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March 5, 1996

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

Attention: Public Information

Re: Proposed Amendments to Sentencing Guidelines, Policy Statements, and Commentary

Dear Sir/Madam:

Pfizer Inc (Pfizer) submits the following comments concerning the proposed amendments to the Sentencing Guidelines ("Guidelines"), policy statements, and commentary, pursuant to the request of the Sentencing Commission ("Commission") set forth in the January 2, 1996 Federal Register (61 Fed. Reg. 79-83). Pfizer's comments are limited to the proposed amendments to §2N2.1 of the Guidelines, entitled "Violations of Statutes and Regulations Dealing With Any Food, Drug, Biological Product, Device, Cosmetic, or Agricultural Product" and the corresponding amendments to §2F1.1, entitled "Fraud and Deceit; Forgery; Offenses Involving Altered or Counterfeit Instruments Other than Counterfeit Bearer Obligations of the United States", which are set forth at 61 Fed. Reg. 83. Pfizer is a corporation engaged in the research, development, manufacture, and distribution of various healthcare products, including human and animal drugs and medical devices, and thus has an interest in the proposed amendments.

The Commission is proposing to eliminate §2N2.1 in its entirety and fold all offenses that currently fall under its scope into §2F1.1, the fraud provision. Pfizer opposes this proposal because it would result in assessment of excessive sentences in those instances where the violation was the result of mere negligence rather than intentional fraud. The amendments, as proposed, attempt to address a narrowly defined problem (possible failure to consistently and correctly follow cross-referencing requirements) by revising wholesale the sentencing scheme for violations of food, drug, biological product, and device statutes and regulations. Further, elimination of the discretion that is currently allowed under §2N2.1 may result in the imposition of harsher penalties than are warranted by a specific offense. In addition, the proposed

amendments appear to characterize all violations currently covered by §2N2.1 as offenses involving fraud and deceit. These concerns are explored more fully below.

The Commission's proposal apparently is based upon the concern, expressed in the February 1995 Food and Drug Working Group Final Report ("Final Report") at p. 12, that the courts have failed to correctly or consistently cross-reference to the fraud guideline, which in turn may have resulted in the assessment of inadequate penalties. Although this concern may be appropriate, the proposed amendments fail to target the narrow area of concern, namely the correct and consistent application of the cross-reference requirement. In fact, the proposed amendments attempt to eliminate the problem by severely curtailing discretion in the sentencing of all violations of food and drug statutes and regulations, regardless of a finding of fraudulent activity.

The current guideline that addresses such offenses, §2N2.1, is, on its face, broad enough to allow the fashioning of a sentence that specifically addresses a particular offense and the unique circumstances surrounding that offense. The cross-references listed under §2N2.1(b) (requiring application of other offense guidelines, including the fraud guideline, in those situations where it is warranted), combined with Application Note 1 (allowing a downward departure in situations where only negligence is involved) and Application Note 3 (allowing for an upward departure in situations involving death or bodily injury, extreme psychological injury, property damage or monetary loss), comprise an appropriately flexible sentencing scheme to address the spectrum of offenses that fall under the scope of this guideline. Although the proposed amendments maintain the ability to increase the sentence in those situations that warrant it, they eliminate the ability to decrease the sentence in those situations where a less severe penalty is warranted, such as where negligence is involved. As the Food and Drug Working Group admits in the Final Report at p. 12, "The impact of sentencing under §2F1.1 rather than §2N2.1 can be dramatic . . ." The proposed amendments mandate, rather than permit or restrict, this possibly dramatic increase in sentencing results.

Furthermore, eliminating the current guideline merely to address a perceived problem in the application of the cross-reference requirements results in the assessment of an inappropriately burdensome penalty in those instances where the offense would currently be addressed by a downward departure of the sentence, as allowed by Application Note 1 when the offense involves only negligence. The guideline should allow enough discretion to fashion a sentence, by applying upward or downward departures, that is appropriate for a specific offense.

In addition, the proposed amendments appear to characterize all violations that would currently be covered by §2N2.1 as offenses involving fraud and deceit. Unlike the offenses covered by §2F1.1, such as fraud and deceit, forgery and counterfeiting, certain violations covered by §2N2.1 occur through mere negligence, and it is incorrect and unfair to characterize these types of violations as involving fraudulent activity. Further to this point, the proposed amendments

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do not appear to contemplate that the title to Part F, "Offenses Involving Fraud Or Deceit," would be revised to indicate that this part would also now cover violations of statutes and regulations dealing with foods, drugs, biological products, devices, cosmetics, and agricultural products, regardless of a finding of fraud.

We respectfully request that the above comments and recommendations be considered by the Commission when determining promulgation of amendments to the Guidelines. We appreciate the opportunity to present our comments for the Commission's consideration.

Respectfully,

A handwritten signature in cursive script, reading "Jill M. Bruzga".

Jill M. Bruzga