

**Food and Drug Working Group
Preliminary Report**

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FOOD AND DRUG WORKING GROUP PRELIMINARY REPORT

I. INTRODUCTION

The Food and Drug Working Group was established as a two-year working group to study the feasibility of developing organizational guidelines for offenses covered by §2N2.1. The Group decided to use the first year to study food and drug offenses and the operation of §2N2.1 as it applied to individual defendants, and then use the second year to focus more specifically on the formulation of organizational guidelines. *See* Appendix A.

Set forth in this preliminary report is a summary of the information collected by the Group in order to become familiar with food and drug offenses and the application of §2N2.1, and a description of the work the Group will undertake in the coming year. It comprises: (1) an overview of §2N2.1, and the most commonly prosecuted crimes sentenced under it; (2) a description and analysis of food and drug cases involving individuals sentenced under §2N2.1 in fiscal years 1991 and 1992; (3) a description of food and drug cases involving organizational defendants sentenced under pre-guidelines law; (4) an examination of relevant case law; (5) an analysis of application issues under §2N2.1 that the Group identified as meriting consideration before organizational guidelines are developed; (6) an identification of specific issues that the Working Group will focus on; and (7) a description of additional research that the Group will undertake in the second year of its mission.

II. BACKGROUND

In 1991, the Commission adopted Chapter Eight of the Sentencing Guidelines, dealing with the sentencing of organizational defendants. According to the Commission's Supplementary Report on Sentencing Guidelines for Organizations, "most food, drug, and agricultural products offenses (Part N of Chapter Two) were excluded" from the operation of the fines provisions (Part C) of Chapter Eight "pending additional discussion and research on appropriate fine determinants." *Id.* at 8. As a result, fines for organizational defendants convicted of offenses covered by §2N2.1 continue to be determined under pre-guidelines law.

III. SCOPE OF §2N2.1

A. Guideline

Section §2N2.1 has been in effect since November 1, 1987, and was intended to cover violations of "statutes and regulations dealing with any food, drug, biological product, device, cosmetic, or agricultural product." The base offense level is 6; no specific offense

characteristics are set forth in the guideline. The commentary to §2N2.1 indicates that a downward departure may be warranted if only negligent conduct was involved (§2N2.1, Comment. n.1), and that an upward departure may be warranted if "death or bodily injury, extreme psychological injury, property damage or monetary loss resulted" (§2N2.1, Comment. n.3).

Effective November 1, 1992, two cross references were added to the guideline listed in §2N2.1(b): First, "if the offense involved fraud," the fraud guideline, §2F1.1, is to be used. Second, "if the offense was committed in furtherance of, or to conceal, an offense covered by another offense guideline," then the other offense guideline is to be used if the resulting offense level is greater (U.S.S.G., App. C, amend. 451). Prior to November 1, 1992, a similar, but more limited cross reference instruction was in Application Note 2 to §2N2.1. However, this cross reference was moved directly to the text of the guideline to insure consistent application.

Otherwise, the guideline has changed little since it was first adopted. Effective November 1, 1990, the list of statutory provisions was augmented to indicate that subsections (a)(1), (a)(2), and (b) of 21 U.S.C. § 333 were included (U.S.S.G. App. C, amend. 359). Application Note 4 was also added to the commentary to explain that the Commission had not promulgated a guideline for anabolic steroids and, according to the explanation for the amendment, that §2N2.1 does not apply to convictions under 21 U.S.C. §333(e) which involves steroids (U.S.S.G., App. C, amend. 340).

Effective November 1, 1991, Application Note 1 was amended in two respects; first, it changed the phrase "anabolic steroids" to "human growth hormones," thus indicating that §2N2.1 does not apply to offenses involving human growth hormones. Second, it added the cross reference to Chapter Two, Part D for offenses involving steroids and to §2F1.1 for offenses involving counterfeit steroids (U.S.S.G., App. C; amend. 432). This amendment also modified Application Note 1 to indicate that the guideline covered reckless as well as knowing conduct.

B. Statutes

In fiscal year 1992, the most frequently used statutes in cases sentenced under §2N2.1 were those relating to adulterated or misbranded meat (21 U.S.C. § 610), and those relating to adulterated or misbranded food, drugs, cosmetics, or devices (21 U.S.C. § 331). A description of these statutory provisions is useful in evaluating the operation of §2N2.1.

Section 610 prohibits a variety of acts relating to the production of meat products from cows, horses, sheep, swine, goats, or mules. Subsection (a) prohibits slaughtering these animals or preparing human food products from them in conditions that do not comply with the statutory requirements for meat production (such as inspection and sanitary conditions). Subsection (b) requires adherence to humane methods of slaughter. Subsection (c) prohibits selling, transporting, and offering or receiving for sale or transportation, any meat products

capable of use as human food that are adulterated or misbranded, or articles required to be inspected that have not passed inspection. Finally, subsection (d) prohibits, during the period that meat products capable of use as human food are being transported or held for sale, taking any action that is intended to cause or has the effect of causing the products to become adulterated or misbranded.

The terms "adulterated" and "misbranded" are defined in 21 U.S.C. §§ 610(m) and (n), respectively. Adulterated generally refers to the presence of impermissible contaminants or the presence of permissible contaminants at impermissible levels. Misbranding, on the other hand, generally refers to acts that misrepresent or fail to accurately disclose the content of meat products.

The penalty for violating section 610 is imprisonment for a maximum of one year, a fine of up to \$100,000 (for individuals), or both. 21 U.S.C. § 676(a).¹ If, however, the violation "involves intent to defraud, or any distribution or attempted distribution of an article that is adulterated," the penalty increases to a maximum imprisonment term of three years, a fine of \$250,000 (for individuals), or both. The three-year maximum penalty does not apply to cases in which the offense involved the distribution or attempted distribution of a product that is adulterated because "a valuable constituent" was left out, a substance was substituted for it, "damage or inferiority has been concealed in any manner," or any substance has been added or mixed or packed so as to increase its bulk or weight or reduce its quality or strength or make it appear better or of greater value than it is. Furthermore, section 676(a) contains a proviso that no criminal penalty attaches for good faith receipt for transportation of any meat product in violation of the law (unless accompanied by refusal to furnish relevant information about the shipment).

Similar prohibitions and penalties apply in the case of poultry products (*See* 21 U.S.C. §§ 458, 461). With respect to egg production, 21 U.S.C. §§ 1037 and 1041 for the most part track the requirements and penalties pertaining to meat production.

¹The fines reported here are those set forth in 18 U.S.C. § 3571, rather than in the particular statutes under discussion. Under section 3571, fines for Class A misdemeanors committed by individuals are \$100,000, and \$250,000 for felonies committed by individuals. For organizations, section 3571 sets the maximum fines at \$200,000 for Class A misdemeanors and \$500,000 for felonies, with an alternative fine schedule based on twice the gross gain or gross loss. Section 3571(e), however, provides that if the law defining the offense sets forth a lower fine "and such law, by specific reference, exempts the offense from the applicability of the fine otherwise applicable under this section," then the lower fine controls. Some of the offense provisions discussed in this report were enacted after section 3571 but contain no express reference to it, despite the fact that the provisions set forth lower fine levels (\$1,000 for misdemeanors and \$10,000 for felonies) than section 3571. An examination of the cases revealed that in most instances 18 U.S.C. § 3571 set the statutory fine parameters.

The Food, Drug, and Cosmetic Act, (21 U.S.C. § 301, *et seq.*), prohibits a number of acts relating to any adulterated or misbranded food, drug, device, or cosmetic. The prohibited acts cover a wide range of behavior, such as adulterating or misbranding; counterfeiting trademarks; revealing trade secrets; failing to enclose necessary information in shipments of prescription drugs; and failing to register as a drug producer (21 U.S.C. § 331). The terms "adulterated" and "misbranded" are defined in 21 U.S.C. §§ 342 and 343, respectively, for food; in 21 U.S.C. §§ 351 and 352, for drugs and devices; and in 21 U.S.C. §§ 361 and 362, for cosmetics. Although "adulteration" generally relates to safety or wholesomeness while "misbranding" relates to the accuracy of the labeling of the product, certain acts of misbranding can implicate the safety of the product for its intended use. For example, misbranding may occur by virtue of failure to disclose an ingredient; if that ingredient is one to which certain persons may be allergic, the misbranding could create a health risk.

Other prohibitions relating to prescription drugs can be found in 21 U.S.C. § 353. For example, it is unlawful to sell or purchase drug samples, or to dispense certain drugs without a prescription.

Depending on the nature of the conduct, a violation of the Food, Drug, and Cosmetic Act may be a felony or a misdemeanor. Misdemeanor violations of section 331 are punishable by a maximum prison sentence of one year and a maximum fine of \$100,000 (21 U.S.C. § 331(a)(1)).² If, however, the violation is committed after the defendant has been convicted of another violation of section 331, or is committed with intent to defraud or mislead, then the offense is a felony punishable by a maximum prison term of three years, and a maximum fine of \$250,000 (21 U.S.C. § 333(a)(2)). Certain acts relating to prescription drugs are punishable by a maximum prison term of ten years, and a maximum fine of \$250,000 (21 U.S.C. § 333(b)). Offenses involving the distribution of or possession with intent to distribute human growth hormones are punishable by a maximum prison term of five years and a maximum fine of \$250,000, unless the offense involved a person less than 18 years old, in which case the maximum prison term is increased to ten years (21 U.S.C. § 333(e)).

IV. PROFILE OF CASES SENTENCED UNDER §2N2.1

A. Monitoring Data

The monitoring data for fiscal year 1992 reveal that relatively few cases have been sentenced under §2N2.1.³ There were 26 cases for which §2N2.1 produced the highest

²See n. 1, *supra*.

³Monitoring data for fiscal years 1989 and 1990 were also reviewed. The availability of information for these cases, however, was limited for several reasons. First, for both years a

offense level of all guidelines counts in the case, and for which the Commission received complete documentation. The mean final offense level for these offenders was 5.2, and the median 4. All defendants were in Criminal History Category I. A majority of cases involved persons charged with a single count (57.7%; $n = 15$). Only two defendants (7.7%) received a prison sentence (mean and median = 4.5 mos.), and two received a sentence of probation with conditions of confinement (mean and median = 4 mos.' confinement). See Appendix B for a statistical profile of cases sentenced under §2N2.1 in 1992 and 1991.

None of the fiscal year 1992 cases resulted in an offense level higher than 10, and two received downward departures (one for substantial assistance; the other for general mitigating circumstance). All cases received adjustments for acceptance of responsibility. Six cases received adjustments for abuse of trust (23.1%), two cases received adjustments for aggravating role (7.7%), and one case received an adjustment for official victim (3.9%). Fines were imposed in 17 cases (65.4%), with the mean fine \$4,150, the median fine \$2,000, and the mode \$1,000 (minimum = \$250; maximum = \$25,000).

In fiscal year 1991, §2N2.1 resulted in the highest offense level of all guideline counts in 38 cases. Of those 38 cases, a majority involved persons in Criminal History Category I (97.4%; $n = 37$), persons charged with a single count (71.1%; $n = 27$) and individuals receiving sentences of probation (81.6%). Prison sentences were given to only three defendants (mean and median = 4 mos.). Probation with conditions of confinement was imposed in four cases (10.1%).

None of the fiscal year 1991 cases resulted in an offense level higher than 6. There were no departures. In most cases, a reduction for acceptance of responsibility was given (89.5%; $n = 34$). An adjustment for official victim was given in one case. Fines were imposed in 29 cases (76.3%), with the mean fine \$3,006, the median fine \$3,000, and the mode \$5,000 (minimum = \$200; maximum = \$10,000). See Appendix B.

B. Case Review

In order to further study cases sentenced under §2N2.1, the Working Group reviewed the case files for fiscal years 1991 and 1992. A number of variables were coded, including the type of conduct, risks associated with the defendant's conduct, the number of counts, plea bargaining, application of the grouping rules, and the defendant's culpability. See Appendix C for the Group's coding instrument.

high percentage of cases (58% and 48%, respectively) were excluded because information in the case files was incomplete. Second, as to fiscal year 1989, the resulting number of cases was only ten. Third, certain variables relevant to the Group's analysis were not collected in the monitoring data set until fiscal year 1991. Accordingly, the Working Group concluded that the data for fiscal years 1989 and 1990 were of limited utility and elected not to present them in this Report.

The monitoring data reported in Part IV A above comprise only cases in which §2N2.1 produced the highest offense level of all guidelines counts in cases in which the Commission received complete documentation. The data includes cases involving steroids. In this supplemental case review project, the Working Group looked at all cases in which §2N2.1 was applied, regardless of whether the documentation was complete. The Group, however, excluded cases involving steroids. As a result, the totals reported in this section of the Report do not match those reported in Section IV A.

For fiscal year 1992, the Group reviewed 24 cases in which §2N2.1 was applied. For fiscal year 1991, 20 cases were reviewed. The results of the coding project are described in greater detail below.

1. Conduct Involved

Fifteen of the twenty-four cases in fiscal year 1992 involved adulterated or misbranded meat, egg products, or drugs. The Group found that a fair range of conduct was covered by the cases sentenced under §2N2.1. For example, one case involved the importation of agricultural products of South Africa in violation of federal laws concerning economic sanctions against that country. Within the category of offenses relating to meat production, the conduct included such acts as: assaulting a Department of Agriculture inspector; adding sodium sulfite to meat (an outlawed additive that enhances the appearance of meat and thus diminishes the appearance of spoilage and aging); producing meat products without federal inspection; mislabeling products containing beef as "all pork"; and selling meat contaminated by fecal matter and slaughtered in unsanitary conditions. Drug offenses ranged from possession of a device to counterfeit a drug trademark, to diversion of prescription drugs, to distribution of an unapproved new drug.

In 15 cases the offense conduct occurred in a business setting. The defendants in these cases occupied positions as president (2), vice president (1), secretary (1), sole proprietor (7), sales manager (1), manager or co-manager (2), or butcher (1). In most of the offenses persons other than the defendant also participated.

Of the 20 cases examined in fiscal year 1991, 14 involved adulterated or misbranded meat or drugs. Two additional cases involved the sale of uninspected meat. Three cases involved the sale of drug samples. The final case involved the forgery of U.S. Department of Agriculture tobacco inspection certificates. Again, these general offenses included a wide range of conduct: adding sodium sulfite to meat; selling as "all beef" meat products containing beef hearts and pork; selling meat products without federal inspection; selling outdated or rancid meat; and selling products containing meat from cancer-eyed or downed cattle.

Every offense in fiscal year 1991 occurred in a business setting. The defendants in these cases occupied positions as president (2), vice-president (2), sole proprietor or co-owner (10), sales representative or sales manager (3), unit manager (2), or butcher (1). Again, in most of the offenses persons other than the defendant also participated.

2. Culpability⁴

All of the offenses in fiscal year 1992 ($N = 24$) involved conduct that was purposeful or intentional. Of these, 16 (66.7%) involved some element of risk to health or safety of which the defendant was actually aware. Typically, the offenses were committed to enhance the profitability of the business by extending the product's shelf-life, by obtaining some return on spoiled products that could not otherwise be sold, or by substituting cheaper ingredients.

The Working Group found that most offenses in fiscal year 1991 (90.0%, $n = 18$) involved purposeful/intentional conduct. Of the 18 cases, 13 (72.2%) involved some element of risk to health or safety. Offenses included attempts to circumvent federal inspections, attempts to enhance business profitability by extending product shelf-life, and the sale of sample pharmaceuticals.

3. Plea Bargaining

In fiscal year 1992, most of the cases (87.5%, $n = 21$) resulted in a plea of guilty pursuant to a plea agreement. Only one case went to trial. In several cases, specific agreements regarding sentencing were included, such as: the government would not recommend jail time or would not oppose the defendant's request for a particular sentence; a specific sentence should be imposed (e.g., probation and a \$1,000 fine) or that incarceration not exceed a certain amount (e.g., three months); the government would seek a downward departure based on the defendant's substantial assistance; the defendant would not seek a downward departure; the government would recommend that the defendant receive a two-level reduction for acceptance of responsibility; or the offense level would be a particular number.

In fiscal year 1991, most of the convictions (90%, $n = 18$) similarly resulted from a guilty plea. Of the 18 cases involving a guilty plea, 15 of these convictions were pursuant to a written plea agreement (83.3%). Two cases went to trial. The plea agreements contained recommendations regarding sentence similar to those in fiscal year 1992 cases.

4. Misdemeanor/Felony; Number of Counts

The Working Group found that half the cases in fiscal year 1992 involved conviction of one or more felony counts, while the other half involved misdemeanor dispositions. Eleven of the cases involved a single count, five were felonies and six were misdemeanors. The other 13 cases involved multiple counts, either mixed felony and misdemeanor counts or multiple felony or misdemeanor counts.

In fiscal year 1991, nine of the cases involved a conviction for one or more felony counts. Ten cases involved only misdemeanors. One case included both felony and

⁴Case analyses of defendant culpability were based on defendant admissions.

misdemeanor counts. Twelve of the cases involved a single count (six felonies and six misdemeanors), and the remaining eight cases involved multiple counts.

C. Cross References

As noted above, §2N2.1 contains cross references to other offense guidelines. The court is referred to §2D1.1 for cases involving steroids or to §2F1.1 for cases involving counterfeit steroids. Similarly, the court is referred to §2F1.1 for product substitution cases. In addition, there is a general instruction to cross reference to another offense guideline if the offense was committed in furtherance of, or to conceal that other offense and the offense level is higher than that resulting from the application of §2N2.1. The Working Group reviewed the operation of these cross references.

1. §2N2.1 and Steroids

The 1988 Drug Abuse Act created 21 U.S.C. § 333(e) to specifically address the distribution of or possession with intent to distribute steroids. Effective February 27, 1990, anabolic steroids became a Schedule III controlled substance, and section 333(e) was amended to cover human growth hormones rather than steroids. 1990 Crime Control Act § 1902(d), P.L. 101-647. As noted, §2N2.1 was not intended to cover offenses involving either steroids or human growth hormones; however, commentary to that effect was not added to §2N2.1 until 1990. Before that change, offenses involving steroids were sentenced under §2N2.1 because they were prosecuted under 21 U.S.C. §§ 331 or 333, statutes for which §2N2.1 is listed in the statutory index as the applicable guideline.

In fiscal years 1991 and 1992, a number of cases involving steroids continued to be sentenced under §2N2.1. Although it is not entirely clear from the case files why this occurred, it appears that, with one exception,⁵ the only steroid cases sentenced under §2N2.1 were those involving offenses that were committed before November 1990. In these cases, court's sentenced under §2N2.1 apparently because they used a version of the Guidelines Manual that predated the addition of commentary regarding steroids. A total of 24 such cases can be found for fiscal year 1991 and eight such cases for fiscal year 1992, approximately 57 percent of the 1991 cases and 20 percent of the 1992 cases in which §2N2.1 resulted in the highest offense level for the guidelines counts in the case. In fiscal year 1991, two cases involving steroids were cross referenced to §2F1.1 from §2N2.1, and in fiscal year 1992 one case was cross referenced to §2D1.1 from §2N2.1.

⁵In this case, the date of the offense was November 2, 1990, the day after the effective date of the 1990 amendments.

2. §2N2.1 and Fraud

As noted above, §2N2.1 contains a cross reference to §2F1.1 for cases involving product substitution. One of the most significant aspects of the cases sentenced under §2N2.1 was the failure of courts to cross reference to §2F1.1 in cases involving adulterated food products or drugs. In some of the cases involving adulterated meat, poultry, eggs, other food products, or drugs, the defendant purposely adulterated the product in question with the intention of saving production costs. The gist of these offenses is product substitution, and in some cases, an element of the offense was "intent to defraud." Given these circumstances, these cases should cross reference to §2F1.1.

The impact of sentencing under §2F1.1 rather than §2N2.1 can be dramatic, since the offense level in §2F1.1 is increased depending on the amount of "loss." In United States v. West, 942 F.2d 528 (8th Cir. 1991), for example, the defendant was sentenced under §2F1.1 for his conviction for selling adulterated meat. Under §2F1.1 his offense level was apparently 16,⁶ high enough to generate a 21-month sentence, compared to the probable offense level of 7, with a resulting sentencing range of 1 - 7 months that sentencing under §2N2.1 would have generated.⁷

Furthermore, sentencing under §2F1.1 allows a wider range of "relevant conduct" than §2N2.1. Under §1B1.3(a)(2), "relevant conduct" includes "all acts and omissions" that the defendant committed or willfully caused "that were part of the same course of conduct or common scheme or plan as the offense of conviction," but "solely with respect to offenses of a character for which §3D1.2(d) would require grouping of multiple counts." While §2F1.1 is listed as such an offense in §3D1.2(d), §2N2.1 is not. The impact of "relevant conduct" may be quite substantial in increasing the offense level for multiple sales of adulterated products sentenced under §2F1.1. Conversely, under §2N2.1, conduct not included in the offense of conviction would not increase the offense level unless repeated conduct under §2N2.1 is seen as groupable under §3D1.2(d) because it is ongoing or continuous in nature.

3. Other Cross References

Prior to November 1, 1992, §2N2.1 required a cross reference to another guideline if the offense was committed in furtherance of or to conceal another offense. In fiscal year 1992, two §2N2.1 cases were cross referenced to §2B1.1. Effective November 1, 1992,

⁶This represents a base offense level of 6, plus 7 offense levels for "loss," plus 2 offense levels for "more than minimal planning," plus 3 offense levels for "aggravating role," minus 2 offense levels for "acceptance of responsibility." The offense level should have been 17, but there was an apparent arithmetical error. 942 F.2d at 530, 531-32 n.3.

⁷This represents a base offense level of 6, plus 3 offense levels for "aggravating role," minus 2 offense levels for "acceptance of responsibility."

application of the cross reference is required only when the other guideline results in a higher offense level.

The Working Group's case review discussed above in Section IV indicates that the proper execution of the cross references should be considered as an area for further study. The cases reviewed can be placed in three general categories: 1) cases involving product substitution or counterfeit steroids; 2) cases involving steroids; and 3) cases involving regulatory violations of food and drug statutes or requirements. Generally, the cases in the first category should be sentenced pursuant to a cross reference to §2F1.1, the cases in the second category should be sentenced pursuant to a cross reference to §2D1.1, and the cases in the final category should be sentenced pursuant to §2N2.1. However, the cases reviewed did not appear to reflect a consistent application of the cross references in keeping with these general categories.

As described above, whether or not a cross reference to another offense guideline is applied correctly can have a dramatic impact on the resulting sentence. Therefore, the correct application of cross references can similarly affect the evaluation of whether §2N2.1 provides adequate penalties. In its second year, the Working Group would like to focus on the application of the cross references in §2N2.1.

D. Case Law

No cases were discovered that contained a substantive discussion of §2N2.1. One tangentially relevant case is United States v. Cambra, 933 F.2d 752 (9th Cir. 1991), which dealt with whether §2N2.1 or §2F1.1 should be applied in a case involving the sale of counterfeit steroids. That situation is now expressly addressed in the cross references in §2N2.1. Perhaps the most significant of related cases is United States v. West, 942 F.2d 528 (8th Cir. 1991), discussed above, because it demonstrates the impact of sentencing under §2F1.1 in a case involving the sale of adulterated meat.

V. PRE-GUIDELINES FOOD AND DRUG CASES

In an effort to gain more information about the sentencing of defendants convicted of pre-guidelines food and drug offenses, the Working Group explored three sources: the Administrative Office's FPSSIS data; case law; and court documents. The results of this research are set forth below.

A. FPSSIS Data

The Administrative Office's Federal Probation Sentencing and Supervision Information System (FPSSIS) data represents individual and organizational offenses from 1984 through 1990. The data reveal that most food and drug cases involved adulterated or misbranded meat

(21 U.S.C. § 610) or drugs (21 U.S.C. §§ 331, 333). Due to limitations of the data, it is unknown how many of these cases involved steroids.

Set forth below is a chart depicting the food and drug cases sentenced from 1984 through 1990 and the sentences that were imposed in those cases.

AVERAGE SENTENCE IMPOSED - INDIVIDUAL DEFENDANTS													
Number of Cases = 467													
YEAR	TOTAL	PRISON				PROBATION				FINE ONLY			
		N	%	Mean	Median	N	%	Mean	Median	N	%	Mean	Median
TOTAL	467	98	21.0	21.2	6.0	307	65.7	32.8	36.0	62	13.3	2,925	1,000
1984	45	8	1.7	14.0	4.5	28	6.0	27.0	24.0	9	1.9	500	500
1985	74	15	3.2	14.5	6.0	42	9.0	34.3	30.0	17	3.6	3,865	1,000
1986	63	8	1.7	23.9	9.0	43	9.2	28.1	24.0	12	2.6	3,610	1,500
1987	56	18	3.9	49.1	10.0	27	5.8	33.6	36.0	11	2.4	977	500
1988	42	8	1.7	4.6	4.5	31	6.6	29.2	24.0	3	0.6	3,333	5,000
1989	121	30	6.4	12.7	6.0	82	17.6	37.1	36.0	9	1.9	3,564	3,000
1990	66	11	2.4	23.0	12.0	54	11.6	33.6	36.0	1	0.2	15,000	15,000

AVERAGE SENTENCE IMPOSED - ORGANIZATIONAL DEFENDANTS									
Number of Cases = 80									
YEAR	TOTAL	PROBATION				FINE ONLY			
		N	%	Mean	Median	N	%	Mean	Median
TOTAL	80	20	25.0	31.5	30.0	60	75.0	34,463	5,000
1984	12	2	2.5	12.5	12.5	10	12.5	12,210	3,250
1985	10	1	1.3	24.0	24.0	9	11.3	5,722	3,500
1986	13	4	5.0	45.3	60.0	9	11.3	19,100	6,000
1987	13	3	3.8	36.0	36.0	10	12.5	22,625	2,500
1988	11	2	2.5	36.0	36.0	9	11.3	12,222	5,000
1989	9	4	5.0	30.8	30.0	5	6.3	179,810	75,000
1990	12	4	5.0	24.0	24.0	8	10.0	60,875	21,000

B. Reported Cases

Although there are many pre-guidelines food and drug cases involving organizational defendants, reported decisions typically are not exhaustive, nor do they typically deal with

sentencing issues. A noteworthy case, however, is the prosecution of the Beech-Nut company for its sales of misbranded and adulterated apple juice. See United States v. Beech-Nut Nutrition Corp., 659 F. Supp. 1487 (E.D.N.Y. 1987), aff'd in part, rev'd in part, 871 F.2d 1181 (2d Cir. 1989). Beech-Nut marketed its product as pure apple juice with no sugar added. It became aware, however, that the product it was receiving from its sole supplier, whose price for the concentrate was \$0.50 to \$1 per gallon lower than Beech-Nut's previous supplier, was almost pure corn syrup. Beech-Nut nonetheless continued to sell the product as pure apple juice due to economic pressures. 871 F.2d at 1185. The defendants in that case included (among others) the corporation, its president, and its vice president. The corporation pleaded guilty to 215 felony violations of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(a), 333(b), and was sentenced to a fine of \$2 million and ordered to pay the Food and Drug Administration (FDA) for the costs of the investigation. 871 F.2d at 1187.

C. Case Review

In connection with the research that led to the development of Chapter Eight, the Sentencing Commission studied presentence reports for organizational defendants. Of these presentence reports, 30 related to food and drug offenses and are summarized in Appendix D. The 30 cases mirror the kinds of conduct found in cases relating to individual defendants in that the predominant offenses were those involving adulterated or misbranded meat products, foods, or drugs. Ten cases involved a felony disposition. Fines in these 10 cases ranged from \$1,200 to \$623,000. The median fine was \$52,500 and the mean \$121,820. Sixteen cases involved a misdemeanor disposition. The highest fine imposed in these 16 cases was \$50,000 and the lowest \$100. The median fine was \$8,562.50 and the mean \$11,785.94. The remaining four cases did not involve a fine. Overall, there was a fairly wide variation in sentences among seemingly similar cases. There was no apparent pattern to explain why a case was resolved as a felony or as a misdemeanor or to explain the number of counts of conviction.

With respect to felony cases, two cases involving large corporations represent the high end of the spectrum. One involved misbranded and adulterated drugs, the other adulterated and misbranded devices; both involved false statements to the government. In the first case (No. 97), one of two corporate defendants⁸ had repeatedly been investigated by the FDA for violating the requirements relating to the production of drugs. These investigations led to a suit by the FDA for an injunction to halt the production of drugs. Under the terms of a settlement agreement, the company was not permitted to manufacture injectable drugs, but was allowed to produce a test batch of liquid penicillin. This test batch was grossly contaminated with bacteria, but the company falsified and hid records to prevent the FDA from learning that the company had produced five additional batches of penicillin in violation of the settlement agreement. Although none of these contaminated injectable drugs was ever

⁸Although two separate entities were named as defendants, they were considered to be essentially interchangeable.

marketed because the FDA was alerted to the falsification of records, the company repeatedly sought permission to market contaminated drugs on the basis of records the company knew to be false.

The second company sought the FDA's approval to put aspartame in its penicillin to mask the bitter taste of the drug, but the FDA disapproved the application, in part because of the failure to warn of the possibility of irreversible brain damage in a small segment of the population sensitive to excess amounts of aspartame. Notwithstanding the FDA's disapproval of its application, the corporation put aspartame in its penicillin anyway, and falsified records to hide that fact. Each company was convicted of two felony counts of distributing misbranded drugs and adulterating drugs, under 21 U.S.C. §§ 331(a) and (k), and each was fined \$185,000.

Case No. 346 involved a company that produced pacemakers and pacemaker programmers. The company distributed a number of pacemakers that had the potential to fail suddenly or that had batteries with the potential to deplete sooner than represented. It also distributed a number of pacemaker programmers without the FDA's approval and falsely reported to the FDA that there were no reports of medical complications with its pacemakers and pacemaker programmers. The organization was convicted of 25 counts of transporting adulterated and misbranded pacemakers and pacemaker programmers with the intent to defraud and of making false statements to the FDA (in violation of 21 U.S.C. §§ 331(a) and (q)(2)), and was fined \$623,000 and ordered to pay costs of \$141,000.

The lower end of the spectrum is represented by case No. 1 in which a successor corporation was convicted for the acts of its predecessor in distributing adulterated wheat. The predecessor company hid 185,500 pounds of insect-damaged wheat inside a shipment of 607,570 pounds of wheat. The FDA approved repacking and selling the remaining 422,070 pounds of wheat for human consumption, but the damaged wheat was to be sold only for livestock feed. An overpayment of \$8,448 was attributable to the damaged wheat. The defendant was convicted of one misdemeanor count of distributing adulterated wheat, in violation of 21 U.S.C. § 331(a), and was fined \$100.

Cases No. 33 and No. 176 are more typical of the misdemeanor cases. Case No. 33 involved a corporation engaged in the wholesale distribution of meat and poultry products that sold almost 1,000 pounds of meat contaminated with rodent feces and gnaw marks, and another 800 pounds of uninspected meat packed in boxes originally used for household cleaning products. The corporation had earlier offered uninspected meat for sale by repacking it in boxes containing meat inspection labels from contents previously packed in them. The defendant was convicted of three counts and fined \$30,000.

In Case No. 176, a meat production company was convicted of one count of preparing misbranded meat by offering for sale 1,000 pounds of corned beef that contained excess water. The company was fined \$10,000.

VI. ISSUES RELATING TO §2N2.1

A. Cross References

As previously mentioned in this report, the Working Group found what appeared to be inconsistent application of the cross references in §2N2.1. This obviously could affect resulting fines for organizations. This issue should be revisited when the Commission evaluates appropriate penalties. If the fraud guideline were used instead of §2N2.1 in appropriate cases, it may be that the fine determinants under §2F1.1 would provide appropriate sanctions. For those food and drug cases where guideline application is appropriate under §2N2.1, the issue remains whether this guideline as currently drafted provides for adequate fines and whether any further commentary or specific offense characteristics would be useful. Thus, the core of the problem may be with the interpretation of the cross references under §2N2.1.

Likewise, it should also be considered whether §2F1.1 as currently drafted results in appropriate sentences for food and drug cases and whether any further commentary or specific offense characteristics would be useful. For example, certain characteristics associated with food and drug cases, such as risk of illness, may not be adequately accounted for under the fraud guideline.

B. Grouping Rules

Another area of concern with the application of §2N2.1 is the issue of consistent application of the grouping rules. There were 13 multiple count cases in fiscal year 1992. In six of those cases, the counts were grouped pursuant to §3D1.2 and resulted in no incremental increase for the additional counts. In the remaining seven cases, the counts were not grouped, resulting in incremental increases pursuant to §3D1.4. There were eight multiple count cases in 1991. In four of those cases, there was no mention of grouping whatsoever. Consequently, there were no incremental increases pursuant to §3D1.4.⁹ In one case, the counts were grouped pursuant to §3D1.2, but the probation officer nevertheless proceeded to run through the §3D1.4 analysis and compute the number of units.¹⁰ Of the remaining three cases, two were grouped pursuant to §3D1.2 and resulted in no incremental increase, and one

⁹The offenses described in these cases include a conspiracy count and one or more substantive counts that were the object of the conspiracy. In these cases, the counts should have been grouped pursuant to §3D1.2. Therefore, the failure to address the grouping issue may not have resulted in an incorrect final offense level.

¹⁰In this case, since the counts had all been grouped pursuant to §3D1.2, there was a single group to which the probation officer allotted one unit. One unit does not result in any incremental increase under §3D1.4, so the application error did not result in an incorrect final offense level.

resulted in an incremental increase pursuant to §3D1.4. There was no consistency in FY 1992 nor in FY 1991 as to which cases or counts would be grouped and which would not, indicating a need for clarifying instruction.

In addressing the need for clarifying instruction, the Commission may wish to address as a matter of policy whether, and to what extent, multiple counts of conviction under §2N2.1 should result in incremental punishment rather than being grouped. The existing §2N2.1 contains no specific offense characteristics for multiple victims or ongoing offenses.¹¹ The only mechanism for additional punishment is to apply units pursuant to §3D1.4 instead of grouping. Thus, the decision whether to group may be based on the parties' perception of the adequacy of the resulting punishment rather than a precise application of the multiple count rules.

In addition to questions of adequate penalties, there is the question of the identification of the proper "victim" in applying the multiple count rules. The Working Group found that in several cases multiple counts were grouped under §3D1.2(b) because they were viewed as multiple acts connected by a common criminal objective with a single societal victim.

Although it may be appropriate to treat "society" as the victim in offenses involving technical or simple regulatory violations of Food and Drug regulations (involving no actual threat to human health), there is reason to question whether "society" is the victim in a case involving the sale of adulterated products. For instance, who is the victim when multiple sales were made to a single retail outlet for ultimate resale to consumers? Even if the individual consumers who purchased the adulterated items cannot be identified, they nonetheless exist and are indirect victims of the offense in addition to the retail distributor.

One way of addressing the issue of grouping multiple counts is to provide that offenses under §2N2.1 be grouped under §3D1.2(d). This grouping rule calls for multiple counts to be grouped if the offense level is based primarily on quantity or contemplates ongoing or continuous behavior. Section 2N2.1 could be amended to consider appropriate increases based on relevant measures of aggregate harm. Quantifiable aspects of the defendant's offense conduct, *e.g.*, number of victims, repetitive conduct, risk of harm, etc., could result in appropriate increases through specific offense characteristics under §2N2.1.

Placing §2N2.1 on the list for grouping under §3D1.2(d) would also allow the court to consider a broader range of conduct for sentencing purposes. Under §1B1.3(a)(2), relevant conduct in §2N2.1 cases could then reach beyond the count of conviction to encompass

¹¹Unlike §2F1.1, which enhances both for "loss" and for repeated acts (by means of the "more than minimal planning" specific offense characteristic), there is no mechanism in §2N2.1 to distinguish between multiple sales of adulterated products and a single sale of such products.

additional criminal conduct that was part of the same course of conduct or common scheme or plan as the offense of conviction.

The Working Group has identified the grouping rules as an area for further study and analysis. The Working Group could fully explore alternative approaches to handling multiple counts under §2N2.1. This analysis is essential before reasoned consideration of appropriate organizational sanctions can be undertaken.

C. Statutory Maximum Fines

Because of the high percentage of misdemeanor dispositions among food and drug cases, the statutory maximum amount of a fine may be a more critical issue in developing organizational sanctions.¹² It should be noted that, as a practical matter, the charging pattern may influence the options available under any guideline. Because of the statutory maximum, a defendant permitted to plead to a single misdemeanor count can never be fined more than \$200,000 (for a Class A Misdemeanor) or \$10,000 (for a Class B or C misdemeanor), irrespective of the operation of Chapter Eight.¹³

VII. FURTHER RESEARCH

This preliminary report suggests several areas of additional research to be undertaken by the Working Group. These areas include:

- 1) consultation with outside groups, such as the Department of Justice;
- 2) a review of the monitoring data and files for food and drug cases in fiscal year 1993;
- 3) a review of any available monitoring information regarding pertinent cases sentenced under §2F1.1 and Chapter Eight;
- 4) further study and review of the application of cross references under §2N2.1 with particular emphasis on food and drug cases in fiscal year 1993 monitoring data; and

¹²In this regard, the resolution of the legal question whether the enhanced fines of 18 U.S.C. § 3571 apply in food and drug cases, discussed in n.1, supra is important because the substantive statutes defining various food and drug offenses may limit misdemeanor fines to \$1,000.

¹³Higher statutory maxima apply if the offense results in death or involves substantial pecuniary loss or gain.

- 5) further study and analysis of the grouping rules under Chapter 3, Part D.

After this additional research is completed, the Group will be in a position to recommend a course of action specifically relating to the application of Chapter Eight to food and drug offenses.

**Appendix A:
Purpose Statement**

FOOD AND DRUG WORKING GROUP PURPOSE STATEMENT

I. INTRODUCTION

The Food and Drug Working Group was created to develop organizational guidelines relating to the Food and Drug offenses governed, as to individual defendants, by §2N2.1. This Working Group was placed upon a two-year cycle. The members of the Group are: Bob Bentsen, Marguerite Cephas, Nolan Clark, Susan Kuzma (chair), and Frank Larry.

II. PROPOSED SCOPE OF WORK AND TIME-TABLE

As a first step to considering organizational guidelines, the Group is gathering information relevant to Food and Drug offenses, in order to present an overview of those offenses for the Commission's consideration and to distill the discrete areas of inquiry that should be pursued. The information-gathering will encompass the following steps: (1) reviewing statutes, regulations, and other materials (such as reports of legislative hearings) that are relevant to Food and Drug offenses; (2) obtaining information from the Office of Consumer Litigation of the Civil Division of the United States Department of Justice, which is responsible for prosecuting Food and Drug violations; (3) compiling statistics from the monitoring data regarding the application of §2N2.1, and Chapter Eight (if any cases applying Chapter Eight are available for consideration); (4) examining individual §2N2.1 cases in order to develop a more detailed understanding of the nature of Food and Drug offenses and any guidelines issues that may have arisen in them; (5) reviewing the case law for Food and Drug cases, both pre-guidelines and guidelines; (6) reviewing TAS and Attorney Hotline calls regarding Food and Drug offenses; and (7) requesting input from various outside groups, such as the Probation Officers Advisory Group and the Practitioners Advisory Group.

In addition to serving an educational purpose, this process should enable the Group to identify the issues that require particular scrutiny in developing organizational guidelines. By April 1993, the Group expects to present to the Commission an abbreviated summary of the preliminary research it has conducted and the issues to be further considered.

III. CURRENT STATUS OF RESEARCH

The Group has undertaken a case-coding project to develop a detailed profile of the §2N2.1 cases for which the Commission received relevant sentencing documents. The project will encompass both FY 1991 and FY 1992 cases. Although the Group contacted the Justice Department in December 1992, it has yet to receive any information from them; however, the Justice Department indicated

that it would provide information about what it considers to be typical Food and Drug cases, including copies of charging documents; input regarding specific sentencing issues that have arisen; and basic background information about Food and Drug offenses, including particular noteworthy investigations (such as the investigation of the generic drug industry).

A preliminary review of TAS Hotline calls disclosed that there were few calls relating to §2N2.1. The Group has gathered relevant monitoring information for §2N2.1 for each year the guidelines have been in effect, and is putting the data into chart format for easier understanding.

**Appendix B:
Monitoring Data**

PROFILE OF FOOD AND DRUG OFFENSES - FY92*

Primary Guideline: 2N2.1

Number of Cases = 26

	Food and Drug Cases				All Guideline Cases			
	Number	%	Mean	Median	Number	%	Mean	Median
Final Offense Level	(26)	--	5.2	4.0	(31,347)	--	17.6	16
Criminal History Category	(26)	--	1.0	1.0	(31,347)	--	2.0	1.0
Final Guideline Range	(26)	--	--	0-6	(31,347)	--	--	24-30
Acceptance of Responsibility								
Received	26	100.0	--	--	25,753	82.3	--	--
Not Received	0	--	--	--	5,550	17.7	--	--
Sentence								
Prison	2	8.0	4.5	4.5	22,900	73.2	69.9	40.0
New Split Sentence	0	--	--	--	1,010	3.2	8.0	8.0
Probation and Alternative	2	8.0	4.0	4.0	3,216	10.3	3.4	3.0
Probation	21	84.0	28.0	24.0	4,075	13.0	31.3	36.0
Other	0	--	--	--	74	--	--	--
Chapter Three Adjustments Received								
	Number	%	Mean	Median	Number	%	Mean	Median
Vulnerable Victim	0	0.0	--	--	134	0.4	--	--
Official Victim	1	3.9	--	--	93	0.3	--	--
Restraint of Victim	0	0.0	--	--	46	0.1	--	--
Aggravating Role	2	7.7	--	--	2,348	7.0	--	--
Mitigating Role	0	0.0	--	--	2,859	8.5	--	--
Abuse of Trust/Special Skill	6	23.1	--	--	872	2.6	--	--
Obstruction of Justice	0	0.0	--	--	1,366	4.1	--	--
Reckless Endangerment	0	0.0	--	--	91	0.3	--	--
Mode of Conviction								
	Number	%	Mean	Median	Number	%	Mean	Median
Plea	25	96.2	--	--	27,102	86.9	--	--
Trial	1	3.9	--	--	4,084	13.1	--	--
Departure Status:								
No Departure	24	92.3	--	--	23,850	76.2	--	--
Upward Departure	0	--	--	--	481	1.5	--	--
Departure for Substantial Assistance	1	3.9	--	--	5,010	16.0	--	--
Other Downward Departure	1	3.9	--	--	1,942	6.2	--	--

Top Reasons Most Frequently Given For Departure:	Upward Departures	Downward Departures	Upward Departures	Downward Departures
1st	N/A	Substantial Assistance: 1 (50.0%)	Adequacy of Criminal History: 264 (48.5%)	Substantial Assistance: 5,478 (71.6%)
2nd	N/A	General Mitigating Circumstance: 1 (50.0%)	General Aggravating Circumstance: 49 (9.0%)	Pursuant to a Plea Agreement: 607 (7.9%)

These data have been selected from the Commission's fiscal year 1992 data file (October 1, 1991 through September 30, 1992). The 2N2.1 sample represents amendment years 1987 through 1991, but excludes about 35 percent of the cases due to missing or incomplete information from the sentencing judge. Fiscal year totals for any given variable may not equal the total number of cases due to missing information about that variable.

PROFILE OF FOOD AND DRUG OFFENSES - FY91*

Primary Guideline: 2N2.1

Number of Cases = 38

	Food and Drug Cases				All Guideline Cases			
	Number	%	Mean	Median	Number	%	Mean	Median
Final Offense Level	(38)	--	4.3	4.0	(26,820)	--	16.7	14.0
Criminal History Category	(38)	--	1.0	1.0	(26,820)	--	2.0	1.0
Final Guideline Range	(38)	--	--	0-6	(26,820)	--	--	21-27
Acceptance of Responsibility								
Received	34	89.5	--	--	21,518	80.2	--	--
Not Received	4	10.5	--	--	5,300	19.8	--	--
Sentence								
Prison	3	7.9	4.0	4.0	19,965	74.8	62.2	33.0
New Split Sentence	0	--	--	--	577	2.2	8.0	8.0
Probation and Alternative	4	10.5	2.0	2.0	2,436	9.1	3.1	3.0
Probation	31	81.6	1.0	1.0	3,646	13.7	31.6	36.0
Other	0	--	--	--	59	0.2	--	--
Chapter Three Adjustments Received								
	Number	%	Mean	Median	Number	%	Mean	Median
Vulnerable Victim	0	0.0	--	--	157	0.6	--	--
Official Victim	0	0.0	--	--	96	0.4	--	--
Restraint of Victim	0	0.0	--	--	36	0.1	--	--
Aggravating Role	1	2.6	--	--	2,096	7.8	--	--
Mitigating Role	0	0.0	--	--	2,238	8.3	--	--
Abuse of Trust/Special Skill	0	0.0	--	--	701	2.6	--	--
Obstruction of Justice	0	0.0	--	--	1,300	4.9	--	--
Reckless Endangerment	0	0.0	--	--	39	0.2	--	--
Mode of Conviction								
	Number	%	Mean	Median	Number	%	Mean	Median
Plea	35	92.1	--	--	22,771	85.2	--	--
Trial	3	7.9	--	--	3,955	14.8	--	--
Departure Status:								
No Departure	38	100.0	--	--	21,352	79.9	--	--
Upward Departure	0	--	--	--	453	1.7	--	--
Departure for Substantial Assistance	0	--	--	--	3,323	12.4	--	--
Other Downward Departure	0	--	--	--	1,575	5.9	--	--

Top Reasons Most Frequently Given For Departure:	Upward Departures	Downward Departures	Upward Departures	Downward Departures
1st	N/A	N/A	Adequacy of Criminal History: 309 (57.2%)	Substantial Assistance: 3,786 (68.7%)
2nd	N/A	N/A	Drug Amount: 49 (9.1%)	Pursuant to a Plea Agreement: 526 (9.5%)

These data have been selected from the Commission's fiscal year 1991 data file (October 1, 1990 through September 30, 1991). The 2N2.1 sample represents amendment years 1987 through 1990, but excludes about 9 percent of the cases due to missing or incomplete information from the sentencing judge. Fiscal year totals for any given variable may not equal the total number of 2N2.1 cases due to missing information about that variable.

**Appendix C:
Coding Instrument and Instructions**

CASE CODING PROJECT
FOOD AND DRUG CASES
CODING INSTRUCTIONS

Please read the following instructions carefully before beginning to code the cases assigned to you.

Part A: The information elicited in Part A consists of basic components of the count(s) of conviction. With respect to question A8 (Brief Description of Offense), the coder is requested to capture in an abbreviated fashion the gist of the offense and the defendant's involvement in it. E.g., "defendant, as manager of meat-packing company, on five occasions sold to grocery stores beef that he knew contained contaminants such as animal hair and dirt." As a point of comparison, "the sale of adulterated food" would be too brief a description, but it would not be necessary to list details such as every date of sale.

Part B: The information elicited in Part B relates to the sentence imposed. In question B1, the final offense level is the level that was arrived at after all enhancements and adjustments were applied and from which the sentencing range was derived.

Part C: The information elicited in Part C relates to guideline application. In question C2, the coder should make clear whether the guideline version applied is actually known from the PSR, or whether the coder is inferring which version was used from other facts, such as the date of conviction. If the guideline version is not known with certainty, the coder should be sure to describe the facts that formed the basis of the coder's inference. In question C3, the coder should list all specific offense characteristics (if any) that were applied, while in question C4 the coder should list adjustments outside Chapter 2 that were applied, including acceptance of responsibility.

One of the issues for study is whether and how courts are applying cross-references under §2N2.1. For example, if an element of the offense was "intent to defraud" (such as a felony violation of 21 U.S.C. § 331) but the court did not cross-reference to §2F1.1, that should be noted in the answer to question C6.

Part D: The information elicited in Part D comprises more detailed information about the offense and the defendant's culpability. For questions D6 through D14, the coder should rely on the facts described in the presentence report that were accepted by the sentencing judge, even if the defendant disputes them. The defendant's justification or excuse can be described in the answer to question D14.

In questions D7 and D8, the coder should differentiate between conduct that comprised the count(s) of conviction, and other related conduct as to which the defendant either was not prosecuted or was not convicted. For example, if a defendant pleaded guilty to two counts of mislabeling a product, but two counts of distributing the product were dismissed, the coder should describe the former in question D7 and the latter in question D8.

In question D9, the coder is asked to quantify the financial magnitude of the offense. The coder should be sure to describe how the amount was determined. For example, a defendant may have sold adulterated meat for a contract price of \$50,000. The coder should record, "\$50,000 - contract price for adulterated meat sold by defendant." If multiple figures are known (e.g., sale price and replacement costs), each figure should be recorded.

In questions D11 through D14, the coder is asked to characterize the defendant's level of involvement in and awareness of the offense conduct, as reflected in the presentence report. In questions D15 through D20, the coder is asked to characterize the creation of risk and the defendant's awareness of that risk, as reflected in the presentence report. In both questions D13 and D20, the coder is to select the answer that best describes the defendant's state of mind with respect to the occurrence of the offense or of risk(s) caused by the offense, as the facts in the presentence report reflect it.

A. Offense Information

- 1) Statute(s) of Conviction _____
- 2) Name of Offense(s) _____
- 3) Number of Counts _____ 4) Felony/Misdemeanor _____
- 5) Plea or Trial _____ 6) Plea Agreement? _____
- 7) Terms of Agreement Regarding Sentence _____
- _____
- 8) Brief Description of Offense _____
- _____
- _____
- _____
- _____

B. Sentence

- 1) Final Offense Level _____ 2) Crim. Hist. Category _____
- 3) Sentencing Range _____ 4) Fine Range _____
- 5) Sentence (including fine and restitution) _____
- _____
- 6) Departure? _____ 7) If departure, give reason.
- _____
- 8) Was defendant found unable to pay a fine? _____

C. Guideline Application

1) Chap. 2 Guideline Applied _____ 2) Guideline Version, if known, or best guess (explain basis) _____

3) Specific Offense Characteristics Applied _____

4) Adjustments Applied _____

5) If multiple counts, were the counts grouped? Under what grouping rule? _____

6) Were there any unusual guideline application issues? Describe. _____

D. Offense Characteristics and Offender Culpability

Part I: Participants in the Offense; Organizational Involvement

1) Was the defendant working for a business organization when s/he committed the offense? _____

2) If yes, what was defendant's position within the organization? _____

3) Nature of the business organization _____

4) If known, was the organization also prosecuted? (Describe outcome) _____

5) Were other individuals involved in committing the offense, whether or not they were codefendants? If yes, how many (if known, or describe generically)? _____

6) Were other individual defendants prosecuted? If yes, describe their offenses and the outcomes of their cases (if known). _____

Part II: Scope of the Offense

7) Describe the scope and duration of the conduct embraced by the count(s) of conviction. _____

8) Describe any other related conduct set forth in the PSR, whether or not it constitutes relevant conduct under §1B1.3. _____

9) What was the financial magnitude of the offense? Describe what the monetary amount recorded represents (e.g., defendant's profit, sale price, amount of loss to the victim, etc.) _____

Part III: Culpability

10) Describe the defendant's participation in the conduct constituting the offense. _____

11) Did the defendant participate in the decision to engage in the conduct constituting the offense? _____

12) Did the defendant admit that he intended to engage in the conduct constituting the offense or knew that the conduct constituting the offense was occurring? _____

13) If the answer to question 12 is no, which of the five descriptions below best characterizes the defendant's state of mind as to the occurrence of the conduct constituting the offense?

a) Defendant had the purpose to engage in the conduct constituting the offense. (Purpose or intent)

b) Defendant knew that the conduct constituting the offense was occurring. (Knowledge)

c) Defendant was not actually aware that the conduct was occurring, but was aware of a high probability that it was occurring and deliberately avoided learning the facts. (Willful ignorance)

d) Defendant was not actually aware that the conduct was occurring, but was aware of a risk that it might occur and was indifferent to whether it occurred. (Recklessness)

d) Defendant did not actually know that the conduct was occurring, but should have known. (Negligence)

e) Defendant did not actually know and could not have known that the conduct was occurring. (Strict liability)

14) Defendant's explanation or justification for the offense (if any). _____

Part IV: Harms and Risks Caused by the Offense

15) Did the offense involve risk of bodily injury or illness? If yes, describe nature of risk. _____

16) Did actual injury or illness result from the offense? Describe. _____

17) Did the offense involve risk of infestation or transmission of disease? If yes, describe nature of risk. _____

18) Did actual infestation or transmission of disease occur as a result of the offense? Describe. _____

19) Did the defendant admit awareness of the risk(s) created by his or her conduct? _____

20) If the answer to question 19 is no, which of the three descriptions below best characterizes the defendant's state of mind as to the existence of the risk(s) created by the offense?

a) Defendant knew the risk was caused.

b) Defendant did not actually know of the risk, but should have known that the risk was caused.

c) Defendant did not actually know and could not have known that the risk was caused. (Strict liability)

21) Was the offense a recordkeeping or reporting violation? _____

22) If the answer to question 21 is yes, were there indications that the offense represented an effort to conceal a substantive violation? _____

**Appendix D:
Summaries of Pre-guidelines Cases Involving Organizational Defendants**

CASE SUMMARIES
PREGUIDELINES ORGANIZATIONAL FOOD AND DRUG CASES

I. FELONY CASES

Case No. 2: A family-owned corporation involved in a meat producing business and retail grocery operation was convicted of one count of selling adulterated meat with intent to defraud, in violation of 21 U.S.C. §§ 610 and 676. From January 1987 through October 1989, defendant prepared and sold \$113,057.83 of beef, all of which was adulterated with sodium sulfite. On October 18, 1989, 3,746 lbs. of meat products were voluntarily destroyed, and on October 19, 1989, 4,042 lbs. of meat were recalled and destroyed, of which five samples (out of 15) contained sodium sulfite. The meats had been sold on account to 33 regular customers, but no complaints were made because of the meat.

In 1987 defendant had been charged with seven counts and pleaded guilty to one count of selling uninspected meat and falsely representing that the meat had been inspected, for which defendant was fined \$10,000, with \$9,000 suspended, and placed on probation for three years. Defendant also had a civil injunction against it in 1982 for selling uninspected meat. The present case stemmed from a surreptitious purchase of uninspected meat from defendant. The retail grocery operation had terminated by 1990.

Defendant was sentenced to a fine of \$12,000. (Note that the corporation had negative net worth, and may have been going out of business.)

Case No. 3: A meat packing corporation was convicted of one count of distributing adulterated and misbranded meat, in violation of 21 U.S.C. §§ 610 and 676(a). Between March and April 1990, 14 samples of defendant's pork products were found to contain sodium sulfite. FDA recalled and destroyed 1,194 lbs., and another 1,200 lbs. of meat on the premises were destroyed.

Defendant was sentenced to 60 months' probation and a \$100,000 fine.

Case No. 68: A corporation engaged in wholesale and retail sales of cheese, meats, and provisions was convicted of three counts of selling adulterated meat in violation of 21 U.S.C. §§ 610(b)(1), 661(c)(3), and 676. On each of three days in October and December 1985, defendant sold to retail food companies 20 lbs. of canned ham that was putrid and decomposed, as evidenced by the swollen condition of the cans. There was evidence that defendant also sold adulterated canned hams to other purchasers during this

time. Defendant voluntarily recalled all the meat products in question.

Defendant was sentenced to a fine of \$75,000.

Case No. 80: A meat-packing corporation was convicted of two counts of preparing for sale and distributing meat products without the supervision of a federal inspector, in violation of 21 U.S.C. §§ 607(a), 610(a) and (c), and 676(a). Defendant requested USDA's permission to operate on weekends but request was denied. An after-hours inspection disclosed that on August 4, 1984, defendant had processed 3,000 lbs. of meat and defrosted food without an inspector present. Defendant's president stated that company had been doing so for 15 to 20 years. Defendant also charged with two counts of receiving meat products without federal inspection in March 1984 (these counts were dismissed through a plea bargain). Defendant was in an intensive regulation program because of past problems with food products, such as excessive water content in ham, and had engaged in harassment of USDA inspectors during the program.

Defendant was sentenced to a \$2,000 fine.

Case No. 97: Two corporations involved in the manufacture of generic drugs, mostly antibiotics for human and veterinary use, were convicted of two counts of distributing misbranded drugs and adulterating drugs, in violation of 21 U.S.C. §§ 331(a) and (k) and 333(b). The charges related to the production of 45 batches, worth millions of dollars, of penicillin tablets containing undisclosed aspartame, and the production of bacteria-contaminated injectible drugs. The remaining 18 counts (including obstruction of agency proceedings, conspiracy, and making false statements) were dismissed pursuant to plea agreement.

Defendants were large corporations, but controlled by one and the same individual, and operated jointly. One corporation had been the subject of repeated FDA investigations since 1976, which determined that it repeatedly violated the Food, Drug, and Cosmetic Act requirements for the manufacture of drugs, in that the drugs produced were nonsterile and subpotent and that defendant failed to maintain required records. FDA had seized and destroyed large amounts of such drugs. FDA sought an injunction to halt drug production, resulting in a settlement agreement that required FDA approval before drugs could be manufactured. FDA refused permission to manufacture injectible drugs, but permitted defendant to make a test batch of liquid penicillin. The test batch was grossly contaminated with bacteria, but defendants falsified and hid records from FDA to prevent it from learning of the existence of five additional batches (each worth \$200,000) defendant had made in violation of the settlement agreement from the same source of

raw penicillin as the first batch. Injectable drugs not marketed, due to the fact that FDA learned of the falsification. During the execution of search warrant, defendants hid records from FDA. Various records submitted to FDA regarding test results and procedures for producing drugs were falsified; defendants repeatedly sought permission to market contaminated drugs on the basis of records known to be false. Drugs were condemned, and FDA withdrew defendants' licenses in 1987.

In 1983, one corporation wanted to put aspartame in penicillin to mask its bitter taste. FDA disapproved the application in part because a warning label was needed for one ingredient of aspartame, which, in excessive amounts, causes irreversible brain damage in a small segment of the population. The corporation put aspartame into its penicillin anyway and falsified records to hide the fact that it had done so, including by threatening the owner of a company that sold saccharin in order to force him to create false invoices showing sales of saccharin to defendants.

Each defendant was sentenced to \$185,000 fine.

Case No. 107: A one-man corporation engaged in distributing meat products convicted of one count of selling adulterated meat, in violation of 21 U.S.C. §§ 610(c)(1) and 676(a). From August 1986 to December 1987, defendant put sodium sulfite into its sausage and hid the sulfite so USDA inspectors would not know about it. Sodium sulfite reduces the appearance of aging in meat, and therefore is a prohibited additive.

Defendant was fined \$5,000 and placed on probation for two years.

Case No. 115: A pharmaceutical corporation was convicted of seven counts of wire fraud and transportation of misbranded drugs, in violation of 18 U.S.C. § 1343 and 21 U.S.C. §§ 331(a) and 333(b). The remaining 27 counts were dismissed pursuant to plea agreement. The case concerned the large-scale distribution of steroids to persons without a prescription, involving 100,000 bottles of steroid pills valued at over \$1 million and 5,000 bottles of injectable steroids valued at over \$600,000 during the period January 1985 through July 1987. The evidence also indicated that company refused FDA entry to the building for an inspection. The company was defunct at the time of sentencing.

Imposition of sentence suspended; defendant was placed on three years' unsupervised probation.

Case No. 214: A organizational defendant was convicted of violating 21 U.S.C. §§ 331(a) and 333(a) by introducing misbranded

drugs into interstate commerce. A \$30,000 fine was imposed. (No presentence report was provided to the Sentencing Commission.)

Case No. 237: Defendant, a family-owned wholesale meat processing company, was convicted of one count of preparing and selling adulterated meat with intent to defraud, in violation of 21 U.S.C. §§ 610(b) and 676. From October 1, 1987, through October 26, 1988, defendant supplied 334,000 lbs. of meat products to the state, for \$285,188.216, samples of which were adulterated with meat by-products and pet food. Of 196,000 lbs. of ground meat, costing \$191,000, 30 percent (or 58,800 lbs., costing \$57,330) were unauthorized ingredients. The quantity of unauthorized ingredients in other meat products sold to the state could not be determined.

Defendant was sentenced to five years' probation and restitution of \$285,188.16. In light of the restitution, no fine was imposed.

Case No. 238: A corporation engaged in a retail butcher business was convicted of one count of selling adulterated meat with intent to defraud, in violation of 21 U.S.C. §§ 610 and 676. The count of conviction relates to defendant's preparation of meat products from January through March 1988, by adding sodium sulfite, a prohibited substance that makes meat appear fresh and thereby impedes detection of spoiling and aging. Defendant was also involved during that period in adding water, cereal, and meat by-products to purportedly all-meat products. Similar findings were made again in 1989. The adulteration was detected through sampling of products sold through a retail establishment; those samples were destroyed. Defendant's president reported that he had been using additives for fifteen years.

Defendant (then undergoing a Chapter 7 proceeding in bankruptcy) was sentenced to a fine of \$1,200.

Case No. 346: A corporation engaged in the sale of pacemakers was convicted of 25 counts of transporting adulterated and misbranded pacemakers and pacemaker programmers with intent to defraud, and making false statements to FDA, in violation of 21 U.S.C. §§ 331(a), (q)(2), and 333(b). In July 1982 through January 1983, defendant distributed 10 pacemakers that had the potential to fail suddenly, and in November 1980 and March 1982, defendant distributed two pacemakers, the batteries to which had the potential to deplete earlier than represented. In October 1984, defendant distributed 10 pacemaker programmers for which no FDA approval had been granted. In December 1984 and March 1985, defendant falsely reported to FDA that changes to its pacemaker programmers were not being made because of reports of medical complications or adverse reactions relating to its pacemaker

programmers, when in fact the changes were due to reports of such complications. In October 1984, defendant falsely reported to FDA that there were no reports of complications with its pacemakers.

Defendant was fined \$623,000 and ordered to pay costs of \$141,000.

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II. MISDEMEANOR CASES

Case No. 1: A grain company was convicted of one count of distributing adulterated wheat, in violation of 21 U.S.C. § 331(a). Defendant was the successor of another company that operated a grain elevator and actually committed the offense. In July 1988, predecessor company hid insect-damaged wheat inside a load of good wheat in an effort to sell the damaged wheat without detection. Of 607,570 lbs. of wheat, FDA approved repacking and shipping 422,070 lbs.; the remaining 185,500 lbs. were segregated and returned, to be used only for livestock feed. An overpayment of \$8,448 attributable to the insect-damaged wheat.

Defendant was sentenced to a \$100 fine.

Case No. 25: A corporation engaged in the wholesale distribution of food was convicted of one count of violating 21 U.S.C. § 458(a)(2) by distributing adulterated poultry products. On June 4, 1986, defendant distributed 99 boxes (4,880 lbs.) of "putrid, stinky, sticky, smelly, and unwholesome" chicken parts at a reduced price (totaling \$600).

Defendant was sentenced to three months' probation and a \$600 fine.

Case No. 33: A corporation engaged in the wholesale distribution of meat products was convicted of three counts of causing the adulteration of meat and poultry products held for sale, in violation of 21 U.S.C. §§ 453(g)(3), 610(d), and 676. The counts of conviction related to an inspection on March 16, 1986, in which defendant was found holding 260 lbs. of beef and 700 lbs. of poultry adulterated with rodent feces and rodent gnaw marks, and 800 lbs. of uninspected pork packed in boxes that originally contained a household cleaning product. On May 4, 1984, defendant had been found to have offered for sale 953 lbs. of uninspected meat products repacked in used boxes bearing meat inspection labels from contents previously packed in them.

Defendant was sentenced to a \$30,000 fine.

Case No. 110: Defendant caused meat to become adulterated,

in violation of 21 U.S.C. §§ 610(d) and 676(a), by, on one day, subjecting 38,890 lbs. of frozen pork tenderloins to doses of cobalt gamma radiation. Defendant was sentenced to a \$15,000 fine. (No presentence report was provided to the Sentencing Commission.)

Case No. 154: A corporation that operated food storage warehouses was convicted of two counts of holding adulterated food for sale, in violation of 21 U.S.C. §§ 331(k) and 333(a). During the period of July 14 to September 9, 1984, defendant was storing flour, which became contaminated with insects, larvae, and pupae. On May 30, 1986, the defendant was storing cookies in the warehouse, which became contaminated with insects and larvae.

Defendant was sentenced to a \$6,000 fine, which was suspended for three years' unsupervised probation.

Case No. 176: A corporation engaged in meat production was convicted of one count of violating 21 U.S.C. §§ 610(a) and 676 by preparing misbranded meat. A sample taken on May 7, 1986, from 1,000 lbs. of corned beef prepared by defendant contained excessive added water (30.1% rather than 20%). The remaining counts of 23-count indictment dismissed pursuant to plea agreement.

Defendant was sentenced to a \$10,000 fine.

Case No. 201: A meat company was convicted of five counts of transportation and sale of misbranded meat, in violation of 21 U.S.C. § 610(c). Soybean additives and water had been added to the meat, but were not disclosed on the label of the meat packages. Defendant was sentenced to consecutive \$500 fines on each count. (No presentence report was provided to the Sentencing Commission.)

Case No. 214: A corporation was convicted of one count of distributing misbranded drugs, in violation of 21 U.S.C. §§ 331(a) and 333(a). Defendant was sentenced to a fine of \$30,000. (No presentence report was provided to the Sentencing Commission.)

Case No. 225: A corporation that manufactured livestock feed was convicted of one count of illegally receiving and distributing drugs intended for food-producing animals, in violation of 21 U.S.C. §§ 331(k) and 333(a)(1). Defendant put into livestock feed a drug for which no application pertaining to its intended use had been filed with FDA. Under federal regulations, the drug in question could be used in livestock feed, but only in its granulated form because in its powdered form, which the defendant used, the drug did not mix evenly with the food, and thus could be over- or under-ingested by the livestock. Defendant also failed to

maintain required records. Gross amount realized by sales of the feed in question was \$12,000.

Defendant was sentenced to a fine of \$12,000.

Case No. 231: A meat company was convicted of two counts, statute of violation unspecified. A \$1,250 fine was imposed. (No presentence report was provided to the Sentencing Commission.)

Case No. 246: A corporation engaged in producing corned beef was convicted of one count of violating 21 U.S.C. § 610(c) by selling and transporting adulterated meat. The percentage of water and curing solution in defendant's corned beef exceeded the 10 percent permitted by federal regulations in six samples taken: 46.9 percent, 24.7 percent, 23.9 percent, 25.2 percent, 29.7 percent, 44.1 percent. Pursuant to a plea agreement, the total amount of noncomplying corned beef was set at 400 cases, representing 8,000 lbs., which was sold at \$1.50 per lb. Another 31,000 lbs. were recalled for reprocessing.

Defendant was sentenced to a \$50,000 fine. (Pursuant to the plea agreement, defendant was to establish a monitoring program to prevent future violations, and to recall any noncomplying product in the event of future violations.)

Case No. 262: A meat company was convicted of one count of selling misbranded meat in violation of 21 U.S.C. §§ 610 and 676. Defendant sold 31,022 lbs. of meat that was falsely marked "USDA Choice." Defendant was sentenced to pay \$30,000 restitution. (No presentence report was provided to the Sentencing Commission.)

Case No. 268: A food company was convicted of one count of violating 21 U.S.C. § 458(a)(3) by exposing to adulteration poultry products while they were being transported, thus causing them to be adulterated. (No presentence report was provided to the Sentencing Commission.) Imposition of the sentence was suspended, but a \$10,000 fine was imposed.

Case No. 317: A corporation involved in plasmapheresis (a procedure for removing whole blood, separating plasma from red blood cells, and reinjecting the donor with his or her own red blood cells) was convicted of three counts of distributing misbranded drugs, in violation of 21 U.S.C. §§ 331(a). Defendant violated various regulations regarding plasmapheresis, and falsified records to hide those violations, including: (1) extracting more whole blood than federal regulations allow, and misrecording the weight of the blood extracted; (2) failing to

determine the weight of whole blood extracted, but recording a weight nonetheless; (3) accepting donations from persons who failed to meet donor specifications, and falsely representing in records that these donors had been screened; (4) mistakenly injecting one donor with the blood cells of another donor and falsifying records to cover it up; (5) failing to record instances of procedural irregularity in carrying out transfusions. Felony counts of conspiracy and false statements were dismissed pursuant to plea agreement.

Defendant was sentenced to three years' probation and a \$7,125 fine.

Case No. 363: A candy company was convicted of one count of causing adulteration of food, in violation of 21 U.S.C. §§ 331(k) and 333(a). From February 2 to March 3, 1988, defendant stored chocolate for candy production in a place infested with rodents and insects, thereby causing it to become exposed to contamination. Defendant also stored candy so that it became contaminated with insect fragments. (No presentence report was provided to the Sentencing Commission.)

Defendant was sentenced to two years' probation and a \$1,000 fine.

Case No. 385: A corporation operating as a public cold storage warehouse was convicted of six counts of causing adulteration of food held for sale, in violation of 21 U.S.C. §§ 331(k) and 333(a). In 1986 FDA inspections disclosed that various lots of peanuts stored by defendant were exposed to contamination by human urine, live insects, rodents, and/or rodent urine during the period October 1984 to October 1986. Defendant was told by FDA not to ship contaminated peanuts, but sent them anyway to a peanut butter company. Twice in 1983 and once in 1985, defendant had been the subject of FDA forfeitures due to rodent contamination.

Defendant was sentenced to a \$10,000 fine on Count 1, which was suspended in favor of two years' probation, and a total of \$13,000 in fines on the remaining counts.

Case No. 425: A meat business was convicted of two counts of selling misbranded meat in violation of 21 U.S.C. §§ 610 and 676. In February and May 1988, defendant sold purportedly "all-beef" hot dogs, bologna, and similar products to hospitals and other establishments, but products contained pork and beef hearts. Some patients at the hospitals were restricted from eating pork for health or religious reasons. Defendant also created false records to hide its actions from inspection personnel.

Defendant was sentenced to a \$2,500 fine. (Note that in plea agreement, defendant agreed to pay a \$5,000 fine.)

Case No. 462: A corporation apparently involved in supplying blood products was convicted of two counts of distributing misbranded drugs, two counts of refusing to permit an inspection by FDA, and one count of distributing adulterated drugs, in violation of 21 U.S.C. §§ 331(a), (f), and 333(a). Defendant was sentenced to pay \$5,000 fine. (No presentence report was provided to the Sentencing Commission.)