

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:

This comment is submitted by the American Feed Industry Association (AFIA) 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). United States Sentencing Commission, Guidelines Manual, § 2N2.1 (Nov. 1995). See 61 Fed. Reg. 79, 83 (1996) (hereinafter "Proposal").

AFIA is the national trade association representing manufacturers of both medicated and non-medicated animal feeds. AFIA's members produce more than 70% of the commercial livestock, poultry, and aquaculture feed sold in the United States. AFIA's members also manufacture and distribute feed ingredients, feed manufacturing machinery, and animal health products. Because members of AFIA are regulated under the FFDCA, which authorizes criminal penalties for regulatory offenses, AFIA has a keen interest in the Commission's January 2 Proposal.

AFIA strongly opposes the Proposal to delete USSG § 2N2.1. If the Proposal is adopted, all 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

¹ Currently, such organizations are fined by federal judges outside the confines of the Federal Sentencing Guidelines.

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from the industry groups most affected, the Proposal proposes to dramatically increase the likelihood of unjustified jail sentences and massive fines on individuals and corporations convicted of misdemeanor "strict liability" offenses. Although AFIA supports, and will continue to support, strict sentences against individuals and corporations convicted of felony food and drug offenses where fraudulent conduct is established, similar stiff sentences for misdemeanor "strict liability" food and drug offenses are simply not warranted.

A. THE PROPOSAL'S IMPACT ON AFIA MEMBERS

The Proposal will potentially have serious and unwarranted ramifications for AFIA's members and their executives and employees. AFIA's members are primarily regulated under both the food provisions and the animal drug provisions of the FFDCA and their implementing regulations. These provisions set forth numerous detailed requirements intended to ensure that medicated and non-medicated animal feeds are safe 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.

Because of the FFDCA's broad definition of "food," 21 U.S.C. § 321(f), all animal feeds, both non-medicated and medicated, are subject to the Act's general requirements for food. The Act provides the means for bringing safe and wholesome animal foods to the market by requiring all food and color additives and other added substances to be proven safe before they are used in animal feeds. See 21 U.S.C. § 348; 21 U.S.C. § 379e; 21 U.S.C. § 346. The Act also mandates that all animal feeds must be prepared, packed, and held under sanitary conditions. 21 U.S.C. § 342(a)(4).

Medicated feeds must meet additional FFDCA requirements. Depending on the particular starting drug ingredients used and their concentrations, feed manufacturers may have to hold an approved medicated feed application. 21 U.S.C. § 360b(m). In addition, all animal feeds containing drugs must comply with FDA's separate current good manufacturing practice (CGMP) regulations for medicated feeds. 21 C.F.R. Part 225. These CGMPs establish controls for all aspects of manufacturing medicated feeds, including production and process controls, packaging and labeling controls, storage and distribution controls, and laboratory controls. The CGMPs also mandate strict recordkeeping and reporting requirements.

The failure to comply with any of the above food or animal drug requirements may lead to a FDA determination that animal feed is adulterated or misbranded in violation of the FFDCA. See 21 U.S.C. § 342 (food adulteration), § 343 (food misbranding), § 351 (drug adulteration), and § 352 (drug misbranding). 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).

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Feed manufacturers 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 case demonstrates how the sometimes technical requirements of the FFDCA have lead to criminal prosecutions. In Park, John Park (whose conviction was upheld in the case), had consulted with legal counsel upon hearing that his company's Baltimore warehouse had sanitation problems. Mr. Park, who lived and worked in Philadelphia, was assured that the subordinate who managed that facility was investigating the situation and that the matter was apparently under control. However, the FDA subsequently brought charges against Mr. Park alleging that the company's food had become adulterated because of insanitary conditions. The Supreme Court upheld Mr. Park's conviction even though Mr. Park did not order the FFDCA violations or even know they were occurring. The Court found that Mr. Park could be convicted because, as President, 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 his company did not violate the law. If those measures were inadequate, he could be criminally prosecuted.²

It is easy to realize that the type of prosecution brought in the Park case bears no resemblance to a fraud case where FDA alleges that someone violates the FFDCA with the intent to defraud or mislead the government, 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 was participating in illegal conduct.

AFLA is not proposing that misdemeanor (strict liability) cases under the FFDCA are never warranted. However, 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 law with the specific intent of defrauding someone.

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).

Although there are thousands of companies in the animal feed industry, there have been remarkably few criminal prosecutions brought against such companies or their officials. Nevertheless, AFIA 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. AFIA has no quarrel with that proposition. However, AFIA 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" food and drug offenses, particularly in cases where a large volume of product is implicated. 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 animal feed industry.

Such stiff punishments, for non mens rea criminal conduct, would have a severe impact on feed manufacturers and their officials. A jail sentence would be devastating for a corporate executive or official with a respectable career, family, and a previously untarnished background. Indeed, many persons may well choose to forego a career in the animal feed business if they know that they can be subject to sanctions under the fraud Guideline simply because of their position as a high level executive in a company. Moreover, as many feed manufacturers are small businesses, massive fines would be crippling.

B. THE PROPOSAL LACKS A VALID BASIS

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.^{3/}

³ In fact, the Working Group stated that "the issue remains whether [§ 2N2.1] as currently drafted provides for adequate fines. . . ." United States Sentencing Commission Food and Drug Working Group Final Report at 19 (Feb. 1995).

In addition to the Working Group's study, AFIA 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.

AFIA 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 a rush to delete 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.

AFIA 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 § 2N2.1.⁴ 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.

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. US, 500 U.S. 344, 348 (1991); Neal v. US, 116 S. Ct. 763, 766 (1996) ("Congress intended the Commission's rulemaking to respond to judicial decisions in developing a coherent sentencing regime"). AFIA 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 entities to spend their money on remedial measures.

⁴ 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).

Further, the Proposal seems wholly inconsistent with the Commission's General Application Principles. USSG Ch. 1, Pt. A § 4(f) 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." AFIA 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 food and drug offenses would simply be inequitable. One of the primary purposes of the Guidelines is to preserve proportionality in sentencing. See Neal v. US, 116 S. Ct. at 767. See also, Mistretta v. US, 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 FDA involve only technical violations of the FFDCA and do not present a true risk of harm to the public or to animals. Accordingly, under USSG § 2N2.1, courts have traditionally imposed no jail sentences for such "non-serious" crimes. However, applying the "fraud" guideline to misdemeanor food and drug 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.

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 similar regulatory guidelines.

Like USSG § 2N2.1, the Commission has promulgated regulatory offense guidelines for individuals convicted for 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 the two categories of cases similarly.

However, the Commission has not proposed to include environmental cases involving fraud under the fraud guideline, USSG § 2F1.1.⁵ Nor has the Commission promulgated organizational guidelines for environmental offenses. AFIA 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 food and drug offenses different 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 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.

⁵ Indeed, in United States v. Carpenter's Goldfish Farm, 998 F.2d 692 (9th Cir. 1993), the Ninth Circuit 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 were 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 sentence for the strict liability offense by employing the Guideline applicable to felony environmental offenses. This case reinforces AFIA's position that regulatory strict liability misdemeanor offenses must be accorded different sentencing status than more serious felony charges. The case also demonstrates the need to have a general regulatory Guideline that will cover regulatory offenses that are not now subject to the Sentencing Guidelines.

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Reg. 65,764 (1993) (Commission established independent working group to promulgate organizational guidelines for environmental offenses). Similarly, AFIA 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, AFIA urges the Sentencing Commission to refrain from adopting the Proposal, insofar as it would delete USSG § 2N2.1. Further, AFIA 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. AFIA 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,



David A. Bossman
President

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