

021-96

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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: 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.

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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

[100]

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 . . .

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,

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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,

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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.

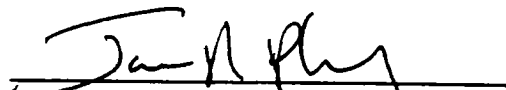
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Conclusion

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.

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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.

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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.

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). Although the Commission is within the Judiciary, it is not a court. The Supreme Court emphasized this distinction, saying:

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

Moreover, the Court said:

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Id. at 393. And:

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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

11087

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

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^{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; . . .

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5 U.S.C. § 553(b).

Section 553 of the APA further states:

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. . . .

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The legislative history of the APA 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.

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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
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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

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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 § 2N2.1, the Working Group never identified even a single case in which a judge, prosecutor, defense attorney, or defendant

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 § 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.

[111]

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

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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. 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.

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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.

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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

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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

[115]

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:

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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).

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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.

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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,

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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.

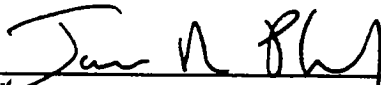
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Conclusion

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,

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