



U. S. Department of Justice

Criminal Division

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

Dear Judge Conaboy:

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

Food and Drug Offenses

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

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

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

[123]

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

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

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

933 F.2d at 756.

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

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

11249

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

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

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

11257

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

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

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

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

[126]

deterrence of criminal activity. Additionally, a sentencing regime dependent upon upward departures is likely to result in wide disparity in sentences imposed for similar criminal offenses committed by similar offenders.

Given the concerns discussed above, we suggest that the Commission's present proposal for merging section 2N2.1 into section 2F1.1 be coupled with an amendment of section 2F1.1(b)(1) and a new Application Note to section 2F1.1. The proposed new language should give instructions consistent with the Ninth Circuit's approach in *Cambra*, and, more generally, with the principle that subverting the regulatory process by defrauding authorities causes a *per se* "loss" to the public that can fairly be approximated for purposes of section 2F1.1(b)(1) by resultant gain. In addition, the new language should recognize that a minimum guideline increase is needed for every case where a regulatory scheme protects the public health or safety.

The following language is an example of how appropriate guidance could be formulated:

Amend section 2F1.1(b)(1) to provide at the end thereof:

In cases in which fraud on regulatory authorities is the gravamen of the fraud, as opposed to cases of more conventional consumer fraud involving direct economic loss to identifiable victims, "loss," for purposes of subsection (b)(1), should be measured by the gross amount received or expected from the enterprise facilitated by the fraud. Where the regulatory scheme violated protects the public health or safety, an increase under this subsection shall be no less than 4 levels.

Add an Application Note to section 2F1.1 to provide:

In pervasively regulated areas, regulatory authorities protect the public's interest in safe, effective and reliable products and services. For purposes of subsection 2F1.1(b)(1), an example of fraud on regulatory authorities would be making false or misleading statements in a matter within the jurisdiction of the Food and Drug Administration in order to secure or maintain regulatory approval, to divert the attention of investigators from areas of noncompliance, or otherwise to facilitate the distribution or use of nonconforming products. Another example would be taking affirmative steps to evade detection in the first instance, such as dealing exclusively or primarily in cash, operating at clandestine business premises, assuming fictitious names, and adopting other measures of stealth.

11277

6

The above suggestion is, of course, preliminary and may depend upon further action by the Commission in the area of guideline simplification and our own further consideration of these issues. It represents one option for addressing the problems discussed above, but the Department will continue to address these issues as the broader question of possible revision of the fraud guideline is considered. In addition, there may be a need for further refinement to address those relatively few food and drug offenses that are prosecuted as misdemeanors -- that is, where a specific intent to defraud or mislead is not required for conviction. See, e.g., *United States v. Park*, 421 U.S. 658, 672-73 (1975); *United States v. Dotterweich*, 320 U.S. 277, 281 (1943).

Child Sex Offenses

Amendment 1

The Commission has published proposed amendments for comment in response to the recently enacted "Sex Crimes Against Children Prevention Act of 1995." In general, we believe that the proposed amendments are responsive to the statutory directives.

Amendment 1 addresses section 2 of the Act, which directs the Commission to increase the base offense level for offenses under sections 2251 and 2252 of title 18, United States Code (producing or advertising child pornography and trafficking, receiving, or possessing child pornography) by at least two levels. The Commission proposes increasing the offense level under section 2G2.1 (for producing child pornography and related offenses) from level 25 to 27, 28, or 29. Amendment 1 also proposes increasing the offense level under section 2G2.2 (for trafficking in or receiving child pornography and related offenses) from level 15 to 17, 18, or 19; and the offense level under section 2G2.4 (for possessing child pornography) from level 13 to 15, 16, or 17.

While a two-level increase would comply with the statutory directive, there may be cases where a greater increase is needed. We urge the Commission to pay special attention to offenses involving the distribution of child pornography for other than pecuniary purposes and the production of child pornography. In this regard, the results of the study required by section 6 of the Sex Crimes Against Children Prevention Act should be instructive.

Amendment 1 also implements section 3 of the Act, which directs the Commission to increase the offense level by at least two levels for advertising, trafficking in, receiving, or possessing child pornography if a computer was used to transmit the notice or advertisement or to transport or ship the visual depiction. The amendment would provide an enhancement of two,

[128]

three, or four levels for offenses sentenced under sections 2G2.2 and 2G2.4. The use of computers to distribute child pornography has enabled violators to reach a large audience instantaneously and has made the offenses more difficult to detect. The results of the Commission's study should be instructive as to whether more than a two-level increase in the applicable offense levels is appropriate.

The Commission has invited comment as to whether section 2G2.1 should be amended to add an enhancement for the use of a computer to solicit the participation of minors in sexually explicit conduct for the purpose of producing a visual depiction of such conduct, in violation of section 2251(c)(1)(B). While the Sex Crimes Against Children Prevention Act directed the Commission to provide at least a two-level increase for offenses involving the computer advertising of child pornography in violation of section 2251(c)(1)(A), it did not direct the Commission to provide an enhancement for computer advertising to solicit minors for the purpose of producing child pornography in violation of section 2251(c)(1)(B). We believe that the use of computers for soliciting minors in violation of this latter provision is equally worthy of an increased sentence.

However, to provide an increase under the current guideline structure would mean that computer advertising to solicit minors for the purpose of producing child pornography would have a higher offense level than actually producing the child pornography. See §2G2.1. Such a result would produce disproportionality in sentencing in our view. An increase applicable both to the production of child pornography, which may be called for independently, and the use of computers to solicit minors would remedy this proportionality problem. However, the sentences produced by this scheme would be trumped by the 10-year statutory maximum in too many cases, particularly in light of the four-level increase applicable to offenses involving children under 12 years of age. Thus, we urge the Commission in studying sentences relating to the sexual exploitation of children to consider whether the ten-year statutory maximum (15 years with a five-year mandatory minimum for repeat offenders) for violations of section 2251 is adequate. This section provides the same penalties as offenses involving the distribution and receipt of child pornography under section 2252 -- offenses that may be less serious than the production of child pornography.

Finally, the Commission has invited comment on whether the guidelines applicable to the sexual exploitation of minors should be amended to indicate that an upward departure may be warranted if the defendant's criminal history includes a prior sentence for conduct that is similar to the instant offense. We favor substantially increased sentences for repeat offenders, particularly in light of the statutory increase for repeat offenders and its limitation to prior federal offenses. However,

11297

we do not believe that commentary inviting departures is sufficient or that it will contribute toward the goal of reducing unwarranted sentencing disparity. The Commission should study repeat child pornography and child sex offenses and should provide a guideline enhancement that at least meets the degree of increase mandated by statute but that would also apply to repeat offenders whose prior offenses violated State law. It is our view that the need for incapacitation and deterrence is particularly great regarding repeat offenders in the area of child pornography and child sex offenses and that the guidelines should provide a significant increase in the sentence.

Amendment 2

Amendment 2 responds to the directive in section 4 of the Sex Crimes Against Children Prevention Act. It directs the Commission to provide at least a three-level increase for offenses under section 2423(a) of title 18, United States Code, which prohibits the interstate transportation of a minor with the intent that the minor engage in prostitution or criminal sexual activity. The Commission has presented two options. The first raises the base offense level under section 2G1.2 from level 16 to 19, 20, or 21. The second accomplishes this goal but combines section 2G1.2 with section 2G1.1, which addresses transportation for the purposes of prostitution or prohibited sexual conduct generally.

Although Option 2 has some advantages, we question whether it is wise to promulgate a major revision of sections 2G1.1 and 2G1.2 before the Commission can evaluate the study required by section 6 of the Act in conjunction with its simplification project. We are concerned that the many cross-references in section 2G1.2, which would be incorporated into the combined guideline, may be confusing. In particular, we question to what extent sentences under section 2G1.2 are imposed in keeping with these cross-references. Thus, we would recommend simply complying with the statutory directive regarding offenses under section 2423(a) and determining as part of the guidelines simplification project whether consolidation of the two guidelines is advisable.

T/307

9

We would be pleased to provide further assistance to the Commission regarding these and other areas of the guidelines.

Sincerely,



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[131]