In the
United States Court of Appeals
For the Seventh Circuit

Nos. 94-1866 and 94-1926

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

CLINTON D. ANDERSEN and
DOUGLAS M. VAN DAMME,

Defendants-Appellants.

Appeal from the United States District Court
for the Western District of Wisconsin.
No. 93 CR 77--Barbara B. Crabb, Chief Judge.

ARGUED OCTOBER 4, 1994--DECIDED JANUARY 18, 1995

Before CUDAHY and FLAUM, Circuit Judges, and ROSZKOWSKI, Senior District Judge.*

CUDAHY, Circuit Judge.

I. FACTS

The defendants-appellants Van Damme and Andersen owned and operated a veterinary clinic, treating primarily food-producing animals, especially dairy cattle. During 1984-1986 they also ran a "side business" in veterinary drugs. They bought drugs in bulk, first from both legitimate commercial suppliers and from illegitimate private suppliers in the United States, and later from overseas. Some were raw ingredients, which the defendants mixed

to form useful drug compounds, others they simply broke down into smaller dosage units and repackaged. The packaging used was clearly "homemade," (plastic tubs, old butter containers, et cetera) and was hand-labeled with its contents. These drugs were sold to customers and also used in the defendants' veterinary practice.

Van Damme and Andersen were popular with their customers and purportedly got good results with the drugs they used in their practice and sold to clients. However, they did not have the site registration and the licenses required by the Food and Drug Administration (FDA) for drug manufacture and sale, nor had the FDA approved many of the drugs sold for use in animals. While some of the drugs prescribed by the defendants were apparently effective in treating certain diseases in cattle, they were not approved for use in food-producing animals. There were concerns about the residual effects of the drugs' entering the human food chain through meat or dairy products. Other drugs sold by Van Damme and Andersen contained ingredients similar to active ingredients in drug products that were approved by the FDA for use in food-producing animals. But the bulk drugs that the defendants used had not been subjected to FDA required purity testing. The defendants also attempted to conceal their drug business from the FDA by coding and disguising information on invoices, rerouting shipments to avoid detection and customs and misrepresenting their activities to the FDA.

Van Damme and Andersen were indicted on July 20, 1993, and pleaded guilty to Count VII of the indictment, charging them with manufacturing and compounding drugs in their basement and failing, with the intent to defraud and mislead, to register the site with the FDA in violation of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. sec. 331(p) and sec. 333(a)(2). They were each sentenced to 15 months imprisonment and fined $250,000.

They now challenge their sentences on grounds that they should have been sentenced under United States Sentencing Guideline sec. 2N2.1 rather than sec. 2F1, and that the sentence should not have been enhanced based on their profits.

We AFFIRM in part, VACATE in part, and REMAND.

II. DISCUSSION

A. Choice of Sentencing Guideline

Van Damme and Andersen argue that the district court erred in sentencing them under U.S.S.G. sec. 2F1.1 instead of sec. 2N2.1. United States Sentencing Commission, Guidelines Manual, /82F1.1, sec. 2N2.1 (Nov. 1993). The district court's choice of which guideline to apply is a question of law, and we review this choice de novo. United States v. Johnson, 965 F.2d 460, 468 (7th Cir. 1992).

Section 2N2.1 covers "violations of statutes and regulations dealing with any food, drug, biological product, device, cosmetic or agricultural product," and has a base offense level of six. Section 2F1.1 has broader application and deals with offenses involving fraud or deceit. It also has a base offense level of six, but provides for substantial increases in offense level based on the amount of loss. The defendants argue that because they pleaded guilty to a violation of the Food and Drug Act, 21 U.S.C. sec. 331 and sec. 333, sec. 2N2.1 is the most clearly applicable Guideline and thus should have been used by the district court. See U.S.S.G. sec. 1B1.2(a) (Guideline used should be that most applicable to the offense of conviction).

The defendants are correct that sec. 2N2.1 applies directly to violations of the Food and Drug Act. However, sec. 2N2.1 itself directs us to apply sec. 2F1.1 "if the offense involved fraud." In addition, the Statutory Index to the Guidelines, which specifies the Guideline "section or sections ordinarily applicable to the statute of conviction," indicates that both sec. 2F1.1 and /82N2.1 are ordinarily applied to 21 U.S.C. sec. 333(a)(2). U.S.S.G. Appendix A.

The district court here found "overwhelming" evidence of fraud, Sent. Tr., R.O.A. 96, p.10, including mislabeling drugs and altering invoices, rerouting shipments to avoid detection and misrepresenting current and intended future actions to the FDA. In addition, the defendants themselves pleaded guilty to Count VII of the indictment, admitting that they did fail to register their drug manufacturing "fa-

cility" (a bed-and-breakfast inn) with the FDA "with the intent to defraud and mislead." Indictment, R.O.A. 1, p. 14 (emphasis added).

Nevertheless, Van Damme and Andersen claim that this evidence of fraud is insufficient to support the application of sec. 2F1.1. They argue that the evidence establishes only that they defrauded a regulatory agency, not their customers, and that fraud on a regulatory agency does not support the use of sec. 2F1.1. We also fail to find this argument persuasive.

Section 2F1.1 is "designed to apply to a wide variety of fraud cases," U.S.S.G. sec. 2F1.1, comment. (backg'd), and it does not specify that the victim must be a consumer rather than a regulatory agency. As other circuits addressing this issue have held, "there is no meaningful distinction between the government as a victim and individual consumer victims; . . . it is possible for either or both to be defrauded." United States v. Cambra, 933 F.2d 752, 756 (9th Cir. 1991); United States v. Von Mitchell, 984 F.2d 338 (9th Cir. 1992); United States v. Arlen, 947 F.2d 139 (5th Cir. 1991), cert. denied, 112 S. Ct. 1480 (1992)./1

In Cambra, 933 F.2d 752, the defendant sold misbranded human growth hormones, which he counterfeited to represent different products made by reputable manufacturers. He pleaded guilty to distributing misbranded hormones with intent to defraud and mislead, and stipulated that the dollar value of the counterfeit steroids was $500,000. Id. The Ninth Circuit held that "at least federal agencies were defrauded" by Cambra's acts, and that fraud on a federal agency was enough to support the use of sec. 2F1.1. Id. at 756. In Arlen, 947 F.2d 139, the defendant also ran a business selling, buying and trading steroids through the mail, taking great pains to keep this business hidden from the FDA. Arlen argued that fraud against a regulatory agency was not sufficient to constitute an "intent to defraud or mislead" under 21 U.S.C. sec. 333(a)(1) and that it was not enough to invoke U.S.S.G. sec. 2F1.1. The Fifth Circuit recognized that there was no evidence of fraud against Arlen's customers, but held that fraud on a regulatory agency was sufficient to support charges of fraud

and deceit under both the Statute and the Guidelines. Id. at 143, 146-47.

The defendants here attempt to distinguish Cambra and Arlen on their facts, arguing that there was more evidence in both Cambra and Arlen of fraud on consumers as well as regulatory agencies. However, we find these attempted distinctions insignificant. Both cases involved illegal marketing of drugs and fraud on the FDA, and both courts specifically held that regulatory fraud alone is sufficient basis for the application of sec. 2F1.1. See Cambra, 933 F.2d at 756; Arlen, 947 F.2d at 143-44, 146-47.

The defendants also rely on United States v. Shields, 939 F.2d 780 (9th Cir. 1991) to support their argument that regulatory fraud cannot be the basis for application of sec. 2F1.1. However, that reliance is also misplaced. In Shields, the defendants were sentenced under sec. 2N2.1 for distribution of steroids in violation of 21 U.S.C. secs. 331, 333 and 353. The district court had, in fact, departed upward from sec. 2N2.1, and the Ninth Circuit found this departure inappropriate and reversed and remanded for resentencing. But, in resentencing Shields' co-defendant on remand, the district court again gave a higher sentence, this time under sec. 2F1.1. That sentence was subsequently upheld in United States v. Von Mitchell, 984 F.2d 338 (9th Cir. 1992), specifically because it was imposed under sec. 2F1.1 and not sec. 2N2.1.

We find Cambra and Arlen persuasive. Here, as in those cases, the district court found substantial evidence of fraud. The FDA represents the public, and a deliberate attempt to mislead the FDA should be considered as clearly a fraud as are attempts to mislead customers or other individuals. Further, a straightforward application of the Guidelines regarding fraud requires the use of sec. 2F1.1. We thus join the Ninth and the Fifth Circuits in finding evidence of fraud on a regulatory agency sufficient to invoke sec. 2F1.1.

B. Calculation of Loss

Andersen and Van Damme also argue that the district

court's calculation under sec. 2F1.1 of the loss to customers and competitors resulting from their fraud is erroneous. The district court calculated the loss, and thus the defendants' sentence, under sec. 2F1.1 by equating it with the defendants' gain. The court concluded that if the defendants could reap a net profit of $400,000 each over the course of the four year scheme, "the manufacturer of a regulated product could have garnered that money had it not been for the defendants, or the veterinarians in competition with the defendants could have garnered some part of that profit." Sent. Tr., R.O.A. 82, p.5. Thus, the district court decided, the defendants' net gain could be used as a reasonable equivalent of loss. The district court's factual determination of loss is a finding of fact reviewable for clear error only, but the definition of "loss" is a legal question subject to de novo review. United States v. Loscalzo, 18 F.3d 374 (7th Cir. 1994).

Generally the defendant's gain may provide a reasonable approximation of a victim's loss, and may be used when more precise means of measuring loss are unavailable. The Application Notes to sec. 2F1.1 specifically allow the defendants' gain to be used as a basis for calculating an approximate loss when evidence of the exact amount of loss is not available. U.S.S.G. sec. 2F1.1, comment. (n.8) ("the offender's gain from committing the fraud is an alternative estimate [of the loss] that ordinarily will underestimate the loss"). We therefore agree with the district court that gain is usually an appropriate means of estimating loss.

However, we find this case to present an unusual situation where the relationship between the defendants' gain and any loss suffered by consumers or competitors is, at best, extremely tenuous. While gain may normally prove an adequate surrogate for loss, gain may be used only as an alternative method of calculation when there is in fact a loss, and only if use of the gain results in a "reasonable estimate of the loss." U.S.S.G. sec. 2F1.1, comment. (n.8). Here we have no clear evidence that customers or consumers suffered any loss.

The drugs that the defendants were selling, while admittedly effective in treating certain animal diseases, were

not approved by the FDA. Therefore there is no reason to believe that other competitors were selling the same or similar drugs and thus suffered harm as a result of the defendants' competition. The defendants also broke down legal bulk drugs and sold them in smaller quantities, but even then, we do not know that competitors were selling like quantities of these drugs at competitive prices, or that they were selling them at all. The government has presented no evidence of any financial losses suffered by competitors. In fact, there is evidence in the record that the defendants' customers were afraid that they would not be able to obtain veterinary services once the defendants were incarcerated because there are apparently not enough veterinarians in the affected area to meet the demand for their services. R.O.A. 94 (Letters from Customers, Attachment to Pre-sentencing Report). Thus, there is no adequate basis to assume that the defendants' profits represented, or were equivalent to, the losses of competitors.

The government has also provided no evidence that the defendants' customers suffered a loss. Many of the drugs were sold in hand-labeled containers, and the customers appear to have been well aware that the drugs they were purchasing were not approved by the FDA. Sent. Tr., R.O.A. 96, p. 111. Even if, as the government alleges, the customers were given some false information, the government presents no evidence that that misinformation led to any quantifiable loss. The customers themselves, in fact, appear to have been very pleased with the defendants' services. R.O.A. 94 (Letters from Customers, Attachment to Pre-sentencing Report).

Demand is elastic and depends on price, availability, convenience and many other factors. We have no way of knowing whether there were any actual competitors in the market the defendants were serving, whether consumers would have bought from the defendants' competitors or whether the services the defendants offered would simply not have been available.

As we have noted, we do not intend to suggest that gain is not often an appropriate means of establishing loss. As a matter of economic theory at least, assuming a fixed

amount of product to be distributed to a given set of customers, one competitor's gain ought to equal the others' loss. However, the case before us is unique in that there is no persuasive evidence tying the defendants' profits to any competitor's identifiable loss. There is some reason to believe that the defendants were, in economic jargon, serving a niche in the market not served by others. It is very significant that in this case the district court "very strongly" believed that the use of gain to calculate loss resulted in a sentence that "is higher than is necessary in this case." Sent. Tr., R.O.A. 82, p.6. Thus, while in many situations it would be reasonable to use profits as a proxy for loss, where, as here, there is no persuasive evidence of monetary loss, the defendants' gain ought not to be used to measure loss./2 See United States v. Haddock, 12 F.3d 950, 961 (10th Cir. 1993). This does not mean that the defendants caused no harm or that they should not be appropriately punished. The Application Notes to sec. 2F1.1 recognize that some harms are not financial, and allow for upward departure when "a primary objective of the fraud was non-monetary; or the fraud caused or risked reasonably foreseeable, substantial non-monetary harm." U.S.S.G. sec. 2F1.1, comment. (n. 10).

This court faced a similar situation in United States v. Schneider, 930 F.2d 555 (1991). There, the defendants bid for a government contract, and in the course of doing so made false statements about past criminal records and submitted fraudulent payment and performance bonds. They were convicted of defrauding a federal agency, but the court found no evidence of financial loss to the government. Both defendants had performed numerous contracts for the government in the past, and, in fact, the government was likely to gain from the contract in question; every indication was that the defendants would have done the work well and at less expense than the other bidders. Id. at 558. This court held that the amount bid for the contracts was not a reasonable estimate of financial loss, especially because there was no indication that the government would have suffered any financial loss from this fraud. We held that the government had not earned the "bonus punishment points [awarded by the Guidelines under sec. 2F1.1] for different levels of proven loss beginning with $2,000," id. at 559, but recognized that, nevertheless,

the government had non-financial interests that had been harmed. This harm, we concluded, could be factored into the sentencing because "the Guidelines permit an increase in offense level for non-monetizable losses." Id. at 558. See also United States v. Haddock, 12 F.3d 950, 961 (10th Cir. 1993) ("If gain to the defendant does not correspond to any actual, intended, or probable loss, the defendants' gain is not a reasonable estimate of loss.").

We believe the same conclusion is appropriate here. The FDA is in the business of protecting the public. Whether or not the defendants caused direct financial harm to competitors or consumers, they caused harm to the public through their violations of FDA rules. The FDA had not approved some of the drugs the defendants were selling because of possible adverse effects on humans once the drug got into the food chain. Even those drugs that were deemed safe for use in humans were banned from use for animals by the FDA because their use in cattle could eventually create resistance to the drug in humans and lessen its effectiveness.

The defendants defrauded the FDA, thus causing harm to the public, and this non-monetary harm should be recognized and used in calculating their sentence. However, there is no evidence tying this harm directly to financial loss; and therefore a sentencing enhancement of nine points under sec. 2F1.1(b)(1) based on the defendants' financial gain is insupportable. But, upward departure may certainly be warranted by the non-monetizable risk to human and animal health caused by the defendants' failure to follow FDA licensing regulations, failure to conduct required purity testing and intentional marketing of unapproved drugs. And, in calculating the extent of any departure, the net profits earned by the defendants, together with all other relevant information, would not be inappropriate matters for consideration for whatever they may suggest or be worth. For the above reasons, we vacate and remand for resentencing in accordance with this opinion. The district court should carefully consider whether an upward departure is warranted and, if so, what it should be.

AFFIRMED IN PART,
VACATED IN PART,
AND REMANDED.

FOOTNOTES

*
The Honorable Stanley J. Roszkowski, of the United States District Court for the Northern District of Illinois, sitting by designation.

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Cf. United States v. Bradshaw, 840 F.2d 871 (11th Cir.), cert. denied, 488 U.S. 924 (1988) and United States v. Mitcheltree, 940 F.2d 1329 (10th Cir. 1991) (holding that fraud on a regulatory agency is sufficient to constitute the necessary "intent to defraud or mislead" under 21 U.S.C. sec. 333(a)(2)).

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The government argues that a calculation of loss based on gain here is supported by Cambra, in which the defendant was sentenced under the sec. 2F1.1 loss table based on the stipulated value of the counterfeit steroids he sold. However, we do not find Cambra contradictory to our analysis here. There the defendant was admittedly selling drugs made to look like those made by reputable manufacturers. Thus the same product was available from other manufacturers who were serving the same market as the defendant. The fact that the same product could have been purchased from the reputable manufacturers, and that Cambra stipulated that the value of his counterfeiting was $500,000, made this stipulated value a plausible means of estimating loss. In the case before us however, there is no evidence that many of the drugs were otherwise available, that there were in fact competitors serving the same market or that customers were defrauded. Thus, the defendants' gain in this case is not an appropriate method for determining loss.