



020-96

March 6, 1996

HAND DELIVERED

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

Re: Proposed Amendment To Sentencing Guideline On Food and Drug Offenses

Dear Sir or Madam:

These comments are submitted by the Health Industry Manufacturers Association (HIMA) in response to the United States Sentencing Commission's (Commission) January 2, 1996 Federal Register notice proposing to eliminate the current "regulatory" Guideline that is applicable to offenses committed under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 333(a)(1). United States Sentencing Commission, Guidelines Manual, § 2N2.1 (Nov. 1995). See 61 Fed. Reg. 79, 83 (1996) (Proposal).

HIMA is a Washington, D.C.-based national trade association representing more than 700 manufacturers of medical devices, diagnostic products, and health information systems. HIMA's members manufacture more than 90 percent of the nearly \$50 billion of health care technology products purchased annually in the United States. The Association is dedicated to representing the long-term interests, concerns, and needs of the health care technology industry through educational programs that encourage high quality, cost-effective health care. Because members of HIMA are regulated under the FFDCA, which authorizes criminal penalties for regulatory offenses, HIMA has a keen interest in the Commission's January 2 Proposal.

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HIMA strongly opposes the Proposal to delete United States Sentencing Guidelines (USSG) § 2N2.1. If the Proposal is adopted, persons convicted of violating the FFDCA would be sentenced under the "fraud" guideline (USSG § 2F1.1) even if the defendant is not charged with fraudulent conduct. In addition, the Proposal would, for the first time, establish a guideline for corporations and other organizations convicted of "strict liability" offenses under the FFDCA.^{1/} Without benefit of any prior input from the industry groups most affected, the Proposal would, if adopted, have the potential of dramatically increasing the likelihood of unjustified jail sentences and massive fines on individuals and corporations convicted of misdemeanor "strict liability" offenses. Although HIMA supports, and will continue to support, strict sentences against individuals and corporations convicted of felony FFDCA offenses where fraudulent conduct is established, similar stiff sentences for misdemeanor "strict liability" FFDCA offenses, where fraudulent conduct is not an element of the offense, are simply not warranted.

A. THE PROPOSAL'S IMPACT ON HIMA MEMBERS

The Proposal will potentially have serious and unwarranted ramifications for HIMA's member companies and their executives and employees. HIMA's members are primarily regulated under the various sections of the FFDCA that relate to medical devices as enacted in three major pieces of legislation. See Pub. L. No. 94-295, 90 Stat. 540 (1976); Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990); and the Medical Device Amendments of 1992, Pub. L. No. 102-300, 106 Stat. 238 (1992). The FFDCA and its implementing regulations, set forth numerous detailed requirements intended to ensure that medical devices are safe and effective before and after they enter the market. These mandates, if violated, subject the offending persons to a variety of regulatory and judicial sanctions. The most extreme of these sanctions is a criminal prosecution.

The FFDCA covers every aspect of the manufacturing, marketing, and distribution of medical devices. The Act provides the means for bringing safe and effective medical devices to the market by requiring that, for break through technology, a premarket approval application (PMA) be submitted to the United States Food and Drug Administration (FDA) before that medical device is commercially distributed. See 21 U.S.C. § 360c. In addition, the FFDCA establishes a system of

^{1/} The Guidelines for imposing fines on corporations and other organizations, USSG § 8C, does not reference USSG § 2N2.1 and is thus not applicable to misdemeanor food and drug offenses. USSG § 8C2.1. Accordingly, organizations convicted of committing such misdemeanor offenses are currently fined under 18 U.S.C. § 3571 and §3572. However, the organizational fine Guidelines, USSG § 8C, are applicable to fraud offenses subject to USSG 2F1.1. Thus, organizations committing food and drug offenses involving fraud are currently fined under USSG § 8C. If the Proposal is adopted, organizations convicted of misdemeanor food and drug offenses will be fined under USSG § 8C as well.

premarket notification (510(k)) for products that are substantially equivalent to legally marketed devices. In this way, FDA clears for commercial distribution those devices, based on a comparison to an existing product, with demonstrated safety and effectiveness. See 21 U.S.C. § 360k. The PMA and 510(k) requirements ensure that manufacturers of medical devices are currently required to have their devices precleared prior to marketing.

The FFDCA also requires that medical devices be manufactured in compliance with current good manufacturing practices (CGMPs). 21 U.S.C. § 360j(f). The CGMPs establish controls for various aspects of manufacturing of medical devices, including production and process controls, packaging and labeling controls, storage and distribution controls, and laboratory controls. The CGMPs also mandate strict record keeping and reporting requirements. See 21 C.F.R. Part 820.

Although the CGMPs contain numerous requirements, they fail to establish precise definitions of acceptable conduct. The regulations use words like "reasonable" and "adequate." A CGMP violation, which could subject an individual and manufacturer to criminal prosecution, often involves a disagreement over interpretations but rarely involves fraud.

The failure to comply with any of the above requirements may lead to an FDA determination that a medical device is adulterated or misbranded in violation of the FFDCA. Any person who manufactures and distributes an adulterated or misbranded product may be subject to criminal penalties. 21 U.S.C. §§ 331 and 333(a). As in the case of many CGMP violations, a medical device may be found to be adulterated or misbranded even though it meets all relevant specifications and does not pose a risk of harm to the consumer or the public. The same is true for many other violations of the FFDCA, where a violation can occur despite the fact that the product is safe and effective.

Medical device corporations and their officials may be held criminally liable despite the fact that they had no intention to violate the FFDCA, or even knew the FFDCA was being violated. Defendants have been criminally charged under the "strict liability" doctrine set forth in United States v. Park, 421 U.S. 658 (1975), which upheld the authority of FDA to obtain a conviction against a corporate officer or organization without having to prove that the defendant had any mens rea. The Park Court concluded that a corporate officer who is in a "responsible relationship" to activity that violates the FFDCA can be criminally prosecuted even though the person did not personally engage in or even know about that activity. In fact, in Park, the Supreme Court noted that the defendant, John Park (whose conviction was upheld in the case), had consulted with legal counsel upon hearing that his firm's Baltimore warehouse had sanitation problems. Mr. Park, who lived and worked in Philadelphia, was assured that the person who controlled that facility was investigating the situation and that the matter was apparently under control. The Court found that even though Mr. Park did not order the FFDCA violations or even know they were occurring, he could be convicted because, as President of the company, he had the power to prevent the violations from occurring. The Court stated that he had a positive duty to implement measures to ensure that

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his company did not violate the law. If those measures were inadequate, he could be criminally prosecuted.^{2/}

The type of prosecution brought under 21 U.S.C. § 333(a)(1) bears no resemblance to a fraud case where FDA alleges that someone violates the FFDCA with the intent to defraud or mislead the FDA, a customer, or a consumer. 21 U.S.C. § 333(a)(2). In the former type of case, FDA prosecutes people with no allegation that the person intended to violate the FFDCA or even knew about the violation. In the latter case, FDA charges a person with a crime based on traditional mens rea where the defendant knew that he or she was participating in illegal conduct. We fail to understand the logic of having persons convicted under the FFDCA's misdemeanor provisions sentenced the same way as persons who have violated the FFDCA with the specific intent of defrauding someone.

Although there are thousands of companies in the medical device industry, there have been remarkably few criminal prosecutions brought against medical device companies or their officials. Nevertheless, HIMA is quite concerned about the potential impact on its members if the proposal is adopted. FDA is committed to vigorous enforcement of the strict liability criminal provisions of the FFDCA. For instance, in 1990 FDA stated that the deterrent power of misdemeanor strict liability violations could not be underestimated. However, HIMA strongly believes that the punishment for these violations should be commensurate with the violation. A person or company should not receive felony sanctions for strict liability violations.

If the Commission's Proposal is adopted, sentencing judges will almost certainly be compelled to impose a term of imprisonment for "strict liability" medical device offenses, particularly in cases where a large volume of product is implicated or the cost of the product is high. This is due to the fact that the "fraud" Guideline sets a sentence according to the "loss" to the victims. Further, the proposal will establish a guideline for a fine to be imposed on corporations and other organizations in regulatory (non-fraud) cases. Consequently, courts will be obligated to increase fines they impose on corporations and other organizations in the medical device industry.

Such stiff punishments, for non mens rea criminal conduct, would have an unduly harsh impact on medical device corporations and their officials. A jail sentence would be devastating for a corporate executive or official at any level within a corporation who takes pride in his job, has a family, and a previously untarnished background. The Commission needs to be aware of the fact that many regulatory requirements are subject to different interpretations and individuals can not always quit their jobs whenever their interpretation differs from that of management. In light of the

^{2/} The government has also brought misdemeanor "strict liability" criminal prosecutions against low level employees of large companies. See United States v. General Nutrition, Inc., 638 F. Supp. 556 (W.D.N.Y. 1986) (misdemeanor criminal prosecution properly initiated under FFDCA against a store clerk at a retail outlet who made promotional statements about products sold at the store).

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subjective way medical devices are regulated, it is unfair to mandate high penalties for what turns out after the fact to be interpreted as violative conduct. Moreover, as many medical device, diagnostic products, and health care information system corporations are small businesses, massive fines would be crippling to the development of innovative products. Additionally, this amendment to the sentencing Guidelines will add to the already existing reservations that companies have about entering an industry where there is a potential for high criminal penalties for inadvertent violative conduct.

B. THE PROPOSAL LACKS A VALID BASIS

HIMA recognizes, and has no quarrel with, the Commission's laudatory goal to simplify the Sentencing Guidelines. See 60 Fed. Reg. 49,316 (Sept. 22, 1995). However, a desire to simplify the Guidelines does not justify deleting USSG § 2N2.1. Nor should a desire to simplify the Guidelines form a basis to fit "strict liability" criminal cases into a Guideline that was promulgated to deal with fraud.

In support of the Proposal, the Commission referenced a two-year study conducted by the Commission's Food and Drug Working Group (Working Group). See 61 Fed. Reg. 83 (1996). However, this Working Group did not propose to eliminate USSG § 2N2.1. Moreover, despite conducting a study of cases sentenced under USSG § 2N2.1, the Working Group never identified even one case in which a judge, a prosecutor, a defense attorney, or a defendant complained that the sentence imposed under USSG § 2N2.1 was inappropriate.

In addition to the Working Group's study, HIMA is unaware of any case in which anyone sentenced under USSG § 2N2.1, the sentencing court, or even the government displayed dissatisfaction with the sentence imposed. In sum, all empirical evidence strongly suggests that USSG § 2N2.1 is working quite well.

HIMA believes that the Commission's stated goal to simplify the Guidelines would be furthered by maintaining and possibly expanding USSG § 2N2.1. There are "strict liability" prosecutions commenced under statutes other than those now explicitly implicated by USSG § 2N2.1.^{3/} The Commission might want to republish its Proposal to expand USSG § 2N2.1 to cover other regulatory statutes, including those statutes that are not now covered by an existing Guideline. Alternatively, the Commission might consider a new guideline that would cover all regulatory violations where fraud is not involved.

3/ See United States v. Luv N' Care International, Inc., 897 F. Supp. 941 (W.D. La. 1995) (prosecution initiated under the Federal Hazardous Substances Act, a statute as to which the Commission has not established a guideline).

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**C. THE PROPOSAL IS CONTRARY TO THE PURPOSE OF THE
GUIDELINES**

The Commission has received a statutory mandate to avoid "unwarranted sentencing disparities among defendants with similar records who have been found guilty of similar criminal conduct." 28 U.S.C. § 991(b)(1)(B). In that regard, Congress intended the Commission to periodically review judicial decisions and revise the Guidelines when sentencing disparities are found to exist. See Braxton v. United States, 500 U.S. 344, 348 (1991); Neal v. United States, 116 S. Ct. 763, 766 (1996) ("Congress intended the Commission's rulemaking to respond to judicial decisions in developing a coherent sentencing regime"). HIMA is unaware of any study or finding suggesting that unwarranted sentencing disparities occur under USSG § 2N2.1. In fact, most courts have invariably imposed low fines on FDA-regulated organizations, to permit the entity to spend its money on remedial measures.

Further, the Proposal seems wholly inconsistent with the Commission's General Application Principles. See USSG Ch. 1, Pt. A § 4(f), which sets forth guiding principles for the Commission's promulgation of guidelines concerning regulatory offenses. It states that a typical guideline for a so-called "regulatory offense" will provide a low base offense level. Nevertheless, under the Proposal, persons convicted of regulatory violations under the food and drug laws would be sentenced according to the monetary loss incurred by "victims." HIMA sees no reason why the Commission should depart from its General Application Principles by deleting USSG § 2N2.1 until the Commission examines whether "loss" should be a relevant sentencing factor in all regulatory offenses.

Application of USSG 2F1.1, rather than USSG § 2N2.1, to misdemeanor FFDCA offenses would simply be inequitable. One of the primary purposes of the Guidelines is to preserve proportionality in sentencing. See Neal v. United States, 116 S. Ct. at 767, (1996). See also, Mistretta v. United States, 488 U.S. 361, 374 (1989); United States Sentencing Commission, Guidelines Manual at 2 (Nov. 1994) ("Congress sought proportionality in sentencing through a system that imposes appropriately different sentences for criminal conduct of differing severity"). Accordingly, the Commission was directed to "insure that the guidelines reflect the general appropriateness of imposing a sentence other than imprisonment in cases in which the defendant is a first offender who has not been convicted of a crime of violence or an otherwise serious offense." 28 U.S.C. § 994(j).

As explained above, many prosecutions brought against officials and corporations regulated by the FDA involve only technical violations of the FFDCA and do not present a true risk of harm to the public or the consumer. Accordingly, under USSG § 2N2.1, courts have traditionally imposed no jail sentences for such "non-serious" crimes. However, applying the "fraud" Guideline to misdemeanor medical device offenses will certainly increase the potential for incarceration, possibly reaching jail sentences at the statutory maximum. Certainly, Congress did not intend the Commission to mandate stiff sentences on relatively minor criminal offenses.

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D. THE PROPOSAL IS INCONSISTENT WITH OTHER ANALOGOUS GUIDELINES

If the Proposal is adopted, it will establish, for the first time, a guideline for fines to be imposed on corporations and other organizations convicted of strict liability FFDCA offenses. As such, the Proposal is inconsistent with the Commission's treatment of other similar regulatory guidelines.

Like USSG § 2N2.1, the Commission has promulgated regulatory offense guidelines for individuals convicted of environmental crimes. See USSG § 2Q. The USSG § 2Q Guidelines encompass misdemeanor offenses, and in some cases, strict liability environmental offenses. See, e.g., 33 U.S.C. § 411 (sentenced under USSG § 2Q1.3). There are close parallels between the FFDCA and the environmental statutes in terms of their purposes, effects, deterrent value, and statutory structure. A careful analysis should be conducted comparing how the FFDCA does and does not compare to the environmental laws. Where similar, it is reasonable to suggest that the Sentencing Commission treat similarly the two categories of cases.

However, the Commission has not proposed to include environmental cases involving fraud under the fraud Guideline, USSG § 2F1.1.^{4/} Nor has the Commission promulgated organizational guidelines for environmental offenses. HIMA believes that the Commission should defer any modification to USSG § 2N2.1 until the Commission has studied the extent to which FFDCA cases should be sentenced under the same basic principles as environmental cases. The Commission has not asserted any ground to treat strict liability FFDCA offenses differently than strict liability environmental offenses. As both types of offenses closely parallel each other, so too should their respective guidelines.

E. CONSULTATION WITH OUTSIDE GROUPS IS ESSENTIAL

In promulgating or revising guidelines, the Commission is required to "consult with authorities on, and individual and institutional representatives of, various aspects of the Federal criminal justice system." 28 U.S.C. § 994(o). The Commission's Proposal was apparently not preceded by any dialogue with the industry (or their legal representatives), academicians, public

4/ Indeed, in United States v. Carpenter's Goldfish Farm, 998 F.2d 692 (9th Cir. 1993), the Court vacated a sentence in an environmental case. The defendant had committed two offenses that were subject to sentencing. One of the offenses was properly subject to USSG § 2F1.1 because fraud and deceit was involved. However, the other offense (a strict liability environmental crime) was not covered by any guideline. The Court vacated the sentence because the district court had imposed the Guideline applicable to felony environmental offenses. For the strict liability environmental crime, this case reinforces HIMA's position that regulatory strict liability misdemeanor offenses must be accorded different sentencing status than more serious felony charges.

interest groups, or other organizations which have a wealth of knowledge in this area. The limited comment period to respond to the Proposal is simply inadequate for this purpose.

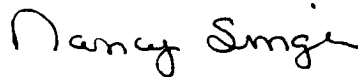
With respect to environmental offenses, the Commission has met its "consultation" obligations by forming an advisory working group composed of government officials, law professors, lawyers in private practice, in-house corporate lawyers, and others. See e.g., 58 Fed. Reg. 65,764 (1993) (Commission established independent working group to promulgate organizational guidelines for environmental offenses). Similarly, HIMA submits that the Commission should form an advisory working group consisting of individuals from the government, defense bar, business community, and academia who specialize in matters relating to the FDA. Such members would provide valuable, first-hand input regarding the adequacy of regulatory Guideline USSG § 2N2.1.

F. CONCLUSION

For all the reasons discussed above, HIMA urges the Sentencing Commission to refrain from adopting the Proposal, insofar as it would delete USSG § 2N2.1. Further, HIMA believes the Sentencing Commission should establish an advisory working group, partly composed of members of the affected industry, to ensure that misdemeanor FFDCA offenses are sentenced fairly under either USSG § 2N2.1 or a new guideline that would apply to all regulatory misdemeanor offenses. HIMA stands ready and willing to participate in that working group or to provide any further assistance to the Commission that it can.

We appreciate this opportunity to present our views.

Sincerely yours,



Nancy Singer
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