COMMENT BY THE US FOOD AND DRUG ADMINISTRATION

On January 28, 2008, the United States Sentencing Commission (the Commission) proposed to amend the United States Sentencing Guidelines to address several offenses set forth in the Federal Food, Drug, and Cosmetic Act (FDCA). Specifically, the Commission requested comment on its proposal to sentence illicit human growth hormone (hGH) distribution under § 2D1.1 of the guidelines, as well as on several specific questions related to hGH sentencing. In addition, the Commission requested comment regarding the sentencing of Prescription Drug Marketing Act (PDMA) violations and other FDCA violations currently sentenced under § 2N2.1. FDA's recommendations concerning these areas of proposed amendment follow. First, the comment addresses the issues related to illicit distribution of hGH under 21 U.S.C. § 333(e). Second, the comment provides information and recommendations for certain PDMA violations. Third and finally, the comment responds to the Commission's request for comments regarding the adequacy of § 2N2.1 generally and the Commission's proposed amendments in particular.

I. HUMAN GROWTH HORMONE

The FDCA prohibits the knowing distribution, or possession with the intent to distribute, hGH for any use not authorized by FDA. See 21 U.S.C. § 333(e). As the Commission is aware, there currently is not a sentencing guideline to cover these hGH offenses. See USSG § 2N2.1, comment (n.4). The Commission has proposed adding "references to §§ 2D1.1 and 2D1.2 in Appendix A for violations of 21 U.S.C. §§ 333(e)(1) and (e)(2), respectively; amend[ing] the specific offense characteristics at § 2D1.1(b)(6) to include hGH offenses; and delet[ing] language in the commentary to § 2N2.1 stating that the Commission has not established a guideline for hGH offenses." 73 Fed. Reg. 4931, 4934 (Jan. 28, 2008). The Commission has also requested comment in response to several issues related to its proposal, including: how hGH should be quantified under § 2D1.1; what quantity of hGH should be used to determine a "unit" for purposes of calculating the base offense level; whether and to what extent should a maximum base offense level apply; and whether certain enhancements should be expanded to include certain hGH offenses, as well as whether any modifications should be made to an existing Application Note.

The United States Food and Drug Administration (FDA), which is the agency charged with the responsibility of investigating criminal violations of the FDCA, believes that a sentencing guideline for hGH offenses is necessary, and it is submitting this comment in support of the Commission's proposal. As discussed below, FDA recommends that the Commission establish that: (a) hGH be quantified under § 2D1.1 by measuring the total amount of powder containing hGH; (b) ten milligrams (10 mg) of the weight of the powder containing hGH be equated to one "unit" for purposes of calculating the base offense level; (c) a maximum base offense level of twenty (20) should apply for now; (d) the scope of enhancements be expanded to cover the distribution of a masking agent for hGH testing and the illegal distribution of hGH to an athlete; and (e) the relevant application note be modified to provide that the adjustment for abuse of trust applies to a coach who influences an athlete to use hGH.

A. A Sentencing Guideline Is Needed For hGH Offenses

FDA's ability to pursue enforcement actions for hGH offenses is currently hampered by the uncertainty that results from the current lack of a sentencing guideline. Prosecutors, probation officers, and others have expressed confusion about how to calculate the guidelines for hGH offenses. Because there currently is substantial interpretive room in selecting an analogous guideline, as courts are directed to do by § 1B1.2(a) when no specific guideline is available, probation officers and courts may refer to any number of guidelines to calculate hGH sentences, including § 2N2.1 (Food and Drug Offenses), § 2B1.1 (Theft, Property Destruction, and Fraud), § 2D1.1 (Drug Offenses), or § 2X5.1 (which states that courts should make use of the criteria in 18 U.S.C. § 3553 when no sufficiently analogous guideline is available).[1] These differing approaches may result in widely varying sentences, which can result in perceived unfairness to defendants and in diminished deterrence. Defendants may face substantial uncertainty estimating their likely sentencing exposure, and a defendant in one jurisdiction with identical conduct might find himself sentenced more harshly than a defendant in another jurisdiction that uses a different approach to sentencing hGH violations. In addition, as the Commission is aware, uncertainty also diminishes deterrence when the criminally-minded underestimate the consequences of their conduct. The same uncertainty exists for the probation officers and judges charged with calculating and applying sentencing criteria. FDA believes that the Commission's proposed guideline would be a positive step in resolving the uncertainty that currently exists for sentencing violations of 21 U.S.C. § 333(e).

B. FDA Supports The Commission's Proposal

FDA supports the Commission's proposal to sentence illicit hGH distribution under §2D1.1, which currently addresses certain controlled substances offenses. Although hGH is not a controlled substance, its well-known adverse effects, ease of illegal distribution, and potential for abuse -- especially in conjunction with anabolic steroids -- establish a logical nexus for sentencing hGH under § 2D1.1.

As discussed in detail in the previously submitted written statement of Dr. Robert Perlstein, hGH is a 191-amino acid polypeptide hormone secreted by the anterior pituitary gland. It has important metabolic effects, including stimulation of protein synthesis and cellular uptake of amino acids, and stimulates normal growth in children. The approved indications in adults include biochemically-documented severe growth hormone deficiency due to defined organic diseases (hereafter, referred to as "severe growth hormone deficiency"), AIDS wasting, and short bowel syndrome.

All hGH products are prescription drugs because, due to the potential for well-known adverse effects, they are not safe for use except under the supervision of a practitioner licensed by law to administer such products. See 21 U.S.C. § 353(b)(1). The use of hGH is frequently associated with fluid retention, which can cause edema, arthralgia (joint pain), myalgia (muscle

[1] Also, as noted in the previous oral testimony of FDA Special Agent Alex Davis, hGH is often distributed with anabolic steroids. Because anabolic steroids have defined sentencing guidelines, some prosecutors focus on the controlled substances offenses and ignore the hGH offenses. Moreover, even when prosecutors charge both the hGH and controlled substances offenses, the hGH charges may be disregarded during sentencing.

pain), and carpal tunnel syndrome. It can also exacerbate pre-existing hypertension (high blood pressure) and congestive heart failure. The risk of incurring the side effects associated with fluid retention increases with age. hGH also has anti-insulin, diabetogenic effects that may contribute to the development of diabetes mellitus, especially in those predisposed to this disease.

As FDA Special Agent Alex Davis discussed in his written testimony, the illegal distribution of hGH appears to be increasing, which can be attributed to the perceived effects of hGH on athletic performance and on stopping or slowing the aging process,[2] coupled with the relatively low cost of black-market hGH and the ease of obtaining it without a prescription.

Most of the hGH that is promoted to stop or slow the aging process or to increase athletic performance is unapproved product that is primarily manufactured by foreign drug sources and imported into the United States. Internet websites and discussion boards have made it very easy for anyone to order hGH that originates from one of the numerous foreign sources and have it delivered to his or her door. The hGH purchased from a website or internet discussion board is almost always significantly cheaper than FDA-approved hGH. Depending on the brand offered for sale, 100 International Units (IUs) of black-market hGH can be purchased for $200 - $700. However, 100 IUs of FDA-approved hGH that is properly dispensed by a pharmacist costs approximately $2000, which is more than twice as much as the most expensive black-market price. As explained infra Section I.C.2., those using hGH for anti-aging will use amounts near to or greater than amounts for adults with severe growth hormone deficiency, and those using hGH to increase athletic performance will typically use amounts far in excess of the amounts for adults with severe growth hormone deficiency.

Anabolic steroids, which are Schedule III controlled substances, are distributed in much the same manner as hGH -- that is, they typically are imported from a foreign source and sold over the internet, either through a website or a bodybuilding discussion board. Because of the perception that hGH increases lean muscle mass, hGH is often used in conjunction with anabolic steroids and a bodybuilding routine to increase athletic performance. Therefore, those who are distributing steroids are very often the same individuals who are distributing hGH, and many of the websites and internet discussion boards that offer hGH for sale will also offer anabolic steroids for sale.

Likely because hGH has a potential for abuse in conjunction with anabolic steroids and, as discussed infra Section I.C.2., a potential for harm that is equal to that of anabolic steroids, 21 U.S.C. § 333(e) is more closely analogous to a provision of the Controlled Substances Act ("CSA") than to a typical drug offense under the FDCA. For instance, although most food and drug offenses under the FDCA carry a maximum penalty of three years in prison, Congress established greater penalties for the unlawful distribution of hGH. Cf. 21 U.S.C. § 333(a) and (e). The penalties for hGH distribution are similar to the penalties for Schedule III controlled

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[2] See, e.g., Hau Liu, MD, MBA, MPH, et al., Systematic Review: The Safety and Efficacy of Growth Hormone in the Healthy Elderly, 146 ANNALS OF INTERNAL MED., 104 (Jan. 16, 2007) (concluding that, based on the evidence, growth hormone cannot be recommended as an antiaging therapy); Hau Liu, MD, MBA, MPH, et al., Systematic Review: The Effects of Growth Hormone on Athletic Performance, 148 ANNALS OF INTERNAL MED., to be published May 20, 2008, available at http://www.annals.org/cgi/content/full/0000605-200805200-00215v1 (concluding that the limited available evidence suggests that growth hormone increases lean body mass, but it may not improve strength, may worsen exercise capacity, and may increase adverse events).

substances, such as anabolic steroids, in that whoever violates 21 U.S.C. § 333(e) "is guilty of an offense punishable by not more than 5 years in prison," and whoever violates said provision "and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment . . . ." 21 U.S.C. § 333(e)(1) and (2); cf. 21 U.S.C. § 841(b)(1)(D). Also, unlike other violations of the FDCA, a conviction for violating 21 U.S.C. § 333(e), "shall be considered a felony violation of the Controlled Substances Act for the purposes of forfeiture under [the CSA]." 21 U.S.C. § 333(e)(3). Finally, the Drug Enforcement Administration, which is charged with investigating violations of the CSA, is also authorized to investigate hGH offenses. See 21 U.S.C. § 333(e)(5). Because of these similarities, it is reasonable and appropriate to sentence hGH offenses under § 2D1.1.

In fact, the similarities between hGH and Schedule III controlled substances are such that there have been recent efforts by some members of Congress to add hGH to the list of Schedule III controlled substances under the CSA. These efforts, however, should not delay the Commission from establishing a guideline for hGH offenses under the FDCA. Proposed legislation to add hGH to the list of controlled substances has been pending since March 14, 2007, and it is by no means a certainty that Congress will schedule hGH any time soon. See e.g., Controlling the Abuse of Prescriptions Act of 2007, S. 877, 110 Cong. (2007). Also, none of the proposed legislation that has been introduced in Congress to date would repeal 21 U.S.C. § 333(e); therefore, a sentencing guideline for such offenses would be necessary regardless of whether Congress schedules hGH. But even if Congress were to repeal 21 U.S.C. § 333(e) and schedule hGH in the CSA, prosecutors, defendants, and courts would be without a sentencing guideline until at least the next amendment cycle, when the Commission would have another opportunity to establish an hGH guideline. Therefore, FDA does not believe that the Commission should delay establishing a guidelines because regardless of what action, if any, Congress takes, the Commission's proposal would still further Congress' intent for sentencing hGH offenses.

C. FDA's Responses To The Commission's Specific Requests for Comment

As discussed below, FDA recommends that: (1) hGH be quantified under § 2D1.1 using the total weight of powder containing hGH; (2) the appropriate base offense level for hGH offenses be determined using a 1 unit = 10 milligrams of total powder formula; (3) the maximum base offense level for hGH offenses be equivalent to that for anabolic steroids offenses; and (4) enhancements be added for a masking agent and distribution of hGH to an athlete and the relevant application note be amended to address abuse of trust by a coach.

1. Quantifying hGH Under Section 2D1.1

FDA recommends that the Commission use the total weight of hGH powder as the unit of measurement that is equivalent to 1 gm of marihuana. As the Commission is aware, calculation of quantity based on total weight of the substance is the approach used for most substances in Table C of § 2D1.1, including anabolic steroids, and the Supreme Court has approved such an approach. See Chapman v. United States, 500 U.S. 453, 461 (1991) (noting that "Congress adopted a 'market-oriented' approach to punishing drug trafficking, under which the total

quantity of what is distributed, rather than the amount of pure drug involved, is used to determine the length of the sentence.").

Using the total weight of the powder as the unit of measure is reasonable considering that hGH is illegally distributed in powder form. A person wishing to use hGH for an anti-aging or bodybuilding use will usually purchase multiple "kits" of hGH over the internet. Each kit typically consists of several vials containing hGH in the form of a lyophilized (freeze-dried) powder mixed with several excipients (inactive ingredients), such as mannitol, glycine, and phosphate. These excipients are included in the formulated product to help solubilize the hGH, for pH control, and to promote the stability of the hGH once it is in solution. Although hGH must be injected to be metabolized by the body, the vials always contain hGH in the form of a lyophilized powder until they reach the customer because liquid hGH quickly loses potency if it is not refrigerated.

FDA believes that using the total weight of the powder containing the active hGH ingredient will be the most efficient means of measure. To determine whether hGH is present in a particular sample and thus to confirm whether 21 U.S.C. § 333(e) has been violated, FDA's Forensic Chemistry Center (FCC) uses a method (liquid chromatography with mass spectral detection) that requires at least three hours of labor. If FCC were also then required to test for the amount of the active hGH ingredient for sentencing purposes, FCC would need to use a different test (size exclusion chromatography). This additional procedure would require approximately three additional work-hours per unit being tested. Thus, from FDA and FCC's perspective, using total weight as the measure of hGH quantity is significantly less resource and time intensive than the alternative of requiring the government to test hGH samples for quantity of active ingredient. Using the total quantity of hGH powder decreases the testing time literally in half. Because FCC's resources are finite and the demands on their facilities for other types of testing are high, the additional burden of testing for the quantity of active hGH would be significant.

FDA also believes that, while perhaps expedient, the use of the number of hGH vials as the appropriate measure of hGH quantity for guideline purposes would present problems. Equating a number of vials of hGH with a number of "units" would create an incentive for illicit distributors to increase the size of their vials and thereby decrease the number of vials counted for sentencing purposes for the same quantity of hGH. Vial size could easily be changed at any point in the distribution chain. FDA can, with minimal burden, determine the total weight of powder contained in a particular or average vial. Therefore, FDA does not believe that there is any significant benefit to using the number of vials as opposed to the total weight of hGH powder. Rather, FDA believes that total weight of hGH powder can provide a consistent, accurate, and fair measure of the quantity of hGH involved in the offense without significantly increasing the burden on FDA's testing facilities by requiring a determination of the quantity of active ingredient in each sample or vial.

2. Quantities for Purposes of Calculating the Base Offense Level

The Commission has requested comments on the harmfulness of hGH offenses relative to steroids offenses and, based on that comparison, input regarding the appropriate quantity of hGH that should be used to determine a "unit" for purposes of calculating the base offense level.

While FDA considers relative harm between hGH and steroids to be relevant to the determination of the proper quantity of hGH to calculate a base offense level, FDA believes that such a comparison does not tell the entire story. FDA has looked at a number of factors in determining a fair and accurate conversion factor for hGH, including: the typical dosage of hGH for adults with severe growth hormone deficiency compared to the dosages for anti-aging and to enhance athletic performance, the potential harm caused by such dosages, the total amount of powder containing hGH used for such dosages, and the typical amount of powder illicitly distributed. Taken together, FDA recommends that the Commission equate 1 unit to 10 milligrams of total powder of hGH to calculate base offense levels.

As discussed above, FDA has approved several hGH products for three adult indications. However, the majority of hGH lawfully prescribed for adults is for the treatment of severe growth hormone deficiency. Adults who are diagnosed with severe growth hormone deficiency take 5 to 10 micrograms of hGH per kilogram of body weight per day. The well-known adverse effects of hGH can occur at those dosages, and such users of hGH are supervised by medical professionals who carefully titrate the dose and supervise its administration so that its use is both safe and effective. Those using hGH for anti-aging purposes will typically take 0.33 to 1.0 milligrams of hGH active ingredient per day, and those using hGH to increase athletic performance will take 1.3 to 3.3 milligrams of active hGH ingredient per day. (One milligram is equal to 1,000 micrograms). The dosages for anti-aging purposes or to increase athletic performance generally are not connected to body weight. Thus, to get a meaningful comparison of the anti-aging and athletic performance dosages to the dosages for adults with human growth hormone deficiency, the anti-aging and athletic performance dosages must be converted to a dosage per kilogram per day. For the sake of comparison, FDA has chosen a hypothetical 80 kg (176 lbs.) adult.

In an 80 kg (176 lbs.) adult, the dosages for anti-aging are equal to 4 to 12 micrograms per kilogram per day and the dosages for athletic performance are equal to 16 to 41 micrograms per kilogram per day. A comparison of those dosages to the dosages for adults diagnosed with severe growth hormone deficiency shows that those using hGH for anti-aging purposes typically are using amounts that are near to or greater than the typical dosages taken by severely growth-hormone deficient adults and those using hGH to increase athletic performance are taking amounts far in excess of those dosages. These higher doses increase the risk of the well-known adverse effects of hGH at the typical dosages, and the lack of adequate monitoring by a well trained physician enhances these risks.

As discussed by Dr. Robert Perlstein in his statement to the Commission, if excessive amounts of hGH are injected over a prolonged period of time, it may lead to the development of acromegaly (typically the result of an unusual pituitary tumor that secretes hGH in an unregulated, autonomous fashion). Adults with acromegaly have enlarged hands and feet, a

protruding jaw and forehead (so-called acromegalic facies), and often develop enlarged internal organs including the heart (so-called acromegalic cardiomyopathy), hypertension, diabetes mellitus and sleep apnea. If left untreated, patients with acromegaly die prematurely, most often due to cardiovascular disease. It is possible, but not yet proven, that the prolonged use of hGH (either directly or via its mediator/surrogate insulin-like growth factor I [IGF I]) may increase the risk of de novo cancer or the growth rate of preexisting cancer. In this regard, patients with naturally occurring acromegaly have an increased risk of colonic polyps and colon cancer. In the opinion of Dr. Perlstein, the unique adverse effects associated with the inappropriate, inadequately monitored use of hGH, and the unique adverse effects associated with such use of anabolic steroids are potentially equally dangerous to the user.

Very little lyophilized hGH powder is needed to achieve potentially dangerous dosages. Data gathered by FDA's Forensic Chemistry Center (FCC) from over two-hundred seventy five criminal investigations show that, on average, the active hGH ingredient makes up 6.4% of the total weight of the illicit product. Therefore, a person on a typical anti-aging regimen would use 5 to 15 milligrams of total powder per day, and a person taking hGH for athletic performance would typically use 20 to 52 milligrams of total powder per day. Compare those amounts to an 80 kg adult who would use 6 to 12.5 milligrams of total powder to get 5 to 10 micrograms of hGH per kilogram for severe growth hormone deficiency. [3]

As explained above, the 80 kg adults who are using as little as 6 to 12.5 milligrams of total powder per day for severe growth hormone deficiency (and those under 80 kg use even less), could experience the well-known side effects of hGH even when supervised by a medical professional. A similar rate of side effects is likely to be experienced by adults who use 5 to 15 milligrams of total powder per day for anti-aging without the supervision of a medical professional, and it is reasonable to project that persons using greater amounts for athletic performance will experience more severe adverse effects.

Based on the typical dosages discussed above and the risk of harm related to these dosages, FDA is convinced that its proposed conversion, where 1 unit = 10 milligrams of total powder, is an appropriate ratio. FDA believes that its proposal is consistent with the potential for harm in relation to anabolic steroids and would result in fair and appropriate sentences for hGH offenses. An analysis of several recent investigations into illegal hGH distribution schemes indicates that FDA's proposal, when compared to a 1 unit = 45 milligrams or 1 vial ratio,[4] would be more effective in stratifying high-level, mid-level, and low-level hGH distributors while also accounting for the potential harm caused by the product. Because there currently is not a sentencing guideline for hGH offenses, it has not been necessary for the government to calculate the amount of hGH involved in most distribution schemes.[5] However, FDA reviewed the available information from ten investigations since 2005. We believe that this information is

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[3] These numbers are based on the amount of active ingredient typically contained in the forms of hGH distributed in illicit schemes investigated by FDA. The amount of total powder typically used by an 80 kg. severely growth-hormone deficient adult might differ.

[4] According to FCC, each vial of illicitly distributed hGH contains approximately forty five (45) milligrams of total powder, on average.

[5] As discussed supra note 1, when a defendant has been accused of committing a controlled substance offense and hGH offense (which happens often), the hGH offense may ultimately not be charged or, if charged, disregarded during sentencing.

fairly representative of the number of hGH vials that are involved in illegal hGH distribution schemes.[6] This information and the relevant unit conversions appear in Table 1 below.

Table 1

Vials	**Mg of Total hGH Powder[7]**	**If 1 Unit = 45 mg or 1 vial (Base Level)**	**If 1 Unit = 10 mg (Base Level)**
100	4500 mg	100 units (6)	450 units (8)
110	4950 mg	110 units (6)	495 units (8)
130	5850 mg	130 units (6)	585 units (8)
200	9000 mg	200 units (6)	900 units (8)
280	12600 mg	280 units (8)	1260 units (10)
355	15975 mg	355 units (8)	1597.5 units (10)
650	29250 mg	650 units (8)	2925 units (12)
900	40500 mg	900 units (8)	4050 units (12)
1001	45045 mg	1001 units (10)	4504.5 units (12)
1150	51750 mg	1150 units (10)	5175 units (14)

These investigations reveal that most of the cases where judicial action was obtained would fall at level 6 or 8 if one vial or 45 milligrams of hGH constituted one "unit" under Table C of § 2D1.1. With a substance as potent as hGH, not only does the culpability differ dramatically between a distributor who sells 4.5 grams (4,500 milligrams) and distributor who sells 40.5 grams (40,500 milligrams), but the public health implications also differ dramatically. Yet, based on the quantities of hGH seen in recent FDA cases, and assuming a conversion rate of 45 milligrams of total powder or at one "vial" per "unit" for sentencing purposes, the individual distributing 4.5 grams would receive a base level of 6 and the individual distributing 40.5 grams -- almost 10 times as much product -- would receive a minimally greater base offense level of 8. FDA believes this result would not adequately deter mid-level and high-level hGH distributions.

FDA's recommended unit conversion would effectively deter illicit conduct by matching sentencing to the quantity of hGH being illicitly distributed by an individual defendant and would result in a meaningful distribution of offenders based on the quantity of hGH they distribute. Moreover, this result is consistent with Congress's intention that illegal hGH distribution be punished as a five year felony, similar to anabolic steroids and other Schedule III controlled substances. See 21 U.S.C. § 333(e).

3. Maximum Base Offense Level

Although FDA is concerned that a maximum base offense level could hinder the prosecutions and punishments of very large scale distributors, it does not oppose a maximum base offense level for hGH offenses equal to that for anabolic steroids. As discussed above, hGH

[6] FDA has encountered a few illegal hGH distribution schemes that exceed the numbers in Figure 1. These illegal distributions involve large entities and multiple individuals, rather than the typical illegal distribution schemes described above. Such entities and individuals would likely reach a cap of 20 (see infra Section I.C.3.) regardless of the unit conversion.

[7] See supra note 3.

trafficking is very similar to, and often occurs with, anabolic steroids trafficking, and the adverse effects of hGH pose a danger that is equal to danger posed by the adverse effects of anabolic steroids.

4. Enhancements And Modifications

FDA also urges the Commission to expand the scope of § 2D1.1(b)(7) to include a two-level enhancement if the distribution involved hGH and a masking agent, and to expand the scope of § 2D1.1(b)(8) to include a two-level enhancement if the defendant distributed hGH to an athlete. FDA also urges the Commission to modify Application Note 8 to instruct the court to apply the adjustment in § 3B1.3 for abuse of trust in cases where a coach uses his or her position to influence an athlete to use hGH.

Until recently, FDA had no opinion as to whether an enhancement should be added for the distribution of a masking agent because it was not aware of any testing for hGH, and thus, it was not aware of a need for a masking agent for hGH testing. However, Dr. Gary I. Wadler, a member of the World Anti-Doping Agency and a spokesman for the American College of Sports Medicine, has recently indicated that a blood test for hGH will soon be ready. See Stephanie Nano, Growth Hormones Don't Boost Performance, ASSOCIATED PRESS, March 17, 2008. The development of such tests will no doubt promote the development of masking agents to circumvent those tests. Therefore, while FDA is not currently aware of a masking agent for hGH, it anticipates that a masking agent will be developed not long after testing for hGH usage begins.

FDA also urges the Commission to add an enhancement if the defendant distributed hGH to an athlete. Because hGH is perceived as an easy way to increase athletic performance, it is particularly subject to abuse by both amateur and professional athletes. An April 1997 Sports Illustrated article called the use of performance enhancing substances, including hGH, the "dirty and universal secret of sports, amateur and pro, as the millennium draws near." Michael Bamberger and Don Yeager, Over the Edge: Aware that Drug Testing Is a Sham, Athletes Rely More than Ever on Banned Performance Enhancers, SPORTS ILLUSTRATED, Apr. 14, 1997, at 60. Also, former Senator George Mitchell, in his recent report to the Commissioner of Major League Baseball, discusses accusations made against numerous professional baseball players for purchasing and/or using hGH. See George J. Mitchell, Report to the Commissioner of Baseball of an Independent Investigation Into the Illegal Use Of Steroids And Other Performance Enhancing Substances By Players In Major League Baseball, December 13, 2007 at 145-230. Many of the professional baseball players who allegedly purchased and/or used hGH also allegedly purchased and/or used anabolic steroids. See id. Therefore, it appears that hGH is being abused by both amateur and professional athletes and should be addressed by an appropriate enhancement under the guidelines.

The allure of the perceived benefits of hGH on athletic performance cannot be limited to athletes. Indeed, it is safe to assume that coaches may also be seduced by hGH's perceived benefits on an athlete's performance. Coaches are driven to produce favorable results, and the pressures to achieve those results may lead them to facilitate the distribution of hGH to one or more of their athletes. Such behavior is especially heinous because coaches have great access to

their athletes and are in a unique position of authority and trust over them. The abuse of that position should be deterred and appropriately punished. Accordingly, FDA recommends that the Commission modify Application Note 8 for §2D1.1 to expressly instruct the court on how to apply § 3B1.3 (Abuse of Position of Trust or Use of Special Skill) in a situation in which a coach used his or her position to influence an athlete to use hGH.

D. Conclusion

FDA fully supports the Commission's proposal and believes that it will significantly improve the government's ability to combat and prosecute illegal distributions of hGH. FDA also believes that its recommendations in response to the Commission's specific requests for comment are consistent with Congressional intent for sentencing hGH offenses, will result in fair and appropriate sentences, and would further FDA's public health mission by deterring the illegal distribution of hGH.

II. PRESCRIPTION DRUG MARKETING ACT VIOLATIONS

The Prescription Drug Marketing Act (PDMA) prohibits, among other things, the unlicensed wholesale distribution of prescription drugs; the sale, purchase, or trading of prescription drug samples and coupons; and the reimportation by anyone other than the manufacturer of prescription drugs manufactured in the United States. Congress enacted the PDMA to prevent the distribution of counterfeit, misbranded, adulterated, or expired prescription drugs to American consumers. See H.R. Rep. No. 100-76 at 2 (1987). The PDMA is primarily aimed at preventing prescription drug diversion, which threatens the integrity of the nation's drug supply. Congress concluded that the various forms of prescription drug diversion created an "unacceptable risk" that counterfeit or substandard drugs would be sold to American consumers. Id. The recent passage of the FDA Amendments Act of 2007 (FDAAA) demonstrates that Congress remains concerned about the serious risk that drug diversion poses to the health of the American consumer; FDAAA directs the FDA to devote additional resources and to undertake enhanced enforcement efforts to combat drug diversion and counterfeiting and to protect the prescription drug supply chain. See 21 U.S.C. § 355D.

A. Existing Guidelines for PDMA Offenses

As stated in the written testimony previously submitted to the Commission, the conduct that is typically subject to criminal prosecution under the PDMA presents a significant public health risk. Illicit prescription drug diverters are driven by greed and create a risk to the public health by distributing drugs, often obtained from questionable sources, that may be stolen, unapproved, expired, counterfeit, or otherwise substandard. This public health risk is compounded by the fact that illicit diverters generally lack the motivation to store and handle prescription drugs properly; improper storage and handling can adversely affect the drugs' potency, stability, and effectiveness. Ultimately, these diverted drugs end up on the shelves of pharmacies for dispensing to consumers who remain unaware that the drugs came from an illicit and potentially dangerous source. Offenders who violate the PDMA undermine the integrity of the prescription drug supply and place the health and safety of American consumers at risk.

Congress believed that certain knowing violations of the PDMA presented a sufficient public health risk to warrant a statutory maximum sentence of ten years in prison. 21 U.S.C. § 333(b)(1). In contrast, most other felony violations of the Federal Food, Drug, and Cosmetic Act are subject to a maximum sentence of three years in prison and require proof that the offender acted with intent to defraud or mislead. 21 U.S.C. § 333(a)(2). Despite these differences, the existing sentencing guidelines do not distinguish between these PDMA offenses and other FDCA violations.

FDA believes that the existing guidelines do not provide for adequate sentences for most PDMA violations. In fact, in FDA's experience, prosecutors often are reluctant to charge PDMA violations due to inadequacies and uncertainties in the existing guidelines. As a result, many PDMA violations investigated by FDA's Office of Criminal Investigations are not prosecuted; criminal charges are sometimes pursued only if FDA is able to demonstrate a violation of other criminal statutes.

One problem with the existing guidelines is the requirement that the government prove that the offense involved fraud in order to obtain an enhancement above the base offense level of 6 provided for in § 2N2.1. In many cases, offenders knowingly violate the PDMA without committing clearly demonstrable fraud and courts, therefore, may not apply the cross-reference to § 2B1.1. For example, when an unlicensed wholesale distributor sells diverted prescription drugs to another wholesale distributor, the recipient wholesaler often is aware that the wholesaler from whom he purchased the drugs is not licensed and that the drugs may have come from an illicit source. The unlicensed wholesale distributor has committed a knowing violation of the PDMA, but the court may not find that the offense involved fraud if the defendant has not misrepresented his licensing status or the source of the drugs to the purchaser and has not taken affirmative steps to conceal his conduct from FDA, state licensing authorities, or consumers. Thus, courts may not apply the cross-reference to § 2B1.1, even though the offense presents a potentially serious public health risk.

Even if a particular PDMA offense involves clearly provable fraud and the cross-reference to § 2B1.1 applies, the calculation of "loss" under 2B1.1 is problematic in most PDMA cases. Under § 2B1.1, "loss" means "pecuniary harm that resulted from the offense." USSG § 2B1.1 cmt. (3)(A). This definition ignores the non-economic public-health harm that is the primary focus of PDMA violations: the high risk that subpotent, adulterated, or counterfeit prescription drugs will enter the supply chain. For example, a defendant who violates the PDMA by engaging in unlicensed wholesale distribution of prescription drugs may sell genuine product or product from an unknown source that has been stored in the trunk of a car or repackaged under filthy conditions. Assuming that the offense involves fraud, the current guidelines do not provide clear guidance on whether the <u>risk</u> that the distributed drugs are substandard results in a loss under 2B1.1 and, if so, how that loss should be calculated.[8]

[8] While many diverted drugs may be subpotent or otherwise contaminated as a result of the conditions in which they are manufactured, stored, or repackaged, it is often difficult for the government to prove that a particular drug is substandard. In many cases, either there is no reliable testing method to determine whether a particular drug has been compromised, or the drugs have already been distributed and are not available for testing.

B. Recommendations

This lack of clarity in the existing guidelines undermines FDA's ability to protect the nation's prescription drug supply by creating uncertainty for prosecutors who are considering whether to pursue PDMA violations. FDA supports any amendment scheme that would address these uncertainties and improve FDA's ability to use the criminal provisions of the PDMA to ensure the safety of the prescriptions drugs distributed to American consumers. Two possible solutions are discussed below.

One possible solution would be to amend § 2N2.1 to increase the base offense level for PDMA violations and include enhancements for specific conduct that increases culpability. If the Commission decides to amend § 2N2.1 to address PDMA offenses, FDA believes that a higher base offense level and certain specific offense characteristics would be necessary to ensure adequate offense levels for PDMA offenders. FDA suggests that § 2N2.1 be amended to provide a base offense level of 12 for PDMA violations subject to enhanced penalties under 21 U.S.C. § 333(b)(1). Proposed amendment language along these lines was included as an attachment to FDA's earlier written testimony. A base offense level of 12 would be appropriate because Congress has assigned a ten year statutory maximum to these offenses and because the only PDMA offenses addressed by this proposed amendment require knowing conduct that undermines the closed prescription drug distribution system and the safety and effectiveness of prescription drugs. We also note that a base offense level of 12 for these knowing PDMA violations would still permit defendants who accept responsibility, and who are not subject to the enhancements suggested below, to reduce their offense level pursuant to § 3E1.1 in order to be sentenced under Zone B and possibly avoid imprisonment.

The recommended specific offense characteristics mentioned above would be enhancements based on inadequate storage or handling of prescription drugs; the distribution of unapproved, previously dispensed, expired, or counterfeit drugs; the failure to maintain records; and the distribution of significant quantities of drugs. The enhancements correspond with motivating concerns that Congress addressed when it enacted the PDMA.

For example, Congress expressed concerns about the dangers associated with inadequate storage of prescription drugs. Furthermore, a great deal of the potential public health harm resulting from PDMA offenses derives from improperly stored drugs. Such diverted drugs risk contamination, becoming subpotent due to exposure to improper temperatures and/or light conditions, and failing to function effectively when purchased and used by unsuspecting consumers. The PDMA is aimed at preventing drug diversion precisely because of the risk that diversion will introduce subpotent or adulterated drugs into the distribution system. A significant enhancement is warranted when that risk is heightened by individuals holding prescription drugs under improper storage conditions.

Congress was also concerned with the distribution of substandard, expired, or counterfeit drugs to American consumers. Defendants who introduce such drugs into the prescription drug distribution system create a heightened health risk above and beyond defendants who distribute otherwise legitimate, FDA-approved, drug products in violation of the PDMA. Therefore, FDA

believes that an enhancement for the distribution of unapproved, expired, previously dispensed, or counterfeit drugs is appropriate.

In FDA's experience, the failure by a distributor to maintain distribution records is a strong indicator of an illicit source, prevents FDA from disrupting illicit channels of distribution, and inhibits FDA's ability to adequately investigate these offenses. Under the minimum guidelines for state licensing of wholesale prescription drug distribution, enacted by FDA pursuant to the PDMA, wholesale drug distributors must, under state licensing schemes, maintain records of all transactions regarding the receipt and distribution of prescription drugs. 21 C.F.R. 205.50(f). Thus, this proposed enhancement would be applicable only when a distributor violates both these minimum guidelines and knowingly violates the PDMA statutory provisions.

The actual or intended quantity of drugs distributed is another valuable index of the seriousness of the violation of the PDMA. Logically, the greater the quantity of drugs being knowingly distributed by an illicit source in violation of the PDMA, the greater the public health risk posed by that particular individual's illegal distribution. We suggest that the average retail value of the drugs be used in this enhancement calculation because it relates directly to the amount of drugs involved and the degree of public exposure to the harm posed by such drugs.

Under this proposal, a defendant in Criminal History Category I who knowingly committed a PDMA offense subject to enhanced penalties under 21 U.S.C. § 333(b)(1) and who received all of these proposed enhancements mentioned here would still only receive a resulting offense level of 30 (e.g., base offense level 12 for knowingly distributing + 4 for inadequately storing prescription drugs + 4 for distributing an illicit type of drugs + 2 for failure to maintain records of distribution + 8 for distributing over $1,000,000 of prescription drugs), reducible to 27 following substantial assistance. This offense level, resulting in a 70-87 month range in the most extreme case, is clearly appropriate for the ten year statutory maximum (120 months), allowing more than adequate "head room" for upward movement as a result of criminal history or for upward departures based on individual case factors not captured by these proposed guidelines.

Another possible solution would be to amend § 2N2.1 to provide a cross-reference to § 2B1.1 for knowing PDMA offenses subject to ten year maximum sentences under 21 U.S.C. § 333(b)(1) (without necessitating a showing of fraud) and to amend § 2B1.1 to clarify the appropriate calculation of loss. Specifically, the Commission could amend § 2N2.1(b)(1) to read: *If the offense involved fraud or involved a violation subject to 21 U.S.C. § 333(b)(1), apply § 2B1.1 (Theft, Property Destruction, and Fraud).* This would ensure that § 2B1.1 would govern the PDMA offenses subject to the higher statutory penalties.

To clarify the calculation of loss under § 2B1.1, Application Note 3(F)(v) to § 2B1.1 could be amended to add subsection (IV): *goods sold in violation of a statutory or regulatory requirement,. . .* to ensure that no credit is given to the offenders for drugs sold in violation of the PDMA. To clarify what value should be used to determine loss, the following concluding sentence could be added to the application note: *For offenses involving violations of 21 U.S.C. § 331(t), loss shall include the average retail price of the drugs involved in the offense.* In the context of "loss," FDA feels the best representation is the retail price that would have been paid

for diverted drugs by the unknowing consumer whose health is placed at risk by the receipt of contaminated or subpotent drugs.

These suggested solutions are by no means exclusive, and FDA is amenable to other approaches that would address the concerns raised herein and more accurately reflect Congressional intent. We believe that these or similar amendments would significantly increase the effectiveness of the PDMA as a means to protect the public health, and would promote fairness by providing for consistent sentences for like offenders.

III. THE INADEQUACY OF EXISTING GUIDELINES FOR FDCA OFFENSES

The Commission has also proposed two specific amendments to the existing guidelines that relate to FDCA offenses and called for comment related to whether § 2N2.1 adequately addresses the numerous statutes currently referenced to that guideline. FDA supports both proposed amendments and welcomes the opportunity to address what we believe are some of the particular inadequacies of § 2N2.1.

A. Proposed Upward Departure Provision For Substantial Risk Of Injury Or Death

FDA supports the Commission's proposal to add a comment to § 2N2.1 recommending an upward departure if an offense "created a substantial risk of bodily injury or death." For FDA, "the public health" is not an abstract concept but translates all too readily into precisely the risks of bodily injury and death identified here. FDA's Office of Criminal Investigations typically focuses on defendants whose conduct poses a demonstrable risk to the public health and hence creates a substantial risk of injury or death to individual members of the public. As a result, many cases presented for criminal prosecution by FDA involve a substantial risk of bodily injury or death.

By way of example, in 2006 a federal district court sentenced two defendants for the illicit manufacture and distribution of dextromethorphan (DXM) that had resulted in the deaths of at least five individuals known to have bought these drugs from defendants. Although the top of the guidelines range was 61 months, United States District Judge John Tinder sentenced the defendants to 77 consecutive months based largely on the public health harm that occurred. See United States v. Johnson, 471 F.3d 764, 765 (7th Cir. 2006). One defendant appealed the sentence, but Judge Posner, writing for the Seventh Circuit, agreed that the trial court's upward departure from the Guidelines range was appropriate given the defendant's disregard for the risk of harm his actions created for members of the public. Id.

After United States v. Booker, 543 U.S. 220 (2005), such an upward departure is not likely to be overruled by an appellate court on legal grounds. However, as Suzanne Ferreira confirmed in her recent testimony before the Commission on behalf of the Probation Office, it is also true that such upward departures are more likely to occur in the presence of a comment from the Commission recommending them under specific circumstances. In short, even though upward departures are always possible under the current guidelines where a significant risk of injury or death is present, FDA feels that the Commission's proposed comment explicitly recommending such a departure will encourage judges to depart upward in appropriate

circumstances, as Judge Tinder did in Johnson, where a significant risk to the public health is present.

While an upward departure is preferable to the current guidelines structure, it is also important to recall that violations involving the risk of harm to the public represent the cornerstone of FDA's criminal enforcement actions under the FDCA. As such, we believe that a specific offense characteristic may be a more appropriate way to address the need to sentence defendants who inflict such a risk on the public because, unfortunately, this risk is present in a significant number of FDCA criminal cases. Because a risk of harm is present and demonstrable in many FDCA violations, particularly those for which FDA seeks criminal prosecution, we believe that a specific offense characteristic would be a more appropriate and consistent vehicle to guide sentencing in this class of cases on an ongoing basis. Despite our belief that a specific offense characteristic would be useful in this area, the recognition through the proposed comment that the risk of harm warrants an upward departure would be a very positive step toward more appropriate sentencing.

B. Proposed Specific Offense Characteristic For Second-Offense Violations

The Commission has also proposed adding a specific offense characteristic that would enhance the offense level of defendants with previous convictions under the FDCA. The Commission requests comments on the amount of the enhancement, providing a range of between two and seven levels. FDA supports the addition of this specific offense characteristic and believes that a seven (7) level enhancement for offenders with a prior FDCA convictions is appropriate.

FDA agrees with the Commission's suggestion that second time violators of the FDCA warrant a specific enhancement. Not only do these violators have a heightened level of knowledge with respect to the FDCA that should allow them to avoid reoffending should they choose to do so, but Congress expressly authorized a more severe punishment for violators of the FDCA who had already sustained a previous conviction. Compare 21 U.S.C. 333(a)(1) to 333(a)(2) (authorizing a three year statutory maximum rather than a one year maximum for the offense if the defendant has been previously convicted for an FDCA violation). As a result, we believe that the Commission's proposed enhancement is consistent with Congress's explicit recognition of the need for higher sentences for this group of violators and with the heightened need to deter such repeat offenders.

Because the proposed enhancement would only apply to individuals who had already been convicted of an offense under the FDCA, FDA believes that a seven (7) level enhancement is appropriate. Repeat offenders cannot reasonably claim ignorance of the legal requirements of the FDCA and demonstrate, by their recidivism, a disregard of their responsibility to ensure that the products that they distribute to American consumers are safe, uncontaminated, and otherwise compliant with the FDCA. Where a first time FDCA offender may claim a lack of awareness and violate without full knowledge of the illegality of his conduct, second offenders have received a significant warning by way of their prior criminal conviction and demonstrate that the prior punishment was not an adequate deterrent. Repeat offenders not only place the public

health at risk by again violating the FDCA but also do so with a much greater understanding of what constitutes violative conduct and its potential public health consequences.

As a result, this class of violators may be among the most culpable of FDCA offenders -- placing the public health at risk for a second time despite having already been warned by way of a criminal conviction of an FDCA offense. As discussed above, Congress has recognized the need to punish repeat offenders significantly more severely by providing harsher statutory penalties for repeat violators. In addition, the United States Supreme Court has recognized the appropriateness of punishment for individuals "who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them" because the consuming public is "wholly helpless" to ensure the safety of these products themselves. United States v. Park, 421 U.S. 658, 672 (1975) and United States v. Dotterweich, 320 U.S. 277, 285 (1943). Therefore, FDA believes it is appropriate for the Commission to apply a seven (7) level enhancement to this end to ensure that offenders who twice show disregard for the public health by violating the FDCA face prison time.

C. Inadequacy of Section 2N2.1 For FDCA Violations

As mentioned earlier in this section, the Commission has requested comment regarding whether the existing guideline at § 2N2.1 (with its cross-reference to § 2B1.1) is adequate to address the numerous statutes currently referenced to that guideline.[9] As the Commission is aware, seventy two (72) separate statutory provisions are currently sentenced under § 2N2.1, and the breadth of substantive violations that § 2N2.1 currently addresses is extremely varied. There are more than 30 separate prohibited acts under the FDCA, each of which individually encompasses a large range of conduct. For example, one provision of 21 U.S.C. § 331 prohibits the introduction of a misbranded or adulterated food, drug, device, or cosmetic into interstate commerce. Because "misbranded" and "adulterated" are statutorily defined terms as well, this single prohibited act covers conduct that ranges from failure to include a drug's expiration date on the labeling of a product shipped interstate to the interstate shipment of a food containing a lethal chemical left in the product following improper manufacturing.

Violations of the FDCA range widely, from instances of application fraud directed at FDA's regulatory process of drug and device approval to the dispensing of a prescription drug without a valid prescription, from counterfeiting of drugs to the failure of clinical investigators to maintain accurate case records. Each of these divergent violations of the law, despite their varying degrees of implications for the public health, is currently sentenced under § 2N2.1. While we recognize the magnitude and complexity of reforming § 2N2.1 in order to sentence such a broad range of conduct more appropriately, FDA believes that the current guidelines are inadequate to address the wide variety of FDCA offenses and their significantly varying implications for the public health.

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[9] In general, any violation of the FDCA is a misdemeanor punishable without any showing of criminal intent by a maximum prison term of one year. 21 U.S.C. § 333(a)(1). A violation of the FDCA that is committed with the intent to defraud or mislead either consumers or a government agency, or that is a second conviction under the FDCA, is a felony with a maximum prison term of three years. 21 U.S.C. § 333(a)(2). Both of these violations are sentenced under § 2N2.1.

The current guidelines treat FDCA misdemeanor violations as relatively minor regulatory offenses with a base offense level of 6, with no enhancements for specific offense characteristics. The problem with the low base offense level is compounded by the lack of enhancements for specific offense characteristics under § 2N2.1. Misdemeanor violations of the FDCA encompass a wide range of conduct, from strict liability record-keeping offenses to the willful distribution of dangerous products that could seriously injure or kill consumers. For example, FDA investigates the distribution of drugs, biologics, and medical devices that have not been approved by FDA. In the most egregious cases, these offenses involve the sale of unproven, potentially dangerous drugs to seriously ill patients who may forego FDA-approved treatments. Other cases involve the dispensing of prescription drugs without a valid prescription, which presents a health risk to consumers who may not be aware of potentially dangerous drug effects and interactions and may forego diagnosis by a licensed physician. Although these offenses may lack fraudulent conduct, they can inflict serious harm on large numbers of people.

FDA believes that Section 2N2.1 is inadequate to address the wide ranging degrees of culpability that may occur in FDCA misdemeanors. Despite the lack of fraud, the conduct addressed in these situations fully warrants prosecutorial attention and meaningful redress by the courts. FDA-regulated products are vital to society, and consumers expect and assume that the products will be safe, pure, and effective. The current guidelines should be amended to provide for stiffer sentences for misdemeanor offenses that, while not involving fraud, involve a cognizable risk to the public health or knowing, intentional, or willful conduct.

While felony violations of the FDCA are cross-referenced to § 2B1.1, this cross reference does little to address the seriousness of felony conduct in several categories of cases where the focus of the fraudulent activity does not generate significant or demonstrable monetary loss to identifiable victims. Although the application of the fraud guideline to felonies under § 2B1.1 may provide appropriate punishment when the offense involves significant pecuniary loss, this cross reference to § 2N2.1 does not address the underlying public health purposes of the FDCA and does not provide for an appropriate range of sentences for those offenses that do not involve pecuniary loss commensurate with their public health harm.

Therefore, beyond the proposed additions to § 2N2.1 provided in the Commission's call for comment, we also recommend that the Commission consider addressing two other areas where the existing guidelines are inadequate. Amendments to address the two issues described below would go a long way toward alleviating significant inadequacies in the current guidelines, although we recognize that the complexity of sentencing the breadth of FDA and other offenses under §2N2.1 will remain an issue. Nonetheless, we feel that the areas identified below warrant particular and prompt attention.

1. Calculations of "Loss" for Adulterated or Misbranded products

Most FDCA offenses involve FDA-regulated products that are adulterated or misbranded. A product may be adulterated or misbranded for numerous reasons set forth in the FDCA. For example, a drug or medical device is adulterated if, inter alia, it is not manufactured in conformance with good manufacturing practice or if it is prepared or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health.

See 21 U.S.C. § 351. A drug or medical device is misbranded if, inter alia, its labeling is false or misleading in any particular or if its labeling fails to bear adequate directions for use. See 21 U.S.C. § 352. Misbranded or adulterated products may not lawfully be introduced into or received in interstate commerce and are subject to seizure and destruction under 21 U.S.C. § 334. The existing guidelines, however, do not directly address whether misbranded or adulterated FDA-regulated products can nevertheless be viewed as having value when loss is calculated under § 2B1.1.

We suggest revising the Application Notes to § 2B1.1 to provide that, for the purposes of calculating loss for offenses involving FDA-regulated products that are adulterated or misbranded within the meaning of the FDCA, loss includes the amount paid for the product, with no credit provided for the claimed value of the product. This would be consistent with current Application Note 3(F)(v), which provides that, in cases involving products that require but lack regulatory approval by a government agency, the loss includes the full amount paid for the product with no credit for the value of the product.[10] This amendment would also be consistent with the approach taken by the court in United States v. Gonzalez-Alvarez, 277 F.3d 73, 77-80 (1st Cir. 2002), which held that adulterated milk that cannot lawfully be sold has a value of zero for the purposes of calculating loss under the guidelines. Moreover, because there may remain some uncertainty between federal courts as to how to calculate loss for adulterated or misbranded products,[11] a comment from the Sentencing Commission would help to alleviate any existing confusion. We believe that including an application note that clarifies that, for sentencing purposes, misbranded or adulterated FDA-regulated products have no value would promote consistent application of the guidelines and would help ensure that the sellers of these illegal and often dangerous products receive adequate punishment.

2. Non-Monetary Fraud On The Public Health

Certain FDCA offenses do not necessarily involve any pecuniary loss but significantly undermine FDA's mission and thereby jeopardize the health and safety of the American public. The existing guidelines do not, in FDA's view, adequately address these offenses. For example, fraud related to a clinical trial, such as incomplete and false recordkeeping or using inappropriate patient populations to study a drug, does not necessarily involve any significant pecuniary loss but severely undermines the reliability of FDA's drug and device approval process and thereby jeopardizes the health and safety of the American public. Several other felony offenses involve a similar fraud on FDA's regulatory process, such as the failure to report adverse drug events and

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[10] While the current Application Note addresses unapproved drugs, it does not address drugs that are adulterated or misbranded.

[11] The question of how to measure "loss" under § 2B1.1 for a misbranded or adulterated product remains an unsettled issue. Although the recently added Application Note to 2B1.1 at 3(F)(v) settles the issue for unapproved products, the question of appropriate loss evaluation remains an unnecessary source of contention for misbranded and adulterated products. Compare, e.g., United States v. Marcus, 82 F.3d 606, 610 (4th Cir. 1996) (finding that whether a loss exists for sentencing purposes hinges on whether a modification to a drug's formula was significant) with United States v. Gonzalez-Alvarez, 277 F.3d 73, 77-80 (1st Cir. 2002) (holding adulterated milk without value for the purposes of the loss calculation).

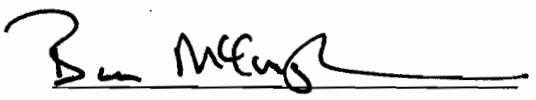
the failure to comply with medical device reporting requirements. This category of offenses poses a significant risk to the public health by undermining the basis for FDA's approval and regulatory decisions, but the harm they inflict is not readily monetized or understood as pecuniary loss. As a result, the harm resulting from this category of cases is not effectively captured by existing guidelines. Although fraudulent conduct is involved and § 2B1.1 is applicable (through the § 2N2.1 cross-reference), no significant enhancement occurs because the fraud does not result in a demonstrable pecuniary loss.

Because the currently available enhancements do not track the seriousness of this category of conduct and its implication for the public health, amendments to capture that harm are necessary in FDA's view. We are aware that other commentators have suggested establishing a Working Group to discuss the specific means of implementing guidelines amendments to address these inadequacies, and FDA welcomes the opportunity to participate in that process, should the Commission believe it to be appropriate here.

IV. CONCLUSION

We greatly appreciate this opportunity to provide our comments regarding the Commission's current proposals and commend the Commission members for their time and attention to the guidelines governing criminal offenses enforced by FDA. As the Commission has recognized by its inclusion of these issues in this year's amendment cycle, the effective sentencing of food and drug offenses affects all of us in numerous and important ways. FDA looks forward to continuing to work with the Commission to provide any additional assistance that would be useful.

Sincerely,



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