale of these crimes.⁷ For instance, in 2009 an organized crime ring operating in North Carolina stole 129,000 vials of insulin worth approximately \$11 million.⁸ Some vials were reintroduced into the supply chain, and multiple patients reported adverse reactions after using insulin from the stolen lot.⁹ The spoiled product was ultimately found on pharmacy shelves in 17 states. The Senate Report found that while a number of arrests were made, more than 125,000 vials of insulin remained unaccounted for.¹⁰ In other words, it is impossible to know how many patients these thieves put at risk or harmed when the patients unknowing used ineffective insulin.¹¹

Members of criminal organizations carrying out the offenses punishable under the Act are not petty thieves. In fact, Congress did not intend to punish petty shoplifters or those who unknowingly purchase or possess pre-retail medical products for personal use.¹² The criminal behavior targeted by the Act relates to sophisticated enterprises, some of which employ advanced surveillance methods and techniques to learn exactly where and when they can carry out their crimes.¹³ They then "hijack tractor-trailers at rest stops, break into warehouses and evade alarm systems, forge shipping documents, produce high-quality counterfeit labels with altered expiration dates and lot numbers, and otherwise thwart the intense security measures used by the industry."¹⁴ Thus, from the masterminds to the truck thieves,¹⁵ the members of these organizations knowingly commit serious and dangerous crimes that put the health of patients and consumers at risk.

Due to the seriousness of the offenses under the Act, the Coalition believes that while the Commission should amend Guidelines Manual §2B1.1, a slightly different amendment than that proposed by the Commission is warranted. The Commission proposes to refer the new offense

⁵ H.R. REP. NO. 112-549, at 4.

⁶ S. REP. NO. 112-204, at 1.

⁷ H.R. REP. NO. 112-549, at 5-6.

⁸ H.R. REP. NO. 112-549, at 5.

⁹ H.R. REP. NO. 112-549, at 5.

¹⁰ H.R. REP. NO. 112-549, at 5.

¹¹ For more background on medical product theft see Katherine Eban, *Drug Theft Goes Big*, CNBC, Mar. 31, 2011, <http://video.cnbc.com/gallery/?video=3000014147&play=1> and Eban; see also Katherine Eban, *Drug Theft Goes Big*, FORTUNE, Apr. 11, 2011, available at <http://features.blogs.fortune.cnn.com/2011/03/31/drug-theft-goes-big/>.

¹² S. REP. NO. 112-204, at 2.

¹³ H.R. REP. NO. 112-549, at 4-5.

¹⁴ S. REP. NO. 112-204, at 2.

¹⁵ For anecdotal evidence that the trucks thieves understand the larger criminal operations they participate in see *Inside the World of Cargo Hijacking*, CBS EVENING NEWS, Oct. 25, 2010, <http://www.cbsnews.com/video/watch/?id=6990685n>.

to §2B1.1 and add a new specific offense characteristic with a minimum offense level of 14 with 2- or 4-level enhancements, and an additional possible reference to §2A1.4. The Coalition believes that while a reference to §2B1.1 is appropriate, the proposed amendment does not sufficiently punish the more serious conduct prohibited by the Act—the very conduct posing the most serious health risks to the public that Congress sought to deter by the Act. Thus, the Coalition advocates for an alternative amendment with a minimum base offense level of 18, which would impose penalties commensurate with the severity of the crimes proscribed by the Act.

Accordingly, the Coalition respectfully responds to the Commission's issue for comment as follows:

1. **Guideline(s) To Which Offenses Under § 670, And Other Offenses Covered By The Directive, Should Be Referenced**

(A) *The Coalition Agrees With The Commission That Offenses Under § 670 Should Be Referred To §2B1.1*

The Commission seeks comment on the proposed amendment's reference to §2B1.1, and asks whether the Commission should reference § 670 to one or more guidelines instead of, or in addition to, the proposed references to §2A1.4 and §2B1.1. The Coalition agrees with the Commission that the appropriate guideline to reference for offenses under § 670 is §2B1.1. §2B1 is the appropriate set of guidelines because the Act prohibits a specific category of theft. §2B1.1 is the most appropriate guideline in §2B1, because it is the only guideline that accounts for the risk of death or serious injury to the public, and the monetary considerations, specifically contemplated by the Act.

Additionally, the Coalition agrees with the Commission that a reference to §2A1.4 for Involuntary Manslaughter is appropriate. That said, to ensure that offenses referenced to §2A1.4 are punished in accordance with Congress' intent to impose appropriate minimum offense levels for crimes committed under the Act, the Coalition advocates for a new specific offense characteristic in §2A1.4, so that subsection (a)(2)(C) includes the following:

"24 if the offense involved a pre-retail medical product as defined by 18 U.S.C. § 670, and resulted in death, including death from the use of the medical product involved."

(B) *The Commission Should Reference The Other Offenses Covered By The Directive To The Guidelines To Which They Are Currently Referenced, With Certain Modifications*

The Commission seeks comment on which guidelines the other offenses covered by the directive should be referenced instead of, or in addition to, the guideline or guidelines to which they are currently referenced. The Coalition makes the following recommendations, in accordance with Congress' intent to impose at least as high of a penalty for other offenses covered by the directive as the penalty for such conduct under the Act—which, as set forth herein, should be a minimum base offense level of 18:

- (i) 18 U.S.C. § 659, criminalizing theft from interstate or foreign shipments by carrier, should continue to reference §2B1.1, because the Coalition's proposed amendment to §2B1.1 would adequately address the enhanced penalty that should apply where theft under § 659 involves pre-retail medical products;
- (ii) 18 U.S.C. § 1952, criminalizing travel in aid of racketeering, should continue to reference §2E1.2, entitled Interstate or Foreign Travel or Transportation in Aid of a Racketeering Enterprise, because under §2E1.2, crimes under the Act will carry the same penalty set forth in §2B1.1;
- (iii) 18 U.S.C. § 1957, criminalizing money laundering in aid of racketeering, should continue to reference §2S1.1, entitled Laundering of Monetary Instruments; Engaging in Monetary Transactions in Property Derived from Unlawful Activity, because the penalties under §2S1.1 are at least as high as those under §2B1.1. The Coalition proposes adding a clause to the existing specific offense characteristics, so that subsection (b)(1) reads:

"If (A) subsection (a)(2) applies; and (B) the defendant knew or believed that any of the laundered funds were the proceeds of, or were intended to promote (i) an offense involving the manufacture, importation, or distribution of a controlled substance or a listed chemical; (ii) a crime of violence; (iii) an offense involving firearms, explosives, national security, or the sexual exploitation of a minor; or (iv) *an offense involving pre-retail medical products as defined by 18 U.S.C. § 670*, increase by **6** levels.";

- (iv) 18 U.S.C. § 2117, criminalizing breaking or entering facilities of carriers in interstate or foreign commerce, should continue to reference §2B2.1, entitled Burglary of a Residence or a Structure Other than a Residence; however, to ensure that the penalty is at least as great at the Coalition's proposed base offense level of 18, the Coalition proposes adding a clause to the end of the existing specific offense characteristics, so that subsection (b) includes the following:

"(5) if the offense involved a pre-retail medical product as defined by 18 U.S.C. § 670, increase by 4 levels."; and

- (v) 18 U.S.C. § 2314, criminalizing transportation of stolen goods and 18 U.S.C. § 2315, criminalizing sale or receipt of stolen goods, should both continue to reference §2B1.1, because the Coalition's proposed amendment to §2B1.1 would adequately address the enhanced penalty that should apply where violations of these statutes involve pre-retail medical products. However, the Coalition does not believe it is appropriate to

reference violations of these statutes to §2B1.5, entitled Theft of, Damage to, or Destruction of, Cultural Heritage Resources or Paleontological Resources; Unlawful Sale, Purchase, Exchange, Transportation, or Receipt of Cultural Heritage Resources or Paleontological Resources, because §2B1.5 is inapplicable to the conduct proscribed by the Act.

Additionally, as the Commission noted in its issue for comment, 18 U.S.C. § 2118, criminalizing robberies and burglaries involving controlled substances, is referenced in the directive but is not explicitly amended by the Act. Because this statute is enumerated in the directive, the Coalition believes that amendments to the following guidelines referenced by 18 U.S.C. § 2118 are appropriate:

- (i) The Coalition proposes adding a clause to the end of the existing specific offense characteristics for §2B3.1, entitled Robbery, so that subsection (b) includes the following:

"(3) if the offense involved a pre-retail medical product as defined by 18 U.S.C. § 670, increase by 4 levels."

- (ii) The Coalition proposes adding a clause to the end of the existing specific offense characteristics for §2B2.1, entitled Burglary of a Residence or a Structure Other Than A Residence, so that subsection (b) includes the following:

"(5) if the offense involved a pre-retail medical product as defined by 18 U.S.C. § 670, increase by 2 levels."

- (iii) The Coalition proposes adding a clause to the end of the existing specific offense characteristics for §2A2.1, entitled Assault with Intent to Commit Murder; Attempted Murder, so that subsection (b) includes the following:

"(3) if the offense involved a pre-retail medical product as defined by 18 U.S.C. § 670, increase by 4 levels."

- (iv) The Coalition proposes adding a clause to the end of the existing specific offense characteristics for §2A2.2, entitled Aggravated Assault, so that subsection (b) includes the following:

"(7) if the offense involved a pre-retail medical product as defined by 18 U.S.C. § 670, increase by 2 levels."

- (v) The Coalition proposes adding a clause to the end of the existing specific offense characteristics for §2X1.1, entitled Attempt, Solicitation, or Conspiracy (Not Covered by A Specific Offense Guideline), so that subsection (b) includes the following:

"(4) if the offense involved a pre-retail medical product as defined by 18 U.S.C. § 670, increase by 4 levels."

2. The Commission Should Adopt An Alternative Proposed Amendment To §2B1.1

The Coalition believes that an amendment to §2B1.1 is appropriate, but that the Commission's proposed amendment does not fully address the severity of the offenses prohibited by the Act, or give effect to Congress' policy objectives in passing the Act.

Therefore, the Coalition proposes the following amendment to §2B1.1, each component of which is discussed in further detail in this Section 2:

"If the offense involved a pre-retail medical product *as defined by 18 U.S.C. § 670*, increase to level **18**.

If—

- (A) the offense involved the use of (i) violence, force, or a threat of violence or force; or (ii) a deadly weapon, increase by **2** levels;
 - (B) the offense resulted in serious bodily injury or death, including serious bodily injury or death resulting from the use of the medical product involved (including deprivation of treatment due to ineffectiveness), increase by **4** levels;
 - (C) the defendant was employed by, or was an agent of, an organization in the supply chain for the pre-retail medical product, increase by **4** levels; and
 - (D) the defendant was previously convicted of an offense under 18 U.S.C. § 670, increase by **4** levels."
- (A) *The New Specific Offense Characteristic Should Be Fully Cumulative With Other Specific Offense Characteristics in §2B1.1*

The Commission seeks comment on whether the following specific offense characteristics, both of which carry 2-level enhancements and minimum offense levels of 14, should be fully cumulative with the new specific offense characteristic where more than one applies: (1) §2B1.1(b)(13)(B) for offenses involving an organized scheme to steal or to receive stolen goods or chattels that are part of a cargo shipment; and current (2) §2B1.1(b)(14) for offenses involving a risk of death or serious bodily injury or possession of a dangerous weapon. The Coalition believes that its proposed new amendment should be cumulative with these offense characteristics.

Cumulative application is warranted under these specific offense characteristics because the conduct punished by them is different from, though related to, the specific conduct punished under the Act. In passing the Act, Congress sought to "provide law enforcement with the tools necessary to disrupt and dismantle the criminal organizations" that carry out incidents of pre-

retail medical product theft.¹⁶ Congress acted because existing penalties were not sufficient for criminal activity that "poses significant health risks to patients who are unaware that their medicines have been stolen and improperly cared for before being sold back into the supply chain."¹⁷ While the Act seeks to deter conduct specific to theft of pre-retail medical products because of the public health risk associated with the crime, it does not account for every aggravating circumstance that would make the crime more serious and warrant additional punishment.

Both §2B1.1(b)(13)(B) and current §2B1.1(b)(14) account for circumstances that warrant additional and separate punishment. As to conduct under §2B1.1(b)(13)(B), the penalties under the Act would apply to an offender whose theft involves pre-retail medical products even if the offender was not part of an "organized scheme" involving a "cargo shipment" under §2B1.1(b)(13)(B), and the Act does not account for these additional risk factors. As such, §2B1.1(b)(13)(B) punishes serious conduct outside the scope of the Act, which in every case warrants an additional 2-level upward adjustment.

As to the conduct described in current §2B1.1(b)(14), additional and separate punishment is also warranted. Cumulative application is warranted for some of the aggravating conduct described in proposed §2B1.1(b)(14), because such conduct is not accounted for in the current section, such as where the offense involved the use of violence, force, or a threat of violence or force. Additionally, cumulative application is still warranted for the subsections that contemplate varying degrees of different conduct.

Specifically, offenses involving both a risk of harm and resulting harm, or both the possession and use of a dangerous or deadly weapon, present distinct risks to the public that merit separate and additional punishment. Other guidelines similarly contemplate cumulative enhancements for varying degrees of conduct. For example, under §2A2.3, an offender who commits minor assault is subject to a higher base offense level where the offense involved physical contact, but is also subject to an enhancement if the offense also resulted in bodily injury. Likewise, cumulative application of enhancements under §2B1.1(b)(14) is appropriate.

(B) The Proposed Amendment Does Not Adequately Respond To Requirement (2) Of The Directive, And The Coalition Proposes An Alternative New Specific Offense Characteristic With A Minimum Offense Level Of 18

The Commission seeks comment on whether the proposed amendment sets a minimum offense level that adequately responds to Congress' directive. The Coalition believes that the Commission's proposed amendment's base level of 14 is not commensurate with the serious nature of the offenses punishable under the Act, and a base offense level of 18 is appropriate.

Crimes under the Act warrant a base offense level of 18 because, unlike mere acts of theft, they carry a serious risk to the health of the American public. This distinction is what motivated Congress to decide that, because of the public health risk associated with the theft of pre-retail

¹⁶ S. REP. NO. 112-204, at 6.

¹⁷ H.R. REP. NO. 112-549, at 4.

medical products, the crimes under the Act are not—and should not be punished like—mere property offenses. The House Committee on the Judiciary found that "under current law, the theft of life-saving medical supplies is punished to the same degree as the theft of stereo equipment or clothing."¹⁸ The Commission should respect congressional findings that penalties for property offenses are insufficient for theft of pre-retail medical cargo because "untold amounts of these drugs" may enter the stream of commerce, "potentially endangering those who purchased the drugs without knowing of their suspect origins."¹⁹

Despite this legislative history, the Commission's proposed new amendment to §2B1.1 applies only a minimum base offense level of 14--the same base level that applies to mere property crimes. For example, §2B1.1(13) applies a minimum base level of 14 to organized crimes to steal or receive stolen vehicles and goods that are part of a cargo shipment. Moreover, current §2B1.1(13) applies a base level of 14 where the offense only involves possession of a dangerous weapon or risk of serious injury or death, even if the dangerous weapon is not used and even if serious injury or death does not occur. If they do occur, which the Act contemplates, then higher penalties should apply.

Particularly for the more serious conduct under the Act—namely, where the offender intentionally committed an offense involving expired or stolen products—the theft of pre-retail medical cargo is better analogized to crimes under §2N1.1, involving tampering of consumer products when the crime bears a risk of death or bodily injury.²⁰ Like crimes under the Act, crimes referred to §2N1.1 involve consumer products and the risk of death and/or serious bodily injury. §2N1.1 carries a base offense level of 25, with upward departures where the crime results in actual injury and death. Because the two offenses present a similarly serious risk to the public's safety, a penalty closer to that imposed by §2N1.1 is needed, and a base offense level of 18 is appropriate. This would give effect to congressional intent.

(C) The Proposed Amendment Does Not Adequately Respond To Requirement (3) Of The Directive, And The Coalition Proposes Additional Enhancements For Particular Aggravating Circumstances

The Commission seeks comment on whether the proposed amendment accounts for the aggravating and mitigating circumstances involved in the offenses covered by the Act. As drafted, the Commission's amendment imposes alternative penalties. One would increase the penalty for any infraction referred to §2B1.1 by 2 or 4 levels. The other would increase the penalty by 2 or 4 levels only if the aggravating circumstances under the Act are present—offenses involving violence, resulting serious bodily injury or death, etc. The Coalition believes that the Commission's proposed amendment does not adequately account for the aggravating

¹⁸ H.R. REP. NO. 112-549, at 4.

¹⁹ S. REP. NO. 112-204, at 2.

²⁰ To be clear, the Coalition does not advocate that §2N1.1 should apply to offenses under the Act. Rather, the Coalition wishes to highlight that tampering is a similarly serious offense carrying more severe penalties than those set forth in the Commission's proposed amendment.

circumstances under the Act,²¹ and advocates for additional enhancements to its proposed base level of 18 to account for such circumstances.

As discussed in Section 2(B), *supra*, offenses under the Act warrant a base level of 18, even without the presence of aggravating circumstances that would warrant additional punishment, because every violation of the Act carries risk of harm to the public by use of harmful or ineffective medical products. Each of the aggravating circumstances enumerated under the Act warrant additional 2- or 4-level enhancements because they compound risk to the public. The use of violence, force, or threats thereof; the use of a deadly weapon; and resulting injury or death (including from use of the medical product involved) deserve more serious punishment than other violations of the Act. Likewise, repeat offenders should be subject to harsher penalties for repeated intentional acts putting the public at risk of death or injury. The Coalition's proposed amendment imposes punishment for these aggravating circumstances that is commensurate with the seriousness of the circumstances.

(D) The Coalition Believes That The Commission's Proposed Amendment, Modified As The Coalition Suggests Herein, Adequately Responds To The Requirements Of The Directive In Paragraphs (1), (4), (5), and (6)

The Commission seeks comment on whether the proposed amendment adequately responds to the other requirements of the directive. The Coalition believes that the Commission's proposed amendment does not, as written, adequately account for the nature and seriousness of the offenses punishable under the Act. However, the Coalition's proposed amendment set forth and discussed in this Comment, in conjunction with the Coalition's proposals regarding other guidelines and specific offense characteristics, adequately responds to all paragraphs of the directive from Congress.

3. The Commission Should Adopt The Statutory Definitions of "Pre-retail Medical Product" and "Supply Chain"

The Commission seeks comment on whether (1) the proposed guideline's adoption of the Act's statutory definition of the term "pre-retail medical product" is adequately clear; and (2) the proposed guideline's adoption of the Act's statutory definition of "supply chain" inform the decision of whether the medical product has been made available for retail purchase by a consumer. The Coalition believes that both of the statutory definitions are appropriately defined for purposes of the guidelines. Congress intended these definitions to be expansive but stop short of making shoplifting a federal crime,²² and the statutory definitions made by Congress give effect to such intent. Moreover, § 670(e) refers to statutory definitions from other acts for certain terms, demonstrating that Congress intended precise and preexisting definitions to apply. The Commission should heed Congress' intent with respect to these definitions, which were chosen to maintain consistency and reliability in punishing crimes involving like health and safety issues.

²¹ The Coalition separately addresses offenders employed by organizations in the supply chain in Section 3, *infra*.

²² S. REP. NO. 112-204, at 2.

4. **The Aggravating Factor In § 670, Where The Defendant Was Employed By, Or The Agent Of, An Organization In The Supply Chain, Warrants A 4-Level Enhancement**

The Commission seeks comment on how the guidelines should be amended to account for the Act's aggravating factor that increases the statutory maximum term if the defendant is employed by, or is an agent of, an organization in the supply chain for the pre-retail medical product. The Coalition believes that a 4-level enhancement is warranted for offenders associated with organizations in the supply chain. Congress intended to impose "increased sentences . . . when trust is broken (such as when a defendant is employed by an organization in the supply chain)."²³ While §3B1.3, entitled Abuse of Position of Trust or Use of Special Skill §3B1.3 imposes a 2-level enhancement for defendants who hold positions of trust, it does not account for the public health risk posed by offenders of the Act who break positions of public or private trust. Furthermore, a separate penalty is warranted because offenders of the Act who are members of the supply chain may not always be in positions of trust within the organization subject to enhancements under §3B1.3. Likewise, a mastermind of the organization may not—and is unlikely to—be in a position of trust. Thus, in order to effectuate Congress' intent, the Commission should include an increased penalty in its amendment to §2B1.1 for defendants who are employed by, or agents of, organizations in the supply chain.

5. **Changes To Guidelines To Which The Other Offenses Covered By The Directive Are Referenced To Account For The Statutory Changes Or The Directive, Or Both**

The Commission seeks comment on what changes, if any, it should make to the guidelines to which the other offenses covered by the directive are referenced to account for the statutory changes or the directive, or both. For the reasons set for in Section 1(B), the Coalition recommends the following amendments to guidelines related to other offenses covered by the statute and directive:

- (A) The Coalition proposes adding a clause to the existing specific offense characteristics in §2S1.1, so that subsection (b)(1) reads:

"If (A) subsection (a)(2) applies; and (B) the defendant knew or believed that any of the laundered funds were the proceeds of, or were intended to promote (i) an offense involving the manufacture, importation, or distribution of a controlled substance or a listed chemical; (ii) a crime of violence; (iii) an offense involving firearms, explosives, national security, or the sexual exploitation of a minor; or (iv) an offense involving pre-retail medical products as defined by 18 U.S.C. § 670, increase by 6 levels."; and

²³ S. REP. NO. 112-204, at 2.

- (B) The Coalition proposes adding a clause to the end of the existing specific offense characteristics in §2B2.1, so that subsection (b) includes the following:

"(5) if the offense involved a pre-retail medical product as defined by 18 U.S.C. § 670, increase by 4 levels."

- (C) The Coalition proposes adding a clause to the end of the existing specific offense characteristics for §2B3.1, so that subsection (b) includes the following:

"(3) if the offense involved a pre-retail medical product as defined by 18 U.S.C. § 670, increase by 4 levels."

- (D) The Coalition proposes adding a clause to the end of the existing specific offense characteristics for §2B2.1, so that subsection (b) includes the following:

"(5) if the offense involved a pre-retail medical product as defined by 18 U.S.C. § 670, increase by 4 levels."

- (E) The Coalition proposes adding a clause to the end of the existing specific offense characteristics for §2A2.1, so that subsection (b) includes the following:

"(3) if the offense involved a pre-retail medical product as defined by 18 U.S.C. § 670, increase by 4 levels."

- (F) The Coalition proposes adding a clause to the end of the existing specific offense characteristics for §2A2.2, so that subsection (b) includes the following:

"(7) if the offense involved a pre-retail medical product as defined by 18 U.S.C. § 670, increase by 4 levels."

- (G) The Coalition proposes adding a clause to the end of the existing specific offense characteristics for §2X1.1, so that subsection (b) includes the following:

"(4) if the offense involved a pre-retail medical product as defined by 18 U.S.C. § 670, increase by 4 levels."

The Coalition appreciates the opportunity to provide this Comment on these very important issues, and thanks the Commission and staff members for their attention.

Respectfully submitted,

The Coalition for Patient Safety and Medicine Integrity