IN THE UNITED STATES COURT OF APPEALS

FOR THE FIFTH CIRCUIT

No. 97-41335

UNITED STATES OF AMERICA,

Plaintiff - Appellee-Cross-Appellant,

versus

RONNIE S. HAAS,

Defendant - Appellant-Cross-Appellee.

Appeals from the United States District Court for the Southern District of Texas

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March 29, 1999

Before JOLLY, DUHÉ, and EMILIO M. GARZA, Circuit Judges.

E. GRADY JOLLY, Circuit Judge:

A jury convicted Ronnie Haas, who conducted a pharmaceutical drug importation business, on multiple conspiracy charges involving fraud and other illegal conduct relating to Food and Drug Administration ("FDA") regulations. The jury also convicted him of aiding and abetting others involved in the illegal conduct and of introducing misbranded drugs into this country with the intent to defraud. Haas argues that the government did not produce sufficient evidence for a rational jury to convict him. He also argues that the district court erroneously instructed the jury. Finally, both Haas and the government (which cross-appeals) contend

that the district court incorrectly calculated Haas's sentence under the Sentencing Guidelines. We hold that the evidence is sufficient to support convictions on all counts. We further hold that the district court did not err when instructing the jury. Finally, we agree with the government that the district court did err in calculating Haas's sentence when it failed to consider loss caused by his fraudulent activities. We therefore uphold all convictions, but remand for resentencing.

I

Taken in the light most favorable to the government, see United States v. Ortega Reyna, 148 F.3d 540, 543 (5th Cir. 1998), the evidence established the following facts.

Ronnie Haas was, shall we say, an entrepreneur. He, along with two other partners, founded North American Pharmaceutical Services, Inc. ("NAPS").[1] NAPS operated as a mail-order business that advertised in several states, claiming that it could supply pharmaceutical drugs at prices lower than the average wholesale prices because of "the benefits of International Trade." These "benefits of International Trade," however, had little to do with NAFTA, GATT or any other international trade agreement. Instead, the benefits came by way of avoiding U.S. regulations governing the

[1]Haas took the most active role in operating NAPS while the other partners, Keith Dodson and William Wray, were silent partners.

sale of drugs; NAPS avoided regulatory oversight by purchasing drugs in Mexico and then transporting them into the United States (either through the mail or by way of NAPS employees themselves) without declaring the importation to any customs authority.

NAPS maintained two primary places of business to sustain its mode of operation. The headquarters were located in San Antonio, Texas. Here NAPS received its orders from United States customers. NAPS employees would then transmit the orders to its Mexican pharmacy located in Nuevo Laredo, Mexico. To fill the orders, the NAPS employees at the pharmacy would purchase drugs from a wholesale supplier in Monterrey, Mexico. The NAPS employees would then fill the orders and, at the early stage of this operation, would mail them from Mexico to the U.S. customers.

Over the course of several months, NAPS slightly altered its procedure for moving the drugs from the Mexican pharmacy to the U.S. customers. Instead of mailing the drugs directly from the pharmacy, NAPS employees began transporting the drugs--sometimes by car, and sometimes even by foot--into the United States. Only after entering the United States would NAPS employees place the drugs into the mail. NAPS never reported the importation of the drugs to customs officials as required. It is significant that this alteration of distribution methods occurred after Haas met with FDA agents concerning his questionable operation, and during

a period in which Haas received written warnings from the FDA stating that he appeared to be violating the law.

During the months of September and October of 1994, Haas participated in three meetings with various state and federal government officials who were concerned about the legality of his conduct. At the first meeting, which Haas initiated, Haas met with a customs inspector, Agent Leyendecker, to discuss his importation plans. Importantly, the inspector told Haas that his activities would be considered commercial--as opposed to personal--importation of drugs. The characterization of Haas's activities as "commercial" is a crucial point for both the legality of Haas's activities and Haas's convictions. The characterization is crucial because the facial legality of Haas's importation business turns upon the availability to him of a narrow exemption (the "personal importation exemption") from various customs and FDA importation regulations. Under the personal importation exemption, the FDA waives its standard rule that only drugs manufactured or prepared in foreign facilities registered with the FDA may enter the United States.[2] At this first meeting, however, Haas was instructed that

[2]See 21 C.F.R. § 207.40 (1998):

> Drug listing requirements for foreign drug establishments.
>
> (a) Every foreign drug establishment whose drugs are imported or offered for import into the United States shall comply with the drug listing requirements in

his planned course of business constituted commercial importation and that the personal importation exemption did not apply. Furthermore, Agent Leyendecker suggested that Haas speak with the FDA.

The next day, September 21, 1994, Haas did meet with FDA agents. These agents warned Haas that his activities were commercial and that he must comply fully with customs and FDA regulations. Approximately two weeks later, Haas met with the FDA again. They again informed him that they considered NAPS to be engaged in commercial importation. Furthermore, they explicitly told Haas that his activities were illegal.[3] Undeterred, Haas

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> Subpart C of this part, unless exempt under Subpart B of this part, whether or not it is also registered.
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> (b) No drug, unless it is listed as required in Subpart C of this part, may be imported from a foreign drug establishment into the United States except a drug imported or offered for import under the investigational use provisions of part 312 of this chapter. Foreign drug establishments shall submit the drug listing information in the English language.
>
> (c) Every foreign drug establishment shall submit, as part of drug listing, the name and address of the establishment and the name of the individual responsible for submitting drug listing information. The establishment shall report to FDA any changes in this information at the intervals specified in § 207.30(a) for updating drug listing information.

Haas does not argue that he complied with these regulations.

[3]The FDA agents told Haas that before foreign drugs may be marketed in the United States, they must be approved by the FDA.

continued NAPS's operations without complying with customs or FDA regulations.

In February 1995, the FDA began to confiscate NAPS drug shipments made through the mail from Mexico. After the FDA began confiscating the shipments, Haas and other NAPS employees altered the delivery method by transporting the drugs into the United States before placing them into the mail system. Then, in March 1995, the FDA sent Haas the first of two warning letters. Among other things, the letter stated that NAPS's "drugs may not be legally marketed in this country, and, therefore, your activities are in serious violation of the Federal Food, Drug, and Cosmetic Act." The letter went on to list specific sections of the United States Code that the FDA thought NAPS was violating. Although the letter asked for a response, Haas ignored the letter.[4] The FDA sent another warning letter (repeating the content of the first

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It is undisputed that the FDA had never approved the drugs Haas imported. Nor does Haas contend that the production facility making the drugs was registered with the FDA.

[4]Haas testified that although he did not respond to the FDA after receiving this letter, he did stop advertising in the United States. According to Haas, he did this without stopping NAPS's importation activities because he believed that this was all that the warning letter required. The jury was, of course, free to doubt that Haas actually believed this novel and convenient interpretation of the warning letter at the time he received it. The decision to stop advertising could easily be interpreted as an attempt to lower the profile of NAPS's operations so as to avoid alerting regulatory officials to continuing importation.

letter) in November 1995. Again, Haas ignored the letter; NAPS operations continued without change.

Later that same month, FDA officials sought to determine whether NAPS's was still operating in violation of federal law. To this end, an FDA agent--operating under cover and acting as a typical customer--ordered some drugs from NAPS. In due course the drugs were delivered. The undercover order confirmed that NAPS was still operating in violation of FDA regulations. The drugs were not properly labeled and they did not come from a foreign facility registered with the FDA. Soon thereafter, FDA agents obtained a search warrant, searched NAPS's San Antonio premises, and found paraphernalia indicating that Haas was still conducting NAPS's operations out of that location. Haas was subsequently arrested, indicted, and brought to trial.

II

The government charged Haas with six counts at trial. First, Haas was charged with conspiracy to defraud an agency of the United States (the FDA) in violation of 18 U.S.C. § 371.[5] Section 371

[5]Section 371 states in relevant part:

> If two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.

also supports the charge in the second count for conspiracy to commit an offense against the United States by (1) introducing misbranded drugs into interstate commerce with the intent to defraud and mislead,[6] and (2) entering and introducing imported goods into United States commerce by means of a false statement and

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18 U.S.C.A. § 371 (West Supp. 1998).

[6]21 U.S.C. §§ 331(a), 333(a)(2) form the predicate for this part of the offense. Section 331(a) states:

> The following acts and the causing thereof are prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

21 U.S.C.A. § 331(a) (West 1972). Section 333(a) states:

> (a) Violation of section 331 of this title; second violation; intent to defraud or mislead
>
> (1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.
>
> (2) Notwithstanding the provisions of paragraph (1), if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

21 U.S.C.A. § 333(a) (West Supp. 1998).

false and fraudulent practice.[7] In the remaining four counts, Haas was charged with aiding and abetting the illegal delivery of misbranded drugs into interstate commerce in violation of 18 U.S.C. § 2[8] and 21 U.S.C. §§ 331(a), 333(a)(2).

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[7]18 U.S.C. § 542 forms the predicate for this part of the offense. That provision states in relevant part:

> Entry of goods by means of false statements
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> Whoever enters or introduces, or attempts to enter or introduce, into the commerce of the United States any imported merchandise by means of any fraudulent or false invoice, declaration, affidavit, letter, paper, or by means of any false statement, written or verbal, or by means of any false or fraudulent practice or appliance, or makes any false statement in any declaration without reasonable cause to believe the truth of such statement, or procures the making of any such false statement as to any matter material thereto without reasonable cause to believe the truth of such statement, whether or not the United States shall or may be deprived of any lawful duties; or
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> Whoever is guilty of any willful act or omission whereby the United States shall or may be deprived of any lawful duties accruing upon merchandise embraced or referred to in such invoice, declaration, affidavit, letter, paper, or statement, or affected by such act or omission–
>
> Shall be fined for each offense under this title or imprisoned not more than two years, or both.

18 U.S.C.A. § 542 (West Supp. 1998).

[8]Section 2 states:

> Principals
>
> (a) Whoever commits an offense against the United States or aids, abets, counsels, commands, induces or procures its

The jury returned a verdict of guilty on all six counts. The trial judge then sentenced Haas to a 27-month term of imprisonment for each count, each term to run concurrently. The court also sentenced Haas to three years of supervised release based on counts 1 and 2 and one year of supervised release for each of counts 3-6. The court ordered that all the terms of supervised release would run concurrently.

At the sentencing hearing, the district court enhanced Haas's sentence, under U.S.S.G. § 3C1.1, for obstruction of justice. The court found that Haas obstructed justice by perjuring himself in his testimony at trial. In particular, the court found that Haas falsely testified by claiming that he had not been told that he could not import drugs from Mexico and by denying that NAPS was operating commercially when it brought the drugs into the United States.

The prosecution also argued that the court should enhance Haas's sentence under U.S.S.G. § 2F1.1(b)(1)(H). This subsection calls for a sentence enhancement based upon the dollar amount of loss caused by the offender's fraud. The district court, however,

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commission, is punishable as a principal.

(b) Whoever willfully causes an act to be done which if directly performed by him or another would be an offense against the United States, is punishable as a principal.

18 U.S.C.A. § 2 (West 1969).

disagreed because it could find no "loss" and refused to enhance the sentence under this provision.

Haas now appeals, challenging the sufficiency of the evidence for conviction, the jury instructions, and the calculation of his sentence. The government cross-appeals the calculation of Haas's sentence.

III

A

We first address the sufficiency of the evidence. Viewing all of the evidence and the inferences to be drawn therefrom in the light most favorable to the government, we conclude that a rational jury could find that the evidence was sufficient to remove any reasonable doubt of Haas's guilt.

(1)

We will find the evidence sufficient to support Haas's convictions "if any reasonable trier of fact could have found that the evidence presented at trial established the essential elements of the crime beyond a reasonable doubt." United States v. Ramirez, 145 F.3d 345, 350 (5th Cir.) (citing United States v. Alix, 86 F.3d 429, 435 (5th Cir. 1996)), cert. denied, 119 S.Ct. 602 (1998). We also keep in mind that the evidence presented by the government need not exclude every reasonable hypothesis of innocence. Ramirez, 145 F.3d at 350 (citations omitted). In other words, the

proof need not be “conclusive” in order to “constitute substantial evidence and to authorize a reasonable trier of fact to conclude that [Haas’s] guilt was established beyond a reasonable doubt.” United States v. Richardson, 848 F.2d 509, 514 (5th Cir. 1988).

(2)

Haas first argues that a rational jury could not have found, beyond a reasonable doubt, that he intended to defraud the FDA. Haas argues that, given his numerous attempts to contact and to receive advice from the FDA, the government presented insufficient evidence of an intent to defraud. According to Haas, he and his partners spent time researching regulatory and customs issues for several months before starting up his business. He also testified that, before his initial meeting with Agent Leyendecker, he attempted, on multiple occasions, to contact the FDA about regulations; only after petitioning his congressman did the FDA return his calls. And when the FDA finally responded to his calls, an FDA employee sent Haas information on the personal importation exemption. Haas maintains that he continued to believe that he was operating within the personal importation exemption, despite the repeated refrain from regulatory officials that his activities constituted commercial importation. He also points out that he operated NAPS openly by advertising in several publications--at least until receiving the first warning letter from the FDA. Finally, Haas argues that a rational jury could not have found that he had any intent to defraud the FDA with respect to misbranding. According to Haas, he did not have a subjective understanding of the term "misbranded" as that term is defined in FDA regulations.

Haas also argues that the government provided insufficient evidence for a jury to conclude that the drugs were, in fact, misbranded. The relevant facts surrounding this argument are not in dispute. Haas does not argue that the drugs he distributed complied with the requirements listed in § 352 (b),(c), and (f). See 21 U.S.C.A. § 352. Instead, he argues that the drugs were exempt from these labeling requirements because they were filled by a pharmacist (though the pharmacist was not certified by any authority in the United States). The applicability of this exemption, Haas argues, means that the drugs were not "misbranded."

(3)

We think that the jury had ample evidence before it to conclude that Haas intended to defraud the FDA. The government may, of course, prove the defendant's criminal intent by way of circumstantial evidence. We need not list all of the evidence a jury could have considered in concluding that Haas intended to defraud the FDA--we will only consider a few examples.

In February 1995, the method that NAPS (at Haas's instruction) used in delivering the drugs to U.S. customers changed. Instead of mailing the drugs from Mexico, NAPS employees transported the drugs--sometimes by car, sometimes by foot--over the border before placing them into the U.S. mail system. This change occurred after Haas had had the three meetings with various agents who had

explained that NAPS's activities constituted commercial importation. Also, just before the delivery methods changed, the FDA began confiscating NAPS's deliveries, mailed in Mexico, to the U.S. customers. Haas knew of the FDA seizures because his customers began to complain about FDA detention of their drugs. From these facts, the jury not only could have inferred that Haas knew that the FDA considered the importation of these drugs illegal, but also that Haas changed the methods for importing the drugs so that he could continue the illegal importation.

Haas argues that a rational jury, in the light of his explanations, would have rejected much of the inference of intent that might be drawn from the government's evidence. Haas and the government presented two competing explanations for Haas's conduct after he received multiple warnings from FDA officials.[9] The jury had ample reason to disbelieve Haas's version. His testimony was riddled with suspect assertions as to his subjective beliefs. For example, Haas said that he believed that NAPS's importation of drugs that were delivered to customers for a price was not

[9]According to Haas, the change in delivery methods came about as the result of an innocent business decision. Haas told the jury that his customers began complaining about how long it took to get their drugs. Haas told the jury that he attributed the lengthy delivery time to the inefficiency of the Mexican mail system. That was the reason, he testified, why he sought to avoid the international mail system by walking the drugs over into the United States. The jury obviously could have rejected this explanation.

"commercial" importation, even after being instructed otherwise--on multiple occasions--by regulatory agents. In addition, Haas interpreted the FDA's letters warning that he could not "market" the Mexican drugs to mean only that he could not advertise those drugs to U.S. citizens. To rational jurors, this testimony could have been taken as nothing more than lame and specious excuses for violating the law, denying even the obvious, and could therefore have created, in the minds of the jurors, a presumption of deceit as to many of the controverted issues relating to Haas's intent. When a challenge to a jury verdict is based on an argument that the jury could not have rationally believed that the defendant possessed criminal intent because of the defendant's subjective beliefs, evidence showing that the defendant is wilfully attempting to obfuscate the truth proves particularly damaging to the defendant's case; it is rational for a jury to believe that those who have been deceptive with the truth once are likely to deceive again.[10]

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[10]Haas also makes a sufficiency of the evidence argument based on his assertion that the drugs he imported were exempt from the labeling requirements of the Food, Drug, and Cosmetic Act because they were filled by a pharmacist. This argument is meritless. A pharmacist cannot legally fill prescriptions with illegal drugs, and the lack of FDA approval made NAPS's drugs illegal. The prosecution presented evidence that the drugs he imported were not regulated or approved by the FDA. The jury also learned from a FDA import compliance officer that without FDA approval, the drugs could not be legally marketed in the United States. Thus, the jury could have rationally found that NAPS's drugs did not comply with

The undisputed evidence revealed that Haas's company delivered thousands of drug orders to U.S. citizens from a pharmacy in Mexico without filing any declarations with U.S. Customs or the FDA. Haas was advised repeatedly by government officials that NAPS's operations violated federal law. In the face of this, Haas stubbornly continues to argue on appeal that he actually believed in the legality of his operations. We cannot conclude that the jury was unreasonable in disbelieving him and in accepting the governments evidence and arguments.

B

We turn now to Haas's challenge to the jury instructions. In reviewing a challenge to jury instructions, we ask "whether 'the court's charge, as a whole, is a correct statement of the law and whether it clearly instructs jurors as to the principles of law applicable to the factual issues confronting them.'" United States v. Devoll, 39 F.3d 575, 579 (5th Cir. 1994) (quoting United States v. Pace, 10 F.3d 1106, 1120-21 (5th Cir. 1993). We will find reversible error when "the jury charge, as a whole, misled the jury as to the elements of the offense." Id. Furthermore, in cases involving violations of relatively complex regulatory law, the district court's discretion is especially broad. District courts

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mandatory labeling requirements. Without the exemption, the evidence showed that the drugs were "misbranded" under 21 U.S.C. § 352.

must be given added discretion when they distill the essential concepts from complex legal jargon.

(1)

In his first challenge to the instructions, Haas argues that the district court erred when it failed to define the phrase "intent to defraud." Haas would have us require a specifically worded instruction--which we have in the past upheld, see United States v. Gray, 105 F.3d 956, 968 (5th Cir. 1997)--that acting with intent to defraud "means to act knowingly and with the intention or purpose to deceive or to cheat." We think that this additional language, beyond the instruction that the court gave, would add little to the jurors' understanding of the phrase "intent to defraud." In short, the district court's instruction did not fail to "clearly instruct[] the jurors as to the principles of law applicable to the factual issues confronting them.'" Devoll, 39 F.3d at 579.

(2)

The district court instructed the jury that it could conclude that Haas possessed guilty knowledge if it found that he acted with deliberate ignorance as to the legality of his conduct. Haas does not challenge the content of these instructions, but only argues that the evidence did not support the district court's decision to give a deliberate ignorance instruction. This challenge to the

jury instructions is meritless because Haas bases it--like his sufficiency of the evidence arguments--on his own disputed and controverted view of the evidence.

We have stated that "[t]he purpose of the deliberate ignorance instruction is to inform the jury that it may consider evidence of the defendant's charade of ignorance as circumstantial proof of guilty knowledge." United States v. Lara-Velasquez, 919 F.2d 946, 951 (5th Cir. 1990). More specifically, we have said that the "evidence at trial must raise two inferences: (1) the defendant was subjectively aware of a high probability of the existence of the illegal conduct; and (2) the defendant purposely contrived to avoid learning of the illegal conduct." Id. (citation omitted). The evidence to which we previously referred clearly supports each of these inferences.[11]

C

Both parties find fault with the district court's sentencing decision. Haas appeals the district court's enhancement of his sentence for obstruction of justice under U.S.S.G. § 3C1.1. The

[11]Haas also argues that the jury instructions were deficient because they failed to require a finding that Haas knew of the misbranding. We review Haas's arguments on this point for plain error because he did not raise them before the district court. See generally United States v. Calverley, 37 F.3d 160 (5th Cir. 1994) (en banc). After reviewing the jury instructions, and in the light of the fact that the jury was told that it must find that the defendant "knew the facts that made his conduct illegal as to each element of the offense," we find no plain error.

government cross-appeals the failure of the district court to enhance Haas's sentence based on "loss," as that term is used in U.S.S.G. § 2F1.1. In considering the arguments, we will review the district court's application of the Sentencing Guidelines de novo. The factual findings are reviewed, however, under the clearly erroneous standard. See United States v. Edwards, 65 F.3d 430, 432 (5th Cir. 1995). "A factual finding is not clearly erroneous as long as the finding is plausible in the light of the record as a whole." United States v. Brown, 7 F.3d 1155, 1159 (5th Cir. 1993).

(1)

Section 3C1.1 instructs the sentencing court to increase the sentencing offense level if the defendant has willfully obstructed justice.[12] As the commentary to § 3C1.1 points out, one example of such obstruction is perjury. See § 3C1.1 cmt. 4(b). The district court adopted the findings of the Presentence Report and concluded that Haas committed perjury when he testified at trial. Haas argues that the district court did not make the independent factual findings for perjury as required by United States v. Dunnigan, 507 U.S. 87 (1993). After reviewing the findings of the district

[12]Section 3C1.1 states:

> If the defendant willfully obstructed or impeded, or attempted to obstruct or impede, the administration of justice during the investigation, prosecution, or sentencing of the instant offense, increase the offense level by 2 levels.

court, including those which it adopted from the Presentence Report, see United States v. Storm, 36 F.2d 1289, 1296 n.6 (5th Cir. 1994), we conclude that the district court made independent findings as to the wilfulness and untruthfulness of Haas's testimony. Although the district court made no explicit findings as to the materiality of the perjurious statements, it is clear to us, as a matter of law, that those statements were material. See Id. at 1297 (finding materiality as a matter of law when the district court did not make an explicit finding as to materiality). Haas denied having been told by FDA agents that he could not legally continue his importation operations, and this assertion undoubtedly spoke to a material fact. See U.S.S.G. § 3C1.1 cmt. n.6 ("'Material' . . . statement . . . as used in this section, means . . . statement . . . that, if believed, would tend to influence or affect the issue under determination.").[13] The

[13]Haas also challenges the district court's conclusion as to perjury by arguing that the record does not support the elements of perjury. After reviewing the trial transcript, we are convinced that there exists sufficient evidence for a finding that Haas committed perjury. For example, when Haas's attorney asked him at trial whether any FDA officer told him that he "could not be given any approval to import any medicines," Haas replied, "No." But both testimonial and physical evidence at trial established that the FDA agents told Haas--both verbally and in writing--that his drug importation activities violated federal law. The sentencing judge could easily have found that this evidence both contradicted Haas's flat denial and that it was more credible than that denial.

district court did not err in deciding to enhance Haas's sentence under § 3C1.1.

(2)

In its cross-appeal, the government argues that the district court erred when it refused to enhance Haas's sentence based on "loss" pursuant to U.S.S.G. § 2F1.1. This section requires an incremental increase in the offense level based on the amount of loss caused by the fraud.

Haas argues that the government has not shown that Haas's customers suffered any loss. According to Haas, the customers paid discounted prices for drugs that they knew were coming from Mexico. The government did not show that any of the drugs sold performed differently from the drugs' U.S. counterparts. Furthermore, the government did not produce any customers as witnesses to testify that NAPS had swindled or cheated them. Without any proof of loss to the customers, Haas maintains, there simply is no loss to calculate for sentence enhancement under § 2F1.1. Haas raised this argument in his objection to the Presentence Report, and the district court sustained the objection.

The government argues that the customers did suffer an actual loss. The government asserts that NAPS caused a loss to its customers by failing to inform them that, unlike all drugs legally marketed in the United States, the drugs were not FDA-approved.

NAPS customers suffered loss because they reasonably assumed that they would receive FDA-approved drugs when, in fact, they did not. In short, they paid for something they did not receive, i.e., FDA approval.

There is some evidence, though not much, to indicate that some customers may have thought that the drugs were FDA-approved.[14] There is certainly no expert testimony, however, showing the value of such a loss, if any, and no argument on appeal that such a loss can be quantified based on the record made in the district court. Furthermore, there would be no economic harm done to the customers if they consumed the drugs in ignorance of the lack of FDA approval and those drugs performed just as well as FDA-approved drugs. Thus, it would seem that the government has proved very little, if any, loss. We cannot conclude on the record before us that the district court clearly erred in estimating that Haas's fraud produced no loss for his customers.

Notwithstanding the record in this case, however, our circuit seems to have taken the position that a § 2F1.1 "loss" enhancement is appropriate even when there has been no identifiable loss. In United States v. Smithson, 49 F.3d 138 (5th Cir. 1995), the

[14]For example, a NAPS worker testified that when the FDA began confiscating NAPS shipments, it would sometimes place a flier in the packages to inform customers that the drugs were not FDA-approved. According to the employee, some of the customers called to complain about this fact.

government indicted one Pyron for his conduct in his role as a bankruptcy debtor. In his bankruptcy petition, Pyron failed to include, as assets, two option contracts to purchase real estate. Our court noted that these options were virtually worthless to the bankruptcy estate because the trustee would not have raised the money necessary to exercise the options before they expired. In other words, "[t]he loss to the estate resulting from the concealment was, for all practical purposes, zero." Id. at 144.

Even so, we concluded that the district court should approximate the gain to the defendant as an alternative valuation method.[15] Smithson interprets the commentary note to require the district court to use the defendant's gain as a means to estimate the severity of the fraud when the court cannot calculate any loss for such purpose. Although § 2F1.1 ordinarily requires courts to use the victim's loss as a proxy for the severity of the crime, the offender's gain, i.e., the proceeds from the illicit activity, can

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[15]We reached this result after describing Application Note eight to section 2F1.1 which states:

> For the purposes of subsection (b)(1), the loss need not be determined with precision. The court need only make a reasonable estimate of the loss, given the available information. . . . The offender's gain from committing the fraud is an alternative estimate that ordinarily will underestimate the loss.

U.S.S.G. § 2F1.1 cmt. n.8 (1993). In the current version of the Sentencing Guidelines, this note is now note 9 in the Commentary section.

provide an adequate, alternative method of gauging the crime's just penalty when the loss is incalculable. Cf. United States v. Izydore, No. 97-50537, 1999 WL 55158, at *10 (5th Cir. Feb. 8, 1999) (stating that the "touchstone for determining loss under U.S.S.G. § 2F1.1 is the 'value of the thing taken' . . . because the Sentencing Commission believed that punishment for fraud should reflect a balance between the loss to the victim and the gain to the defendant"). Thus, according to our precedent, if the loss is either incalculable or zero, the district court must determine the § 2F1.1 sentence enhancement by estimating the gain to the defendant as a result of his fraud.[16]

Under the facts of this case, the loss sustained by either the FDA (whom Haas was convicted of defrauding) or Haas's customers (some of whom may or may not have been defrauded) is, for all practical purposes, incalculable--certainly on the record made by the government. The district court can, however, estimate the gain

[16]But cf. United States v. Haddock, 12 F.3d 950, 960 (10th Cir. 1993) ("[T]he enhancement is only for loss to victims, not for gain to defendants. The defendant's gain may be used only as an 'alternative estimate' of that loss; it may not support an enhancement on its own if there is no actual or intended loss to the victims."); United States v. Anderson, 45 F.3d 217, 221 (7th Cir. 1995) ("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.'"); United States v. Chatterji, 46 F.3d 1336, 1340 (4th Cir. 1995) ("gain . . . is not a proxy for loss when there is none").

that Haas received from defrauding the FDA.[17] The record before us suggests that all of NAPS operations circumvented FDA regulations. We come to this conclusion because the entire scheme was to import Mexican made drugs at deep discounts to customers without incurring the costs associated with regulatory approval. Thus, Haas's gain from his fraudulent importation scheme appears to have been those monies he received from NAPS by way of salary and profits.[18] We will remand the case to the district court for further proceedings not inconsistent with this opinion.

V

For the foregoing reasons, we AFFIRM the conviction of Ronnie Haas on all counts. We must VACATE his sentence, however, and REMAND for further proceedings in accordance with this opinion.

AFFIRMED, VACATED, and REMANDED.

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[17]We pause to note that the government has informed us in its briefs that it possesses evidence that NAPS conducted a little over $150,000 in sales. This, the government argues, is an accurate enough estimate of NAPS's gain. Note eight in the commentary to § 2F1.1 provides that loss may be estimated by calculating the offender's gain. The offender in this case is Haas, not NAPS.

[18]Notwithstanding what we have said in this paragraph, we leave to the district court the ultimate determination of all underlying facts that relate to the amount of Haas's gain from the fraud. According to our precedent, on remand the district court may allow further development of the record to establish facts necessary for deciding the § 2F1.1 sentencing issue. See United States v. Kinder, 980 F.2d 961 (5th Cir. 1992); United States v. Marmolejo, 139 F.3d 528, 530-31 (5th Cir. 1998).