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February 20, 1996

BY HAND DELIVERY

The Honorable Richard P. Conaboy
Chairman
United States Sentencing Commission
One Columbus Circle, N.E.
Suite 2-500
Washington, D.C. 20002-8002

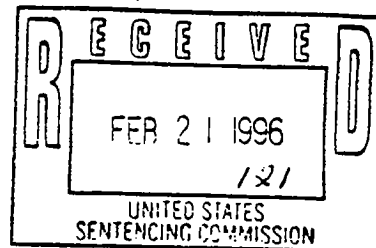
Re: Proposed Amendment To Sentencing Guideline 2N2.1

Dear Judge Conaboy:

On January 2, 1996, the Commission proposed to delete USSG § 2N2.1 ("Food, Drugs, and Agricultural Products"), 61 Fed. Reg. 79, 83 (1996) (hereinafter "the Proposal"). The purpose of this letter is to request the Commission to withdraw the Proposal or, alternatively, extend the comment period so that the Commission will postpone a decision on the Proposal until after May 1, 1996.

The Commission and entities affected by the Proposal would benefit if the March 6, 1996 comment deadline is either withdrawn or extended. The activities of approximately one-fourth of the economy of this country are regulated by the Food and Drug Administration. The effects of a precipitous change to the existing food and drug guideline would be severe.

USSG § 2N2.1 applies to sentences under statutes that regulate foods, drugs, medical devices and certain other consumer products. Where fraud is involved, USSG § 2F1.1 now applies. See USSG § 2N2.1(b)(1). Thus, USSG § 2N2.1 is only employed in regulatory cases not involving fraud. Most defendants in those cases are charged under the doctrine set forth in United States v. Park, 421 U.S. 658 (1975). That case upheld the authority of the United States Food and Drug Administration to obtain a conviction against a corporate officer without having to prove that the defendant had any mens rea. These so-called "strict liability" criminal prosecutions are often referred to as Park cases.



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Most, if not all, of affected industry will continue to support strict sentences against individuals and corporations convicted of felony food and drug offenses where fraudulent conduct is established. They do not oppose application of USSG § 2F1.1 to food and drug cases involving fraud. However, similar stiff jail sentences on individuals and corporations convicted of misdemeanor offenses, which generally are "strict liability offenses," is simply not warranted.

On February 15, 1996, James R. Phelps of the Washington D.C. law firm of Hyman, Phelps & McNamara, P.C., and the undersigned met with four officials from the Sentencing Commission: John R. Steer, Frank Larry, Marguerite Driessen, and Linda Wernery. Mr. Phelps and I represent companies and trade associations with members subject to USSG § 2N2.1. We asked for the meeting to discuss why the Proposal is flawed.

Mr. Phelps and I believe that the meeting was a mutually beneficial opportunity for the participants to engage in a healthy and productive dialogue. We raised issues, facts and opinions that we do not believe were considered fully in a February 1995 Final Report issued by the Commission's Food and Drug Working Group.

Mr. Phelps and I have spoken with many trade associations and others who have a keen interest in the Proposal. Firms (and their representatives) affected by the Proposal have raised a unanimous voice expressing strong opposition. Many of these entities are willing to explain their opposition in comments to be filed with the Commission. However, withdrawing the Proposal before the close of the comment period will relieve the affected industry from undergoing the expense and burden of submitting comments on a fast-track schedule to a Proposal that merits further study.

There is no factual basis for eliminating USSG § 2N2.1. In the Federal Register notice announcing the Proposal, the Commission referred to a two-year study conducted by the Food and Drug Working Group. 61 Fed. Reg. 83 (1996). The Working Group's Report did not propose to eliminate USSG § 2N2.1. Moreover, the Working Group never indicated that any judge, prosecutor, or defense attorney has complained that even one sentence for a misdemeanor food and drug offense was inappropriate under USSG § 2N2.1.^{1/}

We recognize, and have no quarrel with, the Commission's laudatory goal to simplify the Sentencing Guidelines. See 60 Fed. Reg. 49,316 (Sept. 22, 1995). However, a desire to simplify the Guidelines may not justify deletion of USSG § 2N2.1. Nor should a desire to simplify the

^{1/} In fact, the Working Group stated that "the issue remains whether [§ 2N2.1] as currently drafted provides for adequate fines..." Food and Drug Working Group Final Report at 19.

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Guidelines form a basis to fit strict liability criminal cases into a Guideline that was promulgated to deal with fraud.

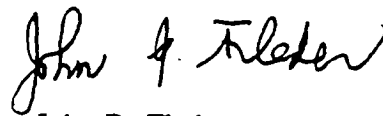
We believe that the Commission's stated goal to simplify the Guidelines would be furthered by maintaining and possibly expanding USSG § 2N2.1. There are strict liability prosecutions commenced under statutes other than those now explicitly implicated by 2N2.1. The Commission might want to republish its Proposal to expand USSG § 2N2.1 to cover other regulatory statutes. Alternatively, the Commission might consider a new Guideline that would cover all regulatory violations where fraud is not involved. Indeed, the Commission could use that proposal to solicit comment on whether "harm" should be a relevant sentencing factor in regulatory cases.

In sum, USSG § 2N2.1 may need some modification. However, that modification should not be in the form of deleting USSG § 2N2.1 in its entirety, resulting in all food and drug cases being sentenced under USSG § 2F1.1.

Mr. Phelps and the undersigned are prepared to provide whatever assistance we can give the Commission. We have extensive backgrounds in food and drug criminal cases. Both of us have been prosecutors and defense counsel in this area. We would be pleased to serve on an Advisory Working Group, if the Commission chooses to form such a group, to deal with the issues raised in this letter.

We appreciate this additional opportunity to present our views.

Sincerely yours,


John R. Fleder

JRF:jch

cc: The Honorable Michael S. Gelacak
The Honorable A. David Mazzone
The Honorable Wayne A. Budd
The Honorable Julie E. Carnes
The Honorable Michael Goldsmith
The Honorable Deanell R. Tacha

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