

VIA Federal Express

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Hoechst Marion Roussel, Inc.

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United States Sentencing Commission
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Attn: Public Information

RE: PROPOSED AMENDMENTS TO U.S.S.G. SECTION 2N2.1;
61 FED. REG. 79 (JANUARY 2, 1996)

Dear Sir/Madam:

The following comments are filed on behalf of Hoechst Marion Roussel, a research based global pharmaceutical company whose North America headquarters are located in Kansas City, Missouri. The company's operations are directly regulated by the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.) ("FFDCA"). Therefore, the changes proposed in the above-referenced Federal Register notice could have an impact on the company. In addition, Hoechst Marion Roussel is a member of the Pharmaceutical Research and Manufacturers of America (PhRMA) and concurs in the comments filed with the Commission on behalf of PhRMA.

The January 2 proposal by the Commission included a section on food and drug offenses affecting how individuals and corporations are treated following a conviction for a violation of the FFDCA, among other statutes. 61 Fed. Reg. at 83. The proposal would delete guideline Section 2N2.1 in its entirety and would instead treat all offenses originally covered by this Section as cases involving fraud, governed by Section 2F1.1.

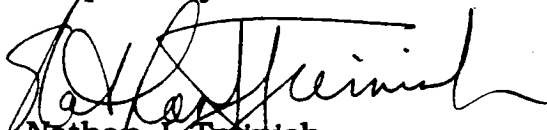
The effect would be that purely regulatory violations would be treated in the same manner as intentionally fraudulent conduct. Sanctions designed to address fraudulent conduct could then be imposed on cases involving violations of the FFDCA which do not require knowledge or proof of fraud. We believe such a change is unnecessary, and that current guidelines more adequately provide the flexibility needed to respond to the broad spectrum of conduct involved in the prosecution of offenses under the FFDCA.

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Under United States v. Dotterweich, 320 U.S. 277 (1943) and United States v. Park, 421 U.S. 658 (1975), the Supreme Court dispensed with the conventional requirements for criminal conduct (i.e., awareness of some wrongdoing) and basically established a standard of strict liability. Under these cases an individual cannot escape criminal liability based upon lack of knowledge of any wrongdoing. The Dotterweich court explained that the FFDCA "puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to the public danger." 320 U.S. at 284-85.

As currently worded, Section 2N2.1 imposes a base offense level for any regulatory violation while permitting enhanced sentences, by cross-reference to Section 2F1.1, in cases where regulatory violations are part of a pervasive scheme. This flexibility should be retained in connection with the investigation and prosecution of cases under the FFDCA. The proposed amendments would have the effect of treating all cases the same. It is important to retain the current distinction and provide for tougher penalties for intentional and fraudulent conduct. Therefore, the proposed amendment should not be adopted.

Respectfully submitted,



Nathan J. Treinish
Corporate Counsel-Regulatory

NJT/usscltr:pb