

March 5, 1996

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

Re: Proposed Amendments to U.S.S.G § 2N2.1

Dear Sir/Madam:

The following comments are submitted on behalf of the Grocery Manufacturers of America, Inc. ("GMA"), the Nonprescription Drug Manufacturers Association ("NDMA"), and the Pharmaceutical Research and Manufacturers of America ("PhRMA") in response to the United States Sentencing Commission's ("the Commission") recently proposed amendments to Section 2N2.1 of the U.S. Sentencing Guidelines ("the Guidelines"). 1/

SUMMARY

On January 2, 1996, the Commission announced a series of proposed amendments to the federal Sentencing Guidelines, including one directed to the manner in which individuals and corporations are treated following conviction for

1/ GMA is a national trade association of approximately 140 companies that manufacture food sold in retail grocery stores through the United States and internationally. Its member companies are responsible for producing more than 85 percent of the packaged food sold at retail in the United States.

NDMA is a national trade association representing approximately 75 manufacturers and distributors of over-the-counter ("OTC") medications. NDMA members represent roughly 95 percent of the retail sales of OTC medications in the United States.

PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies. Investing nearly \$16 billion annually toward the discovery and development of new medicines, PhRMA companies are the source of nearly all new drug discoveries worldwide.

violations of the Federal Food, Drug, and Cosmetic Act, 2/ the Poultry Products Inspection Act, 3/ and the Federal Meat Inspection Act, 4/ among other statutes. See 61 Fed. Reg. 79, 83 (Jan. 2, 1996). This proposed change would delete Guideline Section 2N2.1 in its entirety and would, instead, treat all those offenses originally within its ambit as cases involving fraud, governed by Section 2F1.1. Thus, purely regulatory violations would be treated in the same manner as intentionally fraudulent conduct. We believe the Guidelines as currently worded properly provide the flexibility needed both to respond to the broad spectrum of conduct involved in the prosecution of these so-called "public welfare" statutes and to avoid the injustice that would otherwise result by imposing sanctions designed to address fraud in cases arising out of strict liability regulatory violations. Consequently, we urge that the amendment, as proposed, be rejected.

BACKGROUND

Sentencing in criminal cases involving violations of statutes and regulations dealing with consumer products, including any food, drug, biological product, device, cosmetic or agricultural product, is currently governed by Guideline Section 2N2.1. 5/ That Section provides for a base offense level of six, assuming that the underlying regulatory offense involves "knowing or reckless" conduct. See U.S.S.G. § 2N2.1, comment. (n.1). In cases involving, at most, mere negligence, the Guidelines indicate a downward departure may be warranted. If, on the other hand, the offense involved fraud, Section 2N2.1 is cross-referenced to Guideline Section 2F1.1, which governs more traditional crimes of fraud and deceit, such as mail and wire fraud and bank fraud. 6/ Section 2F1.1 similarly begins with a base

2/ 21 U.S.C. §§ 301 et seq.

3/ 21 U.S.C. §§ 451 et seq.

4/ 21 U.S.C. §§ 601 et seq.

5/ Chapter 2 of the Guidelines governs sentences for individuals. Chapter 8, in turn, sets forth the organizational sentencing guidelines, pursuant to which a corporate offense level and, by extension, base fine, are determined. As currently worded, food, drug, and agricultural products offenses are specifically excluded from the organizational sentencing guidelines. As a result, fines for organizations convicted of offenses covered by Section 2N2.1 continue to be governed by pre-guidelines law. Under the proposed amendments, sentences in cases involving organizational defendants would similarly be calculated in all cases using the fraud guidelines.

6/ Although, as noted, the organizational guidelines are not strictly applicable to food and drug offenses, the existing commentary to Section 8C2.1 similarly cross-references Section 2F1.1, specifically noting that "where the conduct set forth in a

offense level of six, but provides for significant increases in offense level -- and, by extension, the range of the fine and/or term of incarceration that may be imposed -- based upon the amount of "loss" occasioned by a defendant's conduct.

Under the amendments proposed by the Commission, Section 2N2.1 would be deleted in its entirety, sweeping all food, drug, and related regulatory prosecutions of individual and/or corporate defendants under Section 2F1.1. While allowance is made in the proposed amendments for the possibility of an upward departure in a case involving conscious or reckless risk of serious bodily injury, the proposed commentary makes no specific reference regarding the appropriateness of a downward departure, even in a case arising out of a conviction for a simple regulatory offense involving no finding of moral culpability.

DISCUSSION

The apparent motivation behind the proposed changes to Section 2N2.1 is what the Commission's Food and Drug Working Group perceived as an "inappropriate failure" on the part of sentencing courts to apply the fraud guideline in cases involving intentional and fraudulent conduct. See Food and Drug Working Group Final Report at 12 (Feb. 1995). To the contrary, the reported case law indicates that courts routinely have relied upon Section 2F1.1 in appropriate cases. More importantly, by making fraud the rule rather than the exception, the revisions threaten to impose sanctions designed to address fraudulent conduct in cases involving simple negligence or strict liability.

Unlike most other criminal statutes, laws governing foods, drugs, and cosmetics have been characterized as "public welfare" provisions. The upshot of such a classification was first explained in United States v. Dotterweich, 7/ in which the Supreme Court dispensed with the conventional requirement for criminal conduct -- awareness of some wrongdoing -- and instead sustained the conviction of a pharmaceutical company and its president and general manager for shipping misbranded and adulterated drugs under a theory approaching strict liability. In Dotterweich, the Court rejected the notion that an individual defendant could escape criminal liability based upon his lack of knowledge of any wrongdoing. Instead, the Court explained that the statute "puts the burden of acting at hazard

court of conviction ordinarily referenced to § 2N2.1 (an offense guideline not listed in subsection (a) [governing applicability of the organizational guidelines]) establishes § 2F1.1 (Fraud and Deceit) as the applicable offense guideline (an offense listed in subsection (a)), [the organizational guidelines applicable to fraud] would apply because the actual offense level is determined under § 2F1.1." U.S.S.G. § 8C2.1, comment (n.2).

7/ 320 U.S. 277 (1943).

upon a person otherwise innocent but standing in responsible relation to the public danger." 8/

More recently, the Supreme Court reaffirmed the principles established in Dotterweich in United States v. Park. 9/ In that case, the Court held that the government's prima facie case against a corporate officer is established merely by proof that "the defendant has, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of and that he failed to do so." 421 U.S. at 673-74. Indeed, some circuits have taken the Supreme Court's lead so far as to reject defenses based upon objective impossibility and even sabotage. See United States v. Y. Hata & Co., Ltd., 535 F.2d 508 (9th Cir. 1976) (affirming trial court's refusal to give instruction on objective impossibility, despite maintenance by defendant of the highest standard of foresight and vigilance); United States v. Starr, 535 F.2d 512 (9th Cir. 1976) (holding that responsible employee's duty of foresight and diligence extends to anticipating and counteracting the "shortcomings" of delegees, including acts of sabotage).

By contrast, evidence of a "knowing" violation in cases not involving public welfare statutes requires a considerably greater showing of scienter, typically requiring proof that the defendant had actual knowledge not only of his own actions, but also of the fact that those actions constituted a violation of law. 10/

As the Food and Drug Working Group Final Report acknowledges, the required application of the fraud guideline will have a dramatic impact on the severity of sentences imposed in food and drug cases. For example, in a case involving distribution of adulterated meat, and assuming the amount of "loss," by whatever calculation, exceeds \$500,000, application of Section 2F1.1 will result in a base offense level, before adjustment, of not less than 16, subjecting a first-time offender to a minimum of 21 months incarceration. If the sentence is instead determined by application of Section 2N2.1, the resulting base offense level is six, with a corresponding sentencing range of 0-6 months. 11/ Criminal sanctions for

8/ 320 U.S. at 284-85. Accord United States v. Wiesenfeld Warehouse Co., 376 U.S. 86 (1964).

9/ 421 U.S. 658 (1975).

10/ See, e.g., Liparota v. United States, 471 U.S. 419 (1985) (distinguishing statute governing unlawful possession of food stamps from public welfare statutes requiring lesser degree of intent).

11/ Under U.S.S.G. § 2N2.1, a first-time offender would also, based upon this range, be eligible for a sentence of probation. The range resulting from application of Section 2F1.1, on the other hand, would of course preclude the possibility of a

organizational defendants will be similarly affected calling for the imposition of sanctions previously reserved for intentionally fraudulent conduct in cases involving virtually blameless violations of regulatory provisions.

Imposition of the more severe sanctions that result from application of Section 2F1.1 may be entirely just in a case involving intentional or purposeful conduct, traditionally a required element of fraud. However, such a result is plainly inappropriate in cases involving regulatory strict liability that nevertheless would be swept under the fraud guideline if the proposed changes were to become law. Such offenses are, of course, relatively common in the heavily regulated food, drug and cosmetic industry.

It is important to remember that the goal of sentencing reform has been to eliminate unwarranted disparities in sentencing, not to treat all offenders as if they were the same. It is no more rational to treat offenders of widely different culpability as if they were the same than it is to treat similar offenders differently.

More to the point, application of 2F1.1 is currently an available option under the existing provisions. As currently worded, Section 2N2.1 imposes a flat base offense level for any regulatory violation, while allowing for enhanced sentences, by cross-reference to Section 2F1.1, in cases in which the regulatory violations are part of a pervasive scheme. At the same time, in recognition of the virtual strict liability applicable to cases in this highly regulated area of the law since Dotterweich, the present guideline also provides for downward departures in those cases in which the conviction stems from simple negligence or dereliction.

Moreover, based upon a review of the reported decisions involving violations of the food and drug laws, and contrary to the conclusions of the Food and Drug Working Group's Final Report, it is apparent that sentencing courts routinely have applied Section 2F1.1 in food and drug prosecutions involving fraud, consistent with the cross-reference set out in existing Section 2N21. ^{12/} Even if this

probationary sentence. See also United States v. West, 942 F.2d 528 (8th Cir. 1991), in which the defendant was sentenced under Section 2F1.1 for selling adulterated meat. Under the fraud guideline, the defendant's adjusted offense level was 16, calling for a 21-month sentence. Had the sentence been calculated using Section 2N2.1, the defendant would have faced a sentence of between one and seven months.

^{12/} See, e.g., United States v. Andersen, 45 F.3d 217 (7th Cir. 1995) (applying Section 2F1.1 in imposing sentence in case involving sale of drugs without FDA site approval, in violation of 21 U.S.C. §§ 331(p) and 333(a)(2)); United States v. Kohlbach, 38 F.3d 832 (6th Cir. 1994) (applying Section 2F1.1 in case involving distribution of adulterated orange juice from concentrate, in violation of 21 U.S.C. §§ 331(a), 333(a)(2)); United States v. Strassburger, 26 F.3d 860 (8th Cir. 1994)

were not the case, however, such failure does not warrant wholesale abandonment of the existing provision in favor of an overinclusive amendment to Section 2F1.1. Instead, in a case in which the government believes that the sentencing court erred by failing to apply the fraud guideline, the appropriate recourse is appeal. ^{13/}

Indeed, the proposed revisions are inconsistent with the manner in which the guidelines govern sentences in other areas, such as environmental crimes, that are similarly subject to the less rigorous scienter requirements accorded so-called "public welfare" statutes. The guidelines governing the calculation of base offense levels in cases involving the mishandling or unlawful discharge of pollutants, for example, like Section 2N2.1, provide for a base offense level of six. See U.S.S.G. § 2Q1.3. Moreover, the guidelines governing environmental crimes similarly assume knowing conduct, and expressly refer to the appropriateness of a downward departure in cases involving, at most, negligent conduct. U.S.S.G. § 2Q1.3, comment. (n.3). Finally, like existing Section 2N2.1, these guidelines make wise use of various special offense characteristics and application notes to cover a broad spectrum of conduct, stretching from simple negligence to knowing and intentional criminal conduct.

This same flexibility should be retained in connection with the investigation and prosecution of food, drug, and related regulatory cases. As a matter of practice, prosecutors are reluctant to charge only corporate defendants. Indeed, to our knowledge, at least with respect to alleged criminal violations of the food and drug laws, federal prosecutors have, without exception, always charged individual employees and/or officers, as well. However, in light of the relaxed burden of proof under Dotterweich, Park, and their progeny, prosecutors' purposes have often been best served by charging related misdemeanor violations available under the statutes, or stipulating to base offense levels in a range that would permit a court to sentence the defendant to a probationary term. ^{14/} By branding

(applying Section 2F1.1 in case involving sale of misbranded meat and related violations of the Federal Meat Inspection Act); United States v. Von Mitchell, 984 F.2d 338 (9th Cir. 1993) (applying Section 2F1.1 in context of case involving unlawful sale of steroids, in violation of 21 U.S.C. §§ 331, 333 and 353); United States v. Arlen, 947 F.2d 139 (5th Cir. 1991), cert. denied, 112 S.Ct. 1480 (1992) (same); United States v. Cambra, 933 F.2d 752 (9th Cir. 1991) (applying Section 2F1.1 in case involving sale of misbranded drugs).

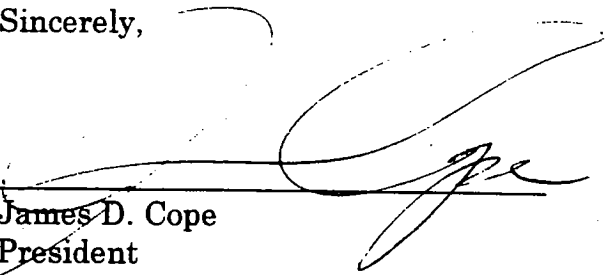
^{13/} None of the reported decisions pertaining to Section 2N2.1 involves a government appeal of the trial court's refusal to apply Section 2F1.1. This fact suggests that courts are applying the cross-reference provision and in a manner consistent with prosecutors' perceptions of the severity of the involved offenses and/or culpability of the individual defendants.

^{14/} See, e.g., 21 U.S.C. § 676(a).

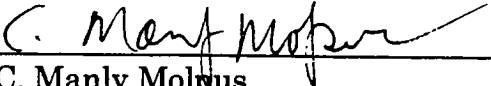
all violations of statutes pertaining to food, drugs, and agricultural products as fraud, the proposed amendments strip away any distinction between negligent, purposeful, and fraudulent acts, and threaten to impose, in cases approaching strict liability, penalties heretofore reserved for intentional and fraudulent conduct. We believe this to be unwarranted and inappropriate, and we therefore, urge that the amendment as proposed not be adopted.

We appreciate this opportunity to comment and your careful consideration of our views.

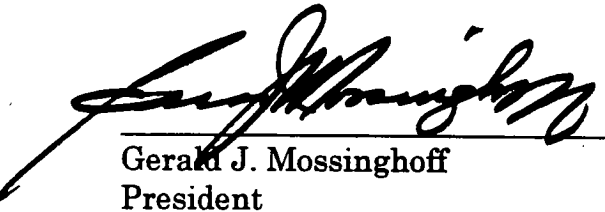
Sincerely,



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