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March 5, 1996

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

via Federal Express

Re: Comments on Proposed Amendments to U.S.S.G. Sec. 2N2.1

Dear Sir/Madam:

Merck & Co., Inc., a worldwide research-intensive pharmaceutical company that discovers, develops, produces and markets a broad range of human and animal health and pharmaceutical products and services, submits the following comments to the proposed revisions to Section 2N2.1 of the U.S. Sentencing Guidelines ("the Guidelines" or "U.S.S.G.").

The Commission proposes to delete Section 2N2.1 which addresses violations by individuals of statutes and regulations dealing with any food, drug, biological product, device, cosmetic or agricultural product and to require federal judges to sentence all violations of food and drug laws under Section 2F1.1, the fraud sentencing guideline. This proposed revision would mean that negligent violations of federal food and drug regulations, which currently are sentenced in accordance with Section 2N2.1, would be sentenced under the same guideline applied to fraudulent violations of the food and drug laws.

Under the current guidelines, sentences for criminal violations by individuals of statutes and regulations governing food, drug and device products are subject to the application of U.S.S.G. Section 2N2.1 which provides for a base offense level of six, when "knowing or reckless" conduct is involved, but allows judicial discretion for downward departures from this level in cases involving simple negligence or oversight. See U.S.S.G. Section 2N2.1 (Application Note 1). Cases involving fraud require the application of Section 2F1.1 which also has a base offense level of six but provides for significant increases in the offense level based on the amount of "loss" caused by the violative conduct. Unlike Section 2N2.1, the fraud guideline does not contain a specific reference to the

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appropriateness of a downward departure for certain cases such as those involving simple negligence.

The stated purpose of the proposed revision is to simplify the application of the sentencing guidelines and address the failure of sentencing courts, in some cases, to cross reference the fraud guideline. The proposed deletion of Section 2N2.1, however, could have the potential result of imposing significantly harsher sentences in cases involving unintended or negligent violations of food and drug laws. Moreover, the apparent failure of some courts to cross-reference the fraud guideline in appropriate cases involving fraudulent conduct could be addressed when it occurs by an appeal of the sentencing court's decision. The wholesale deletion of an existing guideline and wider application of the fraud guideline is too broadsweeping a fix that may result in unjust sentences.

The goal of sentencing reform was to eliminate the inherent unfairness caused by wide disparities in the sentencing of similar defendants for similar crimes. It would be no less unfair to treat defendants with wide-ranging culpability as if their offenses were the same.

For the reasons set forth above, Merck is opposed to the proposed revision to delete Section 2N2.1. Thank you for the opportunity to provide comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "R. M. David", written in dark ink.