

3/6/96 ag
015-96

AD HOC COALITION FOR FAIR
SENTENCING OF REGULATORY OFFENSES

March 6, 1996

HAND DELIVERED

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

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

Dear Sir or Madam:

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

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

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

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

A. THE PROPOSAL LACKS A VALID BASIS

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

The Coalition recognizes, and has no quarrel with, the Commission's laudatory goal to simplify the Sentencing Guidelines. *See* 60 Fed. Reg. 49,316 (Sept. 22, 1995). However, a desire to simplify the Guidelines does not justify a rush to delete USSG § 2N2.1. Nor should a desire to simplify the Guidelines form a basis to fit strict liability criminal cases into a Guideline that was promulgated to deal with fraud.

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

We believe that the Commission's stated goal to simplify the Guidelines would be furthered by maintaining and possibly expanding USSG § 2N2.1. There are strict liability prosecutions commenced under statutes other than those now explicitly implicated by USSG § 2N2.1. The Commission might want to republish its Proposal to expand USSG § 2N2.1 to cover other regulatory statutes. Alternatively, the Commission might consider a new Guideline that would cover all regulatory violations where fraud is not involved.

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

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

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

C. THE PROPOSAL IS INCONSISTENT WITH OTHER ANALOGOUS GUIDELINES

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

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

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

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

D. CONSULTATION WITH OUTSIDE GROUPS IS ESSENTIAL

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

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

E. CONCLUSION

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

Comment to U.S. Sentencing Commission
March 6, 1996
Page 5

We appreciate this opportunity to present our views.

Sincerely yours,

[see attached signature pages]

Attachment

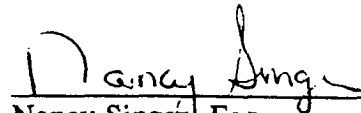
Comment to U.S. Sentencing Commission
March 6, 1996
Page 6

David A. Bossman B.T.S.

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

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

Comment to U.S. Sentencing Commission
March 6, 1996
Page 6



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

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

Comment to U.S. Sentencing Commission
March 6, 1996
Page 6

John R. Block *B.T.S.*

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

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

Comment to U.S. Sentencing Commission

March 6, 1996

Page 6



James H. Skiles

Vice President, General Counsel

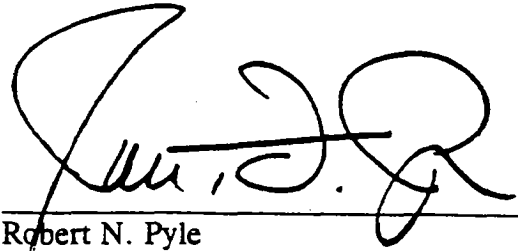
Grocery Manufacturers of America

1010 Wisconsin Avenue, N.W.

Washington, D.C. 20007

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

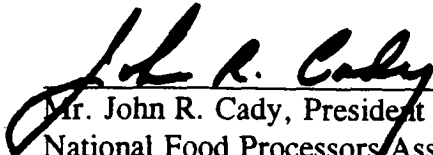
Comment to U.S. Sentencing Commission
March 6, 1996
Page 6

A handwritten signature in black ink, appearing to read "R. N. Pyle", is written over a horizontal line.

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

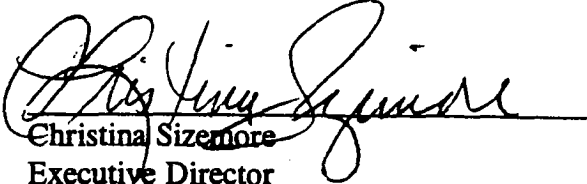
The Independent Bakers Association is a Washington, D.C. based national trade association of over 360 mostly family-owned wholesale bakeries and allied trades to the baking industry. The Association was founded in 1967 to specifically protect and represent the interests of the regional, family-owned,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

Comment to U.S. Sentencing Commission
March 6, 1996
Page 6


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

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

Comment to U.S. Sentencing Commission
March 6, 1996
Page 6


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

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

Comment to U.S. Sentencing Commission
March 6, 1996
Page 6

Diane P. Goyette, Esq.

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

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

OTHER COALITION MEMBERS SUPPORTING THIS COMMENT:

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

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

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

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

**American Veal Association
4714 Orchard Street
Harrisburg, PA 17109**

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

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

National Grocers Association
1825 Samuel Morse Drive
Reston, VA 22090

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

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

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

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