



March 28, 2008

United States Sentencing Commission
Attn: Public Affairs
One Columbus Circle, N.E.
Suite 2-500
Washington D.C. 20002-8002

**Re: Comments Concerning January 28, 2008 Federal Register Notice
Regarding Miscellaneous Food and Drug Offenses**

INTRODUCTION

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is pleased to submit these comments in response to the United States Sentencing Commission's January 28, 2008 Federal Register Notice ("Notice") regarding possible amendments to the Sentencing Guidelines concerning miscellaneous food and drug offenses. 73 Fed. Reg. 4931-35 (2008). PhRMA is a voluntary, nonprofit association that represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. Member companies are leading the way in the search for new cures. In the past decade alone, PhRMA members invested approximately \$300 billion to develop new medicines. *See* PhRMA, *Pharmaceutical Industry Profile 2007* at 42 (2007).

The Notice proposes a number of amendments with regard to Federal Food, Drug, and Cosmetic Act (FDC Act) offenses. Many of these proposals relate to the sentencing of human growth hormone (hGH) offenses. In addition, the Commission has requested comments regarding a few other FDC Act matters, including whether it should alter Guideline 2N2.1 if it does not adequately address the statutes referenced in that Guideline, such as the FDC Act.

SUMMARY OF PhRMA'S POSITIONS

In general, PhRMA supports a rigorous sentencing scheme whereby the government can help protect the public health and safety by employing, when appropriate, criminal sanctions against persons found to have violated the FDC Act. We believe that, with one exception discussed below, Sentencing Guideline 2N2.1 does not require revision at this time, based on the available evidence. Indeed, to the best of our knowledge, not a single federal court has expressed concern about this Guideline in any case. Should the Commission deem further action is warranted, PhRMA supports the

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formation of a working group to study these issues and to make recommendations to the Commission that are supported by a reasoned basis for any suggested revisions. Finally, we suggest, consistent with prior FDA recommendations, that the Commission take this opportunity to strengthen the Guidelines as they relate to pharmaceutical counterfeiting offenses.

I. PHARMACEUTICAL COUNTERFEITING SENTENCES SHOULD BE SIGNIFICANTLY INCREASED

Consistent with prior recommendations of the Food and Drug Administration (FDA) and given the increasing public health risk posed by counterfeit pharmaceuticals, PhRMA believes that criminal sentences for counterfeiting should be significantly increased. *See* Combating Counterfeit Drugs, A Report of the Food and Drug Administration, February 2004, at iii, 18-19. Sentences should be sufficient to deter counterfeiting activities, particularly by organized crime.¹ As recognized by Congress² and FDA, counterfeit drugs pose a significant risk to the public health and safety.³ In

¹ While PhRMA believes that the vast majority of counterfeit drug convictions are currently sentenced under the § 2B1.1 Guideline, there are misdemeanor convictions – whether by plea or following a trial -- which are possible candidates for sentencing under Guideline 2N2.1. Accordingly, we believe an amendment to § 2N2.1 is appropriate for drug counterfeiting cases. *See, e.g.*, FDA's July 27, 2004 letter to the Commission at 5-6 (discussing the need for increased penalties under § 2N2.1 in a hypothetical case involving "a wholesale distributor who sells counterfeit . . . prescription drugs but claims not to have known . . .").

² *See, e.g.*, 21 U.S.C. § 355e(c) ("The Secretary shall expand and enhance the resources and facilities of agency components of the Food and Drug Administration involved with regulatory and criminal enforcement of this chapter to secure the drug supply chain against counterfeit . . . drugs . . . from domestic and foreign sources."); *see also* Feb. 13, 2008 Statement of FDA Associate Commissioner William McConagha at 8.

³ *See* FDA August 22, 2007 letter to the Commission at 2 (discussing the risk to public health from counterfeit drugs in connection with the Prescription Drug Marketing Act); FDA July 27, 2004 letter at 2 ("For example, their blood pressure or cholesterol may not be controlled or their depression may not be treated because their medications are counterfeit."); Statement of William McConagha at 13 ("Congress was also concerned with the distribution of . . . counterfeit drugs to American consumers. Defendants who introduce drugs in these categories 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 [FDC Act]. Therefore, FDA believes that enhancement for the distribution of . . . counterfeit drugs is appropriate."); FDA August 29, 2006 letter to the Commission at 1 (same).

fact, worldwide counterfeit drug sales are estimated to reach \$75 billion by 2010.⁴ PhRMA agrees with FDA that the serious public health risks posed by counterfeit drugs warrant tougher criminal penalties. In the Final Report of the FDA's Counterfeit Drug Task Force, the Agency noted that: "[t]here was overwhelming support and unanimous agreement [in the public comments] that higher penalties for counterfeiting are needed" to deter drug counterfeiters. *See Combating Counterfeit Drugs, A Report of the Food and Drug Administration* 19 (2004). FDA further noted that:

Current sentencing guidelines for counterfeit drug distribution are not commensurate with the public health threat posed by this criminal activity and strengthening the guidelines should help deter such conduct in the first instance. Despite the significant threat to public health posed by counterfeit drug products, current law provides penalties far below the level of some purely economic crimes. For example, counterfeiting a prescription drug label (bearing a registered trademark) is punishable by up to ten years in prison, while counterfeiting the drug itself is punishable by a maximum of only three years in prison. Therefore, FDA plans to continue to pursue its request that the United States Sentencing Commission consider amending the sentencing guidelines to substantially increase criminal penalties for manufacturing and distributing counterfeit drug products and to specifically provide for enhanced penalties based on the level of risk to the public health involved in the offense.

Id.

While PhRMA appreciates the increased attention and resources that FDA has devoted to pharmaceutical counterfeiting in the early 2000s,⁵ we believe more can and should be done in this area, particularly because FDA cannot commit unlimited resources to counterfeiting cases. Based on a limited review of publicly available FDA reports on sentences imposed following criminal convictions in drug counterfeiting cases, and acknowledging that PhRMA does not know the particulars of the cases referenced below, we submit that the sentences imposed in these cases do not appear to reflect the seriousness of the public health threat posed by counterfeit drugs. A few examples appear below:

1. In March 2005, a defendant who admitted that he conspired to import thousands of counterfeit prescription drug tablets into the United

⁴ WHO Fact Sheet No. 275, Nov. 14, 2006, *available at*:
<http://www.who.int/mediacentre/factsheets/fs275/en/index.html>.

⁵ <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html> (showing that FDA increased the number of counterfeit cases it opened in a year from six (6) in 2000, to fifty-eight (58) in 2004).

States was sentenced to 18 months in prison, followed by 3 years probation, and was fined \$6,000.⁶

2. In a case involving a counterfeit birth control patch with no active ingredient, Robert Lawrence was sentenced in February 2006, to 24 months probation and ordered to forfeit \$75,000 in assets. The defendant grossed approximately \$25 million per year from the criminal scheme.⁷

3. In September 2004, Louis Urbina was sentenced to 10 months incarceration and 1 year probation in a case involving counterfeiting two prescription drugs.⁸

4. In October 2004, an Alabama drug wholesaler was sentenced to 5 years probation and fined \$24,000 in connection with its conviction for selling counterfeit drugs.⁹

Based on the serious public health risks posed by counterfeit drugs, PhRMA recommends that the Commission adopt the following three amendments to the Sentencing Guidelines as soon as possible:

I. Add at the end of 2N2.1(a) the following:

“If the offense concerned a violation of 21 U.S.C. § 331(i) (relating to counterfeit drugs), or any other offense relating to counterfeit drugs, increase the base offense level by six (6) levels.”

II. Under the “Cross References” in 2N2.1 add the following:

“(3) If the offense concerned counterfeit goods, apply § 2B5.3 (Criminal Infringement of Copyright or Trademark) if the resulting offense level is greater than that determined above.”

⁶ FDA, COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION ANNUAL UPDATE (2005), <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html>.

⁷ 2006 FDA ENFORCEMENT STORY 6-13, http://www.fda.gov/ora/about/enf_story/ch6/default.pdf.

⁸ 2004 FDA ENFORCEMENT STORY, Office of Criminal Investigations 21, http://www.fda.gov/ora/about/enf_story2004_archive/ch6/default.pdf.

⁹ 2004 FDA ENFORCEMENT STORY, Office of Criminal Investigations 28, http://www.fda.gov/ora/about/enf_story2004_archive/ch6/default.pdf.

III. Under 2B5.3(b)(5) concerning Specific Offense Characteristics, amend that subsection to read as follows:

“(5) If the offense involved (A) the conscious or reckless risk of serious bodily injury; or (B) possession of a dangerous weapon (including a firearm); or (C) trafficking in counterfeit drugs in connection with the offense, increase by 2 levels. If the resulting offense level is less than level 13, increase to level 13.”

We believe that the changes listed above reflect the seriousness of pharmaceutical counterfeiting offenses. *See* 18 U.S.C. § 3553(a)(2)(A). Moreover, because counterfeiters are not acting as legitimate companies concerned with FDA regulatory oversight, these increased penalties are necessary to help deter drug counterfeiting. *Id.* at § 3553(a)(2)(B). Increased penalties may also help to protect the public health from further counterfeiting crimes. *Id.* at § 3553(a)(2)(C).

II. GUIDELINE 2N2.1 DOES NOT OTHERWISE REQUIRE REVISION

Aside from the applicability of the Guidelines to pharmaceutical counterfeiting, there does not appear to be any evidence presented to the Commission that the existing system for sentencing FDC Act offenses is inadequate or deficient. Although we are not commenting on the specific amendments to the 2N2.1 Guideline that the Commission recently proposed (such as for hGH offenses), it is unclear from the public record whether wholesale changes to 2N2.1 as set forth in the Commission’s Notice (73 Fed. Reg. at 4935, first column at numbered paragraph 5) are necessary or appropriate. Our conclusion is grounded on the FDC Act statutory scheme, the current wording and purposes of the Guidelines, and the actual record of FDC Act criminal enforcement. Moreover, we agree with FDA Associate Commissioner McConagha regarding “the magnitude and complexity of reforming this section.” Statement of William McConagha at 15.

A. Misdemeanor Offenses, the *Park* Doctrine and Strict Liability

PhRMA believes that intentional violations of our public health statutes should be punished appropriately. At the outset, it is important to recognize that any potential amendments to Guideline 2N2.1 would *not* relate to those persons who are convicted of intentionally flaunting the public health and safety by engaging in fraudulent conduct. Under the 2N2.1 Guideline, if an offense involves fraud, Guideline 2B1.1 would apply. The overwhelming majority of FDC Act cases prosecuted in federal courts are felony cases, where a defendant is accused of having violated the FDC Act “with the intent to defraud or mislead”—and thus the fraud guideline applies, not the 2N2.1 Guideline.

In contrast, cases sentenced using Guideline 2N2.1 cases are strict liability regulatory offenses, for which the U.S. Supreme Court has established a very low bar for

the Government to meet in order to prove its case. See *United States v. Park*, 421 U.S. 658 (1975). In *Park*, the Supreme Court upheld misdemeanor convictions based on the premise that responsible persons who manage FDC Act-regulated businesses have an affirmative duty to insure that the products they sell are safe. Therefore, a person responsible for FDC Act compliance by virtue of his or her position in a company can be convicted of a criminal misdemeanor, even though he or she did not personally engage in, or even know about, illegal activity. The Court stated that the FDC Act punishes neglect where the law requires care or inaction, and imposes a positive duty to seek out and remedy violations when they occur, and also a duty to implement measures that will insure that violations will not occur.

As a result, the “*Park* doctrine” places a substantial amount of discretion in the hands of a prosecutor, because an FDC Act violation committed by a company can lead to strict criminal liability for corporate officers and others. Indeed, the Department of Justice has published a model jury instruction on charging FDC Act misdemeanors consistent with this doctrine.¹⁰ Thus, officers with responsibility and authority in a food, drug, or medical device manufacturer could face a criminal charge any time there is a single FDC Act violation in one of their company facilities, even if they do not have actual knowledge of the complex regulatory requirements enforced by FDA or the activity in question.

Because of the wide breadth of the FDC Act’s criminal sanctions, which apply to “no intent” offenses of the FDC Act, it is particularly important that the Commission should not increase the sentences for these types of violations unless there is a clear record that the existing sentencing scheme is not working. We are not aware that this record has been presented in any public forum.¹¹ Moreover, as will be discussed below, courts have sufficient mechanisms at their disposal to allow them to appropriately punish violations of the FDC Act.

B. Existing Sentencing and Other Mechanisms Can Increase FDC Act Sentences and Otherwise Deter Violations

Without altering Guideline 2N2.1, there are already sentencing mechanisms in place to increase an FDC Act sentence when the facts so warrant. As the Commission knows, between the Chapter 3 Adjustments, and the Chapter 5 grounds for departure, the existing Guidelines contain a number of bases upon which a court can generally fashion a

¹⁰ United States Attorneys' Manual, Title 4, Civil Resource Manual No. 105, available at http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title4/civ00105.htm.

¹¹ By contrast, because pharmaceutical counterfeiting presents a documented and emerging risk to public health and safety, for the reasons discussed in footnote 1 *supra*, we believe special treatment of such activities under § 2N2.1 is warranted.

sentence appropriate to the particular facts and circumstances. *See, e.g.*, § 3B1.1 (Aggravating Role); § 3B1.3 (Abuse of Position of Trust or Use of Special Skill) § 5K2.1 (Death); § 5K2.2 (Physical Injury); § 5K2.7 (Disruption of Governmental Function); and § 5K2.14 (Public Welfare). These adjustments and departures apply to 2N2.1 cases.

For legitimate pharmaceutical manufacturers, FDA's inspection observations, warning letters, and other administrative actions by FDA are taken extremely seriously. Civil litigation by the Department of Justice on behalf of FDA (whether seizure of particular products, or an injunction against further manufacturing or distribution) can have disastrous consequences. A criminal investigation – let alone charges or a conviction – often has even more significant detrimental consequences. Thus, PhRMA does not accept an assertion that the existing Guidelines are too lenient, particularly when one considers the range of enforcement tools available to FDA that can be taken in conjunction with a criminal prosecution.

Moreover, the vast majority of criminal FDC Act cases do not arise in a vacuum. There is frequently a civil component to the government's enforcement (often under the False Claims Act), and the persons and entities being investigated by FDA may also be subject to administrative remedies, including but not limited to exclusion and debarment. An assessment of the adequacy of the existing Guidelines must recognize this regulatory environment. *See* 18 U.S.C. § 3553(a) (sentence should be "sufficient but not greater than necessary" to comply with sentencing goals).

Therefore, based on the available evidence, the 2N2.1 Guideline, supplemented by other relevant existing Guidelines, adequately provides judges with the necessary authority and flexibility to impose a serious sentence when warranted, and deter most persons from violating the FDC Act. Indeed, we are not aware of a single case (and FDA's letters to the Commission do not cite one) where a judge regarded the existing 2N2.1 Guideline as a barrier to an appropriate sentence.

CONCLUSION

PhRMA supports FDA's prior conclusions that increased penalties for pharmaceutical counterfeiting are necessary, due to the significant increase of counterfeit products worldwide, and the resulting public health and safety risks such products present. Aside from counterfeiting cases, there does not appear to be evidence that the existing system for sentencing FDC Act offenses is deficient or in need of revision. Accordingly, it does not appear that wholesale changes to 2N2.1 in this area are necessary or appropriate. Moreover, before the Commission takes further action to revise this Guideline, we urge a more fully developed factual and legal record than that which has been presented to date that supports the basis for the proposed changes. Thus, apart from PhRMA's proposal to amend the Guidelines with respect to pharmaceutical counterfeiting offenses, for which we think the public record is adequate for the Commission to move forward, if the Commission is inclined to make wholesale changes

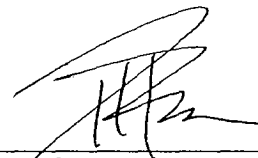
Letter to United States Sentencing Commission
March 28, 2008
Page 8

to the existing 2N2.1 Guideline, we suggest that it first refer these issues to a Food and Drug Working Group, similar to the working group the Commission convened in 1994.

PhRMA appreciates the opportunity to comment on these proposed revisions and would be happy to provide any additional information that may be helpful to the Commission as it considers these important issues.

Respectfully submitted,


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