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012-96

National Wholesale Druggists' Association

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

Attention: Public Information

Dear Commissioners:

This comment is submitted by the National Wholesale Druggists' Association (NWDA). NWDA is the national trade association for wholesale distributors of prescription drugs. Our members operate over 200 distribution centers across the country that handle a majority of the wholesale sales of pharmaceutical products nationwide. Drug wholesalers are subject to the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*)

NWDA members are very concerned about proposed amendments to the Federal Sentencing Guidelines "regulatory" guideline found at United States Sentencing Commission, Guidelines Manual ("U.S.S.G."), § 2N2.1 (Nov. 1994), which published in the January 2, 1996, Federal Register (61 Fed. Reg. 83). The Commission has proposed to delete § 2N2.1 and to sentence persons convicted of offenses previously covered by § 2N2.1 under the fraud guideline found at § 2F1.1. We believe this change would have an unfair impact on individuals and organizations convicted of regulatory offenses.

The offenses currently covered by § 2N2.1 do not require proof of fraud or criminal intent. Indeed, the Application Note to § 2F2.1 states that the guideline assumes an offense involving knowing or reckless conduct. If, however, fraud was involved in the offense, the current language of § 2N2.1 already provides for sentencing by reference to the fraud guideline. We believe that § 2N2.1 provides an appropriate structure for imposition of sentences for offenses that do not involve fraud. The fraud guideline assumes the criminal intent of the offender, a mental state that is not an element of the regulatory offenses. By treating these offenses under the fraud guideline, excessive punishment will result. The application of sentences designed to address fraudulent conduct to misdemeanor regulatory offenses will result in proportionately greater punishment for these offenses, a result which the Guidelines were intended to avoid.

While simplification of the Guidelines is a worthy goal, it should not be accomplished through similar treatment of unlike offenses. Consistency in sentencing is one of the guiding principles of the Guidelines. The Introduction and General Application Principles of the Guidelines state that Congress sought "reasonable uniformity in sentencing by narrowing the wide disparity in sentences

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imposed for similar criminal offenses committed by similar offenders" and "proportionality in sentencing through a system that imposes appropriately different sentences for criminal conduct of differing severity." U.S.S.G. Ch. 1, Pt.A § 3. We note that the Commission has not proposed to subsume environmental offenses under the fraud guideline. We do not propose that the Commission do so, but we suggest that the strict liability offenses currently sentenced under § 2N2.1 are more similar to environmental offenses than to fraud offenses and should be treated similarly.

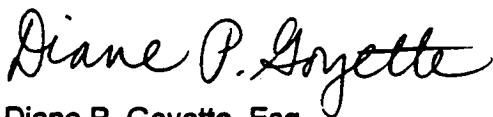
Another effect of the Commission's proposal is that regulatory offenses committed by organizations would be sentenced under the organizational sentencing guidelines. Our objections are the same as our objections to sentencing of individuals convicted of regulatory offenses under the fraud guideline. Imposition of the full weight of the organizational guidelines is heavy-handed and unwarranted for regulatory offenses.

The Commission has also invited comments on "whether 'gain' should be a substitute for 'loss' when the essence of the offense is fraud against regulatory authorities with no economic loss." 61 Fed. Reg. 83 (proposed January 2, 1996). Application Note 8 of § 2F2.1 provides that gain realized as a result of the offense may be used as an alternative estimate of loss, but that gain ordinarily will underestimate the loss. In the context of regulatory offenses, we strongly disagree that gain will ordinarily underestimate the loss. Where no economic loss can be shown, we maintain that gain vastly overstates the loss, especially in those situations where courts have used gross profits as a measure of a defendant's gain. This effect would be even more egregious if applied to strict liability regulatory offenses, as contemplated in the Commission's proposal to include these offenses under § 2F2.1.

Whether applied to strict liability regulatory offenses, or regulatory offenses committed through fraud, measurement of punishment by reference to gain, in the absence of demonstrable loss, flies in the face of the Guidelines' Resolution of Major Issues regarding Regulatory Offenses which provides a low base offense level with increases based on specific offense characteristics "designed to reflect substantive harms." U.S.S.G. Ch.1, Pt.A § 4(f). The Commission should reaffirm its goals of punishing technical, recordkeeping and reporting offenses through low base offense levels. Where no loss can be proved, the potential penalties are lower, which is appropriate where the goal is to punish the harm caused by the conduct. Carefully drawn grounds for an upward departure from the regulatory guideline may be a more appropriate remedy.

Thank you for the opportunity to express our views on this important proposal.

Sincerely,



Diane P. Goyette, Esq.
Director of Regulatory Affairs