



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

August 11, 2005

Michael Courlander
Public Affairs Officer
United States Sentencing Commission
One Columbus Circle, N.E.
Suite 2-500, South Lobby
Washington, DC 20002-8002

Attention: Public Affairs - Priorities Comment

Dear Mr. Courlander:

As you may recall, I wrote a detailed letter at this time last year setting forth the reasons that the United States Food and Drug Administration (FDA) believes that the current sentencing guidelines are not adequate to address serious criminal violations of the Federal Food, Drug, and Cosmetic Act (FDCA). It is my understanding that the United States Sentencing Commission initially agreed to consider amendments to address FDA's concerns but, as a result of the United States Supreme Court's decision in United States v. Booker, 543 U.S. ____ (2005), the Commission understandably postponed its work on this and other important issues. I am writing again because FDA remains concerned that the sentencing guidelines are too lenient for certain violations of the FDCA and are hampering FDA's efforts to effectively combat this dangerous criminal conduct. Rather than restating FDA's concerns at length, I am attaching a copy of last year's letter, which describes the public health significance of FDA's criminal cases, identifies particular problems with the guidelines, and suggests amendments to address those problems.

FDA's concerns are even more pressing today. During the past year, FDA's Office of Criminal Investigations has seen significant increases in the number of investigations relating to counterfeit drugs, prescription drug diversion, human growth hormone, and other offenses that pose serious threats to the public health. This trend is likely to continue unless the relevant guideline is amended to deter criminal offenders by imposing more significant sentences for these violations. Accordingly, I respectfully request that the Commission add to its list of priorities for the amendment cycle ending May 1, 2006, the review and amendment of the sentencing guidelines for certain FDCA violations, as set forth in the attached letter.

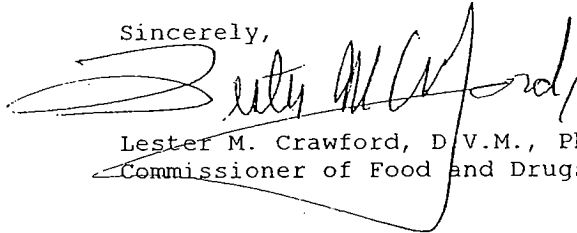
I would like to address briefly what I understand to be one of the Commission's priorities for this amendment cycle: consideration of amendments to increase the penalties for offenses involving anabolic steroids in accordance with the Anabolic Steroid Control Act, Pub. L. 108-358. Although anabolic steroids are now regulated by the Drug Enforcement Administration, FDA believes that increasing the guidelines for anabolic steroid offenses without simultaneously promulgating a guideline to address human growth hormone offenses would significantly undermine Congress' efforts to crack down on the use of dangerous performance-enhancing drugs.

Michael Courlander
August 11, 2005
Page 2

In FDA's experience, illegal use of anabolic steroids to enhance athletic performance is often accompanied by illegal use of human growth hormone. Title 21, United States Code, Section 333(e) prohibits the use of human growth hormone for any use not approved by FDA. As detailed on page 5 of the attached letter, the Commission has not yet promulgated a guideline to address human growth hormone offenses. FDA believes that it is critical that the Commission, as part of its review of the guidelines for anabolic steroid offenses, review and amend the guidelines to address human growth hormone offenses in a manner that reflects the serious nature of these offenses. At the Commission's request, FDA will provide additional information concerning the frequent association of illegal use of human growth hormone and anabolic steroids, the dangers associated with the illegal use of human growth hormone, and any other information that would assist the Commission.

In closing, FDA remains committed to seeking appropriate amendments to the sentencing guidelines and is available to provide assistance and additional information at the Commission's request. Please contact Associate Chief Counsel Sarah Hawkins by telephone at (301) 827-1130 or by email at sarah.hawkins@fda.gov if you have any questions or if there is any assistance that FDA can provide regarding these matters.

Sincerely,



Lester M. Crawford, D.V.M., Ph.D.
Commissioner of Food and Drugs

cc: Margaret O'K. Glavin, Associate Commissioner for Regulatory Affairs, FDA
Terry Vermillion, Director, Office of Criminal Investigations, FDA
Sheldon Bradshaw, Chief Counsel, FDA
Sarah Hawkins, Associate Chief Counsel, FDA
Michelle Morales, Office of Policy and Legislation, USDOJ
Eugene Thirolf, Office of Consumer Litigation, USODJ



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

July 27, 2004

Michael Courlander
Public Affairs Officer
United States Sentencing Commission
One Columbus Circle, N.E.
Suite 2-500, South Lobby
Washington, D.C. 20002-8002

Attention: Public Affairs-Priorities Comment

Dear Mr. Courlander:

I am writing on behalf of the U.S. Food and Drug Administration (FDA) to respectfully request that the United States Sentencing Commission amend its list of proposed priorities to include consideration of amendments to the sentencing guidelines that govern certain violations of the Federal Food, Drug, and Cosmetic Act (FDCA). This letter reiterates many of the points made by Associate Commissioner John Taylor in his letter to the Commission dated July 31, 2003. As explained in more detail below, FDA believes that the current guideline at Section 2N2.1 is too lenient and does not adequately address some serious criminal violations of the FDCA. In this letter, I will discuss the public health significance of FDA's criminal enforcement efforts, identify specific problem areas in the guideline, and suggest amendments.

FDA regulates the manufacture, labeling, and distribution of food, human and animal drugs, medical devices, and biologics. These products, which collectively account for approximately 25 percent of every dollar spent by American consumers, are critical to everyday life in our country. Physicians and consumers rightfully expect that the products they dispense and consume will be safe and effective and will bear adequate and accurate labeling.

In support of its public health mission, FDA presents a wide variety of criminal cases for prosecution. Many of them involve serious offenses with the potential to cause great harm to large segments of our society. These cases include the sale of unapproved, ineffective, and sometimes harmful drugs and devices to treat HIV, cancer, arthritis, and other serious diseases; failure by drug and device manufacturers to report product failures and adverse events; and the distribution of food contaminated with potentially life-threatening bacteria. Several recent investigations have involved the sale of products marketed as "all natural" dietary supplements that contained significant amounts of the active ingredients of prescriptions drugs, such as Viagra and Cialis, or the banned substance ephedrine hydrochloride, without declaring these ingredients on the label. FDA also investigates the illegal sale of dangerous substances as street drug alternatives and "rave" drugs to teenagers for recreational use--which often results in deaths, sexual assaults, and medical complications--and the sale of dangerous designer steroids to enhance athletic performance.

Also, a significant number of FDA's criminal investigations involve unlawful wholesale distribution and diversion of prescription drugs. Frequently, these cases involve the distribution of prescription drugs from unknown sources that are repackaged and relabeled to appear to be genuine, FDA-approved products. Recent cases targeted wholesale distributors of drugs intended to treat schizophrenia and bipolar disorder. Illegal repackaging resulted in the bottles containing different drugs or different strength drugs than stated on the label. Another investigation involved the sale of counterfeit Pergonal and Metrodin (injectable fertility drugs) tainted with active bacteria and endotoxins. Prescription drug diversion offenses can result in the dispensing of misbranded and otherwise substandard prescription drugs to consumers, provide avenues for counterfeit drugs to enter the marketplace, and thwart the ability of the manufacturers and public health authorities to conduct effective recalls.

Such offenses undermine the safety and integrity of the Nation's supply of food, drugs, medical devices, and biologics. In the case of counterfeit, misbranded, unapproved, and adulterated drugs, unsuspecting patients may be harmed by the very medications they are taking to treat their diseases. In these cases, consumers are not getting the health benefits they rightfully expect from their medications. For example, their blood pressure or cholesterol may not be controlled or their depression may not be treated because their medications are counterfeit. Or they may be unwittingly taking unapproved drugs that are not therapeutically equivalent to the U.S.-approved products proven to provide the claimed benefits that consumers have come to expect from their drugs. In other instances, patients facing the hopelessness of a debilitating or terminal illness may forego FDA-approved treatments in favor of unapproved and ineffective treatments. We are fearful that unless the guidelines are amended to treat these types of offenses more seriously than is currently the case, criminal offenders will not be deterred. The high profit margin often outweighs the minimal sentences that may be imposed when an offender is prosecuted.

In general, any violation of the FDCA is a misdemeanor punishable, without the need to show criminal intent, by a maximum prison term of 1 year under 21 U.S.C. § 333(a)(1). A violation of the FDCA 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 3 years under 21 U.S.C. § 333(a)(2). Certain FDCA offenses that involve prescription drugs are 10-year felonies under 21 U.S.C. § 333(b)(1). Offenses involving the distribution of human growth hormone are punishable by up to 5 years in prison under 21 U.S.C. § 333(e)(1), or up to 10 years if the offenses involve distribution to a person under 18 years of age under 21 U.S.C. § 333(e)(2).

FDCA offenses are governed by two sections of the guidelines. Section 2N2.1 provides for a base offense level of six, with no enhancements for specific offense characteristics. Section 2B1.1 applies if the offense involves fraud. This section also provides for a base

offense level of six but includes enhancements for specific offense characteristics, most notably incremental increases of the base level for crimes involving losses that exceed \$5,000.

FDA believes that the primary guideline, Section 2N2.1, inappropriately treats some FDCA violations as minor regulatory offenses. This guideline applies to offenses with statutory maximum sentences ranging from 1 to 10 years. However, as noted, Section 2N2.1 does not include enhancements for specific offense characteristics to account for the wide range of offenses that it addresses. In addition, Section 2N2.1 does not provide for any enhancements to address the public health purposes of the FDCA. Therefore, FDA believes Section 2N2.1 should be amended to ensure that all criminals who endanger the public health by violating the FDCA receive appropriate punishment.

Particular Concerns with the Existing Guidelines and Suggested Amendments

I. Offenses with Higher Statutory Penalties

Most violations of the FDCA are felonies with a 3-year maximum sentence if the offense is committed with an "intent to defraud or mislead." However, certain FDCA offenses are felonies whether or not the offense involves fraudulent intent, and some of these offenses have statutory maximum sentences that exceed 3 years. The current guideline at Section 2N2.1 fails to account for these offenses that warrant more significant penalties without requiring a showing of fraud.

A. Certain Prescription Drug Marketing Act Offenses

The Prescription Drug Marketing Act of 1987 (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 [see 21 U.S.C. §§ 331(t), 353(c), 353(e)(2)(A), and 381(d)]. Congress enacted these prohibitions because it found that such conduct created, as stated in H. Rep. No. 100-76 at 2 (1987), "an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers."

These PDMA prohibitions are an important tool to combat the large-scale distribution of counterfeit or substandard prescription drugs. Unlicensed wholesale distributors of prescription drugs are less likely than legitimate licensed wholesalers to store and handle prescription drugs properly and are more likely to purchase prescription drugs from disreputable sources that sell counterfeit, misbranded, adulterated, or expired drugs. Sellers of prescription drug samples typically repackage the drugs to remove any indication that the drugs are not intended for sale and, in the process, mislabel the drugs with inaccurate lot numbers, expiration dates, and, in some cases, the wrong drug name or strength.

Because of the public health risk posed by these PDMA offenses and the importance of protecting the integrity of the Nation's prescription drug supply, Congress made these offenses felonies without requiring proof that the defendants acted with intent to defraud or mislead, as is required for most other FDCA felonies. And, unlike other FDCA violations that have a maximum penalty of 3 years in prison, Congress provided for a maximum prison sentence of 10 years for these PDMA offenses [21 U.S.C. § 333(b)(1)].

The guidelines, however, do not distinguish between these PDMA offenses and other FDCA violations under Section 2N2.1. The guidelines treat all FDCA offenses the same and provide for a base offense level of six. The higher maximum penalties for these PDMA offenses generally come into play *only* when there is evidence of fraud *and* significant pecuniary loss under Section 2B1.1(b)(1). It is difficult to prove fraud because buyers and sellers are often complicit in the offense, and, even when the government can prove fraud, it is difficult to demonstrate substantial pecuniary loss, because the buyers and sellers involved in the fraud often do not retain records pertaining to the illegal drug distributions.

In FDA's view, the current guidelines do not carry out the intention of Congress: to provide significant penalties for these PDMA offenses without requiring a showing of fraud. FDA believes that an amendment to Section 2N2.1 to provide for a higher base offense level (e.g., 12-14) for these PDMA offenses, with incremental increases based on the quantity or dollar value of the drugs involved in the offense, would better reflect congressional intent and significantly increase the effectiveness of the PDMA as a means to protect the integrity of the Nation's prescription drug supply.¹

B. Second Offense Felonies

Under 21 U.S.C. § 333(a)(2), a second conviction for violating the FDCA is a felony punishable by up to 3 years imprisonment, even absent a showing of intent to defraud or mislead. Without a showing of fraud, however, the prior FDCA conviction will likely have no effect under the current guidelines because it will not have resulted in a sentence of imprisonment (see U.S.S.G. § 4A1.1). The prior FDCA conviction probably would not increase a defendant's criminal history category, and Section 2N2.1 does not provide for any increase of the base offense level for a second FDCA conviction, even though Congress made a second FDCA offense a felony.

The guidelines should be amended to include a specific offense characteristic under Section 2N2.1 for repeat FDCA offenders. FDA believes that an increase of six levels for a prior FDCA

¹ To give greater effect to this and the other suggested amendments, we believe that Section 2N2.1(b)(1) also should be amended to provide that Section 2B1.1 would apply only if the resulting offense level would be greater than the offense level under Section 2N2.1.

conviction, with an increase of two levels for each additional unrelated prior FDCA conviction, would be appropriate.

C. Human Growth Hormone Offenses

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 5 years in prison under 21 U.S.C. § 333(e)(1). When the offense involves distribution to a person under age 18, the statutory maximum increases to 10 years in prison under 21 U.S.C. § 333(e)(2). The Commission has not yet promulgated a guideline to cover these human growth hormone offenses (see U.S.S.G. § 2N2.1, comment (n.4)). As a result, it is unclear how the offenses will be treated under the guidelines. This lack of clarity undermines the goals of uniformity, transparency, and deterrence. In recent years, FDA has investigated an increasing number of cases involving the distribution of human growth hormone for unapproved uses. We request that the Commission promulgate a guideline to address such offenses. An amendment to Section 2N2.1 that provides for a higher base offense level [e.g., 12-14, for violations of 21 U.S.C. § 333(e)] with incremental enhancements based on the quantity or dollar value of human growth hormone involved in the offense, and a separate enhancement for offenses that involve a person under 18 years of age, would adequately address the conduct.

II. Offenses that Do Not Involve Fraud

FDCA cases frequently arise in which prosecutors cannot prove intent to defraud or mislead to establish felony liability. Misdemeanor violations of the FDCA encompass a wide range of conduct, from record-keeping offenses to the willful distribution of dangerous products that could seriously injure or kill consumers. Section 2N2.1, which provides for a base offense level of six with no enhancements, is inadequate to address the wide-ranging degrees of culpability that may occur in FDCA misdemeanors. Despite the lack of provable fraud, the conduct addressed in most FDCA misdemeanor prosecutions warrants more significant punishment than is available under the current guidelines, either because of the defendant's state of mind or a significant risk to the public health, or both.

An example is a wholesale distributor who sells counterfeit or diverted prescription drugs but claims not to have known that the drugs were counterfeit or diverted. In such cases, it is often difficult to prove that the distributor acted with intent to defraud and mislead, even though such distributors often deliberately choose not to verify the legitimacy of the drugs under circumstances where the source is highly suspicious.² This lack of fraud (or difficulty proving it)

² If the distributor acted in good faith and had no reason to believe that the drugs were counterfeit, he would not be subject to criminal penalties under the FDCA [see 21 U.S.C. § 333(c)(5)].

in no way undercuts the potentially serious public health consequences caused by a wholesale distributor who recklessly distributes drugs of unknown origin to an unsuspecting public. The distributor's willful blindness endangers the public by ignoring the risk that counterfeit or otherwise substandard prescription drugs may enter the retail market.

Another type of misdemeanor offense that we believe warrants more significant punishment than is available under the current guideline is the distribution of dangerous or ineffective drugs for the treatment of disease. Even when these offenses do not involve fraud, they often involve substantial risk to the public health, take advantage of patients who are desperate for a cure, and are perpetrated by defendants who are aware that their conduct is unlawful. For example, FDA's Office of Criminal Investigations has investigated the illegal sale of DNP (a notoriously deadly product commonly used as a pesticide) as a weight-loss drug and cancer treatment. If a defendant sells DNP openly, it may be difficult to prove fraud sufficient to establish felony liability, even in those cases where the defendant is aware of the illegality of his conduct.

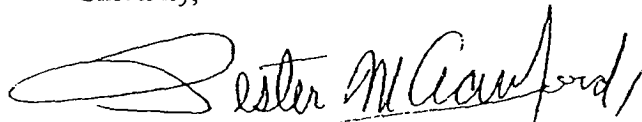
In the foregoing types of cases, the sentence will be governed by Section 2N2.1, with a base offense level of six and no enhancements for specific offense characteristics. FDA believes that Section 2N2.1 should be amended to provide for stiffer sentences for misdemeanor offenses that --while not involving demonstrable fraud--involve reckless, knowing, or willful conduct, a significant risk to the public health, or both. The amendments should enhance the offense level based on the defendant's level of criminal intent by, for example, enhancing the offense level for reckless, knowing, and willful conduct. These enhancements would serve to distinguish knowing, reckless, and willful offenses from those involving mere negligence or no criminal intent whatsoever.

In addition, enhancements based on the risk of harm created by the offense conduct, similar to the enhancements for likelihood of serious bodily injury used in the guidelines for environmental offenses, would be appropriate in certain cases [see, e.g., U.S.S.G. § 2Q1.3(b)(2)]. Enhancements for risk of harm or serious bodily injury would serve to distinguish mere technical, regulatory offenses from those with the potential to cause significant harm to the American public. Appropriate amendments would ensure that misdemeanor offenses involving, for example, the distribution of counterfeit drugs that lack active ingredients or the sale of ineffective or toxic drugs for the treatment of cancer would be treated more seriously than offenses involving mere record-keeping or regulatory violations that pose no cognizable risk to the public health. The amendments could provide for different levels of enhancement depending on the nature of the risk and the number of people placed at risk. Such enhancements, together with enhancements based on the defendant's culpable state of mind, would help provide an appropriate range of punishment for the wide range of conduct that falls under the misdemeanor provisions of the FDCA.

Conclusion

For the above reasons, FDA believes that the guidelines applicable to FDCA offenses should be amended to establish offense levels that reflect the serious nature of the conduct, promote deterrence, and address offenses with differing levels of culpability and disregard for the public health. At the Commission's request, FDA will provide any assistance and input to help draft appropriate amendments. If you have any questions regarding this matter, please contact Associate Chief Counsel Sarah Hawkins by telephone at (301) 827-1130 or by e-mail at sarah.hawkins@fda.gov.

Sincerely,



Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs

cc: John M. Taylor, III, Associate Commissioner for Regulatory Affairs, FDA
Terry Vermillion, Director, Office of Criminal Investigations, FDA
Sarah Hawkins, Associate Chief Counsel, FDA
Jonathan Wroblewski, Office of Policy and Legislation, DOJ
Eugene Thirolf, Office of Consumer Litigation, DOJ