March 27, 2008

VIA HAND DELIVERY

Honorable Ricardo H. Hinojosa, Chair
United States Sentencing Commission
Attention: Public Affairs
One Columbus Circle, N.E.
Suite 2-500
Washington, DC 20002

Subject: Comments to Notice of Proposed Amendments to Federal Sentencing Guidelines
Federal Register: F.R. Doc. E8-1426
F.R. Publication Date: January 28, 2008

Dear Chairman Hinojosa:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to provide public comments on the notice of proposed amendments to federal sentencing guidelines, policy statements and commentary, as published in the Federal Register on January 28, 2008.[1] HDMA and its members are the vital link in a healthcare system that assures medicine safety, quality, integrity and availability in the marketplace. A detailed description of the role of HDMA in the pharmaceutical supply chain is enclosed as an addendum to these comments.

The following comments are submitted in response to a proposed amendment to the federal sentencing guidelines which would change how certain violations of the Federal Food Drug and Cosmetic Act, ("FFDCA") 21 U.S.C. Section 301 et seq., and the Prescription Drug Marketing Act of 1987 ("PDMA"), are treated under Section 2N2.1 of the sentencing guidelines. Section 2N2.1 of the federal sentencing guidelines applies to violations of statutes and regulations involving any food, drug, biological product, device, cosmetic or agricultural product. HDMA's comments shall be limited to this proposed amendment, which is of primary importance to wholesalers of drugs, biological products, devices, and cosmetics.

Proposed Amendment Comments

HDMA shall address two issues for comment regarding Section 2N2.1 of the proposed guidelines:

I. The need for increased or alternative base offense levels for certain offenses under Guideline Section 2N2.1

II. The proposed amendments should not negatively affect the role of wholesale pharmaceutical distributors in conducting legitimate commercial drug transactions under Guideline Sections 2N2.1 and 2D1.1

[1] 73 Fed. Reg. 4931 (January 28, 2008).

I. The need for alternative base offense levels under the proposed amendment

The Commission has requested comment on whether Section 2N2.1 violations should be amended in order to adequately address numerous statutes referenced in that guideline. Specifically, the Commission invites comment on whether it should provide alternative base offense levels for violations of statutes under the FFDCA and PDMA that would warrant increased sentences as listed in the sentencing guidelines. Individuals and entities found to have violated the statutes referenced in the sentencing guidelines are subject to both civil and criminal penalties, ranging from fines and monetary penalties of $1,000 to $1,000,000 and imprisonment from one year to ten years for serious violations of the statutes.

HDMA supports the overall goals of the Commission to strengthen and enhance the sentencing guidelines that are used by the courts against individuals for violations of the FFDCA and PDMA. Violations of these statutes threaten the safety, security and integrity of the pharmaceutical distribution industry and the supply chain system. HDMA endorses the Commission's efforts to re-examine the need for enhancing the base offense levels designated in the federal sentencing guidelines in order to assess the propriety and reasonableness of such penalties imposed against individuals who violate these statutes.

Because the proposed amendment to 2N2.1 could have a substantial impact on sentences imposed under such a wide range of regulatory offenses, adoption of the measure could lead to unforeseen consequences. Adopting the proposed amendments to the guideline would affect a substantial number of statutes referenced in the commentary to Section 2N2.1 of the guideline, including those statutes listed in Appendix A to the guidelines. Statutes affected under the proposed amendment range from misdemeanors to felonies with knowledge and intent requirements. Title 21 U.S.C.A. Section 331 and Section 333, contain descriptions of numerous prohibited acts and penalties, such as counterfeiting, illegal drug purchases and sales, and prescription drug marketing violations that could be directly affected by the proposed amendment.

At present, there is no indication that changes to Section 2N2.1 with respect to Food, Drug, and Cosmetic (FDC) Act offenses are necessary or appropriate.[2] In view of the structure of the FDC Act and the actual enforcement of the Act, it would appear that the Food and Drug Administration does not suffer any impediment to vigorous enforcement and maintenance of important deterrence incentives over regulated industries.

[2] These comments are limited to offenses to which the Section 2N2.1 guideline is applicable, and not to any offense implicating "intent to defraud or mislead" under the FDC Act, in which case the Section 2B1.1 guideline applies. Specifically, HDMA has an extensive public record regarding its concerns about the serious issue of counterfeit drugs entering the U.S. supply system. Such criminal conduct, however, would involve fraud, and therefore be governed by the Section 2B1.1 Guideline. HDMA will continue its efforts with FDA and other federal and state authorities to develop and implement the most effective and efficient methods for tracking, tracing, and authenticating pharmaceutical products' movement across the supply chain. HDMA urges federal authorities to vigorously investigate and prosecute prescription drug counterfeiting cases, and to seek the strongest possible sentences against those who would defraud vulnerable patients when they are seeking therapy and healing. HDMA further urges the Congress to conduct appropriate oversight over the Department of Justice and FDA to ensure that departmental and agency resources are appropriately deployed to address the significant public safety risks engendered by counterfeit prescription drugs.

HDMA recommends that the Commission study this matter further before it takes any final action to ratify the adoption of this amendment. HDMA believes that the Commission should have an opportunity to examine and evaluate all of the empirical data available that addresses the need to amend Section 2N2.1. Specifically, the Commission should review the historic record of prosecutions under the misdemeanor provisions of the FDC Act only and those prosecutions under of the felony provisions of the Act. We respectfully submit that such a historical review will disclose that those cases that presented substantial risks to the public health have consistently been prosecuted under the "intent to defraud or mislead" felony provisions of the Act, making the Section 2N2.1 guideline inapplicable. Enhancement of the Section 2N2.1 guideline to include the basis for an upward departure in the event of substantial risk of bodily harm or death is therefore unwarranted. Misdemeanor FDC Act prosecutions are effectively strict liability cases. *United States v. Park*, 421 U.S. 658 (1975). Enhancing that strict liability based upon the nature of the product (especially where the nature of and inherent risks of pharmaceutical products distributed can vary so widely) does not serve the underlying deterrent value of the FDC Act's misdemeanor provisions but only adds unquantifiable risk to legitimate distribution of these products.

We believe that a review of all available data supporting the addition of alternative base offense levels under Section 2N2.1 would help to ensure that the issues intended to be remedied by the adoption of guideline Section 2N2.1 are adequately addressed. Additional consideration by the Commission could avoid or reduce the chances of encountering unforeseen consequences when Section 2N2.1 guidelines are applied to violations of the referenced statutes.

II. The role of distributors in conducting legitimate commercial drug transactions

Distributors provide a broad range of essential services to their customers, and maintain the reliability, safety and efficiency of the pharmaceutical supply chain. Distributors consolidate regional shipments of medications, maintain product safety inventory stocks, and disseminate products when and where they are needed. These and many more services are provided by distributors to meet the needs of their customers and to ensure that needed medicines and other pharmaceutical products will be available to them safely, efficiently, and on time.

Because of the vital role of wholesale distributors in the pharmaceutical supply chain, HDMA urges the Commission to consider the following recommendations concerning prohibited acts and penalties contained in 21 U.S.C. A. Section 331 and Section 333 as they relate to the proposed amendment to Sections 2N2.1 and 2D1.1:

1. We urge the Commission to recognize the unique role of pharmaceutical distributors when it considers alternative base offense levels for prohibited acts under the sentencing guidelines. Specifically, we ask that the Commission consider the unique role of pharmaceutical distributors as it deliberates amending the sentencing guidelines for violations of counterfeiting, or the doing of any act which causes a drug to be a counterfeit drug, under 21 U.S.C.A. Section 331. We believe that the Commission should refrain from adopting any alternative amendment to the sentencing guidelines that would incorporate base offense levels for the unknowing and unintentional distribution of counterfeit drugs through the supply chain by wholesale distributors. In those cases in which the

government has found it necessary to seek lengthy sentences, there have been circumstances which fully enable prosecutors to use a panoply of criminal statutes to achieve appropriate charging decisions. *E.g.*, *United States v. TAP Pharmaceutical Products, Inc.*, 1:01-cr-10354-WGY (D. Mass.) (judgment Dec. 10, 2001) (conspiracy, conspiracy to defraud, anti-kickback, and False Claims Act counts charged).

Under 21 U.S.C.A. 353, a wholesale distributor is an entity that has been granted a license by the State, and is thereby authorized to engage in commercial transactions involving the purchase and sale of prescription medications. These transactions include the purchase and sale of controlled substances not safe for use unless under the supervision of a physician. The language contained in Section 331 and Section 353 referenced above recognize the authority of distributors to conduct transactions involving these substances, and therefore prohibitions in the statute against the sale, or purchase of drugs applicable to individuals or unlicensed entities, do not apply to them. We ask that amendments to Section 2N2.1 or related guidelines reflect the language contained in these statutes.

2. The Commission also requested comment regarding the harmfulness of human growth hormone (hGH) offenses relative to offenses involving anabolic steroids. Specifically, the Commission invites comment on whether the trafficking of hGH is more harmful, less harmful, or of equal harm to the trafficking of steroids. The proposed amendment would potentially expand the scope of base level offenses under Section 2D1.1(b)(6) of the sentencing guidelines, and would equate hGH to a controlled substances for purposes of their treatment under the sentencing guidelines.

   In its consideration of base offense levels for hGH violations, HDMA urges the Commission to maintain the distinction between the use of the term distribution as a legitimate commercial service provided by wholesale distributors in the normal course of business, from the term as it is used in the context of the prohibited acts and penalties under 21 U.S.C.A. section 331. In the former context, the term distribute means to sell, offer to sell, deliver or offer to deliver a drug to a recipient as part of a wholesale distribution transaction. Wholesale distribution is defined under the PDMA as the distribution of prescription drugs to persons other than a consumer or patient. HDMA's concern is that the use of the term in the context unrelated to wholesale distribution transactions may be used inappropriately when considering the application of the proposed amendment to Section 2D1.1 of the guideline, and could result in avoidable confusion over its use and interpretation.

Conclusion

In summary, HDMA believes that the Commission should recognize the importance of the current role of the wholesale pharmaceutical distributors as it considers the consequences of adopting amendments to the proposed sentencing guidelines. We urge the Commission to refrain from adopting any amendment that would result in directly or indirectly having a negative effect on the necessary commercial activities and administrative services performed by wholesale distributors in the normal course of business.

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On behalf of HDMA and our member companies, thank you for the opportunity to provide our comments on the Commission's proposed amendment to Section 2N2.1 violations under the federal sentencing guidelines. We are grateful for the opportunity to relay our perspective about important supply chain issues, and we continue to stand ready to address any questions you may have about the issues, concerns, and suggestions discussed above.

Sincerely,

Brian M. Cherico, Esq.
Government Affairs

ADDENDUM

HDMA – The Vital Link in the Safe Delivery of Medicines in the U.S.

The Healthcare Distribution Management Association (HDMA) is the national association representing primary, full-service healthcare distributors. Each day, the member companies of HDMA are responsible for ensuring that more than 13 million prescription medicines and healthcare products are safely delivered to 144,000 pharmacies, hospitals, nursing homes, physician offices, clinics, government and other providers in all 50 states. This essential public health function is provided with tremendous efficiency, saving the nation's healthcare system nearly $34 billion each year. HDMA and its members are the vital link in the healthcare system, working daily to provide value, remove costs and develop innovative solutions to deliver care safely and effectively.

Healthcare Distribution At-A-Glance

- Through value added-services, including streamlined logistics and efficient operations, distributors save the healthcare system nearly $34 billion each year
- 80% of prescription medicines sold in the United States are stored, managed and delivered by HDMA member companies
- Healthcare distributors represent 3% of the total cost of prescription medicines
- At only 1.1 % the distribution industry net profit margin is very low

Distributors Save the Healthcare Billions of Dollars Each Year

A landmark study by the research firm Booz Allen Hamilton, commissioned by HDMA's knowledge partner, the Center for Healthcare Supply Chain Research, reported that healthcare distributors save the healthcare system nearly $34 billion a year by providing value-added services and creating business efficiencies.

HDMA members manage many of the most sophisticated and efficient distribution facilities in the world. These distribution centers are critical to the efficient delivery of prescription medicines and healthcare products from more than 1,100 different manufacturers to pharmacy settings across the country.

Distributors Are Highly Regulated By State And Federal Governments

The U.S. healthcare supply chain is one of the most sophisticated in the world, providing a strong system for the safe and efficient delivery of prescription medicines to patients nationwide. Manufacturers, distributors and pharmacies work daily to help ensure patients receive the right medicine, at the right place, at the right time. These companies together must remain vigilant in monitoring, protecting and enhancing this secure system against increasingly sophisticated criminals who may try to introduce counterfeit or diverted drugs into the legitimate supply chain.

Healthcare distributors are regulated at both federal and state levels to help ensure the integrity and security of the supply chain. At the federal level, distribution centers are subject to inspection by: The U.S. Food & Drug Administration (FDA), Drug Enforcement Administration (DEA), Environmental Protection Agency (EPA), Occupational Safety & Health Administration (OSHA) and Department of Transportation (DOT).

Furthermore, states are responsible for licensing distributors, and many states apply regulatory standards in addition to those required under federal law. These state standards apply to companies conducting business in the state, even if the company's distribution center is located in another state. HDMA continues to strongly advocate for tougher state licensing requirements for healthcare distributors to further enhance supply chain integrity and patient safety.

The Nation's Healthcare Distributors Deliver Healthcare Products And Services Every Day

HDMA member companies are the vital link in the healthcare system, providing the highest-quality business solutions that remove costs and empower providers to deliver care more effectively. The development of products requiring advanced and/or special handling, as well as the increased demand for specialized treatments among home users, would be difficult, if not impossible, to manage without the expertise of the nation's healthcare distributors.