

UNPUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff-Appellant.

v.

No. 96-4228

SUHAS V. SARDESAI; EDMUND J.

STRIEFSKY,

Defendants-Appellees.

Appeal from the United States District Court
for the District of Maryland, at Greenbelt.

Peter J. Messitte, District Judge.

(CR-94-167-PJM)

Argued: November 1, 1996

Decided: October 10, 1997

Before ERVIN, Circuit Judge, BOYLE,
United States District Judge for the
Eastern District of North Carolina, sitting by designation, and
JACKSON, United States District Judge for the
Eastern District of Virginia, sitting by designation.

Affirmed by unpublished opinion. Judge Ervin wrote the opinion, in
which Judge Boyle and Judge Jackson joined.

COUNSEL

ARGUED: Lawrence McDade, Deputy Director, Office of Consumer
Litigation, UNITED STATES DEPARTMENT OF JUSTICE, Wash-

ington, D.C., for Appellant. L. Marc Durant, DURANT & DURANT, Philadelphia, Pennsylvania; Catherine N. Recker, WELSH & RECKER, Philadelphia, Pennsylvania, for Appellees. **ON BRIEF:** Lynne A. Battaglia, United States Attorney, Raymond A. Bonner, Assistant United States Attorney, Greenbelt, Maryland, for Appellant. Robert E. Welsh, Jr., WELSH & RECKER, Philadelphia, Pennsylvania, for Appellee Sardesai.

Unpublished opinions are not binding precedent in this circuit. See Local Rule 36(c).

OPINION

ERVIN, Circuit Judge:

Suhas Sardesai and Edmund Striefsky were both convicted of conspiracy to defraud the United States Food and Drug Administration, in violation of 18 U.S.C. § 371; two counts of introduction of adulterated pharmaceuticals into interstate commerce in violation of 21 U.S.C. §§ 331(a) and 333(a)(2); and several counts of making false statements to a federal agency in violation of 18 U.S.C. § 1001. Appellants moved for new trials under Federal Rule of Criminal Procedure 33 on the basis of United States v. Gaudin, 115 S. Ct. 2310 (1995), which was decided shortly after Sardesai and Striefsky were convicted. The district court read Gaudin to mean that it had erred in the instant case when it failed to allow the jury to decide materiality, an essential element of the false statement charges. The district court further found that the instructional error had infected the verdicts on all of the charges and it vacated the convictions and granted a new trial for Sardesai and Striefsky. The government appeals the grant of the new trials. For the reasons explored below, we affirm.

I

During the relevant years, Sardesai and Striefsky were executives at Mutual Pharmaceutical Company, and both had been there since

the mid-1980s. Beginning in 1987 Mutual began to experience difficulty in manufacturing several drug products according to the methods that had been approved by the Food and Drug Administration ("FDA").¹ Under the direction of Sardesai and Striefsky, Mutual failed to follow the supplemental approval process established by the FDA for changes to drug formulae and manufacturing methods. Instead Mutual began to make some drug products using unapproved ingredients and processes, mixed batches of failed products with successful ones, and remilled and remixed flawed tablets. Many Mutual employees testified at trial about making these and other changes pursuant to the instruction of Sardesai and Striefsky. Testimony also showed that employees were often told to sign records documenting work they had not done and not to document the work they had done in violation of FDA procedures. Mutual submitted false documents to the FDA indicating that "no significant changes" had been made in the approved manufacturing process. Following the manufacturing changes and the false documentation, Mutual introduced the altered drugs into interstate commerce and allowed them to be sold to consumers. At least six different drugs were affected by Mutual's illegal practices.

II

The government first argues that the false statement counts themselves need not be retried in light of Gaudin. We note from the outset that we review the district court's decision to grant a new trial pursuant to Rule 33 for an abuse of discretion. See United States v. Campbell, 977 F.2d 854, 860 (4th Cir. 1992); see also United States v. Christy, 3 F.3d 765, 768 (4th Cir. 1993) (employing abuse of discretion standard for review of denial of a motion for a new trial based upon newly discovered evidence); United States v. Arrington, 757 F.2d 1484, 1486 (4th Cir. 1995) (same); United States v. McBride, 862 F.2d 1316, 1319 (8th Cir. 1988) (applying abuse of discretion

¹ Federal law requires that a drug manufacturer submit detailed data to the F.D.A. regarding the exact process which will be used in making and testing a drug product. 21 U.S.C. § 355. Drugs not made in accordance with approved processes or drugs for which inaccurate records are kept regarding manufacturing and testing are "adulterated," and cannot be sold. 21 U.S.C. § 351(a)(2)(B); 21 C.F.R. part 211.

standard to district court's decision to grant a new trial in light of trial errors.)

A

In Gaudin, the Supreme Court held that when materiality is an essential element of a crime, it must be decided by the jury and not reserved as a question of law to be decided by the judge. 115 S. Ct. 2310 (1995). Both Gaudin and the instant case concern violations of 18 U.S.C. § 1001, which criminalizes the making of false statements to an agency of the United States.² Based upon Gaudin, the district court in the instant case found that it erroneously prevented the jury from deciding whether the false statements made by Sardesai and Striefsky were material in violation of § 1001, and granted a new trial.

The government argues that Gaudin does not apply to this case. Specifically the government points out that materiality is not an explicit element of violation of all portions of § 1001, but is only mentioned in the first clause of § 1001;³ the government implies that Sardesai and Striefsky were charged with violating a portion of § 1001 which does not include materiality as an element. The government points out that the Gaudin Court did not decide whether materiality was an element of the § 1001 violation at issue in that case, but instead assumed it was an element because of the concession of the prosecutor to that effect. See Gaudin, 115 S. Ct. at 2313 (noting that

² Prior to 1996, 18 U.S.C. § 1001 read:

Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined under this title or imprisoned not more than five years, or both.

In 1996 it was substantially amended, but those amendments are not relevant for the instant case.

³ The 1996 amendments altered § 1001 so that it is now divided into lettered sections and materiality is specifically included as an element of each section.

the government is not contesting that materiality is an element of the crime charged).⁴ The government's position is somewhat supported by United States v. Wells, 117 S. Ct. 921 (1997), in which the Supreme Court, addressing 18 U.S.C. § 1014, a false statement statute similar to § 1001, held that because materiality is not explicitly stated as an element of a crime, it will not be read into the text, and it need not be decided by the jury. Wells can be read to support the government's position that materiality is not an element of the second clause of § 1001, either implicitly or explicitly.

However, these arguments are inapposite to the instant case. The indictment against Sardesai and Striefsky did not indicate which clause of § 1001 is at issue; this is to be expected, as the version of § 1001 in effect at the time was not divided into formal sections or even paragraphs. However, the language in the false statement counts of the indictment specifically uses the word material and incorporates language directly from the first clause of § 1001.⁵ There is no question but that the charges against Sardesai and Striefsky have materiality as an essential element. Wells does not apply because it holds that materiality cannot be read into statutes where it is not explicit, but it does not in any way affect those false statement statutes which explicitly include materiality.

Moreover, in United States v. David, 83 F.3d 638, 641 n.3 (4th Cir. 1996), we reiterated that materiality is, according to our precedent, an element of § 1001 and we held that in light of Gaudin, failure to instruct on that element is error. Although David did not explore in detail the different clauses of § 1001, the government concedes in its reply brief that David means that we have found materiality to be an element.

⁴ Chief Justice Rehnquist's concurrence seems to support the government's reading; he suggests that the government in Gaudin should not have conceded that materiality is in fact an element of all the offenses covered by § 1001. Gaudin, 115 S. Ct. at 2320.

⁵ For instance, Count Four charges, in part, that the defendants "did intentionally, knowingly and unlawfully falsify, conceal and cover up and caused to be falsified, concealed, and covered up by a trick, scheme and device a material fact" (emphasis added).

Given David and the plain language of the indictment, the trial court was correct in presuming that materiality is an element of the crimes with which Sardesai and Striefsky were charged. Therefore, contrary to the government's assertions, Gaudin does apply to this case.

B

The government next argues that, even if the jury should have been instructed about the element of materiality, the failure to do so was harmless within the meaning of F. R. Crim. P. 52(a) and a new trial is not warranted. We have held that failure to instruct the jury about an essential element of a crime will rarely be harmless. Specifically, in United States v. Forbes, 64 F.3d 928, 935 (4th Cir. 1995), we stated, "we must set aside the conviction unless we can say beyond a reasonable doubt that the jury actually made the finding that the Sixth Amendment requires it to make." (emphasis in original). Similarly, in United States v. Johnson, 71 F.3d 139, 144 (4th Cir. 1995), we held that failure to instruct the jury regarding an essential criminal element cannot be harmless unless it can be inferred from the jury's other findings that the jury necessarily found the omitted element. See also United States v. Aramony, 88 F.3d 1369, 1387 (4th Cir. 1996) ("A verdict of guilty must rest on an actual jury finding of guilty. Speculation about the probable finding that the jury would have made in view of the evidence before it had it been properly instructed does not satisfy this requirement." (citations omitted)), cert. denied, 117 S. Ct. 1842 (1997); David, 83 F.3d at 647 (applying similar analysis in a Rule 52(b) plain error context).⁶

⁶ We note that the Supreme Court's recent holding in United States v. Johnson, 117 S. Ct. 1544 (1997), does not alter our conclusion that the error in the instant case cannot have been harmless. Johnson held that the failure to submit materiality to the jury in that case did not require reversal because it did not seriously affect the "fairness, integrity or public reputation of judicial proceedings," as required by the fourth prong of the test set forth in United States v. Olano, 507 U.S. 725 (1993). Id. at 1550. That finding is distinguishable from the instant case, however, because both Olano and Johnson address cases which are governed by Rule 52(b) which allows correction of certain plain errors affecting substantial rights even when they were not properly objected to at trial; the instant question, in contrast, concerns Rule 52(a).

The government argues that harmless error analysis nonetheless applies in the instant case because the jury found the "factual equivalent" of materiality beyond a reasonable doubt. The government presents a very convoluted argument to support this position. Indictment counts four through seven charged that defendants had knowingly falsified or covered up a material fact when they falsely asserted in annual reports that four different batches of drugs underwent "[n]o significant change in manufacturing procedures." The jury found the defendants guilty of knowingly and wilfully making false statements to the F.D.A. for making these assertions in the reports. The government points out that the jury must have found beyond a reasonable doubt that the changes made had been significant. The government argues that "material" and "significant" are synonymous, and because the jury found that the changes in the process had been significant, it necessarily found that the fact of the changes had been material. Therefore the government asserts that the failure to require the jury to find materiality was harmless because the jury essentially found materiality anyway.

Despite the superficial appeal of the government's argument, we affirm the trial court's decision to grant the defendants a new trial on the fourth through seventh counts of the indictment, the false statement charges. We are simply not certain beyond a reasonable doubt that the jury found that material false statements were made by the defendants. Specifically, we agree with the district court's conclusion that, although the jury necessarily found that the changes in the manufacturing process had been significant, it did not necessarily find that the statements omitting these changes were material. As the district court ruled from the bench:

It is perhaps true that the third prong of the Olano test -- whether the error affects substantial rights -- is essentially the same as the harmless error analysis done under Rule 52(a). See, e.g., David, 83 F.3d at 647. Had the Johnson court relied upon that prong to support its conclusion, we might be directly bound by the decision. However, the Johnson court explicitly declined to decide whether failure to instruct on materiality necessarily violates substantial rights and instead relied solely upon the final Olano prong to support its decision to affirm the convictions. Id.

I cannot necessarily equate the term significance with materiality, particularly because there is the difference between what might be material to a chemist and a biologics company and what might be material or significant to a juror determining the case.

(Joint Appendix 98.) Furthermore, it appears that the district court, in its instructions to the jury, never defined the word "significant" in the context of significant changes in the manufacturing process. We simply do not know what the jury found with respect to those changes or the reports about them. As we pointed out in Forbes, 64 F.3d at 934, it is not enough that the jury "would surely have found" the required element; we must be certain that they in fact found it. We conclude, therefore, that the district court did not abuse its discretion in granting a new trial.

III

The government argues that even if the false statement counts must be retried, the remaining counts for which Sardesai and Striefsky were convicted may stand. We will address first the conspiracy count and then the substantive drug adulteration counts and decide whether the district court was correct to grant a new trial on all of them. Again, we review for an abuse of discretion.

A

The conspiracy count of the indictment against Sardesai and Striefsky alleged that defendants conspired to defraud the government by (a) making false and fictitious statements, (b) concealing and covering up material facts, (c) failing, with intent to commit fraud, to maintain adequate records, and (d) manufacturing and introducing adulterated drugs into commerce. This count only cites 18 U.S.C. § 371 and does not refer to any other statutes by number.⁷

⁷ 18 U.S.C. § 371 (1995) provides, in part:

If two or more persons conspire either to commit any offense against the United States, or to defraud the United States . . . 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.

The government argues that the conspiracy conviction on count one was not tainted by the Gaudin error because materiality is not an element of conspiracy to defraud the government under 18 U.S.C. § 371. According to this analysis a person can be guilty of conspiring to defraud the government through false statements and deception even if the false statements are immaterial; the statements are merely a means to the end of defrauding. That same person may be not guilty of making false statements to the government because the statements are immaterial.

Sardesai and Striefsky argue that the government's position might have merit if the conspiracy count in the indictment had referred solely to the conspiracy to defraud language of § 371. The appellees point out that the government chose instead to rely explicitly on reference to the false statement violations which were also at issue in counts four through seven when it drafted the conspiracy count. The appellants point out that the government even chose to use the word "material" in one clause of the conspiracy count of the indictment which refers to the false statements. Therefore the vacation of the false statement verdicts requires vacation of the conspiracy charge, because the jury was not allowed to decide whether the false statements which formed a part of the conspiracy were in fact material.

There is considerable dispute among our sister circuits as to whether a new trial for an 18 U.S.C. § 371 conspiracy, which incorporates false statement charges in violation of § 1001, is required when the substantive § 1001 counts themselves require retrial. Most, it appears, have adopted the position advocated by the government in this case. See United States v. Toussaint, 84 F.3d 1406 (11th Cir. 1996) (holding that materiality is not an element of § 371 even when the charge is conspiracy to make false statements). See also United States v. Wapnick, 60 F.3d 948, 953 (2d Cir. 1995) (holding, in a case concerning different substantive offenses than the instant case, that § 371 conspiracy to defraud government is not dependent on any substantive charge but can stand alone), cert. denied, 116 S. Ct. 1672 (1996). But see United States v. Jerke, 896 F. Supp. 962, 965 (D. S.D. 1995), aff'd sub nom United States v. Raether, 82 F.3d 192 (8th Cir. 1996) (reversing a § 371 conviction because it relied on a substantive § 1001 count as an object of the conspiracy).

We decline to reach whether reversal in such cases is always required. Instead we find that, in this case, the district court did not abuse its discretion by granting a new trial on the conspiracy count. We are persuaded by the fact that, although the conspiracy invoked only § 371 by number, the indictment referred to the false statement violations as objects of the conspiracy as well as to other substantive violations which were not themselves erroneous. It is impossible to discern which of these underlying offenses the jury found when it convicted Sardesai and Striefsky of conspiracy. We have discovered no precedent in which we have reversed a district court's decision to grant a new trial as an abuse of discretion. We therefore defer to the district court's assessment that a new trial is required in the instant case.⁸

⁸ The government argues that the conspiracy charge should be treated differently from the § 1001 charge discussed above because, although the defendants did object to the failure to instruct on materiality in the latter, they did not object to the instruction on conspiracy which included no mention of materiality. We do not agree for two reasons. First, Sardesai and Striefsky challenge the conspiracy charge in this appeal because it was bootstrapped onto the illegitimate false statements count. It is not at all clear that a separate objection to the instructions for the conspiracy charge would be required, as there was a proper objection to the underlying substantive count.

Second, we believe that United States v. McBride, 862 F.2d 1316 (8th Cir. 1988), supports our conclusion to affirm the grant of the new trial on all counts. In McBride, the district court granted a new trial because errors to which the defendant had not objected had so infected the trial as to, in the court's assessment, render it unfair. The Eighth Circuit acknowledged that it was within the district court's discretion to do so, even though the district court did not explicitly find that the errors had each been "plain errors" which would require reversal pursuant to Rule 52(b). We agree with this cogent analysis; we are not holding that the flaws in the conspiracy count are necessarily "plain error" which would require reversal by an appellate court even absent objection at trial. Instead, we are finding that the trial court's discretion pursuant to Rule 33 was not abused when it decided that a new trial was required. We find that "the trial judge, not an appellate court, can best weigh the errors against the record as a whole to determine whether those errors in the conduct of the trial justify a new trial." Id. at 1320.

B

Finally, the government argues that even if the conspiracy count and the false statement counts require retrial, the convictions on counts two and three must nonetheless stand because they concern introduction of adulterated pharmaceuticals into interstate commerce and are completely unrelated to the materiality issue from Gaudin. Sardesai and Striefsky reply, and the district court found, that even the two substantive counts for adulterated drugs were tainted by the Gaudin error because the court gave a Pinkerton instruction which made the substantive counts dependent, to a degree, on the conspiracy count. The Pinkerton doctrine imposes vicarious liability on a conspirator for the substantive offenses committed by other members of the conspiracy if those crimes are reasonably foreseeable to that conspirator. Pinkerton v. United States, 328 U.S. 640 (1946).

At the trial of Sardesai and Striefsky the district court instructed the jury that it could convict a defendant of any substantive count if it found that that defendant was guilty of the conspiracy count and that the defendant could have reasonably foreseen that the charged substantive crime might be committed as a part of the conspiracy. This charge was legitimate and is not itself at issue in this case. However, as Sardesai and Striefsky argue and the district court found, the Pinkerton charge spreads the taint from the Gaudin error in the false statement charges to the other substantive charges of the indictment, including counts two and three which address adulterated drugs.

We therefore conclude that the district court did not abuse its discretion when it granted a new trial on the adulterated drugs substantive counts. The court specifically found:

Counts two and three, clearly because of the nature of the Pinkerton instruction that I gave in that case, reluctantly lead me to the same conclusion, that because I did tell the jury in this case that they could find the defendants guilty on those counts if any member of the conspiracy was guilty of those counts, that they could be found guilty of the substantive crimes even though they did not personally participate in the acts.

(Joint Appendix 99.) Although we might not, ourselves, reach the same conclusion as the district court regarding whether a new trial is required on each count for which Sardesai and Striefsky were convicted, we do not find that the district court abused its discretion in being cautious and preventing a clear Gaudin error from irrevocably affecting the rights of criminal defendants.

Because we are not persuaded that the district court abused its discretion in granting new trials to Sardesai and Striefsky pursuant to Rule 33, we

AFFIRM.