The vote of disapproval, while disheartening, highlights the importance of the Commission's role in making controversial decisions Congress would like to avoid. Your agency is unique for a number of reasons. Unlike the typical "regulatory" agency such as FDA or FCC, the delegation of power to the Commission is not because Congress believes it lacks the expertise to make highly complex technical decisions, because in the case of sentencing, Congress acts regularly. Instead, the delegation is in part designed to insulate the Congress from the electoral consequences of making desirable sentencing revisions that could be called "soft." (The Base Closing Commission serves a similar role in undertaking the politically unpopular "heavy lifting" of recommending the closing of economically important but militarily unnecessary military bases.) In effect, it is the unwritten responsibility of the Commission to push for these sentencing reforms precisely because they are politically objectionable.

However, what -- if anything -- should the Commission do regarding cocaine sentencing in the 1996 "cycle?" Some will counsel that you do nothing. The political climate has not changed. That is true, but in my experience, the political climate regarding drug sentencing changes very little.

Some very important observers will advise the Commission to bring forward exactly the same 1-to-1 ratio as it did last year on the basis that your recommendation was factually correct, logical, and intellectually honest. Those are very strong reasons, but they disregard the political reality which has not changed. If there is to be any reform, the reform proposal must be changed.

Reform is an incremental process. Therefore, advance a less ambitious reform than last year, which if adopted, would promote a more just outcome for those individuals who it helps. Such a proposal would not hinder the Commission in making additional reforms if the political climate does change.

As unsatisfactory as it will be to some, if not all, of the members of the Commission, I urge the members to attempt to reach a unanimous compromise ratio in the neighborhood of 10- or 20-to-1 -- that is, crack cocaine quantities would be raised at each base offense level, but not to equivalence with powder cocaine. This will be difficult for you to argue for except: (1) a significant number of offenders (which your staff can quantify) will receive somewhat less harsh sentences for drug trafficking in relatively small quantities of crack cocaine than would otherwise be the case; and (2) it has a realistic chance of being agreed to by the Attorney General and adopted by Congress. For those men and women sentenced for crack offenses at a new level (and especially for their children, parents and other family members), this would be a benefit.

Those of you who are judges and those who have been prosecutors will find this kind of political compromising extremely unpleasant, even odious. It will feel unethical, perhaps reprehensible -- and indeed if you were to make this type of

political compromise while sitting as a judge or making a decision as a prosecutor it would be unethical. However, as should now be starkly clear to you, this is a *political* decision, and compromise is often a critical ingredient for success in the political realm.

No doubt it will sound like the voice of one who has worked in Washington since 1979, but I urge the members of the Commission to set aside the commitment to intellectual honesty that you bring to the bench, to your teaching, and to your prosecutorial decision-making, and to agree *unanimously* that you will seek a *result* that enables some judges to sentence some offenders to terms of imprisonment that are closer to what the Commission's majority sees as the ideal than is now the case.

As part of your 1996 report, I urge you to expand upon your analysis of "Defendant's Function in Drug Trafficking Operation which you reported in Table 18 of your 1995 report. What Congress intended in the Anti-Drug Abuse Act of 1986 was to encourage the Justice Department to focus on the "major traffickers...the heads of organizations, who are responsible for creating and delivering very large quantities of drugs." (H.Rept. 99-845, Prt. 1, pp. 11-12). Having failed to hold hearings and to obtain testimony from DEA and the Justice Department, Congress made a fairly obvious mistake in choosing the very low quantities that it used as the triggers for identifying such high-level traffickers. Your report shows that only 11.2% of the 1992 sample of Federal drug defendants were "high-level dealers" (only 9.2% of powder cocaine defendants and only 9.5% of heroin defendants). 11% of some 20,000 Federal drug defendants is roughly 2200 high-level offenders.

This data is extremely valuable information for assisting the public in reviewing the performance of the Justice Department in choosing drug prosecutions. As you know, any of the nation's more than 200,000 felony arrests for cocaine or heroin trafficking could be prosecuted in Federal court. Deciding who should be prosecuted in Federal court is a discretionary matter for DEA, other law enforcement agencies and the U.S. Attorneys offices.

Perhaps the 1% of all felony narcotics defendants who are prosecuted in Federal court is the sum total of "high-level" narcotics traffickers in a year. But given the $40 billion in annual narcotics trafficking in the United States and around the world, it would be very disappointing if the government could identify and prosecute only some 2200 high-level traffickers in a year. Perhaps the Justice Department should more carefully screen the nation's 200,000 heroin and cocaine trafficking arrests to find more high-level traffickers.

Perhaps more careful case selection might ameliorate the dissatisfaction of the Federal judiciary that must impose long sentences on crack offenders who are found to be street-level dealers, bodyguards, couriers and mules almost 64% of the time. Perhaps an increased investigative effort should be directed at traffickers

operating outside the United States who direct drugs to U.S. markets, or at money launderers who corrupt the international financial system.

In any event, the Justice Department ought to be encouraged to increase the percentage of high-level traffickers that they investigate and prosecute. If they concentrated more on genuinely high-level offenders, that effort in itself, would tend to reduce the number of low-level and minor offenders who are being subject to unconscionably long sentences.

With very best wishes,

Sincerely yours,

Eric E. Sterling

Eric E. Sterling

009-96

FOOD MARKETING INSTITUTE

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March 5, 1996

United States Sentencing Commission
One Columbus Circle, NE
Suite 2-500
Washington, DC 20002-8002

Attention: Public Information

RE: Proposed Amendments to Sentencing Guidelines
for Food and Drug Offenses

Dear Sir/Madam:

The Food Marketing Institute (FMI) is pleased to submit these comments to the United States Sentencing Commission (the Commission). On January 2, 1996, the Commission proposed revisions to the federal *Sentencing Guidelines*, including amendments to Sections 2N2.1 and 2F1.1 governing the manner in which individuals and corporations are treated following convictions under the Federal Food, Drug, and Cosmetic Act, Poultry Products Inspection Act, and Federal Meat Inspection Act. FMI believes the proposed amendments to Sections 2N2.1 and 2F1.1 would have unintended negative consequences and should not be adopted.

The Food Marketing Institute (FMI) is a nonprofit association conducting programs in research, education, industry relations and public affairs on behalf of its 1,500 members including their subsidiaries — food retailers and wholesalers and their customers in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of $220 billion — more than half of all grocery store sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms and independent supermarkets. Its international membership includes 200 members from 60 countries.

BACKGROUND

Under the existing guidelines, sentences for individuals in criminal cases involving violations of statutes and regulations dealing with any food, drug, biological product, device, cosmetic or agricultural product currently are governed by U.S.S.G. § 2N2.1. That section provides for a "base offense level" of six, assuming that the underlying regulatory offense involves "knowing or reckless" conduct. In the event of a merely negligent or unintentional violation of statute or regulation, the Guidelines permit a sentencing court discretion to grant a "downward departure" in order to more appropriately match a defendant's conduct and sentence.

In particularly egregious cases in which the regulatory violation involves fraud, Section 2N2.1 requires application of U.S.S.G § 2F1.1, which governs crimes involving fraud and deceit. That section similarly begins with a base offense level of six, but provides for significant increases in offense level -- and, by extension, the possible range of any fine and/or jail term imposed -- based upon the amount of "loss" occasioned by a defendant's conduct.

PROPOSAL

Under the proposed amendments, Section 2N2.1 would be deleted in its entirety, and all food, drug, and related regulatory offenses, including violations by corporations and other organizations, would be sentenced under Section 2F1.1. Although an allowance would be made for an upward departure in a case involving conscious or reckless risk of serious bodily injury, the proposed commentary makes no reference to the appropriateness of a downward departure, even in cases involving unintentional regulatory violations. This change would have dramatic impact on the severity of sentences imposed in food and drug cases.

DISCUSSION

Laws governing foods, drugs, and cosmetics are characterized as "strict liability" statutes and, as such, the government need not prove awareness of wrongdoing. Mere proof that "the defendant has, by reason of his position n the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of and that he failed to do so" is sufficient.[1] Grouping all violations of the food and drug laws under Section 2F1.1 would deprive federal prosecutors and sentencing judges of the flexibility they need to fashion appropriate sentences in those cases where the defendant's violative conduct amount to no more than simple negligence or lack of oversight.

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[1] United States v. Park, 421 U.S. 658, 673-74 (1975). See also United States v. Dotterweich 320 U.S. 277 (1943)

The fact that enhanced penalties are already available in food and drug cases involving fraud further underscores the inadvisability of the proposed amendments. Current Section 2N2.1 imposes a flat base offense level for any regulatory violation but permits prosecutors to seek enhanced penalties under Section 2F1.1 for cases involving fraud or where the regulatory violations are part of a pervasive scheme. The proposed amendments, therefore, would have little, if any, impact on sentences in cases in which the conduct involved would have been charged as fraud or otherwise triggered application of Section 2F1.1. Instead, by making fraud the rule rather than the exception, the amendments would substantially increase the penalties in cases that otherwise do not warrant severe punishment.

In proposing these amendments, the Commission has cited no study or evidence that would justify this change. The Commission has not identified any cases in which sentences imposed under § 2N2.1 are inappropriate. The Guidelines in this area appears to be working well. As a matter of fairness, persons convicted of strict liability regulatory offenses without criminal intent should not be sentenced under the guidelines for fraud.

It is our understanding that guidelines for other strict liability regulatory offenses are not treated in this manner. We believe it would be unreasonable and unfair to treat strict liability offenses inconsistently because such treatment would result in disparate treatment among defendants with similar records who have been found guilty of similar crimes.

In sum, the proposed amendments would brand all violations pertaining to food, drugs, and agricultural products as fraud, eliminating any distinction between unintentional or negligent acts, and purposeful or fraudulent acts, and impose, in cases involving mere negligence, penalties previously reserved for intentional and fraudulent conduct. FMI strongly opposes the proposed amendments to Sections 2N2.1 and 2F1.1 of the *Guidelines* for these reasons and urges the Commission to delete these provisions from any recommendations submitted to Congress. If the Commission nevertheless elects to submit the proposed changes in these sections for Congressional consideration, FMI urges the Commission to modify the guidelines to allow prosecutors and judge more discretion in sentencing purely negligent regulatory violations.

FMI appreciates this opportunity to submit comments on this important issue. We would be pleased to participate in further discussion of these issues either informally or as part of a formal working group.

Sincerely,

Timothy M. Hammonds
President and CEO

010-96

Hoechst Marion Roussel

VIA Federal Express

March 5, 1996

Hoechst Marion Roussel, Inc.

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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

011-96

International Community Corrections Association

POST OFFICE BOX 1987 • LA CROSSE, WISCONSIN 54602
(608) 785-0200 • FAX (608) 784-5335 PETER R. KINZIGER, EXECUTIVE DIRECTOR

March 5, 1996

The Honorable Richard P. Conoboy, Chairman
United States Sentencing Commission
One Columbus Circle, NE
Suite 2-500, South Lobby
Washington, DC 20002-8002

Dear Chairman Conoboy:

Enclosed please find for your review copies of testimony on behalf of the International Community Corrections Association, formerly known as the International Association of Residential and Community Alternatives on the most recent Notice for Comment. We are particularly interested in any simplification of the Guidelines that pertains to probation, split sentences and alternatives. If the Community Corrections Association can provide you with additional information, please contact me at 703. 836. 0279. Thank you for this opportunity to comment.

Sincerely,

Mary K. Shilton

Mary K. Shilton
ICCA Washington Representative

enclosure

International Community Corrections Association

POST OFFICE BOX 1987 • LA CROSSE, WISCONSIN 54602
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TESTIMONY CONCERNING PROPOSED UNITED STATES SENTENCING COMMISSION NOTICE FOR PUBLIC COMMENT

March 5, 1996
Submitted by:
The International Community Corrections Association

I am Mary Shilton, Washington D.C. Representative for the International Community Corrections Association (ICCA). ICCA is a professional and educational organization dedicated to promoting and enhancing community-based corrections services and to improving professional development for its members.

My comments relate to two issues that are to be considered by the Commission this year: simplification of sentencing guidelines with respect to the use of probation, split sentences and other alternatives; and cocaine offenses.

Simplification of the sentencing guidelines

We are pleased that the Commission is reviewing the Guidelines in an effort to make them more accessible. The following principles should be considered with respect to simplification: 1) developing improved policies that fit the statutory purposes of restitution, rehabilitation and sentencing equity noted in 18 U.S.C. Sec. 3553(a) (1988); 2) providing clear guidance to judges on what offenders are eligible for alternatives; 3) increasing the full utilization of alternatives to increase restitution, and offender accountability; 4) providing equivalencies between community sentences and term length that satisfy fundamental principles of justice; and 5) addressing the underlying problems of a growing number of low level Federal offenders by sentences including a component of community treatment.

1) Simplify to meet the purposes of the statute.

The Guidelines should expand the opportunities for sentencing a variety of first time offenders to

probation or split sentences. This would enable the purposes of rehabilitation and restitution to be more fully developed under the Guidelines. At the present time, relatively few persons are sentenced to alternatives.

2) Clarify who is eligible.

We believe that the Guidelines should include a non-incarcerative option for all nonviolent first time offenders and for many with low-level priors. A simplification will make it possible for judges to select who will go to community corrections. Judicial discretion is needed to recommend conditions of supervision related to restraining risk, and managing offender compliance. Judges could select appropriate conditions of supervision for the majority of such offenders who are ranked at the lowest and second lowest security levels and are not classified as dangerous. However, the present Guidelines and mandatory minimums often preclude this possibility because most receive prison terms.

3) Increase full utilization of alternatives.

The utilization of community sentencing could be increased if the Guidelines presented judges with a wider range of options including a variety of intermediate sanctions such as means based fines and day reporting centers. Such sanctions should be used for a majority of Federal sentences where there is no violent offense. Options to be considered would be: victim offender reconciliation and reparation, residential facilities, intensive supervision, public service work, boot camps, day reporting and other substitutes for imprisonment.

4) Define equivalencies between community sentences and incarcerative terms.

Equity and fairness can be served by alternatives that are both punitive and that have other elements such as restitution or rehabilitation. The simplification process should expand the notion of various types of punishments as equivalent to prison. The use of equivalencies will allow sentences to be constructed that are proportionate. In addition, the potential number of persons who could be sentenced to probation and split sentences would be increased by reclassifying and consolidating levels and equivalencies. The

equivalencies could also permit a change in transitional release programs for up to twelve months prior to end of prison terms.

5) Address the underlying problems of a growing number of low level Federal offenders by sentences including a component of community treatment.

Making alternative sentences more accessible to a number of low level offenders is supported by the growing research that rehabilitation is more likely to occur with use of halfway houses or other alternatives in lieu of confinement. ICCA has completed three research conferences on this subject. The papers delivered by researchers support the notion that community corrections is an effective and appropriate approach to punishment.

Although the public is increasingly punitive toward violent crime, there is widespread support for intermediate sanctions. Public opinion polls by the Wirthlin Group, the Public Agenda Foundation, Figgie International, Gallup, and Harris polls found that the public wants tough but rehabilitative programs for nonviolent offenders.

Cocaine offenses

We urge the Commission to continue in its efforts to eliminate unnecessary disparity with respect to cocaine. Inequitable sentencing practices for similar drug offenses raise grave issues about the fairness of our present Federal cocaine sentences. We applaud the Commission for its *Special Report to the Congress on Cocaine and Federal Sentencing Policy* and urge the Commission to continue to evaluate the issues set forth therein. We hope the Commission re-evaluates the impact of the Guideline's emphasis on quantity of drug involved rather than other factors such as whether a weapon was involved, whether there was violence or injury to another.

Additionally, ICCA is opposed to the use of mandatory minimum sentences. We believe that mandatory incarceration of drug offenders has little incapacitation or deterrence value. Furthermore, many of these individuals are addicted and in need of detoxification and stabilization treatment. It is about seven times more costly to incarcerate these drug offenders than it is to

supervise, treat and monitor them in a community corrections setting.

In conclusion, we note that ICCA represents more than 250 private and public agencies operating over 1500 programs. Founded in 1964, ICCA has over 600 individual members working to provide community supervision and residential programs. Our members are employed by courts, departments of corrections, probation, the Federal Bureau of Prisons, counties, cities and states. Approximately eighty percent of the adult community-based corrections facilities in the United States are represented by ICCA and its members. Such facilities and services include: community-based centers, educational and vocational services, drug testing and treatment, tutoring services, day treatment, crisis intervention, family or individual counseling, victim services, community service, bail supervision, home detention, neighborhood outreach, and aftercare.

I thank the Commission for this opportunity to comment on proposed policy changes. The Commission's interest in opposing sentencing disparity and more appropriate sentencing options is commendable. We would be happy to provide copies of the papers from our research conferences on the subject of sentencing and community corrections upon request.

012-7.

NWDA

National Wholesale Druggists' Association

[redacted]. McQueary, Chairman of the Board
Ronald J. Streck, President & CEO

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March 5, 1996

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

Attention: Public Information

Dear Commissioners:

This comment is submitted by the National Wholesale Druggists' Association (NWDA). NWDA is the national trade association for wholesale distributors of prescription drugs. Our members operate over 200 distribution centers across the country that handle a majority of the wholesale sales of pharmaceutical products nationwide. Drug wholesalers are subject to the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*)

NWDA members are very concerned about proposed amendments to the Federal Sentencing Guidelines "regulatory" guideline found at United States Sentencing Commission, Guidelines Manual ("U.S.S.G."), § 2N2.1 (Nov. 1994), which published in the January 2, 1996, Federal Register (61 Fed. Reg. 83). The Commission has proposed to delete § 2N2.1 and to sentence persons convicted of offenses previously covered by § 2N2.1 under the fraud guideline found at § 2F1.1. We believe this change would have an unfair impact on individuals and organizations convicted of regulatory offenses.

The offenses currently covered by § 2N2.1 do not require proof of fraud or criminal intent. Indeed, the Application Note to § 2F2.1 states that the guideline assumes an offense involving knowing or reckless conduct. If, however, fraud was involved in the offense, the current language of § 2N2.1 already provides for sentencing by reference to the fraud guideline. We believe that § 2N2.1 provides an appropriate structure for imposition of sentences for offenses that do not involve fraud. The fraud guideline assumes the criminal intent of the offender, a mental state that is not an element of the regulatory offenses. By treating these offenses under the fraud guideline, excessive punishment will result. The application of sentences designed to address fraudulent conduct to misdemeanor regulatory offenses will result in proportionately greater punishment for these offenses, a result which the Guidelines were intended to avoid.

While simplification of the Guidelines is a worthy goal, it should not be accomplished through similar treatment of unlike offenses. Consistency in sentencing is one of the guiding principles of the Guidelines. The Introduction and General Application Principles of the Guidelines state that Congress sought "reasonable uniformity in sentencing by narrowing the wide disparity in sentences

imposed for similar criminal offenses committed by similar offenders" and "proportionality in sentencing through a system that imposes appropriately different sentences for criminal conduct of differing severity." U.S.S.G. Ch. 1, Pt.A § 3. We note that the Commission has not proposed to subsume environmental offenses under the fraud guideline. We do not propose that the Commission do so, but we suggest that the strict liability offenses currently sentenced under § 2N2.1 are more similar to environmental offenses than to fraud offenses and should be treated similarly.

Another effect of the Commission's proposal is that regulatory offenses committed by organizations would be sentenced under the organizational sentencing guidelines. Our objections are the same as our objections to sentencing of individuals convicted of regulatory offenses under the fraud guideline. Imposition of the full weight of the organizational guidelines is heavy-handed and unwarranted for regulatory offenses.

The Commission has also invited comments on "whether 'gain' should be a substitute for 'loss' when the essence of the offense is fraud against regulatory authorities with no economic loss." 61 Fed. Reg. 83 (proposed January 2, 1996). Application Note 8 of § 2F2.1 provides that gain realized as a result of the offense may be used as an alternative estimate of loss, but that gain ordinarily will underestimate the loss. In the context of regulatory offenses, we strongly disagree that gain will ordinarily underestimate the loss. Where no economic loss can be shown, we maintain that gain vastly overstates the loss, especially in those situations where courts have used gross profits as a measure of a defendant's gain. This effect would be even more egregious if applied to strict liability regulatory offenses, as contemplated in the Commission's proposal to include these offenses under § 2F2.1.

Whether applied to strict liability regulatory offenses, or regulatory offenses committed through fraud, measurement of punishment by reference to gain, in the absence of demonstrable loss, flies in the face of the Guidelines' Resolution of Major Issues regarding Regulatory Offenses which provides a low base offense level with increases based on specific offense characteristics "designed to reflect substantive harms." U.S.S.G. Ch.1, Pt.A § 4(f). The Commission should reaffirm its goals of punishing technical, recordkeeping and reporting offenses through low base offense levels. Where no loss can be proved, the potential penalties are lower, which is appropriate where the goal is to punish the harm caused by the conduct. Carefully drawn grounds for an upward departure from the regulatory guideline may be a more appropriate remedy.

Thank you for the opportunity to express our views on this important proposal.

Sincerely,

Diane P. Goyette

Diane P. Goyette, Esq.
Director of Regulatory Affairs

013-96

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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

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,

Legal Division
Pfizer Inc
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Tel 212 573 4567 Fax 212 573 3977

01496

Jill M. Bruzga
Attorney—Food and Drug Law

March 5, 1996

United States Sentencing Commission
One Columbus Circle, N.E.
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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

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,

Jill M. Bruzga

3/6/96 ag

015-96

AD HOC COALITION FOR FAIR
SENTENCING OF REGULATORY OFFENSES

March 6, 1996

HAND DELIVERED

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

Re: Proposed Amendment To Sentencing Guideline On Food and Drug Offenses

Dear Sir or Madam:

This comment is submitted on behalf of the Ad-Hoc Coalition For Fair Sentencing of Regulatory Offenses (hereinafter "the Coalition"). The Coalition consists of a group of trade associations and companies representing a broad-based segment of the food, drug, device, biological product, cosmetic, and agricultural product industries (see signature pages and attached list of organizations supporting this comment). Because members of the Coalition (and the firms they represent) are regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and/or other related statutes which authorize criminal penalties for regulatory offenses, the Coalition has a keen interest in the United States Sentencing Commission's (Commission) January 2, 1996 Federal Register notice, 61 Fed. Reg. 79 (1996) (hereinafter "the Proposal"), insofar as the Commission proposes to delete United States Sentencing Guideline (USSG) § 2N2.1.

The Proposal will have serious and unwarranted ramifications for many food, drug, medical device, and biological companies and their executives and employees. The Commission has proposed to delete the current food and drug "regulatory" Guideline, United States Sentencing Commission, Guidelines Manual, § 2N2.1, (Nov. 1995), applicable to individuals convicted of violating the FFDCA, the FMIA, and the PPIA. 61 Fed. Reg. 83 (1996). Persons convicted under these and other statutes would be sentenced under the "fraud" Guideline (USSG § 2F1.1) if the Proposal is adopted, even if the defendant is not charged with fraudulent conduct. In

addition, the Proposal would, for the first time, establish a guideline for corporations and other organizations convicted of "strict liability" offenses under these statutes. Currently, such organizations are fined by federal judges outside the confines of the Federal Sentencing Guidelines.[1/] For the reasons discussed below, the Coalition strongly opposes eliminating USSG § 2N2.1.

As an introductory note, the Coalition supports, and will continue to support, strict sentences against individuals and corporations convicted of felony food and drug offenses where fraudulent conduct is established. Thus, the Coalition does not oppose application of USSG § 2F1.1 to food and drug cases involving fraud. However, the Proposal would also dramatically increase the likelihood of severe jail sentences and massive fines on individuals and corporations convicted of misdemeanor "strict liability" offenses. To that extent, the Proposal has no valid basis, is patently unfair, and appears inconsistent with other analogous Guidelines.

A. THE PROPOSAL LACKS A VALID BASIS

In support of the Proposal, the Commission referenced a two-year study conducted by the Commission's Food and Drug Working Group (Working Group). See 61 Fed. Reg. 83 (1996). However, this Working Group did not propose to eliminate USSG § 2N2.1. Moreover, despite conducting a study of food and drug cases sentenced under USSG § 2N2.1, the Working Group never identified even one case in which a judge, a prosecutor, a defense attorney, or a defendant complained that the sentence imposed under USSG § 2N2.1 was inappropriate. All empirical evidence strongly suggests that USSG § 2N2.1 is working quite well.

The Coalition recognizes, and has 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 does not justify a rush to delete USSG § 2N2.1. Nor should a desire to simplify the Guidelines form a basis to fit strict liability criminal cases into a Guideline that was promulgated to deal with fraud.

1/ The Guidelines for imposing fines on corporations and other organizations, USSG § 8C, does not reference USSG § 2N2.1, and is thus not applicable to misdemeanor food and drug offenses. USSG § 8C2.1. Accordingly, organizations convicted of committing such misdemeanor offenses are currently fined under 18 U.S.C. §§ 3571 and 3572. However, the organizational fine Guidelines, USSG § 8C, is applicable to fraud offenses subject to USSG § 2F1.1. Thus, organizations committing food and drug offenses involving fraud are currently fined under USSG § 8C. If the Proposal is adopted, organizations convicted of misdemeanor food and drug offenses will be fined under USSG § 8C, as well.

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 USSG § 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.

B. THE PROPOSAL IS CONTRARY TO THE PURPOSE OF THE GUIDELINES

The Commission has received a statutory mandate to avoid "unwarranted sentencing disparities among defendants with similar records who have been found guilty of similar criminal conduct." 28 U.S.C. § 991(b)(1)(B). We are unaware of any study or finding suggesting that this mandate has been ignored by the Courts imposing sentences under USSG § 2N2.1.

Further, the Proposal seems wholly inconsistent with the Commission's General Application Principles. See USSG Ch.1, Pt. A § 4(f), which sets forth guiding principles for the Commissions's promulgation of guidelines concerning regulatory offenses. It states that a typical guideline for a so-called "regulatory offense" will provide a low base offense level aimed at certain regulatory offenses. Nevertheless, under the Proposal, persons convicted of regulatory violations under the food and drug laws would be sentenced according to the monetary loss incurred by "victims." We see no reason why the Commission should depart from its General Application Principles by deleting USSG § 2N2.1 until the Commission examines whether "loss" should be a relevant sentencing factor in all regulatory offenses.

C. THE PROPOSAL IS INCONSISTENT WITH OTHER ANALOGOUS GUIDELINES

If the Proposal is adopted, it will establish for the first time, a guideline for fines to be imposed on corporations and other organizations convicted of strict liability food and drug offenses. As such, the Proposal is inconsistent with the Commissions's treatment of other similar regulatory guidelines.

Like USSG § 2N2.1, the Commission has promulgated regulatory offense guidelines for individuals convicted for environmental crimes. See USSG § 2Q. The USSG § 2Q Guidelines encompass misdemeanor offenses, and in some cases, strict liability environmental offenses. See e.g., 33 U.S.C. § 411 (sentenced under USSG § 2Q1.3). There are close parallels between the food and drug laws and the environmental statutes in terms of their purposes, effects, deterrent value, and statutory structure. A careful analysis should be conducted comparing how the food

and drug laws do and do not compare to the environmental laws. Where similar, it is reasonable to suggest that the Sentencing Commission treat similarly the two categories of cases.

However, the Commission has not proposed to include environmental cases involving fraud under the fraud guideline, USSG § 2F1.1. Nor has the Commission promulgated organizational guidelines for environmental offenses. We believe that the Commission should defer any modification to USSG § 2N2.1 until the Commission has studied the extent to which food and drug cases should be sentenced under the same basic principles as environmental cases. The Commission has not asserted any grounds to treat strict liability food and drug offenses different than strict liability environmental offenses. As both types of offenses closely parallel each other, so too should their respective guidelines.

D. CONSULTATION WITH OUTSIDE GROUPS IS ESSENTIAL

In promulgating or revising guidelines, the Commission is required to "consult with authorities on, and individual and institutional representatives of, various aspects of the Federal criminal justice system." 28 U.S.C. § 994(o). The Commission's Proposal was apparently not preceded by any dialogue with the industry (or their legal representatives), academicians, public interest groups, or other organizations which have a wealth of knowledge in this area. The limited comment period to respond to the Proposal is simply inadequate for this purpose.

With respect to environmental offenses, the Commission has met its "consultation" obligations by forming an advisory working group composed of government officials, law professors, lawyers in private practice, in-house corporate lawyers, and others. See e.g., 58 Fed. Reg. 65,764 (1993) (Commission established independent working group to promulgate organizational guidelines for environmental offenses). Similarly, the Coalition submits that the Commission should form a food and drug advisory working group consisting of individuals from the government, defense bar, business community, and academia. Such members would provide valuable, first-hand input regarding the adequacy of the current food and drug regulatory guideline, USSG § 2N2.1.

E. CONCLUSION

For all the reasons discussed above, the Coalition urges the Sentencing Commission to refrain from adopting the Proposal, insofar as it would delete USSG § 2N2.1. The Coalition urges the Sentencing Commission to establish an advisory working group, partly composed of members of the affected industry, to ensure that misdemeanor food and drug offenses are sentenced fairly under either USSG § 2N2.1 or a new guideline that would apply to all regulatory misdemeanor offenses.

We appreciate this opportunity to present our views.

Sincerely yours,

[see attached signature pages]

Attachment

David A. Bossman B.T.S.

David A. Bossman, President
Animal Feed Industry Association
1501 Wilson Boulevard
Suite 1100
Arlington, VA 22209-2403

The American Feed Industry Association (AFIA) is the national trade association representing manufacturers of both medicated and non-medicated animal feeds. AFIA's members produce more than 70% of the commercial livestock, poultry, and aquaculture feed sold in the United States. AFIA's members also manufacture and distribute feed ingredients, feed manufacturing machinery, and animal health products.

Nancy Singer, Esq.
Associate Vice President and
Special Counsel
Health Industry Manufacturers Association
1200 G Street, N.W.
Suite 400
Washington, D.C. 20005

The Health Industry Manufacturers Association (HIMA) is a Washington, D.C.-based national trade association representing more than 700 manufacturers of medical devices, diagnostics products, and health information systems. HIMA's members manufacture more than 90 percent of the nearly $50 billion of health care technology products purchased annually in the United States. The Association is dedicated to representing the long-term interests, concerns, and needs of the health care technology industry through education programs that encourage high quality, cost-effective health care.

John R. Block B.T.S.

Mr. John R. Block
President
National-American Wholesale Grocers' Association/International Foodservice Distributors Association
201 Park Washington Court
Falls Church, VA 22046

The National-American Wholesale Grocers' Association/International Foodservice Distributors Association (NAWGA/IFDA) member companies supply food and related products to independent supermarkets, convenience stores, restaurants, hotels, schools, hospitals, and military bases. NAWGA/IFDA's 300 member companies operate more than 1,200 distribution centers and employ more than 350,000 people. NAWGA members supply 56% of the groceries sold in the United States; IFDA members annually sell $33 billion in food and related products.

James H. Skiles
Vice President, General Counsel
Grocery Manufacturers of America
1010 Wisconsin Avenue, N.W.
Washington, D.C. 20007

The Grocery Manufacturers of America, Inc. (GMA) is a national trade association of approximately 140 companies that manufacture food sold in retail grocery stores throughout the United States and internationally. GMA's member companies are responsible for producing more than 85% of the packaged food sold at retail in the United States.

Robert N. Pyle
President
Independent Bakers Association
1223 Potomac Street, N.W.
Washington, D.C. 20007

The Independent Bakers Association is a Washington, D.C. based national trade association of over 360 mostly family-owned wholesale bakeries and allied trades to the baking industry. The Association was founded in 1967 to specifically protect and represent the interests of the regional, family-owned, independent segment of the baking industry. The group is a 501 C, tax exempt organization that does lobby Congress.

Mr. John R. Cady, President & CEO
National Food Processors Association
1401 New York Avenue, N.W.
Suite 400
Washington, D.C. 20005

The National Food Processors Association (NFPA) is the voice of the $400 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters, and consumer affairs. NFPA's three laboratories, its scientists, and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications, and crisis management support for the Association's United States and international members, who produce, process, and package foods, drinks, and juices.

Christina Sizemore
Executive Director
National Pharmaceutical Alliance
421 King Street, Suite 222
Alexandria, VA 22314

The National Pharmaceutical Alliance (NPA) is a trade association of more than 165 independent companies that manufacture and distribute prescription drugs and over-the-counter medications. NPA has members in 28 states. The majority of NPA's members distribute prescription drugs throughout the United States.

Diane P. Goyette, Esq.

Diane Goyette
Director of Regulatory Affairs
National Wholesale Druggists' Association
1821 Michael Faraday Drive
Suite 400
Reston, VA 22090-5348

The National Wholesale Druggists' Association (NWDA) represents full-service drug wholesalers who distribute approximately three-quarters of all pharmaceutical products sold in the United States. NWDA's active and affiliate distributor member corporations own and operate more than 225 distribution centers across the country.

OTHER COALITION MEMBERS SUPPORTING THIS COMMENT:

American Bakers Association
1350 I Street, N.W.
Suite 1290
Washington, D.C. 20005-3305

The American Bakers Association (ABA) is the trade association that represents the nation's wholesale baking industry. It consists of more than 300 baker and allied member firms. The ABA's membership consists of companies of all sizes, ranging from family-owned enterprises to companies that are affiliated with Fortune 500 corporations. Together, these companies produce approximately 80% of the nation's baked goods. The members of the ABA collectively employ tens of thousands of employees nationwide in their productions, sales, and distribution operations.

American Meat Institute
1700 N. Moore Street
Suite 1600
Arlington, VA 22209

The American Meat Institute (AMI) represents the interests of packers and processors of beef, pork, lamb, veal, and turkey products and their suppliers throughout North America. Headquartered in Washington, D.C., the Institute provides legislative, regulatory, and public relations services, conducts scientific and economic research, offers marketing and technical assistance and sponsors education programs.

American Veal Association
4714 Orchard Street
Harrisburg, PA 17109

The American Veal Association (AVA) is an industry-funded and governed association which represents the interests of the entire veal industry, including producers, feed representatives, and packers. The mission of the association is to actively promote the veal industry on a national level; to promote the increased consumption of veal; to encourage communication and cooperation between growers; to gather, evaluate, and distribute information pertinent to the veal industry; to provide information and direction to public agencies and/or elected officials on issues concerning the veal industry; and to encourage cooperation between members of the association and all other segments of the special fed veal industry. AVA represents more than 1,200 industry representatives.

AVA conducts two primary programs for its members. An industry-wide Veal Quality Assurance Program is designed to improve the quality and wholesomeness of the product, and services produced by the industry; the Veal Issues Management Program is designed to manage issues confronting the industry.

National Grocers Association
1825 Samuel Morse Drive
Reston, VA 22090

National Soft Drink Association
1101 16th Street, N.W.
Washington, DC 20036

The National Soft Drink Association is the national trade association of the United States soft drink industry. NSDA's members manufacture, bottle and distribute approximately 95% of all soft drinks consumed annually in the United States.

Snack Food Association
1711 King Street, Suite 1
Alexandria, VA 22314

The Snack Food Association is a national not-for-profit trade association of approximately 1,000 company members representing snack manufacturers and suppliers to the snack industry.

AMERICAN FEED INDUSTRY ASSOCIATION 016-96

March 6, 1996

HAND DELIVERED

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

Attn: Public Information

Re: Proposed Amendment To Sentencing Guideline On Food and Drug Offenses

Dear Sir or Madam:

This comment is submitted by the American Feed Industry Association (AFIA) in response to the United States Sentencing Commission's (Commission) January 2, 1996 Federal Register notice proposing to eliminate the current "regulatory" Guideline that is applicable to offenses committed under the Federal Food, Drug, and Cosmetic Act (FFDCA). United States Sentencing Commission, Guidelines Manual, § 2N2.1 (Nov. 1995). See 61 Fed. Reg. 79, 83 (1996) (hereinafter "Proposal").

AFIA is the national trade association representing manufacturers of both medicated and non-medicated animal feeds. AFIA's members produce more than 70% of the commercial livestock, poultry, and aquaculture feed sold in the United States. AFIA's members also manufacture and distribute feed ingredients, feed manufacturing machinery, and animal health products. Because members of AFIA are regulated under the FFDCA, which authorizes criminal penalties for regulatory offenses, AFIA has a keen interest in the Commission's January 2 Proposal.

AFIA strongly opposes the Proposal to delete USSG § 2N2.1. If the Proposal is adopted, all persons convicted of violating the FFDCA would be sentenced under the "fraud" guideline (USSG § 2F1.1) even if the defendant is not charged with fraudulent conduct. In addition, the Proposal would, for the first time, establish a guideline for corporations and other organizations convicted of "strict liability" offenses under the FFDCA.[1] Without benefit of any prior input

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[1] Currently, such organizations are fined by federal judges outside the confines of the Federal Sentencing Guidelines.

[69]

1501 Wilson Blvd., Suite [illegible] Arlington, VA 22209
Tel: 703/524-08[illegible] FAX: 703/524-1921

from the industry groups most affected, the Proposal proposes to dramatically increase the likelihood of unjustified jail sentences and massive fines on individuals and corporations convicted of misdemeanor "strict liability" offenses. Although AFIA supports, and will continue to support, strict sentences against individuals and corporations convicted of felony food and drug offenses where fraudulent conduct is established, similar stiff sentences for misdemeanor "strict liability" food and drug offenses are simply not warranted.

A. THE PROPOSAL'S IMPACT ON AFIA MEMBERS

The Proposal will potentially have serious and unwarranted ramifications for AFIA's members and their executives and employees. AFIA's members are primarily regulated under both the food provisions and the animal drug provisions of the FFDCA and their implementing regulations. These provisions set forth numerous detailed requirements intended to ensure that medicated and non-medicated animal feeds are safe before and after they enter the market. These mandates, if violated, subject the offending persons to a variety of regulatory and judicial sanctions. The most extreme of these sanctions is a criminal prosecution.

Because of the FFDCA's broad definition of "food," 21 U.S.C. § 321(f), all animal feeds, both non-medicated and medicated, are subject to the Act's general requirements for food. The Act provides the means for bringing safe and wholesome animal foods to the market by requiring all food and color additives and other added substances to be proven safe before they are used in animal feeds. See 21 U.S.C. § 348; 21 U.S.C. § 379e; 21 U.S.C. § 346. The Act also mandates that all animal feeds must be prepared, packed, and held under sanitary conditions. 21 U.S.C. § 342(a)(4).

Medicated feeds must meet additional FFDCA requirements. Depending on the particular starting drug ingredients used and their concentrations, feed manufacturers may have to hold an approved medicated feed application. 21 U.S.C. § 360b(m). In addition, all animal feeds containing drugs must comply with FDA's separate current good manufacturing practice (CGMP) regulations for medicated feeds. 21 C.F.R. Part 225. These CGMPs establish controls for all aspects of manufacturing medicated feeds, including production and process controls, packaging and labeling controls, storage and distribution controls, and laboratory controls. The CGMPs also mandate strict recordkeeping and reporting requirements.

The failure to comply with any of the above food or animal drug requirements may lead to a FDA determination that animal feed is adulterated or misbranded in violation of the FFDCA. See 21 U.S.C. § 342 (food adulteration), § 343 (food misbranding), § 351 (drug adulteration), and § 352 (drug misbranding). Any person who manufactures and distributes an adulterated or misbranded product may be subject to criminal penalties. 21 U.S.C. §§ 331 and 333(a).

Feed manufacturers and their officials may be held criminally liable despite the fact that they had no intention to violate the FFDCA or even knew the FFDCA was being violated. Defendants have been criminally charged under the "strict liability" doctrine set forth in United States v. Park, 421 U.S. 658 (1975), which upheld the authority of FDA to obtain a conviction against a corporate officer or organization without having to prove that the defendant had any mens rea.

The Park case demonstrates how the sometimes technical requirements of the FFDCA have lead to criminal prosecutions. In Park, John Park (whose conviction was upheld in the case), had consulted with legal counsel upon hearing that his company's Baltimore warehouse had sanitation problems. Mr. Park, who lived and worked in Philadelphia, was assured that the subordinate who managed that facility was investigating the situation and that the matter was apparently under control. However, the FDA subsequently brought charges against Mr. Park alleging that the company's food had become adulterated because of insanitary conditions. The Supreme Court upheld Mr. Park's conviction even though Mr. Park did not order the FFDCA violations or even know they were occurring. The Court found that Mr. Parks could be convicted because, as President, he had the power to prevent the violations from occurring. The Court stated that he had a positive duty to implement measures to ensure that his company did not violate the law. If those measures were inadequate, he could be criminally prosecuted.[2]

It is easy to realize that the type of prosecution brought in the Park case bears no resemblance to a fraud case where FDA alleges that someone violates the FFDCA with the intent to defraud or mislead the government, a customer, or a consumer. 21 U.S.C. § 333(a)(2).. In the former type of case, FDA prosecutes people with no allegation that the person intended to violate the FFDCA, or even knew about the violation. In the latter case, FDA charges a person with a crime based on traditional mens rea where the defendant knew that he was participating in illegal conduct.

AFIA is not proposing that misdemeanor (strict liability) cases under the FFDCA are never warranted. However, we fail to understand the logic of having persons convicted under the FFDCA's misdemeanor provisions sentenced the same way as persons who have violated the law with the specific intent of defrauding someone.

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[2] The government has also brought misdemeanor "strict liability" criminal prosecutions against low level employees of large companies. See United States v. General Nutrition, Inc., 638 F. Supp. 556 (W.D.N.Y. 1986) (misdemeanor criminal prosecution properly initiated under FFDCA against a store clerk at a retail outlet who made promotional statements about products sold at the store).

Although there are thousands of companies in the animal feed industry, there have been remarkably few criminal prosecutions brought against such companies or their officials. Nevertheless, AFIA is quite concerned about the potential impact on its members if the proposal is adopted. FDA is committed to vigorous enforcement of the strict liability criminal provisions of the FFDCA. For instance, in 1990 FDA stated that the deterrent power of misdemeanor strict liability violations could not be underestimated. AFIA has no quarrel with that proposition. However, AFIA strongly believes that the punishment for these violations should be commensurate with the violation. A person or company should not receive felony sanctions for strict liability violations.

If the Commission's Proposal is adopted, sentencing judges will almost certainly be compelled to impose a term of imprisonment for "strict liability" food and drug offenses, particularly in cases where a large volume of product is implicated. This is due to the fact that the "fraud" guideline sets a sentence according to the "loss" to the victims. Further, the proposal will establish a guideline for a fine to be imposed on corporations and other organizations in regulatory (non-fraud) cases. Consequently, courts will be obligated to increase fines they impose on corporations and other organizations in the animal feed industry.

Such stiff punishments, for non mens rea criminal conduct, would have a severe impact on feed manufacturers and their officials. A jail sentence would be devastating for a corporate executive or official with a respectable career, family, and a previously untarnished background. Indeed, many persons may well choose to forego a career in the animal feed business if they know that they can be subject to sanctions under the fraud Guideline simply because of their position as a high level executive in a company. Moreover, as many feed manufacturers are small businesses, massive fines would be crippling.

B. THE PROPOSAL LACKS A VALID BASIS

In support of the Proposal, the Commission referenced a two-year study conducted by the Commission's Food and Drug Working Group (Working Group). See 61 Fed. Reg. 83 (1996). However, this Working Group did not propose to eliminate USSG § 2N2.1. Moreover, despite conducting a study of cases sentenced under USSG § 2N2.1, the Working Group never identified even one case in which a judge, a prosecutor, a defense attorney, or a defendant complained that the sentence imposed under USSG § 2N2.1 was inappropriate.[3]

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[3] In fact, the Working Group stated that "the issue remains whether [§ 2N2.1] as currently drafted provides for adequate fines. . . ." United States Sentencing Commission Food and Drug Working Group Final Report at 19 (Feb. 1995).

In addition to the Working Group's study, AFIA is unaware of any case in which anyone sentenced under USSG § 2N2.1, the sentencing court, or even the government displayed dissatisfaction with the sentence imposed. In sum, all empirical evidence strongly suggests that USSG § 2N2.1 is working quite well.

AFIA recognizes, and has 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 does not justify a rush to delete USSG § 2N2.1. Nor should a desire to simplify the Guidelines form a basis to fit "strict liability" criminal cases into a Guideline that was promulgated to deal with fraud.

AFIA believes 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 USSG § 2N2.1.[4] The Commission might want to republish its Proposal to expand USSG § 2N2.1 to cover other regulatory statutes, including those statutes that are not now covered by an existing Guideline. Alternatively, the Commission might consider a new Guideline that would cover all regulatory violations where fraud is not involved.

C. THE PROPOSAL IS CONTRARY TO THE PURPOSE OF THE GUIDELINES

The Commission has received a statutory mandate to avoid "unwarranted sentencing disparities among defendants with similar records who have been found guilty of similar criminal conduct." 28 U.S.C. § 991(b)(1)(B). In that regard, Congress intended the Commission to periodically review judicial decisions and revise the Guidelines when sentencing disparities are found to exist. See Braxton v. US, 500 U.S. 344, 348 (1991); Neal v. US, 116 S. Ct. 763, 766 (1996) ("Congress intended the Commission's rulemaking to respond to judicial decisions in developing a coherent sentencing regime"). AFIA is unaware of any study or finding suggesting that unwarranted sentencing disparities occur under USSG § 2N2.1. In fact, most courts have invariably imposed low fines on FDA-regulated organizations, to permit the entities to spend their money on remedial measures.

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[4] See United States v. Luv N' Care International, Inc., 897 F. Supp. 941 (W.D. La. 1995) (prosecution initiated under the Federal Hazardous Substances Act, a statute as to which the Commission has not established a Guideline).

Further, the Proposal seems wholly inconsistent with the Commission's General Application Principles. USSG Ch. 1, Pt. A § 4(f) sets forth guiding principles for the Commissions's promulgation of guidelines concerning regulatory offenses. It states that a typical guideline for a so-called "regulatory offense" will provide a low base offense level. Nevertheless, under the Proposal, persons convicted of regulatory violations under the food and drug laws would be sentenced according to the monetary loss incurred by "victims." AFIA sees no reason why the Commission should depart from its General Application Principles by deleting USSG § 2N2.1 until the Commission examines whether "loss" should be a relevant sentencing factor in all regulatory offenses.

Application of USSG 2F1.1, rather than USSG § 2N2.1, to misdemeanor food and drug offenses would simply be inequitable. One of the primary purposes of the Guidelines is to preserve proportionality in sentencing. See Neal v. US, 116 S. Ct. at 767. See also, Mistretta v. US, 488 U.S. 361, 374 (1989); United States Sentencing Commission, Guidelines Manual at 2 (Nov. 1994) ("Congress sought proportionality in sentencing through a system that imposes appropriately different sentences for criminal conduct of differing severity"). Accordingly, the Commission was directed to "insure that the guidelines reflect the general appropriateness of imposing a sentence other than imprisonment in cases in which the defendant is a first offender who has not been convicted of a crime of violence or an otherwise serious offense." 28 U.S.C. § 994(j).

As explained above, many prosecutions brought against officials and corporations regulated by FDA involve only technical violations of the FFDCA and do not present a true risk of harm to the public or to animals. Accordingly, under USSG § 2N2.1, courts have traditionally imposed no jail sentences for such "non-serious" crimes. However, applying the "fraud" guideline to misdemeanor food and drug offenses will certainly increase the potential for incarceration, possibly reaching jail sentences at the statutory maximum. Certainly, Congress did not intend the Commission to mandate stiff sentences on relatively minor criminal offenses.

D. THE PROPOSAL IS INCONSISTENT WITH OTHER ANALOGOUS GUIDELINES

If the Proposal is adopted, it will establish, for the first time, a guideline for fines to be imposed on corporations and other organizations convicted of strict liability FFDCA offenses. As such, the Proposal is inconsistent with the Commissions's treatment of similar regulatory guidelines.

Like USSG § 2N2.1, the Commission has promulgated regulatory offense guidelines for individuals convicted for environmental crimes. See USSG § 2Q. The USSG § 2Q Guidelines encompass misdemeanor offenses, and in some cases, strict liability environmental offenses. See

e.g., 33 U.S.C. § 411 (sentenced under USSG § 2Q1.3). There are close parallels between the FFDCA and the environmental statutes in terms of their purposes, effects, deterrent value, and statutory structure. A careful analysis should be conducted comparing how the FFDCA does and does not compare to the environmental laws. Where similar, it is reasonable to suggest that the Sentencing Commission treat the two categories of cases similarly.

However, the Commission has not proposed to include environmental cases involving fraud under the fraud guideline, USSG § 2F1.1.[5] Nor has the Commission promulgated organizational guidelines for environmental offenses. AFIA believes that the Commission should defer any modification to USSG § 2N2.1 until the Commission has studied the extent to which FFDCA cases should be sentenced under the same basic principles as environmental cases. The Commission has not asserted any ground to treat strict liability food and drug offenses different than strict liability environmental offenses. As both types of offenses closely parallel each other, so too should their respective guidelines.

E. CONSULTATION WITH OUTSIDE GROUPS IS ESSENTIAL

In promulgating or revising guidelines, the Commission is required to "consult with authorities on, and individual and institutional representatives of, various aspects of the Federal criminal justice system." 28 U.S.C. § 994(o). The Commission's Proposal was apparently not preceded by any dialogue with the industry (or their legal representatives), academicians, public interest groups, or other organizations which have a wealth of knowledge in this area. The limited comment period to respond to the Proposal is simply inadequate for this purpose.

With respect to environmental offenses, the Commission has met its "consultation" obligations by forming an advisory working group composed of government officials, law professors, lawyers in private practice, in-house corporate lawyers, and others. See e.g., 58 Fed.

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[5] Indeed, in United States v. Carpenter's Goldfish Farm, 998 F.2d 692 (9th Cir. 1993), the Ninth Circuit vacated a sentence in an environmental case. The defendant had committed two offenses that were subject to sentencing. One of the offenses was properly subject to USSG § 2F1.1 because fraud and deceit were involved. However, the other offense (a strict liability environmental crime) was not covered by any Guideline. The Court vacated the sentence because the district court had imposed sentence for the strict liability offense by employing the Guideline applicable to felony environmental offenses. This case reinforces AFIA's position that regulatory strict liability misdemeanor offenses must be accorded different sentencing status than more serious felony charges. The case also demonstrates the need to have a general regulatory Guideline that will cover regulatory offenses that are not now subject to the Sentencing Guidelines.

Reg. 65,764 (1993) (Commission established independent working group to promulgate organizational guidelines for environmental offenses). Similarly, AFIA submits that the Commission should form an advisory working group consisting of individuals from the government, defense bar, business community, and academia who specialize in matters relating to the FDA. Such members would provide valuable, first-hand input regarding the adequacy of regulatory guideline USSG § 2N2.1.

F. CONCLUSION

For all the reasons discussed above, AFIA urges the Sentencing Commission to refrain from adopting the Proposal, insofar as it would delete USSG § 2N2.1. Further, AFIA believes the Sentencing Commission should establish an advisory working group, partly composed of members of the affected industry, to ensure that misdemeanor FFDCA offenses are sentenced fairly under either USSG § 2N2.1 or a new guideline that would apply to all regulatory misdemeanor offenses. AFIA stands ready and willing to participate in that working group or to provide any further assistance to the Commission that it can.

We appreciate this opportunity to present our views.

Sincerely yours,

David A. Bossman
President

DAB:mhc

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American Frozen Food Institute • 2000 Corporate Ridge, Suite 1000 • McLean, Virginia 22102

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March 6, 1996

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

Re: Proposed Amendments to Sentencing Guidelines

Dear Sir/Madam:

The American Frozen Food Institute (AFFI) is the national trade association representing frozen food processors, suppliers, and marketers. AFFI's more than 530 member companies account for over 90 percent of frozen food production in the United States. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution, and sale of products nationwide. AFFI appreciates the opportunity to comment on the above-captioned proposed amendments.

On January 2, 1996, the United States Sentencing Commission (the Commission) announced in the *Federal Register* several proposed revisions to the federal *Sentencing Guidelines*, including amendments to Sections 2N2.1 and 2F1.1 governing the manner in which individuals and corporations are treated following convictions under the Federal Food, Drug, and Cosmetic Act, Poultry Products Inspection Act, and Federal Meat Inspection Act. 1/ AFFI has strong reservations about the proposed amendments to Sections 2N2.1 and 2F1.1.

SUMMARY

The *Sentencing Guidelines* already provide stiff sanctions, in the form of imprisonment and fines, for violations of the nation's food and drug laws. The proposed amendments to Sections 2N2.1 and 2F1.1 would treat all violations of these statutes as cases involving fraud,

1/ 61 Fed. Reg. 79-83 (Jan. 2, 1996)

AFFI Exceeding The Investment

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severely limiting the ability of federal prosecutors and courts to respond appropriately to the broad spectrum of conduct punishable under these laws.

BACKGROUND

Sentences in criminal cases involving violations of statutes and regulations dealing with any food, drug, biological product, device, cosmetic or agricultural product currently are governed by U.S.S.G. § 2N2.1. 2/ That section provides for a "base offense level" of six, assuming that the underlying regulatory offense involves "knowing or reckless" conduct. 3/ In the event of a merely negligent violation of a statute or regulation, the Guidelines permit a sentencing court discretion to grant a "downward departure" in order to more appropriately match a defendant's conduct and sentence.

In particularly egregious cases in which the regulatory violation involves fraud, section 2N2.1 requires application of U.S.S.G. § 2F1.1, which governs crimes involving fraud and deceit. That section similarly begins with a base offense level of six, but provides for significant increases in offense level, and, by extension, the possible range of any fine and/or jail term imposed, based upon the amount of "loss" occasioned by a defendant's conduct.

DISCUSSION

Under the proposed amendments, Section 2N2.1 would be deleted in its entirety, and all food, drug, and related regulatory offenses, including violations by corporations and other organizations, would be sentenced under Section 2F1.1. Although an allowance would be made for an upward departure in a case involving conscious or reckless risk of serious bodily injury, the proposed commentary makes no reference to the appropriateness of a downward departure, even in cases involving mere negligence. This change would have a dramatic impact on the severity of sentences imposed in food and drug cases.

2/ Chapter 2 of the Guidelines governs sentences for individuals. Chapter 8, in turn, sets forth the Organizational Sentencing Guidelines, pursuant to which a corporate offense level and, by extension, base fine, are determined. Food, drug, and agricultural products were, however, specifically excluded from the 1991 amendments which added the organizational guidelines. As a result, fines for organizations convicted of offenses covered by Section 2N2.1 continue to be governed by pre-*Guidelines* law.

3/ See U.S.S.G. § 2N2.1 (Application Note 1).

Laws governing food, drugs, and cosmetics are characterized as "public welfare" statutes and, as such, the government need not prove awareness of wrongdoing. Mere proof that "the defendant has, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of and that he failed to do so" is sufficient. 4/ Grouping all violations of the food and drug laws under Section 2F1.1 would deprive federal prosecutors and sentencing judges of the flexibility they need to fashion appropriate sentences in those cases where the defendant's violative conduct amounts to no more than simple negligence or oversight.

The fact that enhanced penalties are already available in food and drug cases involving fraud further underscores the inadvisability of the proposed amendments. Current Section 2N2.1 imposes a flat base offense level for any regulatory violation but permits prosecutors to seek enhanced penalties under Section 2F1.1 for cases involving fraud or where the regulatory violations are part of a pervasive scheme. The proposed amendments, therefore, would have little, if any, impact on sentences in cases in which the conduct involved would have been charged as fraud or otherwise triggered application of Section 2F1.1. Instead, by making fraud the rule rather than the exception, the amendments would substantially increase the penalties in cases that otherwise do not warrant severe punishment. 5/

In sum, the proposed amendments would brand all violations pertaining to food, drugs, and agricultural products as fraud, eliminating any distinction between negligent, purposeful, and fraudulent acts, and impose, in cases involving mere negligence, penalties previously reserved for intentional and fraudulent conduct. AFFI strongly opposes the proposed amendments to Sections 2N2.1 and 2F1.1 of the *Guidelines* for these reasons and urges the Commission to delete these provisions from any recommendations submitted to Congress. If the Commission nevertheless elects to submit the proposed changes for Congressional consideration, AFFI urges the Commission to include commentary that would allow prosecutors and judges more discretion in sentencing purely negligent regulatory violations.

4/ United States v. Park, 421 U.S. 658, 673-74 (1975). See also United States v. Dotterweich, 320 U.S. 277 (1943).

5/ For example, in a case involving distribution of adulterated meat where the amount of "loss" exceeds $500,000, application of Section 2F1.1 would result in a base offense level, before adjustment, of not less than 16, subjecting a first-time offender to a minimum of 21 months incarceration. Currently, under Section 2N2.1, the base level for such a violation is six, with a corresponding sentencing range of 0 to 6 months. A first-time offender, moreover, would be eligible for a sentence of probation.

AFFI appreciates this opportunity to submit comments on this highly important issue and would be happy to provide any additional assistance the Commission may require in preparing its recommendations to Congress.

Sincerely,

Steven C. Anderson
President

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CUA

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March 6,1996

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

Re: Proposed Guideline Amendments
& Issues for Comment-1996 Cycle

Dear Chairman Conaboy:

On behalf of the Practitioners' Advisory Group (hereinafter called "PAG"), I am writing to you to provide the views of our Group concerning the proposed amendments and issues for comment which are before the Commission on the 1996 amendment cycle. As in the past, I thank you for the opportunity to express the views of the PAG on pending amendments and requests for comment. We are also especially grateful in regards to the willingness of the Commission to facilitate our monthly PAG meetings by allowing us to teleconference in members of the PAG who are unable to attend the meetings. We also wish to commend the Commission on the willingness of the leaders of the various Working Groups of the Commission to meet and work closely with liaison members of the PAG on the various Working Groups.

TO AMEND OR NOT TO AMEND THE GUIDELINES

The views of the PAG on this issue have been consistent throughout the period of our existence: we favor change where wisdom and experience call for change and where inter-Circuit conflicts cry out for resolution by the Commission--especially in light of the fact that the Supreme Court has indicated that it is looking to the Commission to resolve most of the problems in applying and interpreting the guidelines. See, United States v. Braxton, 111 S. Ct. 1854 (1991) [Commission has been given the power by Congress to amend guidelines to resolve Circuit conflicts]. Changes which experience has shown are necessary to promote the purposes of sentencing should be enacted if the

Commission is to truly abide by the duties which were entrusted to it by Congress in the enabling legislation.

* * *

COMMENTS ON SPECIFIC AMENDMENT PROPOSALS AND ISSUES FOR COMMENT

The PAG has broken down its comments by following the index to the proposed guideline amendments for public comment (reader friendly version). Thus, our numbered paragraph 1 will be our comment on proposed amendment (or issue for comment) number 1 and so forth.

Issue for Comment #1--Offenses Involving Drugs (Crack Cocaine)

We strongly endorsed the action which the Commission took last year in what was labelled Amendment #5 for 1995. We reaffirm our support for those changes. In its legislation of October 30, 1995, which rejected Amendment #5, the Congress has requested that the new proposed ratio be higher for crack than powder so our and your preferred one-to-one ratios would be inappropriate.

Given this fact, we recommend a five-to-one ratio. We select five to one because it would make the crack cocaine ratio to powderer cocaine the same as the ratio for Heroin, PCP, Methamphetamine, and their equivalents, which are clearly among the most dangerous, addictive and destructive drugs, to powder cocaine. Also, a five-to-one ratio preserves the inner harmony of the ratios associated with the drug table which increases penalties systematically as societal harms increase. A five-to-one ratio would recognize that the harms associated with crack are significant, but would lessen somewhat the impact of the current racial inequities of crack sentencing which result because crack use is more popular among minorities.

Obviously, a five-to-one ratio with a ceiling of Level 38 for quantity would, along with §3B1.2, result in longer sentences for wholesale distributors rather than for retailers, so that a five to one recommendation would satisfy the concerns articulated by Congress in Subsection (B) of the legislation which rejected one to one.

That legislation's Subsection (C)'s concern about powder cocaine trafficking defendants who knowingly sell to individuals who will convert to crack are currently adequately met by the Pinkerton doctrine embodied in U.S.S.G. §1B1.3(1)B. Likewise, Subsection (D)'s litany of harms are all addressed by specific offense characteristics or enhancements which already exist or which were part of last year's proposed Amendment 5. We believe that those proposals for violence and weapons should be resubmitted, along with the five-to-one ratio.

We further believe that harms not accounted for by any other

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guideline section or by last year's proposed #5, such as neighborhood deterioration, child neglect by parental users, and the spread of sexually transmitted diseases by users who engage in increased sexual activity are adequately addressed by the illegality of the substance in the first instance, and most definitely by a five-to-one ratio. We note that these harms are extremely difficult to quantify and their existence is largely anecdotal, especially insofar as they supposedly occur with any greater frequency among crack rather than powder users. Also, these behaviors occur more frequently in the lower socio-economic strata so that attributing them to drug use is highly speculative.

We believe that a five-to-one ratio is the right choice for this difficult decision. We also recognize that politics largely influenced the Congress in its rejection of last year's proposal. We believe it would help this Congress for the Commission's action to be approved unanimously. When the Warren Court began to integrate America, they did so by unanimous decision so as to send a clear message. Full support by the Commission for a five-to-one ratio would likewise send a clear message to Congress. We ask that all Commissioners support five to one. Not only is this the right thing to do, but it will aid the Congress in doing the right thing.

Proposed Amendment #2--Money Laundering

Proposed Amendment Numbers 2(A) and 2(B) - Money Laundering

The PAG strongly supports the Commission's proposed amendments to §§ 2S1.1-2S1.2, pertaining to money laundering offenses. Unlike the Department of Justice's proposal, which we oppose, the Commission's suggested amendment would tie the base offense levels for money laundering violations more closely to the underlying conduct that was the source of the illegal proceeds. While the Commission's proposal constitutes a much needed reform, we believe that the underlying objective of the amendment, achieving "real offense" sentencing, could best be achieved by incorporating certain modifications which are set forth below.

Initially, the need for some amendment to the existing money laundering guidelines is substantial. The money laundering statutes, 18 U.S.C. §§ 1956 and 1957, are quite expansive. Indeed, the Department of Justice in its policy statement, dated October 1, 1992, recognized that the statutes are "extraordinarily broad," and that they "apply to the movement of funds derived from most serious federal crimes and a larger number of state crimes, as well." In our experience, the statutes have been applied in relatively minor fraud and other cases in which the defendant merely deposited the proceeds of illegal activity into his or her bank account. See, e.g., United States v. Montoya, 945 F.2d 1068, 1076 (9th Cir. 1991) (affirming conviction under 18 U.S.C. § 1956 where state official deposited into his personal checking account a $3000 check representing a bribe). We note that defense attorneys from around