In the
United States Court of Appeals
For the Seventh Circuit

Nos. 00-1523 & 00-2679

United States of America,

Plaintiff-Appellee,

v.

Baldev R. Bhutani and
ALRA Laboratories, Incorporated,

Defendants-Appellants.

Appeals from the United States District Court
for the Northern District of Illinois, Eastern Division.
No. 93 CR 585--John F. Grady, Judge.

Argued April 5, 2001--Decided September 12, 2001

Before Bauer, Ripple, and Evans, Circuit Judges.

Bauer, Circuit Judge. A jury found defendants Baldev Raj Bhutani, Neelam Bhutani, and ALRA Laboratories, Inc. guilty of various violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. sec. 301 et seq. The defendants moved for a new trial, which the district court granted, finding that the government violated Brady v. Maryland, 373 U.S. 83 (1963). The government appealed, and in United States v. Bhutani, 175 F.3d 572 (7th Cir. 1999) we reversed and remanded the case for sentencing. On remand, the defendants again moved for a new trial, which the district court denied. Assuming familiarity with our first opinion, we consider the appeal by the defendants (Neelam does not appeal) from that denial. For the following reasons, we affirm.

A.

The defendants believe that the government's position in the first appeal contradicted its trial theory and that the government's appellate position is newly discovered evidence, and that if the jury had heard the government's appellate theory it would have decided

the case differently. Specifically, they contend that at trial the government said that the defendants had added sodium hydroxide to decomposed Lactulose in hopes of concealing its medical ineffectiveness, but on appeal admitted that the Lactulose was medically effective by iterating that it was within the accepted pH range before the addition of sodium hydroxide. On remand, the district court agreed with the defendants that the government had changed its theory, but the district court refused to entertain the argument, believing that it was foreclosed from doing so since we had held otherwise in our first opinion in this case.

The government counters that its focus at trial was not that the Lactulose was outside of the acceptable pH range or medically ineffective, but rather the fact that the defendants added sodium hydroxide to the Lactulose lots because they wanted the 1986 lots to have a pH similar to the 1988 lots so that they could bear the same expiration date and be sold. The government's position was that the defendants masked the fact that the Lactulose was degrading and past its expiration date in order to make money.

We agree with the government. A second read of the trial transcript reveals that the government's position at trial and on appeal has been consistent. The government did not show at trial that the Lactulose was outside the accepted pH range or medically ineffective; rather it admitted that the pH was at all times within range, but that it was dropping, which signaled degradation, and in order to mask any degradation the defendants raised the pH by adding sodium hydroxide so that the fact that it was being sold past its expiration date could not be detected. The medical efficacy of the Lactulose was only mentioned by the government to explain the significance of expiration dating to the jury. The government wanted to explain why expiration dates are imposed in order to counter the defense theory that the defendants did not intend to put an adulterated product on the market because Lactulose could be stable and medically effective beyond the artificially imposed expiration date assigned by the "paperwork bureaucracy" known as the FDA. The defense again mischaracterizes the

thrust of the government's case and regurgitates its argument from the last appeal, the only difference being that in the first appeal they argued that the newly discovered evidence was the U.S.P. recommendation, see 175 F.3d at 578-79, and here they point to the government's switch in theories. This supposed difference does not affect our decision. There is no new evidence that would have altered the outcome of this case.

B.

The defendants submit that reversal is justified because the district court abused its discretion, see United States v. Butler, 71 F.3d 243, 250 (7th Cir. 1995), by permitting the government to elicit impermissibly prejudicial testimony from Dr. John Senior, offered as an expert in gastroenterology and liver disease, see Trial Tr. at 1691 (December 28, 1995), about the medical consequences of taking ineffective Lactulose. The defendants claim that Dr. Senior testified that patients could die from ingesting ineffective Lactulose. Before Dr. Senior testified, the district court had admonished the government to avoid introducing this sort of testimony. The defendants believe that the government violated this admonition.

Contrary to the defendants' characterization of Dr. Senior's testimony, the transcript reveals that he did not testify in an impermissibly prejudicial manner. Dr. Senior explained that Lactulose works as a substitute liver for patients with liver disease, and that Lactulose would be ineffective if it had degraded into its component parts because the separate sugars would be absorbed into the small intestine before reaching the colon. He also testified that it would be impossible for a physician to know that Lactulose had degraded to the point of ineffectiveness, and therefore a physician might erroneously determine that the Lactulose was ineffective for a patient for some other reason.

The sole mention of the possibility of death from ingesting ineffective Lactulose was not presented by the government, but was elicited on cross-examination by the defense:

Q. [Mr. Branding, Attorney for ALRA] And [Lactulose] doesn’t cure the underlying liver disease, does it?

A. Of course not.

Q. It’s only--

A. It’s only a compensation for a failed organ.

Q. It’s used to treat the symptoms?

A. It’s used to treat--it’s not just symptoms. It’s a whole syndrome that may kill. It’s not just symptoms.

Encephalopathy due to liver failure may be fatal. It’s not just symptoms.

Trial Tr. at 1710-11 (December 28, 1995). The testimony defendants complain about was never offered, and thus there was no abuse of discretion by the district court.

C.

The defendants argue that Count Four, which charged that the defendants "[o]n or about August 12, 1988 . . . with intent to defraud and mislead, failed to establish and maintain accurate drug manufacturing batch production records for the generic drug product, Lactulose Syrup USP" in violation of 21 U.S.C. sec. 331(e), along with the correlating conspiracy charge in Count One, failed to state a crime for which they could be convicted.

In 1938, Congress enacted the FDCA pursuant to its authority to regulate interstate commerce in order to protect the public from dangerous food and drug products. In 1962, Congress amended the FDCA, adding sec. 355(j) to require drug manufacturers to establish or maintain records about the manufacture and testing of drugs. See The Drug Amendments of 1962, Pub. L. No. 87-781, sec. 103(a), 76 Stat. 780. Thereafter, the failure to establish or maintain records under sec. 331(j) was a prohibited act under sec. 331(e) and subject to the imposition of criminal penalties under sec. 333, such as imprisonment, fine, or both.

In 1984, Congress amended the FDCA and the federal patent laws to help make

available more low cost drugs by creating an abbreviated procedure for FDA approval of generic drug applications. See Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, sec. 101, 98 Stat. 1585; see also National Ass'n of Pharm. Mfrs., Inc. v. Ayerst Labs., 850 F.2d 904, 907 (2d Cir. 1988). Congress enacted this new abbreviated drug approval process under sec. 355(j) and redesignated the old sec. 355(j) concerning recordkeeping as sec. 355(k). However, Congress did not alter sec. 331(e). Thus, sec. 331(e) still instructed that the failure to establish or maintain records under sec. 355(j) was subject to criminal penalties, even though the new sec. 355(j) did not require recordkeeping. Whether intentional or not, the penalties for failing to establish or maintain records had been in effect eliminated.

In 1990, Congress passed a short, technical amendment, which stated: "Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. sec. 331(e)) is amended by striking out 'or (j)' and inserting in lieu thereof 'or (k).'" Vaccine & Immunization Amendments of 1990, Pub. L. No. 101-502, 104 Stat. 1285. Thus, by simply replacing "(j)" with "(k)," sec. 331(e) again clearly subjected violators to the same criminal penalties as they had been for more than two decades prior to 1984 for failing to establish or maintain records.

However, there was a gap between 1984 and 1990 where under the plain statutory language the failure to establish or maintain records under sec. 355(k) was not subject to criminal penalties. This time gap is of import to this case; the defendants' conduct charged under sec. 331(e) occurred in August of 1988, which raises the delicate question of whether their convictions for these violations may stand, given that the plain language of the statute did not penalize their conduct. As noted, the defendants argue that under the plain language of the statute they cannot be penalized for failing to establish and maintain records. The government argues that the elimination of the penalty was a scrivener's snafu, and criticizes the defendants' hyper-technical and illogical reading of the statute. This question has all of the trappings of a law school

hypothetical, but with real-world consequences, so although the defendants' brief fails to support this argument with case law discussion or even citation, we nonetheless address this important issue of criminal law and statutory construction.

Generally, courts strictly construe criminal statutes against the government and in the defendant's favor. See Barrett v. United States, 423 U.S. 212, 218 (1976); 3 Norman J. Singer, Sutherland Statutory Construction sec. 59.03 (5th ed. 1992). This is so to ensure that people are fairly warned about what sort of conduct may expose them to criminal penalties and what sort of penalty may be imposed. See United States v. Bass, 404 U.S. 336, 348 (1971); 3 Sutherland Statutory Construction sec. 59.03. But, in strictly construing a statute, courts ought notdeprive it of the obvious meaning intended by Congress, nor abandon common sense. See United States v. Moore, 423 U.S. 122, 145 (1975); 3 Sutherland Statutory Construction sec. 59.06.

Some courts have upheld the imposition of criminal penalties despite the presence of a typographical error in the statute. See United States v. Lacher, 134 U.S. 624, 625-32 (1890) (upholding conviction for embezzling a letter containing an article of value under 18 U.S.C. sec. 318 even though after revision of the statute the wording was alteredbecause "the intention to impose a penalty on [the] commission [of the offense] cannot reasonably be denied; and, although the apparent grammatical construction might be otherwise, the true meaning, if clearly ascertained, ought to prevail"); United States v. Graham, 169 F.3d 787, 790-91 (3d Cir. 1999) (upholding a defendant's sentence for illegally reentering the United States after finding that Congress intended that the actual term of imprisonment imposed determines whether a defendant is classified as an "aggravated felon" under 8 U.S.C. sec. 1101(a)(43) despite the fact that the statutory section was "obviously missing a crucial verb"); United States v. Warren, 149 F.3d 825, 827-28 (8th Cir. 1998) (affirming the defendant's sentence of 151 months for manufacturing 32,000 grams of methamphetamine under 21 U.S.C. sec. 841(b)(1) even though "[a]t the time of

[the] offense, because of a typographical error, the same amount of a quantity of a mixture--100 grams--was listed as triggering both the five-year and the ten-year mandatory minimum sentences," because Congress intended drug trafficking penalties to be graduated according to drug quantity); United States v. Rossetti Bros, Inc., 671 F.2d 718, 720 (2d Cir. 1982) ("Plainly, Congress did not intend its recodification [of the Interstate Commerce Act] to reduce the reach of [its] penalty, but intended merely to transplant that section, renumbered, into the recodified portion . . . . Congressional drafters unfortunately overlooked [this], but, when construed in light of the intent of Congress and in light of common sense, that section clearly applies to the regulations here in question."); United States v. Scrimgeour, 636 F.2d 1019, 1021-24 (5th Cir. Unit B 1981) (reversing dismissal of indictment under 18 U.S.C. sec. 1623(d) for making false declarations before a grand jury because in finding Congress' intention in enacting the statute, the court believed Congress inadvertently used an "or" in the statute but meant to use "and"); United States v. Moore, 613 F.2d 1029, 1039-45 (D.C. Cir. 1979) (same); United States v. Babcock, 530 F.2d 1051, 1053-54 (D.C. Cir. 1976) (holding that, in light of "an inadvertent change" by Congress when reorganizing and renumbering the statute, 2 U.S.C. sec. 441(b) was not to be interpreted to mean that a misdemeanor violation under sec. 440 precluded being sentenced to imprisonment); cf. Whitfield v. Scully, 241 F.3d 264, 272 (2d Cir. 2001) ("Although the statute refers to [28 U.S.C.] sec. 1915(a)(2) for the manner of payment, we have recognized that this reference is a typographical error (as it makes the statute unintelligible) and that the actual process for payment of costs is instead described in sec. 1915(b)(2)."); Estate of Kunze v. C.I.R., 233 F.3d 948, 953 (7th Cir. 2000) ("The erroneous cross-reference in [26 U.S.C. sec. 7430(c)(4)(D)] to a misnumbered subparagraph in (4)(A) can hardly be construed to have changed the legislative intent . . . or to have affected the substantive rights of the parties. The import of the subsection remains clear, in spite of the typo."); In re Chateaugay

Corp., 89 F.3d 942, 952 (2d Cir. 1996) (agreeing with other courts that the improperly renumbered subsections in 11 U.S.C. sec. 507 were the result of typographical errors by Congress rather than substantive changes in the law).

However, some courts have held otherwise. See United States v. Faygo Beverages, Inc., 733 F.2d 1168, 1170 (6th Cir. 1984) (recognizing that Congress unintentionally eliminated a penalty section in recodifying the InterstateCommerce Act, but holding that the defendant was not subject to criminal penalty for his conduct because "it would be unreasonable to require persons confronted with the plain language of a criminal statute to go beyond that statute in order to determine whether Congress really meant what it clearly said"); United States v. RSR Corp., 664 F.2d 1249, 1253-55 (Former 5th Cir. 1982) (noting that Congress inadvertently changed a penalty section in recodifying the Interstate Commerce Act, but holding that the defendant was not subject to criminal penalty for his conduct, stating "although this is what Congress clearly meant to say, intended to say, and wanted to say, still Congress did not say it").

While the plain language of the FDCA clearly prohibited the failure to establish or maintain records, criminal penalties were not clearly imposed. Nevertheless, we agree with the reasoning found in the former set of cases rather than the latter because strictly reading and applying the FDCA as it was at the time of the offense in question would put the plain language at odds with the statute’s purpose and intent. There is no indication in the legislative history that in amending the FDCA Congress intended to eliminate the penalties. The Law Revision Counsel of the House of Representatives, who prepares and publishes the U.S. Code, even placed a footnote in the 1988 edition of the U.S. Code in sec. 331(e) after the proscription on failing to keep records under sec. 355(k), and noted that sec. 335(j) had been redesignated as sec. 355(k). Thus, it seems that the failure to cross-reference the sections was interpreted as a mere typo by the Law Revision Counsel. Also, we agree with the government that Congress would not have eliminated the penalties for failing to

establish or maintain records in this part of the statute while retaining the penalties for failing to do so under other sections. Furthermore, the government points out that the 1984 amendments broadened the recordkeeping requirements in the redesignated sec. 355(k), and that Congress would not have intentionally broadened the requirements and at the same time have eliminated the penalties for not complying with the requirements.

Finally, the defendants do not argue that because of the typographical error they lacked notice; nor could they since they maintained records believing that they were required to (although they did so inadequately, as this case reveals) under the FDCA. Therefore, we hold that the failure to establish or maintain records under sec. 355(k) was subject to criminal penalties despite the typographical error in sec. 331(e) between 1984 and 1990.

D.

Baldev Bhutani also raises several challenges to his sentence imposed under U.S.S.G. sec. 2F1.1 (2000). "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. Andersen, 45 F.3d 217, 219 (7th Cir. 1995); we review factual determinations for clear error, see United States v. Vitek Supply Corp., 144 F.3d 476, 490 (7th Cir. 1998).

First, the defendant finds error in the district court's choice of guideline to apply, claiming that he ought to have been sentenced under sec. 2N2.1(a) rather than sec. 2F1.1. Section 2N2.1(a) covers violations of statutes and regulations dealing with, among other things, drug products, and assigns a base offense level of six to such violations; however, subsection (b)(1) instructs: "[i]f the offense involved fraud, apply sec. 2F1.1 (Fraud and Deceit)." Section 2F1.1 "also has a base offense level of six, but provides for substantial increases in offense level based on the amount of loss." Andersen, 45 F.3d at 219. Bhutani's argument turns on the notion that sec. 2N2.1(a) applies because his wrongs were "knowing, technical" violations of the FDCA, and not as

serious as those of other companies that have been prosecuted. This argument is without merit as there is substantial evidence of fraud in this case. See, e.g., id. at 219-20.

Second, he submits that sec. 2N2.1(b)(1) does not apply to his case since it was made effective on November 1, 1992, but "the offenses of conviction all occurred prior to November 1, 1992." This is of no matter since "judges must apply the Guidelines in force when a defendant is sentenced." United States v. Perez, 249 F.3d 583, 584 (7th Cir. 2001) (per curiam). Bhutani was sentenced on February 15, 2000, and subsection (b)(1) was then in effect, thus it is applicable.

Third, the defendant disputes how the district court measured loss. As noted, sec. 2F1.1 assigns a base offense level of six, which is increased based on the amount of loss attributed to the fraud. In calculating the loss, the district court is not required under the Sentencing Guidelines to "compute the loss with precision; the court need only make a reasonable estimate of the loss based on the information available." United States v. Duncan, 230 F.3d 980, 985 (7th Cir. 2000); see U.S.S.G. sec. 2F1.1, cmt. 9. If it has been shown that the victims of the fraud suffered a loss and a more precise way of measuring the loss is unavailable, the amount of the defendant’s gain may provide a reasonable estimate of the loss. See Andersen, 45 F.3d at 221.

Directing us to United States v. Chatterji, 46 F.3d 1336 (4th Cir. 1995), the defendant maintains that his gain was not the appropriate measure because there was no actual loss to consumers as none of the drugs were shown to be medically effective and there was no evidence that anyone fell ill or died. He argues that the calculation should not be based on whether the consumers got what they bargained for, but rather ought to be based on whether the consumers got medically effective drugs.

In Chatterji, the defendant, sentenced under U.S.S.G. sec. 2F1.1, submitted two abbreviated new drug applications to the FDA, which were approved. See id. at 1338-40. The defendant had submitted false batch records in its application

for one of the drugs, and for the other had changed the formula by adding more of an inactive ingredient after its application had been approved without seeking further FDA approval. The district court held that loss should be measured by the defendant's gain from the sale of the drugs because the defendant's fraud voided the FDA approval, thereby stripping the drugs of market value. See id. at 1340. The Fourth Circuit, over dissent, reversed, finding that the defendant's gain was not the appropriate measure of loss because consumers got medically effective drugs that were exactly what they purported to be. See id. at 1340-43.

Relying on United States v. Marcus, 82 F.3d 606 (4th Cir. 1996), the government in our case argues that there was loss to consumers because consumers paid for-FDA-approved drugs, but received drugs that were not manufactured according to the FDCA and FDA regulations; therefore, the government argues that the amount of the defendant's gain is an appropriate measure of loss.

In Marcus, the defendant, sentenced under sec. 2F1.1, had obtained FDA approval to manufacture a drug, but changed the formula by adding two additional inactive ingredients without obtaining additional FDA approval. See id. at 607-08. The district court found that the defendant's gain was the appropriate measure of loss because the drug did not meet FDA specifications, and therefore, had no value. See id. at 608. The court distinguished Chatterji, which the Fourth Circuit affirmed, reasoning that the formula modification in Chatterji "was merely an insignificant change that implicated only the shelf life of the drug," and not the safety or medical efficacy; however, the formula modification here had a bearing on the medical effectiveness, which would require additional testing to determine whether the drug was still safe and effective. Id. at 610.

In this case, the district court agreed with the government's position and reasoned:

I find the analysis in the Marcus case from the Fourth Circuit to be persuasive. I understand that the defendants believe

Marcus is distinguishable on the basis that the defendant there agreed that there was an issue as to whether the drug involved there was the bioequivalent of the patented drug.

I don't regard that as a distinguishing feature of the case, because whether the defendants stipulate to it or not, and certainly they do not in this case, I find that there was an issue as to whether these drugs had been properly manufactured.

I'm not saying that there was an issue as to whether they would be injurious to health or necessarily even an issue as to whether they would be effective for their pharmaceutical purpose. What I find, rather, is that there was an issue as to whether they had been manufactured in such a way that the consumers of those drugs were being sold something other than what they thought they were buying.

I don't think that any consumer of any of those drugs would have bought those drugs had the consumer known what had happened to them.

* * *

And I think the essence of the loss here to the consumers was the same thing fact [sic] that the Marcus case was talking about, namely, the fact that they didn't get the FDA-approved manufactured drugs that they thought they were getting.

And I emphasize that I don't think Marcus applies only in the situation where the drugs could be dangerous. . . .

Sentencing Hr'g Tr. at 23-24 (February15, 2000). The district court based the amount of loss on the defendant's gain, which it estimated at over $200,000, thereby assigning Bhutani a base offense level of fourteen. See U.S.S.G. sec. 2F1.1(b)(1)(I).

While we do not agree with the district court's reading of Marcus or his reliance on it, we wholly adopt the core of its rationale. Indeed, we find the district court's reasoning to be more sound than that in Chatterji and Marcus./1 The medical effectiveness of the drug or its dangerousness after adulteration ought not be the core of the inquiry; rather,

the district court was justified in determining that there was a loss because consumers did not get what they bargained for. We agree with the district court's decision that there was indeed loss to consumers because consumers bought drugs under the false belief that they were in full compliance with the law.

However, the defendant points out that in Andersen we held that the defendant's gain was not the appropriate measure of loss when there was "no clear evidence that customers or consumers suffered any loss." 45 F.3d at 221. We so held, in part, because the drugs in that case were sold in hand-labeled containers and the customers were aware that the drugs were not FDA approved. See 45 F.3d at 221. That is not so here; here consumers bargained for FDA-approved drugs that were in compliance with the law. This they did not get. We agree with the district court's determination of what constitutes loss in this sort of case, and that the defendant's gain is the appropriate measure of that loss.

E.

The bulk of the defendants' brief is tinged with hyberbole, lamenting that they ought not to have been prosecuted because what they may have done was not so bad compared to what others have done and that their industry is overregulated by the FDA. The judiciary is not the branch to hear these beefs; rather, they ought to be raised with Congress, who makes the law, and prosecutors, who have broad discretion in instituting criminal proceedings. Furthermore, many of the disputes are no more than an invitation to reweigh the evidence based on the defendants' attempt to retry this case on appeal. We are at ease with the jury's work in weighing evidence and assessing credibility and will not engage in second-guessing. The other arguments of the defendants are equally without merit and we shall not address them further.

AFFIRMED.

FOOTNOTE

/1 We decline the defendant's invitation to apply United States v. Maurello, 76 F.3d 1304 (3d Cir. 1996) by analogy to this case. We also find our decision in Vitek Supply inapplicable because it

dealt with whether loss to competitors and down-
stream consumers was to be included in the loss
calculation. See 144 F.3d at 490-92.