



March 12, 1993

Mr. Michael Courlander
Public Information Specialist
United States Sentencing Commission
One Columbus Circle, N.E.
Suite 2-500, South Lobby
Washington, D.C. 20002-8002

Dear Mr. Courlander:

On behalf of the Food and Drug Administration ("FDA"), I wish to submit the following comments on proposed amendments to the sentencing guidelines for United States courts, published in 57 Fed. Reg. 62832 (1992).

Proposed Amendment Five:

(a) The FDA opposes proposed amendment five, which would eliminate from Sections 2B1.1 (theft) and 2F1.1 (fraud and deceit) "more than minimal planning" as a specific offense characteristic providing for a two-level increase in sentence. The amendment would also eliminate from Section 2F1.1 "a scheme to defraud more than one victim" as a specific offense characteristic requiring a two-level increase in sentence. Instead, the amendment would modify the loss tables in Sections 2B1.1 and 2F1.1 to incorporate gradually an increase for "more than minimal planning" with a two-level increase for losses in excess of \$40,000.

The "more than minimal planning" and "scheme to defraud more than one victim" specific offense characteristics have special significance in offenses involving the public health and safety, which often consist of coordinated or carefully planned schemes to defraud that result in substantial non-monetary harm to consumers and to health patients. Indeed, fraud offenses frequently include planned efforts to conceal the wrongful conduct from regulatory agencies and from the public. Therefore, the FDA believes that these characteristics should remain as specific offense characteristics rather than being considered only in terms of economic loss under Sections 2B1.1 and 2F1.1.

(b) Under the heading "Additional Issues for Comment," the Notice also invites comment on various alternatives to proposed amendment five. The FDA opposes eliminating the "more than minimal planning" and "scheme to defraud" specific offense characteristics from Section 2F1.1, or any of the proposals to

otherwise alter the definition of "more than minimal planning" in Section 1B1.1. However, the agency strongly supports increasing the base offense level of Section 2F1.1, and other guidelines that contain an enhancement for "more than minimal planning," in recognition of the pervasiveness and seriousness of fraudulent criminal conduct. The agency also supports setting forth more examples of the application of "more than minimal planning" in fraud and theft cases, specifically including examples of fraud involving the manufacture, distribution, or use of food, drug, device, or cosmetic products.

The FDA believes that the current base offense level six in Section 2F1.1 is disproportionately low in comparison to other guideline offenses. In addition, the agency believes that the guidelines do not sufficiently reflect the serious, non-monetary harm that frequently results from fraud-related offenses within the purview of the Federal Food, Drug, and Cosmetic Act. Accordingly, while the FDA supports the proposal to restructure the loss tables for fraud offenses to provide higher offense levels for losses at the lower end of the loss table, the agency believes that the guidelines' offense levels should be substantially increased for health-related fraud offenses that do not result in substantial economic harm. One way to partially address this concern would be to adopt the proposals set forth in proposed amendment six and issue for comment (no. seven), as set forth below.

Proposed Amendment Six:

The FDA strongly supports proposed amendment six, which would amend Application Note 10 of Section 2F1.1 to (a) provide guidance for an upward departure in cases in which the fraud caused substantial non-monetary harm and to (b) include an example of a fraudulent blood bank operation. Other "guidance" examples of health-related fraud offenses warranting an upward departure would exist in the case of a pharmaceutical manufacturer that conducted or reported fraudulent or false testing to determine the identity, strength, quality, or purity of a drug, or of a person or persons that created, sold or dispensed a counterfeit drug. In each example, the quality or safety of the drug may be seriously deficient based on the improper or inadequate manufacturing operations or processes. Such offenses might result in substantial harm to innocent health victims that is not adequately addressed by considering economic loss alone.

Issue For Comment (No. Seven):

For the reasons set forth in the preceding two paragraphs, the FDA strongly supports amending Sections 2B1.1, 2B1.2, and 2F1.1 to identify specific offense characteristics for circumstances in which the "loss" does not fully capture the harmfulness and seriousness of the conduct, thereby warranting an increased offense level. In particular, the agency suggests establishing respective specific offense characteristics to provide for (a) a two-level increase (or level 13) for circumstances in which some or all of the harm caused by the offense was non-monetary, (b) a four-level increase (or level 24) when the defendant knowingly or recklessly endangered the health or safety of one or more persons, (c) a four-level increase (or level 24) when the offense involved the knowing or reckless risk of serious bodily injury or death to one or more persons, and (d) a six-level increase (or level 26) when the offense results in death. Alternatively, the FDA supports amending the commentary to these sections to include the above examples as circumstances in which an upward departure may be warranted.

Issue For Comment (No. 65):

The FDA supports amending Section 2F1.1 to include the risk of loss as a factor in determining the guideline range for fraud and related offenses when the amount of the risk is greater than the actual or intended loss. The risk of loss should increase the guideline range to the same extent as actual or intended loss, irrespective of whether or not the risk was reasonably foreseeable. Currently, Section 2F1.1 provides that the intended loss shall be used if it is greater than the actual loss. Presumably, this is to hold defendants accountable for the loss intended by their wrongful acts. The agency believes that defendants should likewise be held fully accountable for the risk of loss associated with their intentional wrongful acts.

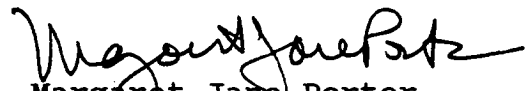
Additional FDA Comments:

The FDA recommends that the Statutory Index (Appendix A), which specifies the guideline section or sections ordinarily applicable to the statute of conviction, be amended. With respect to the Federal Food, Drug, and Cosmetic Act, the current appendix lists Sections 2F1.1 and 2N2.1 as being applicable to offenses under 21 U.S.C. §333(a)(2), but only Section 2N2.1 as being applicable to 21 U.S.C. §§331, 333(a)(1), and 333(b). The agency believes that Section 2F1.1 is also applicable to offenses under 21 U.S.C. §§331, 333(a)(1), and 333(b) (as amended August 26, 1992), and that this information should be included as a Consolidation and Simplification of Chapter Two Offense Guidelines amendment.

Mr. Michael Courlander
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Thank you for this opportunity to comment on the proposed amendments to the sentencing guidelines. If the Sentencing Commission has any questions concerning these comments, please feel free to contact me (301-443-4370) or James S. Cohen, Associate Chief Counsel for Enforcement (301-443-7272).

Sincerely,

A handwritten signature in black ink, appearing to read "Margaret Jane Porter". The signature is fluid and cursive, with the first name "Margaret" being more prominent.

Margaret Jane Porter
Chief Counsel
Food and Drug Administration

FEDERAL PUBLIC DEFENDER

ROOM 174, U.S. COURTHOUSE

MINNEAPOLIS, MN 55401

PHONE: (612) 348-1755

(FTS) 777-1755

FAX: (612) 348-1419

(FTS) 777-1419

DANIEL M. SCOTT
FEDERAL PUBLIC DEFENDER

SCOTT F. TILSEN
KATHERIAN D. ROE
ANDREW H. MOHRING
ANDREA K. GEORGE
ROBERT D. RICHMAN

March 10, 1993

United States Sentencing Commission
ATTN: PUBLIC INFORMATION
One Columbus Circle North East
Suite 2-500 - South Lobby
Washington, D.C. 20002-8002

Re: Comment on Proposed Amendments

To The Honorable United States Sentencing Commission:

I write to you, in as brief a form as possible, to express my comments on the proposed amendments in the sentencing guidelines. The fact that I am an assistant federal public defender for approximately 13 years makes me both a well informed and biased source, of which I am sure you are cognizant.

I applaud and encourage the thought and effort made to amend the loss tables and deal with the problem of more "than minimal planning" insofar as it has resulted in disparate treatments and a considerable amount of litigation. With respect to the additional issues for comment in this section, I definitely believe that the loss tables should have fewer and larger ranges in the lower ends. The loss tables at the higher ends are so large as to be beyond my experience and have no opinion as to whether they need adjustment.

Although more work would need to be done, I would encourage the Commission to modify the definition and approach to a more than minimal planning enhancement as opposed to building it into the loss table or, alternatively, building it into the loss table further from the bottom ranges, maintaining the lesser enhancement as long as possible and perhaps adding a third and additional level increase at the far end.

With respect to redefining more than minimal planning, I do have some suggestions:

- * 1. Build in a two level decrease for spur of the moment or sudden temptation conduct;

2. Do not provide for multiple victim enhancement until the number of victims has reached an appreciably large level i.e. 15 or 20 and perhaps make this enhancement an additional one or two levels at an additionally large number such as 40 or 50;
3. Require, by example, truly more than the ordinary conduct to commit the offense before an enhancement is added. Few if any types of fraud or theft escape the current definition.

The proposal with respect to U.S.S.G. § 3B1.2 (role in the offense) is also an improvement. I would suggest option one is the most preferable of the options under Note 7 reading as follows: Option 1 is preferred because it affords the sentencing judge the most flexibility in determining whether or not to apply the two level adjustment for minor role and, unlike option 2, does not repeat the Application Note position contained in Note 8 concerning burden of persuasion.

The firearms amendments are mostly technical and it would be useful for the Commission to have a period where it does not amend the firearms guideline. I do believe that an appropriate differentiation can be made between different weapons including weapons that fall within 26 U.S.C. § 5845 and its various subdivisions. Whether the differentiation should be made by different offense levels, by placement of the sentence within a the guideline range, or by a Commission-guided departure, depends on the weapon involved. It would seem that a fully automatic machine gun is different from a sawed-off shotgun which is different from a sawed-off rifle which is different from other weapons such as tear gas "pen guns," all of which are prohibited in Title 26.

I have no great criticism of the proposed amendment § 3B1.3 abuse of position of special trust or use of special skill. However, perhaps the time has come to separate these two concepts into separate adjustment sections. It would seem to me be best to leave special trust as a Chapter 3 adjustment with appropriate illustrations in the application notes rather than adding it as a specific offense characteristic in a hit or miss fashion to various guidelines relating to fraud or embezzlement or in general to the embezzlement guideline. Certainly the proposed amendment is superior to the additional issue for comment, particularly as it relates to deleting the example regarding "ordinary bank tellers".

The proposal relating to 5K1.1 - issue 24 - will apply to very few cases if it is intended to exclude "crimes of violence" where that concept includes drug offenses. It also has limited usefulness because of the exclusion of anyone who is not a "first offender".

At least it should include all category I offenders and perhaps all category I and category II offenders. The injustice which it is intended to address is not related or necessarily related to whether the defendant is category I or category VI, but the proposal is at least some improvement over the current requirement for a government motion.

I should add with respect to § 5K that I have, as have other attorneys, experienced cases in which this proposed amendment could well have made a difference.

With respect to the proposal number 25 relating to § 6B1.2 the idea is commendable. Perhaps a stronger word than "encourages" should be utilized. I would suggest a policy statement that requires the government to make such the disclosures at either option point and provides as a ground for downward departure the intentional failure of the government to do so. Experiences has taught that toothless platitudes rarely modify prosecutorial behavior in an adversary system.

The Commission should act on issue for comment number 40 relating to the mandatory minimum and distinction between cocaine and cocaine base. Significant support exists not only from the interjection of the Commissions expertise, but also other sectors of the criminal justice system for the elimination of this distinction.

Proposed numbers 44, 45 and 46 are all poor ideas, poor policy, and should not result in favorable action. They would increase unwarranted disparities and would not further the purposes of sentencing indicated by Congress.

Proposal number 57 submitted by the Department of Justice should not be acted upon. It is an attempt to accomplish exactly the opposite of what it purports to do. The Department of Justice obviously intends to utilize its proposed amendment, if it becomes the guideline, as the Commission's position which ought to be followed by the Courts in prohibiting attacks on prior convictions. It is my understanding that the Commission wishes to take no position and allow the courts to develop their own procedures. If the Commission does intend to take a position on this procedural question, it should study the matter, invite additional comment, and it is hoped, ultimately recommended that the courts permit collateral attacks on prior convictions utilized to enhance sentences.

• United States Sentencing Commission
March 10, 1993
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I had promised to make this letter brief. There are many other things I could or should say, but will not. I will say that the last two cycles of amendments have been encouraging insofar as they have addressed problems of harshness and not simply been "fixes" of guidelines which appear to be too low to some other components of the criminal justice system.

Sincerely,



SCOTT F. TILSEN
Assistant Federal Defender

SFT/tmw

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
PROBATION OFFICE

746 U.S. POST OFFICE
AND COURT HOUSE
5th AND MAIN STREET
CINCINNATI 45202-3980

February 23, 1993

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

Dear Judge Wilkins

Attached hereto are personal comments regarding certain proposed guideline amendments. I have written a separate document for each of the issues on which I commented. Understand that the comments provided are only my own and are not representative of this agency or the Court for which I work.

Thank you for the opportunity to comment on the proposed amendments.

Sincerely



David E. Miller, Deputy Chief
U. S. Probation Officer

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
PROBATION OFFICE

746 U.S. POST OFFICE
AND COURT HOUSE
5th AND MAIN STREET
CINCINNATI 45202-3980

Date: February 16, 1993

To: United States Sentencing Commission
Public Information

From: David E. Miller, Deputy Chief
U. S. Probation Officer

* Re: More than minimal planning

The Commission should remove this as a specific offense characteristic from guidelines in which it is presently incorporated. There is vast disparity in the application of this factor and it is often a bone of contention for the Court to resolve at sentencing.

The intent of the Commission to take this factor into consideration by building it in to loss table when the loss increases means the factor will be adequately considered.

I also think the Commission should adopt an amendment that creates a specific offense characteristic that provides that if the offense, including all relevant conduct, involved a single opportunistic act, a 2 level decrease may be given. It is important the guideline or commentary emphasize all relevant conduct is to be considered in making this determination, otherwise controversy over it and the act underlying the offense of conviction will be rampant.

Making these changes will reduce the amount of time taken by all parties in the dispute resolution process; will more fairly penalize those at higher offense levels, and; will allow a reduction for the true situational offender, thus allowing the straight probation option more often for such defendants.