



July 31, 2003

Food and Drug Administration
Rockville MD 20857

The Honorable Diana E. Murphy, Chair
United States Sentencing Commission
One Columbus Circle, NE
Suite 2-500, South Lobby
Washington, DC 20002-8002

Attention: Public Affairs-Priorities Comment

Dear Judge Murphy:

I am writing in response to the United States Sentencing Commission's Federal Register Notice published July 1, 2003, requesting public comment on the Commission's proposed priorities for the amendment cycle ending May 1, 2004. For the reasons explained in this letter, the United States Food and Drug Administration, an agency of the Department of Health and Human Services, respectfully requests that the Commission amend its tentative list of priorities to include consideration of amendments to the guidelines that govern violations of the Federal Food, Drug, and Cosmetic Act (FDCA). Following the discussion of our concerns, we also propose specific suggestions on how we believe the guidelines may be amended to address our concerns.

FDA regulates the manufacture and distribution of food, human and animal drugs, medical devices, biologics, and cosmetics. Assuring the purity, integrity, and safety of these products, which account for over 20 percent of every consumer dollar spent in this country, is critical to the well-being of the American people. Most criminal violations of the FDCA are not technical, regulatory offenses. Rather, they are serious criminal acts that pose significant risks of harm to large segments of the public. Defendants in FDCA cases have voluntarily assumed a role in the distribution and manufacture of critical commodities such as food, drugs, biologics, or medical devices. With this role comes the responsibility to act in a manner that is not detrimental to the health and safety of the American public. Courts have observed that the products governed by the FDCA "touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection." United States v. Dotterweich, 320 U.S. 277, 280 (1943). This is even more the case today than when the Court originally made this observation in 1943.

Recently, FDA has seen a disturbing increase in particularly dangerous criminal violations of the FDCA, including distribution of counterfeit drugs, prescription drug diversion, and mass distribution of prescription drugs without the supervision or intervention of a physician. The distribution of counterfeit drugs, which appear to be genuine product but often contain no active ingredient and sometimes contain harmful ingredients, poses a significant health risk to patients who may be harmed by the very medications that they are taking to treat their diseases. Diverters of prescription drugs operate outside of legitimate distribution channels and obtain drugs from questionable and often illegal sources. These diverters may handle and repackage the drugs

incorrectly, which can result in the dispensing of substandard, ineffective, or harmful drugs to American consumers. When prescription drugs are dispensed without the supervision of a licensed practitioner, consumers may take inappropriate and dangerous medications without proper medical diagnosis. This conduct threatens the safety and integrity of the nation's drug supply and, if left unchecked, could cause not only an erosion in the public's confidence in these vital products but also substantial public harm and even death. In addition, rising concerns about terrorism make close oversight of the food, drug, and biologics supplies especially critical.

The current sentencing guidelines do not treat criminal violations of the FDCA as significant threats to the public health and are ineffectual to deter such conduct. Convictions under the FDCA typically result in little, if any, prison time.¹ As a result, prosecutors are reluctant to take FDA cases, and, even when convictions are obtained, consequences are trivial. The unscrupulous perceive that the potential gains of adulterating and misbranding foods, drugs, and other products outweigh possible punishment, and FDA's ability to protect American consumers is severely hampered. Accordingly, amendment of the guidelines to ensure that criminals who put the public health at risk by violating the FDCA are punished appropriately should be a priority of the Commission.

A Brief Overview of FDCA Offenses and the Existing Sentencing Scheme

The FDCA prohibits a variety of conduct, including the manufacture and distribution of counterfeit drugs; the distribution of drugs (human and veterinary), biologics, and medical devices that are not FDA-approved; and the distribution of misbranded and/or adulterated food, drugs, biologics, and medical devices. See 21 U.S.C. § 331. A violation of any of these prohibited acts is a strict liability misdemeanor punishable by a maximum prison term of one year.² 21 U.S.C. § 333(a)(1). If, however, the offense is committed with the intent to defraud or mislead,³ or is a second conviction under the FDCA, it is a felony with a maximum prison term

¹ U.S. Sentencing Commission statistics for fiscal year 2001 indicate that only 24.3 percent of Food & Drug offenders received sentences of imprisonment, the lowest percentage of any primary offense category. 2001 Sourcebook of Federal Sentencing Statistics, Table 12. Similarly, in fiscal year 2000, only 23.4 percent of Food & Drug offenders received imprisonment, again the lowest percentage of any primary offense category. 2000 Sourcebook of Federal Sentencing Statistics, Table 12.

² See United States v. Dotterweich, 320 U.S. 277, 281 (1943) (misdemeanor liability under the FDCA "dispenses with the conventional requirement for criminal conduct – awareness of some wrongdoing"); see also United States v. Park, 421 US 658, 672-73 (1975) (same).

³ "Intent to defraud or mislead" can be demonstrated by evidence of intent to defraud or mislead consumers, FDA, or some other identifiable government agency. See, e.g., United States v. Andersen, 45 F.3d 217, 220 (7th Cir. 1995) ("a deliberate attempt to mislead the FDA should be considered as clearly a fraud as are attempts to mislead customers or other individuals");

of three years. 21 U.S.C. § 333(a)(2). Certain FDCA offenses that involve diversion of prescription drugs are ten year felonies. 21 U.S.C. § 333(b)(1). In addition, offenses involving the distribution of human growth hormone are punishable by up to five years in prison, 21 U.S.C. § 333(e)(1), or up to ten years if the offenses involve distribution to a person under 18 years of age. 21 U.S.C. § 333(e)(2).

FDCA crimes are governed by two sections of the guidelines, Sections 2B1.1 and 2N2.1. United States Sentencing Commission, Guidelines Manual, App. A (Nov. 2002). Section 2N2.1, entitled "Violations of Statutes and Regulations Dealing With Any Food, Drug, Biological Product, Device, Cosmetic, or Agricultural Product," applies to FDCA violations that do not involve fraud. The base offense level in Section 2N2.1 is 6, and there are no enhancements for specific offense characteristics. Accordingly, most sentences calculated under 2N2.1 are very low. A defendant in Criminal History Category I would have a guideline range of 0-6 months. Section 2N2.1 provides that, if the offense involved fraud, Section 2B1.1 ("Larceny, Embezzlement, and Other Forms of Theft; Property Damage or Destruction; Fraud and Deceit; Forgery; Offenses Involving Altered or Counterfeit Instruments Other than Counterfeit Bearer Obligations of the United States") applies. Section 2B1.1 applies to any fraudulent violation of the FDCA, regardless of whether the victim is a consumer or the government.⁴ Like Section 2N2.1, Section 2B1.1 provides for a base offense level of 6.⁵ Section 2B1.1, however, includes various enhancements for specific offense characteristics, including incremental increases of the base offense level for crimes involving pecuniary losses that exceed \$5,000.

United States v. Arlen, 947 F.2d 139, 143 (5th Cir. 1991) ("intent to defraud or mislead" can be established by showing that "the defendant intentionally violated § 331 with the specific intent to defraud or mislead an identifiable government agency"); United States v. Micheltree, 940 F.2d 1329, 1350-51 (10th Cir. 1991) ("intent to defraud or mislead" can be established by showing that "a defendant consciously sought to mislead drug regulatory authorities such as the FDA or a similar governmental agency"); United States v. Cambra, 933 F.2d 752, 755 (9th Cir. 1991) (intent to defraud or mislead is established by showing that the defendant tried to hide his activities from FDA); United States v. Bradshaw, 840 F.2d 871, 874 (11th Cir. 1988) ("intent to defraud or mislead" can be shown by evidence that the defendant took actions to avoid detection by FDA and state law enforcement authorities).

⁴ See United States v. Andersen, 45 F.3d 217 (7th Cir. 1995) (holding that fraud on a regulatory agency was sufficient to invoke Section 2F1.1, the predecessor guideline to 2B1.1); United States v. Arlen, 947 F.2d 139, 146 (5th Cir. 1991) (same). See also United States v. Mitcheltree, 940 F.2d 1329 (10th Cir. 1991); United States v. Cambra, 933 F.2d 752 (9th Cir. 1991); United States v. Bradshaw, 840 F.2d 871 (11th Cir. 1988).

⁵ The Commission has proposed an amendment to the guidelines that would increase the base offense level under Section 2B1.1 to 7 for offenses with statutory maximum terms of imprisonment of 20 years or more. This amendment would not affect FDCA offenses, which have statutory maximum prison sentences of between one and ten years.

Why the Existing Scheme is Inadequate

I. Counterfeiting

In recent years, FDA has seen an increase in counterfeit drug activity and a corresponding increase in counterfeit drug investigations.⁶ In fact, the number of counterfeit drug investigations conducted by FDA's Office of Criminal Investigations has quadrupled since 2000. The distribution of counterfeit drugs creates a significant public health risk. Counterfeit drugs, while often visually indistinguishable from genuine product, may contain no active ingredients, be sub- or super-potent, and may even contain bacterial contaminants or other harmful ingredients. Consumers who ingest or inject counterfeit drugs are at risk of therapeutic failures, exacerbation of health problems, and potentially disastrous adverse effects from toxic

⁶ It is unlawful to cause a drug to be counterfeit, to sell or dispense a counterfeit drug, and to hold a counterfeit drug for sale or dispensing. 21 U.S.C. §§ 331(i)(3) and 333(a). A counterfeit drug is defined as:

a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

21 U.S.C. § 321(g)(2).

ingredients. The dangers of counterfeiting are magnified by the fact that counterfeiting is most prevalent in expensive drugs, which often are intended for use by vulnerable patients, such as those suffering from cancer and AIDS.

Recent cases investigated by FDA's Office of Criminal Investigations demonstrate the dangers of counterfeiting. An investigation of counterfeit Procrit, an injectable drug used by cancer and AIDS patients, revealed that the counterfeit product contained non-sterile tap water, which could have caused a serious infection in immune-compromised patients. Another investigation involved counterfeit Serostim, a growth hormone used to treat wasting in AIDS patients. The counterfeit product contained no active ingredient.

The statutory maximum penalty for drug counterfeiting offenses committed with intent to defraud or mislead is three years in prison. 21 U.S.C. §§ 331(i) and 333(a)(2). Other violations are misdemeanors with a maximum penalty of one year in prison. 21 U.S.C. § 333(a)(1). Under the current guidelines, if FDA can identify the person who actually manufactured the counterfeit drugs, it is usually possible to obtain a significant sentence under Section 2B1.1, because it is not difficult to show fraud or significant pecuniary loss. This only applies when FDA convicts the actual counterfeiter, which rarely happens because many counterfeit drugs are received from unknown overseas sources.

Because of the difficulties in locating the actual counterfeiters, FDA's ability to prosecute those who facilitate the distribution of counterfeit drugs by turning a blind eye to the source of their drugs is critical to FDA's success in combating the counterfeit drug problem. However, as a practical matter, it is often difficult to prove that criminals who acted as purveyors, rather than manufacturers, of counterfeit drugs knew that the drugs were counterfeit and, therefore, to demonstrate that the offenses involved intent to defraud or mislead. Without proof of fraud, the base offense level for distributing counterfeit drugs in violation of 21 U.S.C. § 331(i)(3) is 6. USSG § 2N2.1. FDA believes that the guidelines should be amended to provide for more significant sentences for those offenders who claim ignorance that the prescription drugs they were distributing are counterfeit but who are, nevertheless, highly culpable because they failed to verify the legitimacy of the drugs under circumstances where the source was highly suspect.⁷

II. Prescription Drug Diversion

In addition to increasing penalties for counterfeiting violations, FDA believes that strengthening the guidelines for offenses involving prescription drug diversion should be a priority. Drug manufacturers typically distribute drugs to primary wholesale distributors (with whom they typically have contractual relationships) who, in turn, sell the drugs to retail

⁷ Those who distribute counterfeit drugs but act in good faith and have no reason to believe that the drugs are counterfeit are not subject to criminal penalties under the FDCA. See 21 U.S.C. § 333(c)(5).

pharmacies, hospitals, and health care entities that dispense the drugs to patients. However, a significant and increasing quantity of prescription drugs are handled by smaller, secondary wholesale distributors that generally are not authorized distributors for the manufacturer. Sometimes, these secondary wholesalers obtain their drugs from legitimate sources. For example, a secondary wholesaler can purchase drugs that are being sold at a discounted price because of a short expiration date, to reduce overstocked inventories, or to meet periodic corporate sales targets. Other sources are illegal: the drugs can be stolen; illegally purchased from hospitals, clinics, or charities; purchased on the street from Medicaid patients who choose profit over treatment; obtained from health care practitioners who sell drug samples provided at no cost to them by the manufacturer; or illegally imported from other countries where the drugs are sold at lower cost.

The illegal diversion of prescription drugs threatens the integrity of the nation's drug supply in several ways. Many secondary wholesalers operate outside the legitimate distribution system, do not have a license to engage in wholesale distribution of prescription drugs, and lack the training, facilities, and motivation to store and handle prescription drugs properly. Improper storage and handling of prescription drugs can affect the drug's potency, stability, and even effectiveness. In addition, diverted prescription drugs often are repackaged and relabeled to conceal that the drugs came from an illegal source. Relabeling removes the original expiration date, which can result in the dispensing of expired drugs to consumers. Relabeling also removes the lot number, which is critical to an effective recall if a problem with the drug is discovered. Sometimes drugs are repackaged into containers that bear the wrong drug name or the wrong strength.

In addition to these potential dangers, the very existence of an unregulated wholesale submarket provides a ready path by which counterfeit, adulterated and expired drugs can enter the distribution chain. Unscrupulous wholesalers are more concerned with their profits than the integrity of their suppliers and the purity of the products. Drug counterfeiters can easily find a corrupt purchaser that will turn a blind eye and ask no questions. Terrorists could also exploit the diversion market as a means to introduce tainted or poisoned prescription drugs into the marketplace. Once the drugs enter the secondary wholesale market, they eventually make their way to the shelves of local pharmacies, hospitals, and clinics, and are dispensed to unwitting and often vulnerable patients.

Congress recognized the dangers of prescription drug diversion and the secondary wholesale market when it enacted the Prescription Drug Marketing Act of 1987 ("PDMA") to deter prescription drug diversion.⁸ Congress found that the mere existence of the wholesale drug diversion market "prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases." H. Rep. No. 100-76 at 2 (1987).

⁸ Pub. L. No. 100-293, 102 Stat. 95 (1988), codified as amended at 21 U.S.C. §§ 331(t), 333(b), 353(c)-(e), and 381(d).

Congress concluded that the various forms of prescription drug diversion created an "unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers." Id.

The PDMA, as amended by the Prescription Drug Amendments of 1992, places strict controls on the distribution of prescription drugs and 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. Because of the seriousness of these offenses and the importance of protecting the integrity of the nation's prescription drug supply, Congress provided that these offenses are felonies upon a showing that the violations were done "knowingly" and without necessitating proof that the defendants acted with intent to defraud or mislead, as is required for most other FDCA felonies.⁹ And, unlike other FDCA violations that have a maximum penalty of three years in prison, Congress provided for a maximum prison sentence of ten years for these PDMA offenses¹⁰

⁹ The PDMA also criminalizes other conduct, such as the distribution of drug samples in violation of 21 U.S.C. § 353(d) and the failure to provide a pedigree prior to the wholesale distribution of drugs in violation of 21 U.S.C. § 353(e)(1)(A). These other PDMA offenses carry the same penalty as traditional FDCA offenses under 21 U.S.C. § 333(a).

¹⁰ The enhanced penalty provisions for certain PDMA offenses are set forth at 21 U.S.C. § 333(b)(1), which provides:

any person who violates section 331(t) by-

(A) knowingly importing a drug in violation of section 381(d)(1) of this title,

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of 353(c)(1) of this title,

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or

(D) knowingly distributing drugs in violation of section 353(e)(2)(A) of this title,

shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.

Despite Congress's express mandate that these PDMA violations be punished more severely than other FDCA violations, the guidelines treat all FDCA violations the same and provide for a base offense level of 6.¹¹ The higher maximum penalties for these PDMA offenses come into play *only* when there is evidence of fraud *and* significant pecuniary loss under Section 2B1.1(b)(1). In FDA's view, the current guidelines do not carry out the intention of Congress to provide for significant penalties without requiring a showing of fraud.

These guidelines would not be problematic if these PDMA offenses frequently involved both fraud and significant pecuniary loss. However, FDA's experience has shown otherwise. One of the most frequently charged PDMA violations is the distribution by unlicensed wholesalers of prescription drugs in violation of 21 U.S.C. §§ 331(t), 333(b)(1)(D), and 353(e)(2)(A). In many unlicensed wholesale distribution cases, the distribution takes place under circumstances where both parties to the transaction clearly are aware of the illicit nature of the distribution - either because the transaction takes place on the street or because the price of the drugs is so low. Thus, it is often difficult to prove that the seller's failure to obtain a state license amounts to a fraud on the immediate purchaser(s) of the drugs. It is equally difficult to show that the unlicensed transaction amounted to a fraud on the ultimate consumers, because the lack of a state license has no direct effect on consumers. And, unless there is evidence that the defendant took affirmative steps to conceal his conduct from FDA or state licensing authorities, it is difficult to prove a fraud on the government. Even assuming that the government could persuade the sentencing court that the offense involved fraud, it is difficult to quantify the loss involved in unlicensed wholesale drug distribution, because the offense generally does not involve a traceable pecuniary loss to anyone. Nevertheless, the lack of a license should be treated as a serious public health violation because of the dangers created by the distribution of prescription drugs by those without proper credentials.

The lack of stricter guidelines for these PDMA offenses undermines FDA's ability to protect the integrity of the prescription drug distribution system. These PDMA offenses are FDA's primary tool for combating prescription drug diversion and counterfeiting. FDA urges the Commission to amend the guidelines to treat these PDMA offenses as serious offenses warranting prison time. As explained, the very existence of this illegal diversion market creates numerous opportunities for substandard drugs to enter the marketplace and presents a significant risk to the public

¹¹ By way of contrast, other statutes for which Congress prescribed a ten-year statutory maximum prison sentence are treated more strictly by the guidelines. For example, under 18 U.S.C. § 1365(a), it is a crime, punishable by up to ten years in prison, to tamper with a consumer product with reckless disregard for risk of death or bodily injury. The corresponding guideline provides for a base offense level of 25, as compared to a base offense level of 6 for the PDMA offenses. USSG §§ 2N1.1(a) and 2N2.1. Also, violations of 18 U.S.C. § 1505 (obstruction of justice), which have a statutory maximum term of imprisonment of only five years in prison, currently have a base offense level of 12, twice that of PDMA offenses. USSG § 2J1.2(a).

health, regardless of whether the government can prove in a particular case that the diverted drugs were actually counterfeit, adulterated, or misbranded.

III. Other FDCA Violations

In addition to counterfeiting and prescription drug diversion, the FDCA prohibits a wide range of other conduct that affects the public health. 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.

The current guidelines treat FDCA violations as relatively minor regulatory offenses with a base offense level of 6, with no enhancements for specific offense characteristics in the primary guideline. By contrast, the guidelines provide for a base offense level of 12 for tampering with intent to injure a *business* in violation of 18 U.S.C. § 1365(b). This tampering offense, like most FDCA offenses, has a statutory maximum prison term of three years. In fact, the guidelines treat food and drug offenses on par with odometer fraud, which also has a base offense level of 6 and a cross-reference to 2B1.1.¹² USSG § 2N3.1. FDCA offenses, which involve danger to the public health, should be treated more seriously than odometer fraud, an economic crime, and should have a higher base offense level than 6.¹³ The current guidelines, however, treat potential monetary harm more seriously than potential widespread harm to victim's health posed by FDCA crimes.

The problem with the low base offense level is compounded by the lack of enhancements for specific offense characteristics under Section 2N2.1. FDCA cases frequently arise in which prosecutors cannot prove intent to defraud or mislead to establish felony liability. In these cases, the sentence will be governed by Section 2N2.1, and prosecutors are likely to decline the case because the base offense level is 6 and there are no enhancements for specific offense characteristics. Despite the lack of fraud, the conduct addressed in these cases fully warrants

¹² Odometer fraud also has a statutory maximum sentence of three years in prison. 49 U.S.C. § 32709(b).

¹³ Under the guidelines, even offenses involving fish, wildlife, and plants, which also have a base offense level of 6, have several specific offense characteristics that increase the offense level by as much as four levels. USSG § 2Q2.1. Most of the offenses covered by this guideline have lower statutory maximum sentences than FDCA offenses, and it would seem that the American consumers would merit as much protection as endangered species, yet the guidelines appear to treat fish, wildlife, and plant offenses more seriously.

prosecutorial attention and meaningful redress by the courts. FDA-regulated products are vital to society, and consumers expect, even assume, that the products will be safe, pure, and effective. The current guidelines should be amended to provide for stiffer sentences for offenses that, while not involving fraud, involve a cognizable risk to the public health.

In addition, the cross-reference in Section 2N2.1 to Section 2B1.1 is not satisfactory in all cases because the latter section is intended to address economic fraud crimes.¹⁴ The application of Section 2B1.1 is sufficient for crimes where the major offense conduct involves only pecuniary harm. FDCA offenses often cause pecuniary harm, but the major factor in determining the sentencing range should be the degree of risk to the public health involved in the offense, not the pecuniary harm. This is especially true when the defendant has evinced a clear disregard for the welfare of consumers but has caused minimal or no pecuniary harm.

Also, when the offense involves fraud on a government agency, the determination of loss under Section 2B1.1 states that gain should be used as an alternative measure of loss only if there is a loss but the loss "reasonably cannot be determined." USSG § 2B1.1, comment. (n.2). In FDA cases, fraud on a government agency is generally based on the defendant taking affirmative steps to hide his or her conduct from the agency. In such cases, there typically is no pecuniary loss to the government, but there is a risk of harm to the public health. Some courts have departed upward based on the substantial non-monetary harm caused or risked by the offense.¹⁵ See USSG § 2B1.1, comment, (n.15). Although the upward departure may result in an appropriate sentence for the defendant's conduct, there should be a specific enhancement in the guidelines, not just a provision for upward departure, to account for the significant but non-pecuniary risks frequently posed by FDCA offenses.

One final issue warrants mentioning. Under 21 U.S.C. § 333(e), it is unlawful knowingly to distribute, or to possess with intent to distribute, human growth hormone for any use not approved by FDA. The statutory maximum penalty for violating this provision is five years in prison. 21 U.S.C. § 333(e)(1). If, however, the offense involves distribution to a person under age 18, the statutory maximum increases to ten years in prison. The Commission has not yet

¹⁴ Section 2B1.1 was created to "provide similar treatment for similar offenses for which pecuniary harm is a major factor in determining the offense level and, therefore, decrease unwarranted sentencing disparity that may be caused by undue complexity in the guidelines." USSG App. C, amend 617.

¹⁵ See United States v. Kimball, 291 F.3d 726 (11th Cir. 2002) (defendant was convicted of offenses involving the distribution prescription drugs without a prescription with intent to defraud or mislead government agencies; the district court found no loss to the government and declined to use the defendant's gain as an alternative for loss; the district court departed upward because the guidelines did not adequately account for the non-monetary loss caused by the risk of public harm; the Court of Appeals affirmed).

promulgated a guideline to cover these human growth hormone offenses. See USSG § 2N2.1, comment., (n.4). As a result, United States Attorney's Offices are reluctant to prosecute these offenses, because it is unclear how the offenses will be treated under the guidelines. FDA has noticed an increase in the distribution of human growth hormone for unapproved uses and requests that the Commission promulgate a guideline to address such offenses.

Proposals for A New Sentencing Regime

To account for the variety of FDCA crimes and the different statutory maximum prison sentences for certain PDMA and human growth hormone offenses, FDA believes that the Commission should amend the guidelines for FDCA offenses to provide more flexible, more realistic, and more effective sentencing options. Preliminary suggestions include:

- providing a base offense level of 10 for felony offenses with a three year statutory maximum (those governed by 21 U.S.C. § 333(a)(2));
- providing a base offense level of 12 for PDMA offenses with a ten year statutory maximum (those governed by 21 U.S.C. § 333(b)(1));
- adding specific offense characteristics to Section 2N2.1, including enhancements for offenses that involve reckless or intentional conduct that presents a potential risk to the public health and a specific enhancement, providing for a minimum offense level of 12, for offenses involving the distribution or manufacture of counterfeit drugs;
- revising the enhancement at Section 2B1.1(b)(11) for offenses involving conscious or reckless risk of serious bodily injury to provide that the enhancement applies to defendants who knowingly divert prescription drugs in violation of the PDMA or distribute counterfeit drugs in violation of 21 U.S.C. § 331(i)(3);
- revising Section 2B1.1 to provide an increase in the offense level to a minimum of 12 for FDCA offenses that involve fraud but do not involve significant monetary harm
- revising the application notes to Section 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 purported value of the product;
- promulgating a guideline to address human growth hormone offenses in violation of 21 U.S.C. § 333(e), with a starting offense level of 10, with incremental enhancements based on the amount of human growth hormone involved in the offense, and an additional enhancement for offenses that involve a person under 18 years of age;

providing enhancements for terrorism-related offenses, including the use of select agents to adulterate FDA-regulated products or the use of proceeds from FDCA offenses to finance terrorist organizations or criminal enterprises.

Conclusion

For the above reasons, the FDA believes that amending the guidelines applicable to FDCA offenses should be a Commission priority for the amendment cycle ending May 1, 2004. At the Commission's request, FDA will provide any necessary assistance and input to help the Commission draft appropriate amendments to strengthen FDA's criminal enforcement and ensure adequate protection of the public health. If you have any questions regarding this matter, please contact Associate Chief Counsel Sarah Hawkins at (301) 827-1130.

Sincerely,

A handwritten signature in black ink, appearing to read "John M. Taylor, III", with a long horizontal flourish extending to the right.

John M. Taylor, III
Associate Commissioner for Regulatory Affairs

cc: Michael Courlander, U.S. Sentencing Commission