the country have informed the PAG that certain prosecutors are using the statute to prosecute state misdemeanor offenses (e.g., prostitution, gambling) as federal money laundering and, as such, exposing defendants to significant prison sentences for crimes which would have otherwise resulted in the defendants receiving probation.

Furthermore, as noted by the Money Laundering Working Group, the money laundering statute, 18 U.S.C. § 1956, has been used by prosecutors to "up the ante" in selected cases despite the fact that the charged financial transaction offenses do not differ substantially from the underlying unlawful activity. Money Laundering Working Group, "Explanation of Draft Amendments to §§ 2S1.1 through 1.4" at 1 (November 10, 1992) (footnote omitted). Also, as the Money Laundering Working Group recognized, the existing guideline's high base offense level assumed that large scale, sophisticated money laundering would be the norm. The experience of the PAG is that money laundering counts are often added to other cases to increase prosecutorial leverage and obtain harsher sentences. Accordingly, from the perspective of the PAG, the most important aspect of the proposed amendments is that they significantly reduce the potential for actual or threatened sentence manipulation through charging practices.

Unfortunately, based on the Department of Justice's proposal, it would appear that the Department is intent on maintaining its ability to control sentencing exposure through the charging decision. The Department's proposal to increase the base offense levels in § 2S1.1(a)(2) and (3) by four levels would perpetuate a system in which defendants facing a money laundering charge would be exposed to a greater sentence despite the fact that they did little, if anything, more than commit the underlying offense. We urge the Commission to reject the Department's position because, as the Working Group noted, where "the defendant committed the underlying offense, and the conduct comprising the underlying offense is essentially the same as that comprising the money laundering offense[,] the sentence for the money laundering conduct should be the same as for the underlying offense." Id.

Moreover, the Department's doomsday predictions regarding sophisticated money launderers receiving too light a sentence under the Commission's proposal are unfounded. Initially, we are not aware of any examples provided by the Department which support its claim that penalties under the proposed amendment would be too lenient. In fact, the Commission's own prison impact estimate reveals that passage of the Commission's proposal would actually result in a small net increase in the prison population.

Under the Commission's proposal, for example, there would be little, if any, change in the punishment applicable to those cases involving funds which "were the proceeds of, or were used to promote, an offense involving the manufacture, importation, or distribution of controlled substances...; a crime of violence, or an offense involving firearms or explosives, national security or international terrorism." U.S.S.G. § 2S1.1(a)(2) (as proposed). In addition, the amendment provides for enhancements of up to four

additional points whenever there are actual efforts to conceal or disguise criminal proceeds and where there is "sophisticated money laundering." U.S.S.G. § 2S1.1(b)(1-2) (as proposed). Finally, when a convicted defendant has committed the underlying offense, and the underlying offense caries a heavier penalty than the money laundering offense, the more substantial penalties for the underlying offense will "trump" the money laundering guidelines; indeed, in such situations, the enhancements for sophisticated money laundering would be added to the already substantial offense levels for the underlying offense.

Indeed, the PAG continues to believe that the Commission proposal (while far superior to both the current guideline and the DOJ proposal) does not go far enough in "tying offense levels more closely to the underlying conduct." Accordingly, we recommend that the Commission make the following modifications to its proposal:

First, where the defendant committed the underlying offense and the offense level can be determined, the base offense level for the underlying offense should be applied in all cases, not just in those cases where the base offense level would exceed the base offense level in proposed § 2S1.1(a)(2) or (3). This offense level then would be increased by any specific offense characteristics under proposed § 2S1.1(b). To achieve this result, we suggest deleting from the instruction in § 2S1.1(a) "(Apply the greatest)" and suggest inserting the term "otherwise" after subparagraph (2).

Without this modification, the proposed guideline, at least in certain situations, would perpetuate the inequitable system of having the sentence based on the charging decision rather than by the defendant's actual conduct. For example, in a situation where the defendant through illegal gambling obtains $150,000 in proceeds and deposits those proceeds in the bank, the defendant (assuming he was not running a gambling business) would be subject to a base offense level of 6, if charged under the federal gambling statutes. See U.S.S.G. § 2E3.1(a)(2). However, if that same defendant were charged with money laundering, his or her guideline level under the proposed amendment would be 15. See § 2S1.1(a)(3) (base offense level of 8 plus 7 levels based on § 2F1.1). Because the proposed amendment instructs the sentencing judge to "apply the greatest" guideline level, the defendant would receive a nine point enhancement based entirely on the charging decision.[1]

Second, the proposed amendment would eliminate reliance on the table found in § 2S1.1(b)(2) and substitute reliance on the fraud table found in § 2F1.1, despite the substantial difference between loss in a fraud case and the value of funds involved in a money laundering transaction. While we understand the Commission's desire to use the fraud table in order to promote uniformity and consistency in economic crime cases, the attempt to equate the value of funds in a money laundering transaction and the loss

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[1] The situation would be far worse under the Department's proposal: the defendant would receive a 13 point enhancement based solely on the charging decision.

involved from fraud is without any basis in logic. Fraud offenses almost invariably involve loss to a victim; and it is this loss which is the driving force behind the table. See § 2F1.1(b). Money laundering offenses involve financial transactions which do not involve loss to a discrete victim; and, at least under the current Guidelines, it is the value of the funds involved in the transaction which is the driving force behind the table. See § 2S1.1(b)(2).

In addition to the difference in the "victim," the two offenses are completely different in terms of the amount of funds generally involved. While money laundering typically involves relatively large sums of money, fraud comes in all shapes and sizes: using a counterfeit telephone credit card to make long distance telephone calls or a scheme to fraudulently collect on a $5 million dollar insurance policy. See, e.g., United States v. Smith, 13 F.3d 1421, 1428 (10th Cir. 1994) (Noting that money laundering counts should not be grouped for sentencing with wire fraud counts "because there are different victims and separate and distinct losses.")

This difference in the amount of funds involved in each crime and in the nature of the "victim" of each crime makes any reliance on the fraud table ill-advised, and the PAG recommends that the Commission not eliminate the table currently found in § 2S1.1(b)(2), but rather use this table rather than the fraud table as the basis for the adjustments called for in the amendment, §§ 2S1.1(a)(2-3), 2S1.2(1)(1-2). This table should be used in connection with the amendment's proposed lower base offense level in light of the Money Laundering Working Group's recognition that low dollar amount, unsophisticated cases are prosecuted under this statute. In the event that the Commission believes that the existing table is inadequate, a revised money laundering table should be employed.

Third, if the Commission nevertheless determines to incorporate the fraud table into the money laundering guidelines, then the amendment should be revised so that the base offense level in § 2S1.1(a)(3) is the same as the base offense level for fraud and deceit § 2F1.1. The PAG strongly disagrees with the suggestion set forth in last year's Synopsis of Proposed Amendment that the additional two points are required because money laundering typically involves more than minimal planning. As previously noted, our experience is that most money laundering cases involve little more than the deposit of allegedly criminally derived proceeds into a bank account. Indeed, where there is actual money laundering, and not just a bank deposit, the proposed amendment includes a two point adjustment. See § 2S1.1(b)(1). If the base offense level in § 2S1.1(a)(3) is not changed to 6, then the guideline will continue to produce inequitable and irrational sentences. For example, where a defendant commits a $1,600.00 mail fraud and deposits the proceeds in a savings account, the defendant could be charged with mail fraud and/or money laundering. As a mail fraud case, the defendant's base offense level is 6; but, as a money laundering case under the currently proposed amendment, the

base offense level is 8.[2]

Fourth, the proposed guideline amendments fail to recognize the unique nature of the money laundering sting provisions of 18 U.S.C. § 1956(a)(3). Under that section the crime is completed if a defendant with the intent (1) to promote specified unlawful activity; (2) to conceal or disguise property believed to be the proceeds of specified unlawful activity; or (3) to avoid a CTR requirement, engages n a financial transaction with property represented by a law enforcement official to be the proceeds of specified unlawful activity. This section has been used in an ever increasing number of undercover sting operations in which federal agents attempt to engage in money laundering activities and represent that their money comes from unlawful sources. This obviously provides continued opportunities for sentence manipulation given that the government controls the "value of funds" involved in the transaction and exacerbates the problem of using the elevated offense levels which would be dictated by the fraud table. The Ninth Circuit has held, in the context of a drug case, that sentencing manipulation/entrapment provided the basis for a downward departure, see United States v. Stauffer, 38 F.3d 1103 (9th Cir. 1994); however, there is little uniformity among the courts on this subject.

In order to prevent such guideline manipulation in sting cases and to promote uniformity in this area of the law, we suggest that the Commission include the following statement as Application Note 6.

> If a defendant is convicted in an undercover sting, pursuant to 18 U.S.C. § 1956(a)(3), and the Court finds that the government agent influenced the "value of funds" involved in the transaction in order to increase the defendant's guideline level, a downward departure may be warranted.

Proposed Amendment 3--Food and Drug Offenses

The PAG supports proposed amendments 3.(A) and (B). As to the Issue for Comment under 3.(C) we do not support any change to the Guidelines under § 2F1.1 so as to allow "gain" to be a substitute for "loss" when the essence of the offense is fraud against regulatory authorities with no economic loss. We believe United States v. Chatterji, 46 F.3d 1336 (4th Cir. 1995) and United States v. Andersen, 45 F.3d 217 (7th Cir. 1995) were correctly decided.

We note that Chatterji has been held in its own Circuit not to apply to welfare fraud offenses where "gain" to the defendant can be used to calculate "loss" under §2F1.1. See, United States v.

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[2] Under the Department's proposal, the base offense level is 12.

Adam, 70 F.3d 776 (4th Cir. 1995). In short, both Chatterji and Andersen are fact specific holdings.

No amendment in this area is needed and the Commission should simply leave the matter to the Courts for resolution on a case by case basis.

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[END OF COMMENTS]

On behalf of the Practitioners' Advisory Group, we thank you for allowing us to comment on the Proposed Amendments and Issues for Comment and we look forward to working with the Commission during this amendment cycle.

Sincerely,

Fred Warren Bennett

Fred Warren Bennett
Chairman
Practitioners' Advisory Group

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019-96

Congress of the United States
House of Representatives
Washington, DC 20515

March 6, 1996

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

Ladies and Gentlemen:

We are writing to comment on amendments proposed by the United States Sentencing Commission ("Commission") as published in the Federal Register, Vol. 61, No. 1, pp. 80-83. Our comments are directed toward those proposed amendments relating to cocaine offenses included in the section designated Chapter Two, Part D.

As Members of Congress who actively supported the amendments proposed by the Commission last year to eliminate the 100-to-1 disparity in base penalties for crack and powder cocaine trafficking offenses and eliminating mandatory minimum sentences for simple possession of crack cocaine, we urge the Commission to propose these same amendments this amendment cycle. We do so for the following reasons:

First, the amendments proposed last year were correct. After extensive study of all the relevant factors surrounding the sentencing disparity, the majority of Commissioners concluded that there was no justification for treating two forms of the same drug differently. Even those Commissioners who dissented agreed that the 100-to-1 disparity for trafficking offenses could not be justified and that the mandatory minimum penalties for simple possession ought to be eliminated. In light of this, there is no defensible reason for the Commission to retreat from its original proposed amendments.

Second, the Commission was expressly created to make judgments independent of political considerations. It is not the role of the Commission to either consider or accommodate the political will of those public officials who take irrational, racially prejudged positions to prove that they are "tough on crime." Retreating from the position taken last year would compromise the integrity and political independence of the Commission. We believe that proposing the same amendments this year would not be inconsistent with the legislation passed during the first session of the 104th Congress. The Commission should not be influenced by the disapproval of these proposed amendments previously. Nor should the Commission be influenced by the possibility of a similar outcome if it reoffers the amendments during this presidential

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election year. Indeed, we submit that the Commission should continue to offer these proposed amendments every year until justice and fairness prevail over political expediency.

Finally, failing to offer the proposed amendments again this year would allow a racially discriminatory sentencing scheme to remain unchallenged. While we are all concerned about crime and its impact upon innocent victims, in our zeal to be "tough on crime" we cannot ignore statistics which show that 95% of those convicted for crack cocaine offenses are minorities, even though the majority of crack users are white. The continued existence of such a flawed scheme undermines the credibility of our entire system of justice. We can hardly afford any further erosion of the public's confidence.

Cases like United States v. Armstrong, which was argued before the Supreme Court on February 26, have again brought into focus the racially discriminatory impact of one of our laws. Nora Manella, the U.S. Attorney for Los Angeles, has openly and unapologetically admitted that federal law enforcement targets minority communities. Statistics herald the success of such targeting. African Americans account for nearly 90% of all federal crack cocaine defendants in the Los Angeles area. Similarly, court documents in other jurisdictions indicate that only minorities are prosecuted for crack cocaine offenses in federal courts in other large cities, including Boston, Chicago, Dallas, Denver and Miami. Recently, yet another case of unequal recently came to the public's attention in the Washington, D.C. area. Maryland's Prince George's County Police Department released three white defendants who were caught smoking crack cocaine with an infant present. African Americans caught in similar circumstances, on the other hand, are routinely prosecuted to the fullest extent of the law and their children placed in foster care.

We recognize that the Commission takes pride in its Congressional approval record for proposed amendments and that last year's disapproval of the proposed amendments for cocaine sentences represented the first Congressional "veto" of a Commission proposal. We would expect more amendments to be disapproved in the future, if Congress continues to be dominated by members who are willing to ignore evidence and tolerate racism in order to prove their toughness on crime. Rather than be unduly concerned about these rejections, we believe that the Commission should expect them as the natural consequence of exercising political independence.

We appreciate your consideration of these comments.

Sincerely,

Charles B. Rangel

Alcee L. Hastings

Donald M. Payne

Earl F. Hilliard

Cynthia McKinney

Eleanor Holmes Norton

Albert R. Wynn

Sanford D. Bishop, Jr.

Bennie Thompson

James E. Clyburn

Major R. Owens

Melvin L. Watt

Corrine Brown

Eddie Bernice Johnson

Maxine Waters

Eva M. Clayton

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[illegible signature] [illegible signature]

Chaka Fattah Victor O. Frazer

Major R. Owens [illegible signature]

[illegible signature] Cardiss Collins

[illegible signature] Ronald V. Dellums

020-96

HIMA

HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

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:

These comments are submitted by the Health Industry Manufacturers Association (HIMA) 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), 21 U.S.C. § 333(a)(1). United States Sentencing Commission, Guidelines Manual, § 2N2.1 (Nov. 1995). See 61 Fed. Reg. 79, 83 (1996) (Proposal).

HIMA is a Washington, D.C.-based national trade association representing more than 700 manufacturers of medical devices, diagnostic 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 educational programs that encourage high quality, cost-effective health care. Because members of HIMA are regulated under the FFDCA, which authorizes criminal penalties for regulatory offenses, HIMA has a keen interest in the Commission's January 2 Proposal.

World Leaders in Health Care Innovation

1200 G STREET N.W. SUITE 400
WASHINGTON, D.C. 20005
(202) 783-8700
FAX (202) 783-8750

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HIMA strongly opposes the Proposal to delete United States Sentencing Guidelines (USSG) § 2N2.1. If the Proposal is adopted, 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 from the industry groups most affected, the Proposal would, if adopted, have the potential of dramatically increasing the likelihood of unjustified jail sentences and massive fines on individuals and corporations convicted of misdemeanor "strict liability" offenses. Although HIMA supports, and will continue to support, strict sentences against individuals and corporations convicted of felony FFDCA offenses where fraudulent conduct is established, similar stiff sentences for misdemeanor "strict liability" FFDCA offenses, where fraudulent conduct is not an element of the offense, are simply not warranted.

A. THE PROPOSAL'S IMPACT ON HIMA MEMBERS

The Proposal will potentially have serious and unwarranted ramifications for HIMA's member companies and their executives and employees. HIMA's members are primarily regulated under the various sections of the FFDCA that relate to medical devices as enacted in three major pieces of legislation. See Pub. L. No. 94-295, 90 Stat. 540 (1976); Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990); and the Medical Device Amendments of 1992, Pub. L. No. 102-300, 106 Stat. 238 (1992). The FFDCA and its implementing regulations, set forth numerous detailed requirements intended to ensure that medical devices are safe and effective 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.

The FFDCA covers every aspect of the manufacturing, marketing, and distribution of medical devices. The Act provides the means for bringing safe and effective medical devices to the market by requiring that, for break through technology, a premarket approval application (PMA) be submitted to the United States Food and Drug Administration (FDA) before that medical device is commercially distributed. See 21 U.S.C. § 360c. In addition, the FFDCA establishes a system of

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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, are 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.

premarket notification (510(k)) for products that are substantially equivalent to legally marketed devices. In this way, FDA clears for commercial distribution those devices, based on a comparison to an existing product, with demonstrated safety and effectiveness. See 21 U.S.C. § 360k. The PMA and 510(k) requirements ensure that manufacturers of medical devices are currently required to have their devices precleared prior to marketing.

The FFDCA also requires that medical devices be manufactured in compliance with current good manufacturing practices (CGMPs). 21 U.S.C. § 360j(f). The CGMPs establish controls for various aspects of manufacturing of medical devices, including production and process controls, packaging and labeling controls, storage and distribution controls, and laboratory controls. The CGMPs also mandate strict record keeping and reporting requirements. See 21 C.F.R. Part 820.

Although the CGMPs contain numerous requirements, they fail to establish precise definitions of acceptable conduct. The regulations use words like "reasonable" and "adequate." A CGMP violation, which could subject an individual and manufacturer to criminal prosecution, often involves a disagreement over interpretations but rarely involves fraud.

The failure to comply with any of the above requirements may lead to an FDA determination that a medical device is adulterated or misbranded in violation of the FFDCA. 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). As in the case of many CGMP violations, a medical device may be found to be adulterated or misbranded even though it meets all relevant specifications and does not pose a risk of harm to the consumer or the public. The same is true for many other violations of the FFDCA, where a violation can occur despite the fact that the product is safe and effective.

Medical device corporations 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 Court concluded that a corporate officer who is in a "responsible relationship" to activity that violates the FFDCA can be criminally prosecuted even though the person did not personally engage in or even know about that activity. In fact, in Park, the Supreme Court noted that the defendant, John Park (whose conviction was upheld in the case), had consulted with legal counsel upon hearing that his firm's Baltimore warehouse had sanitation problems. Mr. Park, who lived and worked in Philadelphia, was assured that the person who controlled that facility was investigating the situation and that the matter was apparently under control. The Court found that even though Mr. Park did not order the FFDCA violations or even know they were occurring, he could be convicted because, as President of the company, 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/]

The type of prosecution brought under 21 U.S.C. § 333(a)(1) bears no resemblance to a fraud case where FDA alleges that someone violates the FFDCA with the intent to defraud or mislead the FDA, 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 or she was participating in illegal conduct. 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 FFDCA with the specific intent of defrauding someone.

Although there are thousands of companies in the medical device industry, there have been remarkably few criminal prosecutions brought against medical device companies or their officials. Nevertheless, HIMA 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. However, HIMA 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" medical device offenses, particularly in cases where a large volume of product is implicated or the cost of the product is high. 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 medical device industry.

Such stiff punishments, for non mens rea criminal conduct, would have an unduly harsh impact on medical device corporations and their officials. A jail sentence would be devastating for a corporate executive or official at any level within a corporation who takes pride in his job, has a family, and a previously untarnished background. The Commission needs to be aware of the fact that many regulatory requirements are subject to different interpretations and individuals can not always quit their jobs whenever their interpretation differs from that of management. In light of the

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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).

subjective way medical devices are regulated, it is unfair to mandate high penalties for what turns out after the fact to be interpreted as violative conduct. Moreover, as many medical device, diagnostic products, and health care information system corporations are small businesses, massive fines would be crippling to the development of innovative products. Additionally, this amendment to the sentencing Guidelines will add to the already existing reservations that companies have about entering an industry where there is a potential for high criminal penalties for inadvertent violative conduct.

B. THE PROPOSAL LACKS A VALID BASIS

HIMA 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 deleting 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.

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.

In addition to the Working Group's study, HIMA 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.

HIMA 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.[3/] 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.

3/ 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).

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. United States, 500 U.S. 344, 348 (1991); Neal v. United States, 116 S. Ct. 763, 766 (1996) ("Congress intended the Commission's rulemaking to respond to judicial decisions in developing a coherent sentencing regime"). HIMA 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 entity to spend its money on remedial measures.

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. 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." HIMA 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 FFDCA offenses would simply be inequitable. One of the primary purposes of the Guidelines is to preserve proportionality in sentencing. See Neal v. United States, 116 S. Ct. at 767, (1996). See also, Mistretta v. United States, 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 the FDA involve only technical violations of the FFDCA and do not present a true risk of harm to the public or the consumer. Accordingly, under USSG § 2N2.1, courts have traditionally imposed no jail sentences for such "non-serious" crimes. However, applying the "fraud" Guideline to misdemeanor medical device 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 Commission's treatment of other similar regulatory guidelines.

Like USSG § 2N2.1, the Commission has promulgated regulatory offense guidelines for individuals convicted of 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 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.[4/] Nor has the Commission promulgated organizational guidelines for environmental offenses. HIMA 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 FFDCA offenses differently 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

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4/ Indeed, in United States v. Carpenter's Goldfish Farm, 998 F.2d 692 (9th Cir. 1993), the Court 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 was 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 the Guideline applicable to felony environmental offenses. For the strict liability environmental crime, this case reinforces HIMA's position that regulatory strict liability misdemeanor offenses must be accorded different sentencing status than more serious felony charges.

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, HIMA 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, HIMA urges the Sentencing Commission to refrain from adopting the Proposal, insofar as it would delete USSG § 2N2.1. Further, HIMA 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. HIMA 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,

Nancy Singer

Nancy Singer
Associate Vice President and Special Counsel
Technology and Regulatory Affairs

NS/tf

[987]

021-96

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P. C.

JAMES R. PHELPS
PAUL M. HYMAN
ROBERT A. DORMER
ROBERT T. ANGAROLA
STEPHEN H. MCNAMARA
ROGER C. THIES
THOMAS SCARLETT
JEFFREY N. GIBBS
BRIAN J. DONATO
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KENNETH A. OLSEN
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JENNIFER B. DAVIS
JOHN A. GILBERT, JR.
CRAIG B. MENDELSOHN
F. GAIL BORMEL

700 THIRTEENTH STREET, N. W.
SUITE 1200
WASHINGTON, D. C. 20005

TELEPHONE
(202) 737-5600
FACSIMILE
(202) 737-9329
DIRECT DIAL
(202) 737-4280

HYMAN, PHELPS & MCNAMARA
2603 MAIN STREET
SUITE 1066
IRVINE, CALIFORNIA 92714
TELEPHONE (714) 553-7400
FACSIMILE (714) 553-7433

March 6, 1996

BY MESSENGER

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

Re: January 2, 1996 Proposed Amendment To Sentencing Guideline On Food And Drug Offenses

Dear Sir or Madam:

This comment is submitted on behalf of Genentech, Inc. (Genentech). Because Genentech is regulated under the Federal Food, Drug, and Cosmetic Act (FDC Act), and other related statutes which authorize criminal penalties for regulatory offenses, Genentech has substantial concerns regarding the United States Sentencing Commission's (Commission's) January 2, 1996 Federal Register notice, insofar as the Commission proposes to delete United States Sentencing Guidelines (USSG) § 2N2.1. See 61 Fed. Reg. 79, 83 (1996) (hereinafter "the Proposal").

Genentech has reviewed, and adopts as its own, the comments filed in this matter by the Health Industry Manufacturers Association (HIMA). Genentech has business interests that are wider than those of the HIMA membership; Genentech is one of the leading biotech companies in the world, making such products as Tissue Plasminogen Activator (tPA). Nonetheless, the comments of HIMA relating to the technical violations that might be charged as misdemeanors relating to medical devices under the FDC Act apply with the same force to other products regulated under the FDC Act.

[99]

Genentech agrees with HIMA both about the potential unfair impact of the proposal, and that the proposal is lacking a valid basis, that it is contrary to the purpose of the guidelines, and that it is inconsistent with other analogous guidelines. In addition, we believe the procedure used to reach the proposal is so flawed that it cannot be a proper basis for any action.

Administrative Procedure Act

Guidelines promulgated by the Commission are subject to the Administrative Procedure Act (APA) rulemaking requirements and are therefore reviewable. Congress stated in the Sentencing Reform Act of 1984 (Act) that "the provisions of section 553 of title 5 . . . shall apply to the promulgation of guidelines pursuant to this section." 28 U.S.C. § 994(x).

The APA rulemaking requirements pertain to agency action. The APA defines the term "agency" to exclude "the courts of the United States." 5 U.S.C. § 551(1)(B). However, although the Commission is within the Judiciary, it is not a court. The Supreme Court emphasized this distinction, saying:

> The Sentencing Commission unquestionably is a peculiar institution within the framework of our Government. Although placed by the Act in the Judicial Branch, it is not a court and does not exercise judicial power. Rather, the Commission is an "independent" body....

Mistretta v. United States, 488 U.S. 361, 384-85 (1989) (emphasis added).

Moreover, the Court said:

> The Commission . . . is an independent agency in every relevant sense.

Id. at 393. And:

> In contrast to a court, its rulemaking is subject to the notice and comment requirements of the [APA]. . . .

Id. at 394.

Finally, the Commission itself acknowledges that the promulgation of guidelines is subject to the rulemaking requirements of the APA. See 61 Fed. Reg. at 79 ("Ordinarily, the rule-making requirements of the [APA] are inapplicable to

judicial agencies; however, 28 U.S.C. 99(x) makes the rulemaking provisions of 5 U.S.C. 553 applicable to the promulgation of sentencing guidelines by the Commission.")

APA rulemaking requirements are required by law. The Commission's rulemaking activities affect the most fundamental liberties and should therefore be accented by unimpeachable reason and deliberation. In this instance, the Commission has not met the minimum requirements of APA rulemaking.1/

A. POTENTIAL APA VIOLATIONS

1. The Commission Did Not Provide Adequate Notice

The APA provides as follows:

> General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include --
>
> (1) a statement of the time, place, and nature of public rule making proceedings;
>
> (2) reference to the legal authority under which the rule is proposed; and
>
> (3) either the terms or substance of the proposed rule or a description

---

1/ Among other things, a reviewing court must set aside agency action, findings, and conclusions found to be --

> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; . . .
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right . . .

5 U.S.C. § 706(2).

> of the subjects and issues involved.

5 U.S.C. § 553(b).

> After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. . . .

5 U.S.C. § 553(c).

The legislative history states that:

> Agency notice must be sufficient to fairly apprise interested parties of the issues involved, so that they may present responsive data or argument relating thereto.

Sen. Doc. No. 248, 79th Cong., 2d Sess. 200 (1946).

The courts have observed that "[o]bviously, a prerequisite to the ability to make meaningful comment is to know the basis upon which the rule is proposed." Portland Cement Ass'n v. Ruckelshaus, 486 F.2d 375, 393 n.67 (D.C. Cir. 1973), cert. denied sub nom. Portland Cement Corp. v. Administrator, EPA, 417 U.S. 921 (1974).

The Commission's January 2 notice is defective because:

1. The Commission has not articulated a basis or reason for making the proposed changes to the guidelines;

2. FDC Act misdemeanor violations do not constitute fraud under that statute or the ordinary meaning of the word; and

3. The Commission is seeking to overturn existing law by forcing judges to calculate "loss" in cases where no loss may exist,

breeding uncertainty contrary to the purpose of the Guidelines.[2/]

Because the public has not been given notice of important aspects of the proposal nor a reason for it, the public has not been given a meaningful opportunity to comment on the proposed changes.

2. The Administrative Record Does Not Support the Proposal

It is a fundamental principle of administrative law that an agency's actions must be set aside if the agency relies on information not disclosed in its record of consideration. Motor and Equipment Mfrs. Ass'n. Inc. v. Environmental Protection Agency, 627 F.2d 1095 (D.C. Cir. 1979), cert. denied sub nom. General Motors Corp. v. Costle, 446 U.S. 952 (1980). Indeed, for agency action not to be "arbitrary and capricious," the agency must, at a minimum, (1) consider all relevant factors, and (2) articulate a rational basis between the facts found and the choices and decisions made. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

Here, the record does not support the Commission's proposed Guidelines regarding food and drug misdemeanor violations. The Commission itself offers no evidence regarding the appropriateness of treating all FDC Act violations as fraud, it merely attributes such a determination to its Working Group. However, upon examination, the Working Group did not recommend or even deem appropriate that all food and drug cases could appropriately be sentenced under the Fraud Guideline. Rather, the Working Group found that the Fraud Guideline is applied inconsistently and is, perhaps, under-utilized. Moreover, despite conducting a study of food and drug cases sentenced under section 2N2.1, the Working Group never identified even a single case in which a judge, prosecutor, a defense attorney, or a

---

2/ For instance, the medical device good manufacturing practice (GMP) regulations at 21 C.F.R. Part 820 require that all personnel have the necessary training to perform their jobs. 21 C.F.R. § 820.25(a). Such training must be documented. Failure to document training is a GMP violation and therefore a misdemeanor under the FDC Act. Under the section 2N2.1 regulatory guideline, no loss for this kind of violation would be presumed to exist. The Commission fails to explain how such a violation would cause a "loss" to anyone, or how such a loss would be calculated under its Proposal.

defendant complained that the sentence imposed under that section was inappropriate.

The Working Group's specific "conclusions" focussed only on:

1. The need to improve proper application of the existing cross-references;

2. How to achieve consistent application of the existing grouping rules;

3. The need to determine how to adequately address the risk of harm; and

4. Whether the incorporation of the current version of § 2N2.1 into § 8C1.2(a) should result in adequate fines for organizations convicted of food and drug offenses.

Food and Drug Group Final Report 21 (Feb. 1995). Nowhere does the Working Group recommend or justify the subsumption of the § 2N2.1 Regulatory Guideline into the Fraud Guideline. Certainly, the Commission fails to articulate a rational relationship between the facts and the Working Group's conclusions, and its proposal.

3. The Commission is Illegally Departing from Its Own Precedent

"It is an elementary tenet of administrative law that an agency must either conform to its own precedents or explain its departure from them." UAW v. NLRB, 459 F.2d 1329, 1341 (D.C. Cir. 1972). "This court emphatically requires that administrative agencies adhere to their own precedents or explain any deviations from them." Greyhound Corp. v. ICC, 551 F.2d 414, 416 (D.C. Cir. 1977). In Greyhound, the court went on to say that "when an agency decides to reverse its course, it must provide an opinion or analysis indicating that the standard is being changed and not ignored, and assuring that it is faithful and not indifferent to the rule of law." Id. (quoting Columbia Broadcasting System, Inc. v. FCC, 454 F.2d 1018, 1026 (D.C. Cir. 1971)). Another court invalidated an agency order because "an agency cannot abandon a rule established by its precedent without first stating its reasons for doing so . . ." and asserted that "it is vital that an agency justify a departure from its prior determinations." Baltimore and Annapolis R.R. Co. v. Washington Metropolitan Area Transit Comm'n, 642 F.2d 1365, 1366, 1370 (D.C. Cir. 1980). "Failure to explain the reversal of directly controlling precedent is unlawful." RKO General, Inc. v. FCC,

670 F.2d 215, 223 (D.C. Cir. 1981), cert. denied, 456 U.S. 927 (1982).

The Commission is departing from its prior position of treating FDC Act misdemeanor violations as regulatory violations, and not fraud. The only attempted justification for its departure is that the Commission's Food and Drug Working Group --

> determined that food and drug cases for individuals and organizations could appropriately be sentenced under that [fraud] guideline.

61 Fed. Reg. at 83 (emphasis added).

The capacity to change does not justify a change. Moreover, the Commission's attribution that the Working Group determined that food and drug cases could be sentenced under the Fraud Guideline is erroneous. Rather, the Working Group stated that "cases involving regulatory violations of food and drug statutes or requirements . . . should be sentenced pursuant to § 2N2.1" (the Regulatory Guideline). See Food and Drug Working Group Final Report at 13.

Consultation

Other comments to the Proposal have stressed the need for consultation with industry representatives. Genentech wholeheartedly agrees that a dialogue with the regulated industry is necessary for the Commission to understand the implications of the proposed sentencing changes.

The industry regulated by the Food and Drug Administration is subject to the heaviest of regulatory requirements. Part of this system of regulation is the power to enforce misdemeanor violations without proof of guilty intent or knowledge of wrongdoing. In every misdemeanor case brought under the FDC Act, the court instructs the jury that this is the standard. Of itself, this rule is a strong disincentive to many; there are instances of businesses deliberately dropping product lines that are regulated by the agency. If innocent misdemeanor violations under the FDC Act are elevated to the point that they are treated as "fraud," the disincentive will be even greater.

Genentech strongly encourages the Commission to renew the process of consideration of the Proposal, and to take steps to engage the representatives of the regulated industry.

Conclusion

Genentech agrees with the Commission's desire to simplify the Guidelines. The January 2 Proposal to sentence food and drug misdemeanor violations under the Fraud Guideline, however, was done in violation of APA requirements. Renewed consideration of the matter, taking into account the realities of FDC Act regulation practices, and in consultation with the industry, is indicated.

Sincerely,

Hyman, Phelps & McNamara, P.C.,
Attorneys for Genentech, Inc.

by: James R. Phelps, Esq.

022-96

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P. C.

700 THIRTEENTH STREET, N. W.
SUITE 1200
WASHINGTON, D. C. 20005

TELEPHONE
(202) 737-5600
FACSIMILE
(202) 737-9329
DIRECT DIAL
(202) 737-4280

HYMAN, PHELPS & MCNAMARA
2603 MAIN STREET
SUITE 1066
IRVINE, CALIFORNIA 92714
TELEPHONE (714) 553-7400
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JAMES R. PHELPS
PAUL M. HYMAN
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JOHN A. GILBERT, JR.
CRAIG B. MENDELSOHN
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March 6, 1996

BY MESSENGER

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Attn: Public Information

Re: January 2, 1996 Proposed Amendment To Sentencing Guideline On Food And Drug Offenses

Dear Sir or Madam:

This comment is submitted on behalf of Life Technologies, Inc. (LTI). Because LTI is regulated under the Federal Food, Drug, and Cosmetic Act (FDC Act), and other related statutes which authorize criminal penalties for regulatory offenses, LTI has substantial concerns regarding the Federal Register notice dated January 2, 1996 of the United States Sentencing Commission (Commission) insofar as the Commission proposes to delete United States Sentencing Guidelines (USSG) Section 2N2.1. See 61 Fed. Reg. 79, 83 (1996) (hereinafter "the Proposal").

LTI has reviewed, and adopts as its own, the comments filed in this matter by the Health Industry Manufacturers Association (HIMA). LTI has business interests that are wider than those of the HIMA membership, which are largely focused in research rather than in the medical community; however, LTI develops, manufactures and markets in vitro diagnostics and medical devices. Nonetheless, the comments of HIMA relating to the technical violations that might be charged as misdemeanors relate to all products regulated under the FDC Act.

[107]

LTI agrees with HIMA that the proposal is lacking a valid basis, that it is contrary to the purpose of the guidelines, and that it is inconsistent with other analogous guidelines. In addition, we believe the procedure used to reach the proposal is so flawed that it cannot be a proper basis for any action.

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provisions of 5 U.S.C. 553 applicable to the promulgation of sentencing guidelines by the Commission.")

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Because the public has not been given notice of important aspects of the proposal nor a reason for it, the public has not been given a meaningful opportunity to comment on the proposed changes.

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Consultation

Other comments to the Proposal have stressed the need for consultation with industry representatives. LTI wholeheartedly agrees that a dialogue with the regulated industry is necessary for the Commission to evaluate the implications of the proposed sentencing changes.

The industry regulated by the Food and Drug Administration is subject to the heaviest of regulatory requirements. Part of this system of regulation is the power to enforce misdemeanor violations without proof of guilty intent or knowledge of wrongdoing. In every misdemeanor case brought under the FDC Act, the court instructs the jury that this is the standard. Of itself, this rule is a strong disincentive to many, there are instances of businesses deliberately dropping product lines that are regulated by the agency. If innocent misdemeanor violations under the FDC Act are elevated to the point that they are treated as "fraud," the disincentive will be even greater.

LTI strongly encourages the Commission to renew the process of consideration of the Proposal, and to take steps to engage the representatives of the regulated industry.

Conclusion

LTI agrees with the Commission's desire to simplify the Guidelines. The January 2 Proposal to sentence food and drug misdemeanor violations under the Fraud Guideline, however, was promulgated in violation of APA requirements. We respectfully recommend and request renewed consideration of the matter, in consultation with the industry, taking into account the realities of conducting business under the FDC Act and related statutes and regulations.

Sincerely,

Hyman, Phelps & McNamara, P.C.,
Attorneys for Life Technologies, Inc.

by: James R. Phelps, Esq.

023-96

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P. C.
700 THIRTEENTH STREET, N. W.
SUITE 1200
WASHINGTON, D. C. 20005

TELEPHONE
(202) 737-5600
FACSIMILE
(202) 737-9329
DIRECT DIAL
(202) 737-4280

HYMAN, PHELPS & MCNAMARA
2603 MAIN STREET
SUITE 1066
IRVINE, CALIFORNIA 92714
TELEPHONE (714) 553-7400
FACSIMILE (714) 553-7433

JAMES R. PHELPS
PAUL M. HYMAN
ROBERT A. DORMER
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STEPHEN H. MCNAMARA
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March 6, 1996

BY MESSENGER

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 Mallinckrodt Group, Inc. (Mallinckrodt). Because Mallinckrodt is regulated under the Federal Food, Drug, and Cosmetic Act (FDC Act), and other related statutes which authorize criminal penalties for regulatory offenses, Mallinckrodt has substantial concerns regarding the United States Sentencing Commission's (Commission's) January 2, 1996 Federal Register notice, insofar as the Commission proposes to delete United States Sentencing Guidelines (USSG) § 2N2.1. See 61 Fed. Reg. 79, 83 (1996) (hereinafter "the Proposal").

Mallinckrodt has reviewed, and adopts as its own, the comments filed in this matter by the Health Industry Manufacturers Association (HIMA). Mallinckrodt has business interests that are wider than those of the HIMA membership; for example, Mallinckrodt sells bulk pharmaceutical products. Nonetheless, the comments of HIMA relating to the technical violations that might be charged as misdemeanors relating to medical devices under the FDC Act apply with the same force to other products regulated under the FDC Act.

Mallinckrodt agrees with HIMA that the proposal is lacking a valid basis, that it is contrary to the purpose of the

guidelines, and that it is inconsistent with other analogous guidelines. In addition, we believe the procedure used to reach the proposal is so flawed that it cannot be a proper basis for any action.

Administrative Procedure Act

Guidelines promulgated by the Commission are subject to the Administrative Procedure Act (APA) rulemaking requirements and are therefore reviewable. Congress stated in the Sentencing Reform Act of 1984 (Act) that "the provisions of section 553 of title 5 . . . shall apply to the promulgation of guidelines pursuant to this section." 28 U.S.C. § 994(x).

The APA rulemaking requirements pertain to agency action. The APA defines the term "agency" to exclude "the courts of the United States." 5 U.S.C. § 551(1)(B). However, although the Commission is within the Judiciary, it is not a court. The Supreme Court emphasized this distinction, saying:

> The Sentencing Commission unquestionably is a peculiar institution within the framework of our Government. Although placed by the Act in the Judicial Branch, it is not a court and does not exercise judicial power. Rather, the Commission is an "independent" body....

Mistretta v. United States, 488 U.S. 361, 384-85 (1989) (emphasis added).

Moreover, the Court said:

> The Commission . . . is an independent agency in every relevant sense.

Id. at 393. And:

> In contrast to a court, its rulemaking is subject to the notice and comment requirements of the [APA]. . . .

Id. at 394.

Finally, the Commission itself acknowledges that the promulgation of guidelines is subject to the rulemaking requirements of the APA. See 61 Fed. Reg. at 79 ("Ordinarily, the rule-making requirements of the [APA] are inapplicable to judicial agencies; however, 28 U.S.C. 99(x) makes the rulemaking

provisions of 5 U.S.C. 553 applicable to the promulgation of sentencing guidelines by the Commission.")

APA rulemaking requirements are required by law. The Commission's rulemaking activities affect the most fundamental liberties and should therefore be accented by unimpeachable reason and deliberation. In this instance, the Commission has not met the minimum requirements of APA rulemaking.1/

A. POTENTIAL APA VIOLATIONS

1. The Commission Did Not Provide Adequate Notice

The APA provides as follows:

> General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include --
>
> (1) a statement of the time, place, and nature of public rule making proceedings;
>
> (2) reference to the legal authority under which the rule is proposed; and
>
> (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

1/ Among other things, a reviewing court must set aside agency action, findings, and conclusions found to be --

> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; . . .
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right . . .

5 U.S.C. § 706(2).

5 U.S.C. § 553(b).

> After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. . . .

5 U.S.C. § 553(c).

The legislative history states that:

> Agency notice must be sufficient to fairly apprise interested parties of the issues involved, so that they may present responsive data or argument relating thereto.

Sen. Doc. No. 248, 79th Cong., 2d Sess. 200 (1946).

The courts have observed that "[o]bviously, a prerequisite to the ability to make meaningful comment is to know the basis upon which the rule is proposed." Portland Cement Ass'n v. Ruckelshaus, 486 F.2d 375, 393 n.67 (D.C. Cir. 1973), cert. denied sub nom. Portland Cement Corp. v. Administrator, EPA, 417 U.S. 921 (1974).

The Commission's January 2 notice is defective because:

1. The Commission has not articulated a basis or reason for making the proposed changes to the guidelines;

2. FDC Act misdemeanor violations do not constitute fraud under that statute or the ordinary meaning of the word; and

3. The Commission is seeking to overturn existing law by forcing judges to calculate "loss" in cases where no loss may exist,

breeding uncertainty contrary to the purpose of the Guidelines.[2/]

Because the public has not been given notice of important aspects of the proposal nor a reason for it, the public has not been given a meaningful opportunity to comment on the proposed changes.

2. The Administrative Record Does Not Support the Proposal

It is a fundamental principle of administrative law that an agency's actions must be set aside if the agency relies on information not disclosed in its record of consideration. Motor and Equipment Mfrs. Ass'n, Inc. v. Environmental Protection Agency, 627 F.2d 1095 (D.C. Cir. 1979), cert. denied sub nom. General Motors Corp. v. Costle, 446 U.S. 952 (1980). Indeed, for agency action not to be "arbitrary and capricious," the agency must, at a minimum, (1) consider all relevant factors, and (2) articulate a rational basis between the facts found and the choices and decisions made. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

Here, the record does not support the Commission's proposed Guidelines regarding food and drug misdemeanor violations. The Commission itself offers no evidence regarding the appropriateness of treating all FDC Act violations as fraud, it merely attributes such a determination to its Working Group. However, upon examination, the Working Group did not recommend or even deem appropriate that all food and drug cases could appropriately be sentenced under the Fraud Guideline. Rather, the Working Group found that the Fraud Guideline is applied inconsistently and is, perhaps, under-utilized. Moreover, despite conducting a study of food and drug cases sentenced under section 2N2.1, the Working Group never identified even a single case in which a judge, prosecutor, a defense attorney, or a

---

2/ For instance, the medical device good manufacturing practice (GMP) regulations at 21 C.F.R. Part 820 require that all personnel have the necessary training to perform their jobs. 21 C.F.R. § 820.25(a). Such training must be documented. Failure to document training is a GMP violation and therefore a misdemeanor under the FDC Act. Under the section 2N2.1 regulatory guideline, no loss for this kind of violation would be presumed to exist. The Commission fails to explain how such a violation would cause a "loss" to anyone, or how such a loss would be calculated under its Proposal.

defendant complained that the sentence imposed under that section was inappropriate.

The Working Group's specific "conclusions" focussed only on:

1. The need to improve proper application of the existing cross-references;

2. How to achieve consistent application of the existing grouping rules;

3. The need to determine how to adequately address the risk of harm; and

4. Whether the incorporation of the current version of § 2N2.1 into § 8C1.2(a) should result in adequate fines for organizations convicted of food and drug offenses.

Food and Drug Group Final Report 21 (Feb. 1995). Nowhere does the Working Group recommend or justify the subsumption of the § 2N2.1 Regulatory Guideline into the Fraud Guideline. Certainly, the Commission fails to articulate a rational relationship between the facts and the Working Group's conclusions, and its proposal.

3. The Commission is Illegally Departing from Its Own Precedent

"It is an elementary tenet of administrative law that an agency must either conform to its own precedents or explain its departure from them." UAW v. NLRB, 459 F.2d 1329, 1341 (D.C. Cir. 1972). "This court emphatically requires that administrative agencies adhere to their own precedents or explain any deviations from them." Greyhound Corp. v. ICC, 551 F.2d 414, 416 (D.C. Cir. 1977). In Greyhound, the court went on to say that "when an agency decides to reverse its course, it must provide an opinion or analysis indicating that the standard is being changed and not ignored, and assuring that it is faithful and not indifferent to the rule of law." Id. (quoting Columbia Broadcasting System, Inc. v. FCC, 454 F.2d 1018, 1026 (D.C. Cir. 1971)). Another court invalidated an agency order because "an agency cannot abandon a rule established by its precedent without first stating its reasons for doing so . . ." and asserted that "it is vital that an agency justify a departure from its prior determinations." Baltimore and Annapolis R.R. Co. v. Washington Metropolitan Area Transit Comm'n, 642 F.2d 1365, 1366, 1370 (D.C. Cir. 1980). "Failure to explain the reversal of directly controlling precedent is unlawful." RKO General, Inc. v. FCC,

670 F.2d 215, 223 (D.C. Cir. 1981), cert. denied, 456 U.S. 927 (1982).

The Commission is departing from its prior position of treating FDC Act misdemeanor violations as regulatory violations, and not fraud. The only attempted justification for its departure is that the Commission's Food and Drug Working Group --

> determined that food and drug cases for individuals and organizations could appropriately be sentenced under that [fraud] guideline.

61 Fed. Reg. at 83 (emphasis added).

The capacity to change does not justify a change. Moreover, the Commission's attribution that the Working Group determined that food and drug cases could be sentenced under the Fraud Guideline is erroneous. Rather, the Working Group stated that "cases involving regulatory violations of food and drug statutes or requirements . . . should be sentenced pursuant to § 2N2.1" (the Regulatory Guideline). See Food and Drug Working Group Final Report at 13.

Consultation

Other comments to the Proposal have stressed the need for consultation with industry representatives. Mallinckrodt wholeheartedly agrees that a dialogue with the regulated industry is necessary for the Commission to understand the implications of the proposed sentencing changes.

The industry regulated by the Food and Drug Administration is subject to the heaviest of regulatory requirements. Part of this system of regulation is the power to enforce misdemeanor violations without proof of guilty intent or knowledge of wrongdoing. In every misdemeanor case brought under the FDC Act, the court instructs the jury that this is the standard. Of itself, this rule is a strong disincentive to many; there are instances of businesses deliberately dropping product lines that are regulated by the agency. If innocent misdemeanor violations under the FDC Act are elevated to the point that they are treated as "fraud," the disincentive will be even greater.

Mallinckrodt strongly encourages the Commission to renew the process of consideration of the Proposal, and to take steps to engage the representatives of the regulated industry.

Conclusion

Mallinckrodt agrees with the Commission's desire to simplify the Guidelines. The January 2 Proposal to sentence food and drug misdemeanor violations under the Fraud Guideline, however, was done in violation of APA requirements. Renewed consideration of the matter, taking into account the realities of FDC Act regulation practices, and in consultation with the industry, is indicated.

Sincerely,

Hyman, Phelps & McNamara, P.C.,
Attorneys for Mallinckrodt Group, Inc.

by: James R. Phelps, Esq.

U. S. Department of Justice
Criminal Division

02496

Washington, D.C. 20530

MAR 6 1996

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

Dear Judge Conaboy:

The Department of Justice submits the following comments regarding the sentencing guideline amendments recently proposed by the Sentencing Commission in the areas of food and drug offenses and child sex offenses.

Food and Drug Offenses

The proposed amendment would fold the food and drug guideline, §2N2.1, into the fraud guideline, §2F1.1. We have considered this proposed amendment in the overall context of guideline simplification. Preliminarily, we support this merger but only if additional amendment of the fraud guideline and its commentary is promulgated regarding "loss." Of course, the Commission's future actions on guideline simplification may alter our initial position.

The published proposal will be effective in rectifying certain problems which have arisen under the current regime and which were identified by the Commission's Food and Drug Working Group. Those problems include inconsistent application of section 2N2.1's cross-reference to section 2F1.1 in cases involving fraud and confusion about the application of Chapter Three's multiple count rules to offenses governed by section 2N2.1. (*see, e.g., United States v. Pilgrim Market Corp.*, 944 F.2d 14 (1st Cir. 1991)).

We believe, however, that an amendment is necessary to address the Commission's invitation to comment on the computation of "loss," for purposes of section 2F1.1(b)(1), when the essence of the offense is fraud against regulatory authorities, and there is no readily monetizable harm. For instance, it is now settled that under the Federal Food, Drug, and Cosmetic Act (FDCA) a seller of illegal products satisfies the FDCA felony element "intent to defraud" if he takes affirmative steps to evade detection by, and thus "defraud," regulatory authorities. This

is true even if the customers of such products are well aware of their violative status. *See, e.g., United States v. Arlen*, 947 F.2d 139, 143 (5th Cir. 1991), *cert. denied*, 503 U.S. 939 (1992); *United States v. Cambra*, 933 F.2d 752, 755 (9th Cir. 1991); *United States v. Bradshaw*, 840 F.2d 871, 874 (11th Cir.), *cert. denied*, 488 U.S. 924 (1988); *see also United States v. Mitcheltree*, 940 F.2d 1329, 1350-51 (10th Cir. 1991) (adopts the *Bradshaw* analysis concerning "intent to defraud or mislead" but adds a refinement pertinent to misbranding offenses). Appellate courts have uniformly held that FDCA felony cases arising from fraud on regulatory authorities are properly sentenced under section 2F1.1. *E.g., United States v. Andersen*, 45 F.3d 217, 220 (7th Cir. 1995); *Arlen*, 947 F.2d at 143-44, 146-47; *Cambra*, 933 F.2d at 756.

United States v. Chatterji, 46 F.3d 1336 (4th Cir. 1995), and *United States v. Andersen*, 45 F.3d 217 (7th Cir. 1995), cited in the Commission's notice, have clouded the issue of dollar-based adjustments for "loss" in cases in which the U.S. Food and Drug Administration ("FDA") is the defrauded party. In such cases, it has been the practice of the Department to seek "loss" enhancements measured by dollar volume. In this regard, the seminal authority had been *United States v. Cambra*, 933 F.2d 752 (9th Cir. 1991). In that opinion, the Ninth Circuit held that

> [t]he monetary table in the fraud guideline is intended to reflect "the harm to the victim and the gain to the defendant." . . . Federal agencies may be the victims of fraud in counterfeiting and misbranding drugs. There is no meaningful distinction between the government as victim and individual consumer victims . . . . In this case, the district court found that Cambra intended to profit from his activity and that at least federal agencies were defrauded by his acts. Adjusting the guideline range based on the amount involved is therefore appropriate.

933 F.2d at 756.

Until recently, federal district courts and probation offices had fairly uniformly accepted the notion that those who defraud FDA, and thereby subvert the regulatory process, inflict a *per se* "loss" on the public that can be fairly approximated for purposes of section 2F1.1(b)(1) by gain (for which gross sales volume has been the figure used). However, the practice of finding, in cases of fraud on FDA, a *per se* "loss" equal to gross sales volume recently came under question in *United States v. Chatterji*, 46 F.3d 1336 (4th Cir. 1995).

Chatterji held that a direct financial "loss" to someone is a *sine qua non* of a dollar-based upward adjustment under the fraud guideline, irrespective of how much gain the fraud may have

made possible. 46 F.3d at 1340. The defendant in *Chatterji*, who was an owner and employee of a generic drug company, pleaded guilty to offenses stemming from the company's false statements to FDA, and related obstruction of FDA investigations. The District Court applied an upward adjustment of 11 levels under section 2F1.1(b)(1) based on the gross revenues from the sale of two products. 46 F.3d at 1340. However, the Court of Appeals rejected the notion that *per se* "loss" to consumers of regulated products flows from a manufacturer's fraudulently obtaining (or retaining) required FDA approval of the products. The opinion stresses the absence of any evidence that the generic drug products in question failed to meet established specifications or were otherwise deficient. It holds that gain cannot serve as a proxy for "loss," pursuant to section 2F1.1(b)(1), in the absence of some demonstrable economic injury. In addition, there is no standard expressed as to when an upward departure should be considered. 46 F.3d at 1342 n.10.

Similarly, in *United States v. Andersen*, 45 F.3d 217 (7th Cir. 1995), the Seventh Circuit ruled that defendants who had defrauded FDA about their unlawful sales of unapproved veterinary drugs had not necessarily caused anyone a "loss" that would trigger an adjustment under section 2F1.1(b)(1). In that case the defendant-veterinarians had furtively engaged in the unauthorized sale of unapproved drugs intended for use in food-producing animals (primarily dairy cattle). The defendants had not, as required, registered with FDA as drug manufacturers, and they lacked required FDA approval of their drug products. However, their customers were knowledgeable about the "black market" status of the products, and apparently quite happy to have access to cut-rate (unapproved) drugs. 45 F.3d at 218, 221. Although clearly disturbed that the defendant veterinarians had potentially endangered the food supply by trafficking in unapproved drugs, the Seventh Circuit declined to find a *per se* "loss" for purposes of section 2F1.1(b)(1). While recognizing that the guidelines expressly authorized use of a defendant's gain as a proxy for "loss," 45 F.3d at 221, the court insisted that it first must find that someone had incurred a monetary loss. On the record before it, the Seventh Circuit found no such evidence, although it strongly implied that it would have been receptive to a finding of "loss" based on concrete evidence of competitor injury -- *i.e.*, lost sales -- suffered by legitimate providers of regulated products. *Id.*

In remanding for resentencing under section 2F1.1 without a "loss" adjustment, the court in *Andersen* satisfied its apparent concern for the public health by effectively inviting the district court to depart outside the guideline range. The court cited Application Note 10 to section 2F1.1, which suggests the possibility of upward departures to capture the harmfulness and seriousness of non-pecuniary harms, and counseled that an "upward departure may certainly be warranted by the non-monetizable risk

to human and animal health caused by the defendants' failure to follow FDA licensing regulations, failure to conduct required purity testing and intentional marketing of unapproved drugs." 45 F.3d at 222. For the purpose of determining an appropriate departure, the court expressly suggested that gain would be a relevant consideration. 45 F.3d at 222-23.

Although counterbalanced by the Ninth Circuit's decision in *Cambra*, *Andersen* and *Chatterji* are troubling precedents in the area of FDCA sentencing under the guidelines. They augur serious obstacles to felony FDCA prosecutions founded upon fraud on FDA. If fraud on FDA does not result in *per se* "loss" that can be measured by gain, federal prosecutors will be forced to prove pecuniary harm in order to trigger adjustments pursuant to the table in section 2F1.1(b)(1). If, as *Andersen* suggests, competitor injuries can suffice, it might be possible in some cases to establish harm at sentencing through extensive proceedings laden with economic analysis. Although *Chatterji* gives no hint that competitor injuries would suffice, it proposes that the government's investigative costs can be counted. 46 F.3d at 1341. These, however, are unlikely to be well-correlated with the degree of harm in individual cases. Thus, prosecutors will have difficulty in establishing "loss" commensurate with the gravity of the conduct, or will be able to succeed in individual cases only at the cost of protracted proceedings in which sentencing courts will be called upon to make difficult judgments about the quality and value of products tainted by fraud.

We strongly believe the unavailability of predictable "loss" adjustments in FDCA fraud cases would deal a serious blow both to the cause of effective law enforcement and to the goal of uniformity in sentencing. Before *Andersen* and *Chatterji*, the prospect of predictable and appropriate sentences keyed to dollar volume gave would-be violators a powerful incentive to obey the law; gave prosecutors and defense lawyers a clear framework in which to negotiate dispositions; gave defendants (and would-be defendants) good reason to cooperate; and gave prosecutors and sentencing courts the ability meaningfully to reward cooperation. That very useful system of predictable results is disintegrating.

Upward departures, as suggested in the Commission's proposed amendments, are not sufficient to account for the risk of injury to the public health and safety that regulatory schemes seek to prevent. The underlying purpose of the food and drug laws is to protect the public from such risk. Treating risk of harm as a basis for departure from the guidelines, as if such risk presented the unusual case rather than the heartland case, misses the point of these offenses entirely. Moreover, reliance on departures is too unpredictable to be satisfactory from the standpoint of the purposes of sentencing set forth in the Sentencing Reform Act, 18 U.S.C. §3553(a)(2), including