

PUBLISHED

**UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT**

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

v.

MICHAEL BARILE,
Defendant-Appellant.

No. 00-4926

Appeal from the United States District Court
for the District of Maryland, at Greenbelt.
Alexander Williams, Jr., District Judge.
(CR-99-225)

Argued: December 6, 2001

Decided: April 18, 2002

Before WILKINS and WILLIAMS, Circuit Judges, and
HAMILTON, Senior Circuit Judge.

Remanded with instructions by published opinion. Judge Williams wrote the opinion, in which Judge Wilkins and Senior Judge Hamilton joined.

COUNSEL

ARGUED: Joseph Sedwick Sollers, III, KING & SPALDING, Washington, D.C., for Appellant. Bryan Edwin Foreman, Assistant United States Attorney, Greenbelt, Maryland; Steven Neil Gersten, Trial Attorney, Office of Consumer Litigation, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellee. **ON**

BRIEF: Eugene M. Pfeifer, Jeffrey S. Bucholtz, KING & SPALDING, Washington, D.C., for Appellant. Stephen M. Schenning, United States Attorney, Greenbelt, Maryland, for Appellee.

OPINION

WILLIAMS, Circuit Judge:

Michael Barile was convicted of making materially false statements to the Federal Food and Drug Administration (FDA), in violation of 18 U.S.C.A. §§ 1001 and 2. Barile challenges his conviction on the grounds that the district court erred by excluding impeachment evidence and by not permitting opinion testimony regarding the materiality of Barile's false statements. Because we conclude that the district court erred in its determination that prior statements of a key government witness were consistent, we remand for further proceedings. We discuss each challenge in turn.

I.

Barile and three co-workers, Haryash Gugnani, Amrik Sikand, and Theodore Milo, were indicted by a grand jury in May 1999. All four defendants were employed by the Patient Monitoring Division of Datascope Corporation, a manufacturer of medical devices. Gugnani was president of Patient Monitoring, Sikand was vice president of operations, and Milo was director of engineering. Both Sikand and Milo reported to Gugnani. Barile, director of quality assurance and regulatory affairs, reported to Sikand. Datascope manufactures and markets a diverse range of medical devices, including cardiac monitors. A cardiac monitor measures the electric current traversing the heart and displays the data as an electrocardiogram (ECG). Cardiac monitors also measure numerous other vital signs. For example, the Datascope Passport Monitor, released in 1991, in addition to functioning as an ECG, also records heart rate, invasive blood pressure, non-invasive blood pressure, pulse rate, pulse oximetry, temperature, and respiration rate. While each cardiac monitor has multiple functions, it operates as a single unit, taking simultaneous readings of many vital signs. Datascope's cardiac monitors are complex, software-driven devices that are continuously being improved.

Under § 510(k) of the Federal Food, Drug, and Cosmetic Act, when Datascope makes an enhancement it must notify the FDA prior to marketing the product. *See* 21 U.S.C.A. § 360(k) (West 1999). The pre-market notification, known as a 510(k) submission, must demonstrate that the medical device is "substantially equivalent" to a device that is already on the market. *See* 21 U.S.C.A. § 360c(f)(1)(A)(ii) (West 1999). If a medical device is not substantially equivalent to a device already on the market, it is subject to the more rigorous pre-market approval process. *See* 21 U.S.C.A. § 360e(c) (West 1999). The trial below stemmed from allegedly false statements made on 510(k) submissions for three of Datascope's cardiac monitors.

First, on December 1, 1992, Datascope made a 510(k) submission for a 6000 Point of View Monitor (Point of View). This device was similar to the original Passport monitor, released in 1991, but added an "ST segment," which measures marginal changes in portions of the ECG to detect arrhythmic heartbeat patterns. This new component, which was a fully tested and approved feature, was purchased from a company called PCI. The FDA cleared the Point of View monitor on August 6, 1993, and Datascope began distributing it in March 1994. The second 510(k) submission, on January 11, 1994, was for an advanced version of the Point of View, called a 6000 Point of View Monitor with Cardiac Output (Point of View with Cardiac Output). The cardiac output component enhanced the Point of View monitor by adding a means of measuring the flow of blood through the heart. This submission later was withdrawn by Datascope. The third 510(k) submission was filed on May 31, 1994, and related to a monitor called Passport with ST. This monitor added the ST segment, which had already been incorporated into the Point of View, to its existing Passport monitor. This 510(k) submission also was withdrawn by Datascope.

The indictment charged Barile, Gugnani, Sikand, and Milo on four different counts related to the 510(k) submissions described above. Count one charged all defendants with conspiracy to defraud the FDA by making false statements in 510(k) submissions for all three monitors, a violation of 18 U.S.C.A. § 371 (West 2000). Count two charged all defendants except Milo with making false statements on 510(k) submissions for the Passport with ST monitor, in violation of 18 U.S.C.A. §§ 1001 and 2 (West 2000). Counts three and four

accused all defendants except Milo of violating 21 U.S.C.A. §§ 331(a) and 333(a)(2) (West 2000), and 18 U.S.C.A. § 2 (West 2000), by marketing an adulterated and misbranded medical device, the Point of View monitor. After a five-week trial, the jury acquitted Gugnani, Sikand, and Milo on all counts and Barile on counts one, three, and four. The jury convicted Barile on count two, which charged specifically that Barile represented in a 510(k) submission that a completed Passport with ST existed and that testing had been conducted on such a completed device when he knew that no such completed device existed.

Barile appeals from his conviction, challenging the district court's exclusion of impeachment evidence and expert testimony. We examine each challenge in turn, reviewing both of the district court's rulings for abuse of discretion. *See United States v. Gravely*, 840 F.2d 1156, 1163 (4th Cir. 1988) ("A district court's determination that a witness' prior statements are not inconsistent with trial testimony will not be reversed absent an abuse of discretion."); *United States v. Harris*, 995 F.2d 532, 534 (4th Cir. 1993) ("The exclusion of expert testimony under Rule 702 is within the sound discretion of the trial judge."). Under this standard, "[a] district court by definition abuses its discretion when it makes an error of law." *United States v. Stitt*, 250 F.3d 878, 896 (4th Cir. 2001) (internal quotation omitted).

II.

Barile first challenges the district court's exclusion of documents that he offered for the purpose of impeaching Marion Kroen, a witness for the Government. The documents with which Barile sought to impeach Kroen were created by the FDA's Office of Criminal Investigation (OCI) during its inquiry into the fraudulent statements in Datascope's 510(k) submission for the Point of View monitor. Specifically, Barile sought to introduce statements reflected in a Memorandum of Meeting, which detailed a July 26, 1995 meeting between OCI and FDA's Office of Device Evaluation (ODE) regarding the significance of the false statements, and a Report of Investigation, summarizing the OCI's investigation (collectively, the FDA documents). Our review of the record indicates that the district court ruled that the proffered impeachment evidence was not specifically inconsistent with Kroen's testimony. (J.A. at 531.) Moreover, the district

court concluded that Barile was attempting to admit the documents to reveal that after the July 26, 1995 meeting, the FDA decided to end its investigation of Datascope's 510(k) submissions, a fact that the district court, before trial, determined to be irrelevant. (J.A. at 529.) To analyze Barile's challenge to the exclusion of this impeachment evidence, we first must set forth the relevant points of dispute at trial.

At trial, Barile did not dispute that the tests reflected in the 510(k) submission for the Passport with ST were not conducted on a completed device. Instead, he asserted that any representation to the contrary on the 510(k) submission was not material. Barile contended that it is industry practice to make a 510(k) submission while a medical device is still being developed and therefore "[t]esting on parts of the device, which is known as component testing, is absolutely acceptable." (J.A. at 157-58.) Barile admitted that the tests were performed on components and, as Barile's counsel pointed out at oral argument, there was no allegation in count two that false test data were submitted, only that the 510(k) submission for the Passport with ST falsely represented that it reflected testing of a "completed" cardiac monitor. Falsely representing on a 510(k) submission that a completed medical device exists and purporting that tests were run on the completed device, when in fact they were conducted on the individual components, Barile argued, are not materially false statements or representations as required under 18 U.S.C.A. § 1001, which provides, in pertinent part, that "whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully . . . makes any materially false, fictitious, or fraudulent statement or representation . . . shall be fined under this title or imprisoned not more than 5 years, or both."

The Government, on the other hand, asserted that component testing is inappropriate for cardiac monitors. The key evidence supporting the Government's contention was the testimony of Marian Kroen, who works in the ODE and reviewed Datascope's 510(k) submission for the Passport with ST. When asked at trial whether the FDA would grant a 510(k) clearance based on component testing, she responded that "[g]enerally [component testing would suffice] when the components operate in a vacuum or don't have to talk to each other, like don't have this computer connection where they have to talk to each other and acknowledge each other's signals and handshake and pass

data." (J.A. at 516.) She went on to say that "[i]f the components can operate without each other, in a vacuum, then we can qualify them based on component testing. If they have to be integrated and operate as a unit, then it has to be tested as a unit." (J.A. at 516.) Kroen further testified that the multiple functions of cardiac machines are integrated and operate as a unit. (J.A. at 503-05.) Thus, according to Kroen's testimony, cardiac machines cannot be qualified based on component testing.

On cross-examination, Barile attempted to impeach Kroen's testimony with the FDA documents, which included the following statements regarding Datascope's Point of View cardiac machine: "ODE representatives indicated in a 510(k) submission it is acceptable to provide information resulting from component testing, prototype testing, and computer algorithms," (J.A. at 63), and "Marion Kroen, reviewer for the 6000 Point of View monitor, indicated no information presented at the meeting would have caused her to reconsider her original recommendation that the 6000 Point of View Monitor be considered substantially equivalent." (J.A. at 67.) Kroen was one of three ODE representatives at the meeting.

A.

Rule 613(b), which governs the admissibility of extrinsic evidence of a prior inconsistent statement by a witness, "first requires that a prior statement be inconsistent." *United States v. Young*, 248 F.3d 260, 267 (4th Cir. 2001). A prior statement is inconsistent if it, "taken as a whole, either by what it says or by what it omits to say affords some indication that the fact was different from the testimony of the witness whom it sought to contradict." *United States v. Gravely*, 840 F.2d 1156, 1163 (4th Cir. 1988) (internal citation omitted); Weinstein's Federal Evidence § 613.04[1] (2d ed. 2001) ("Any statement is inconsistent if under any rational theory it might lead to any relevant conclusion different from any other relevant conclusion resulting from anything the witness said.").

In this case, the district court ruled that the prior statements were not inconsistent for purposes of Rule 613(b). (J.A. at 537 ("I have not heard anything specific by way of an inconsistent position taken by this woman to justify any impeachment.")) The proffered prior state-

ments indicate that "it is acceptable to provide information resulting from component testing, prototype testing, and computer algorithms" on a 510(k) submission for an integrated cardiac monitor,¹ (J.A. at 63), and that Kroen did not "reconsider her original recommendation that the 6000 Point of View Monitor be considered substantially equivalent" after learning that its 510(k) submission contained test results from component testing. (J.A. at 67.) At trial, however, Kroen testified that component testing would not be accepted for devices that operate as integrated units and that cardiac machines were such units. The prior statement and the trial testimony, therefore, result in starkly distinct conclusions regarding the propriety of component testing for purposes of Barile's 510(k) submission. Kroen testified at trial that component testing is never appropriate for integrated cardiac monitors, yet the FDA documents state that component testing is appropriate for such devices. This inconsistency in plain terms is so palpable as to surpass the threshold for admissibility under Rule 613. *See Gravelly*, 840 F.2d at 1163 ("To be received as a prior inconsistent statement, the contradiction need not be in plain terms."). Thus, the district court erred by excluding the statements under Rule 613.²

Although we conclude that the prior inconsistent statements concerning component testing are admissible under Rule 613(b), our inquiry does not end because, "even if all the foundational elements of Rule 613 are met, a district court is not unequivocally bound to admit any or all extrinsic evidence of a prior inconsistent statement." *Young*, 248 F.3d at 268. "Rather, a district court may still exercise its discretion to exclude such evidence [under Federal Rule of Evidence 403] when its 'probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless pre-

¹Although this statement was made in the course of investigating the 510(k) submission for the Point of View, the parties have failed to identify any material distinction whatsoever between the Point of View cardiac machine and the Passport ST cardiac machine for purposes of the propriety of component testing on each.

²Another foundational element under 613(b) is that the inconsistent statement must have been made by the witness. We discuss the Government's contention that the statements in the FDA Documents do not belong to Kroen in part II.B, *infra*.

sentation of cumulative evidence.'" *Id.* (quoting Fed. R. Evid. 403). When we review a district court's decision to exclude evidence under Rule 403, we are required to "look at the evidence in a light most favorable to its proponent, maximizing its probative value and minimizing its prejudicial effect." *United States v. Russell*, 971 F.2d 1098, 1106 (4th Cir. 1992) (citation omitted).

Here, the district court evaluated the effect of Rule 403 with respect to the admissibility of the FDA documents and ruled that prior inconsistent statements within the documents would be admissible under Rule 403, except to the extent that the inconsistent statements revealed the FDA's decision to end its investigation of the Datascope Point of View monitor. (J.A. at 123-24 ("I'm not going to restrict the defense in their cross-examination of witnesses who may take the stand and who may be making a statement in court that is inconsistent with their previous position on an issue, if it is. The government certainly can't hide that.")) The district court then concluded that Barile's proffer was "simply an indirect way to get before the jury a preliminary determination made by the Food and Drug Administration." (J.A. at 537.) This analysis is untenable, however, because the prior statements indicating that component testing is appropriate on a cardiac machine do not reveal the FDA's decision to abandon its investigation of the Datascope Point of View Monitor.

To the extent that the district court excluded Kroen's prior statements on the ground that they revealed her opinion on materiality, (J.A. at 529 ("materiality is something the jury has to determine")), the district court erred because its determination was based on a faulty premise. Kroen's statements do not constitute a legal conclusion on whether any misrepresentations in the 510(k) submission were material. None of her statements in the FDA documents give an opinion on what constitutes a violation of 18 U.S.C.A. § 1001, or even what is legally required for a 510(k) submission. Instead, her statements provide evidence of what information she, as a 510(k) reviewer, considered significant. (J.A. at 67 ("Marion Kroen, reviewer for the 6000 Point of View monitor, indicated no information presented at the meeting would have caused her to reconsider her original recommendation that the 6000 Point of View Monitor be considered substantially equivalent.")); (*id.* ("ODE representatives further advised the fact that test results and software validation performed on components

was represented as being performed on a completed device in and of itself was not a significant misrepresentation.") Evidence of what information a reviewer of 510(k) submissions deems important does not constitute opinion testimony on the ultimate issue of materiality. See *United States v. Kingston*, 971 F.2d 481, 486 (10th Cir. 1992) ("Government witnesses are permitted . . . to testify as to whether certain truths, if known, would have influenced their decisionmaking for purposes of 18 U.S.C. § 1001."). Further, such evidence will greatly assist the jury in its determination of whether any false statements were material. See *Kungys v. United States*, 485 U.S. 759, 770 (1988) ("[A] concealment or misrepresentation is material if it has a natural tendency to influence, or was capable of influencing, the decision of the decisionmaking body to which it was addressed."). Moreover, inconsistent statements made by the Government's witness regarding what information she deems important when reviewing 510(k) submissions is far too probative to be outweighed by any danger of unfair prejudice or confusion. Kroen's statements in the FDA documents regarding what information in the 510(k) submission she deemed important, therefore, cannot be excluded on the basis that they invade the province of the jury.

Having concluded that the prior statements are inconsistent and that they are not excludable under the district court's Rule 403 analysis, we conclude that the district court should have admitted the prior statements as impeachment evidence, provided proper foundation can be established.³

³The Government asserts that any error that occurred when the district court excluded the impeachment evidence was harmless because Barile was able to ask Kroen about the propriety of component testing in general. (J.A. at 538.) A violation of the rules of evidence is harmless if it does not affect a "substantial right" of a party. See *Ross v. Saint Augustine's Coll.*, 103 F.3d 338, 342 (4th Cir. 1996). Barile's attorney was not permitted to phrase a question that would reveal the inconsistency between Kroen's testimony and her prior statements. Kroen testified that component testing is only acceptable for nonintegrated devices, but in her prior statements she indicated that component testing was acceptable for integrated cardiac monitors. Because Kroen's testimony at trial could lead a reasonable juror to conclude that Barile's 510(k) submission included a material falsification and because she was the reviewer of the

B.

Only prior inconsistent statements made by the witness are admissible as impeachment evidence under Rule 613(b). The Government argues that, even assuming the prior statements concerning component testing are inconsistent and are otherwise admissible under Rule 403, the statements cannot be used to impeach because they are the statements of a third party, OCI, which were not adopted by Kroen. See *United States v. Saget*, 991 F.2d 702, 710 (11th Cir. 1993) ("[W]e conclude that a witness may not be impeached with a third party's characterization or interpretation of a prior oral statement unless the witness has subscribed to or otherwise adopted the statement as his own."). The record lacks evidence upon which to determine whether Kroen has adopted the statements or whether they can be otherwise attributed to her because the Government did not object at trial to the admissibility of the prior statements on this ground.⁴ Thus, prior to conducting a new trial, the district court must determine whether the statements are reasonably attributable to Kroen.⁵ See *United States v.*

510(k) submission at issue, her testimony is key evidence of materiality. The proffered impeachment evidence called into question the credibility of Kroen's conclusions about the propriety of component testing in a 510(k) submission for an integrated cardiac monitor, the very issue critical to Barile's conviction. We therefore cannot conclude that the district court's error in precluding this impeachment evidence was harmless.

⁴Although the Government, in response to Barile's Motion for Release Pending Appeal, contended that "Barile was unable to lay the proper foundation to have the document admitted into evidence [because Kroen] testified that she was unfamiliar with the document and that she had never seen the document before," (Appellee's Opposition to Appellant's Motion for Release Pending Appeal at 6), our review of the trial transcripts fails to reveal that Barile was afforded an opportunity to lay the foundation for these materials. Indeed, the Government fails to provide any citation to support its version of Barile's cross-examination of Kroen. (Appellee's Opposition to Appellant's Motion for Release Pending Appeal at 6, 8.)

⁵Despite our conclusion that a remand is appropriate to develop the foundation of the prior statement, we analyzed the exclusion of the statement on the ground given by the district court in Section II.A., *supra*, because such a remand would be unnecessary if the district court had concluded correctly that the prior statement was otherwise inadmissible.

Branch, 970 F.2d 1368, 1370 (4th Cir. 1992) ("Before admitting evidence for consideration by the jury, the district court must determine whether its proponent has offered a satisfactory foundation from which the jury could reasonably find that the evidence is authentic.").

To the extent that the Government argues that because the prior statements were made by a third party they are inadmissible on hearsay grounds, its position is untenable. If Barile can lay a foundation for the statements, they are admissible over any hearsay objection because Kroen made them in her capacity as a government official on matters within the scope of her employment, and as such, the statements are of a party-opponent and therefore not hearsay. *See* Fed. R. Evid. 801(d)(2)(D).

III.

Barile also contends that the district court erred by excluding opinion testimony regarding the materiality of Barile's allegedly false statement. Robert Sheridan, a former director of ODE and author of the guidance document outlining requirements for 510(k) submissions, was prepared to testify that the misleading statements in the 510(k) submission for the Passport with ST were not material. The district court, however, ruled that Sheridan could not "testify as to intent of the law, application of the law, and anything that is within the province of the jury." (J.A. at 617.) The district court stated two reasons for restricting Sheridan's testimony. First, the district court ruled that Barile did not give proper notice under Federal Rule of Criminal Procedure 16 regarding Sheridan's opinion that any misrepresentations in the 510(k) submissions were not material. Second, the district court concluded that such testimony would not be helpful to the jury. We review both reasons below.

A.

Barile was required under Rule 16(b)(1)(C) to "disclose to the government a written summary of testimony that the defendant intends to use under Rule 702, 703, or 705 of the Federal Rules of Evidence as evidence at trial . . ." Fed. R. Crim. P. 16(b)(1)(C). "This summary shall describe the witnesses' opinions, the bases and reasons for those opinions, and the witnesses' qualifications." *Id.* Barile argues that his

counsel's letter of August 16, 2000, disclosed precisely the opinion testimony Sheridan intended to give: "Mr. Sheridan is expected to testify about the lack of materiality of alleged misrepresentations in the 510(k)s for the devices in the Indictment." (J.A. at 1061.) The district court ruled, however, that the August 16, 2000 letter did not give the government proper notice because it lacked specificity. Because the summary of Sheridan's testimony in the letter did not describe Sheridan's opinions beyond stating the conclusion he had reached and did not give the reasons for those opinions as required under Rule 16(b)(1)(C), we conclude, as the district court did, that the letter did not satisfy the rule. Upon finding a violation of Rule 16, the district court has discretion under the Federal Rules of Criminal Procedure to determine the proper remedy. *See* Fed. R. Crim. P. 16(d)(2); *United States v. Muse*, 83 F.3d 672, 675 (4th Cir. 1996) ("[A] trial court's decision as to the appropriate remedy [for a discovery violation] may only be reversed for abuse of discretion."). In this case, the trial court's remedy was to allow Sheridan to testify on the procedure, practice, and history of 510(k) submissions but not give his opinion regarding the materiality of the misrepresentations in the 510(k) submissions. Rule 16(d)(2) specifically allows the district court to "prohibit the party [who does not comply with the discovery rules] from introducing evidence not disclosed." *See* Fed. R. Crim. P. 16(d)(2). Because Barile did not give a proper summary of Sheridan's opinion on materiality, failing to give the bases and reasons for his opinions, the district court's exclusion of this portion of his testimony is an acceptable remedy under the rule.

B.

The district court also limited Sheridan's testimony on the ground that an expert's opinion regarding the materiality of statements on a particular 510(k) submission would invade the "province of the jury" and that such opinion testimony would "not assist the jury." (J.A. at 617.) Whether the excluded portion of Sheridan's testimony is admissible absent the district court's Rule 16 sanction is an issue that may arise again should a new trial be required on remand, and we therefore address it here.⁶

⁶We express no opinion on whether, in a second trial of the same defendant, a district court may limit the testimony of an expert witness for a Rule 16 violation in the previous trial.

Sheridan was permitted to testify about the procedure, practice, and history of 510(k) submissions and to respond to hypotheticals. The district court, however, did not allow him to testify "as to the particular 510(k) submissions in question and as to whether the submissions were reasonable or correct or in compliance with the law" (J.A. at 617.) He was prepared to testify that "the submissions were not unreasonable and did not contain materially misleading statements." (J.A. at 812.) We conclude that the district court's exclusion of all opinion testimony regarding the particular 510(k) submissions at issue was too broad to be justified on the ground that his testimony addressed an issue exclusively within the province of the finder of fact.

Federal Rule of Evidence 704(a) provides that, with certain exceptions not relevant here, "testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact." Rule 704(a) was designed specifically to abolish the "ultimate issue" rule. Fed. R. Evid. 704 advisory committee's notes. The rule, however, "does not lower the bars so as to admit all opinions." *Id.* "As a condition to admissibility under Rule 704(a), testimony on ultimate issues must be otherwise admissible under the Rules of Evidence." Weinstein's Federal Evidence § 704.03[1] (2d ed. 2001). Therefore, although opinion testimony that embraces an ultimate issue cannot be excluded under Rule 704(a), it may be excludable on other grounds. *See Torres v. County of Oakland*, 758 F.2d 147, 150 (6th Cir. 1985) ("The effect of Rule 704 is merely to remove the proscription against opinions on 'ultimate issues' and to shift the focus to whether the testimony is 'otherwise admissible.'"). As the advisory committee notes make clear,

[u]nder Rule 701 and 702, opinions must be helpful to the trier of fact, and Rule 403 provides for exclusion of evidence which wastes time. These provisions afford ample assurances against the admission of opinions which would merely tell the jury what result to reach, somewhat in the manner of the oath-helpers of an earlier day.

Fed. R. Evid. 704 advisory committee's notes.

Federal Rule of Evidence 702 provides that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert . . . may testify thereto in the form of an opinion or otherwise." Expert testimony on an ultimate issue is therefore excludable under Rule 702 if it does not aid the jury. *Kopf v. Skyrms*, 993 F.2d 374, 377-78 (4th Cir. 1993) (stating that while "[a]n opinion is not objectionable simply because it embraces an ultimate issue to be decided by the trier of fact, . . . such an opinion may be excluded if it is not helpful to the trier of fact under Rule 702") (internal quotation omitted). Expert testimony that merely states a legal conclusion is less likely to assist the jury in its determination.⁷ See *Woods v. Lecureux*, 110 F.3d 1215, 1220 (6th Cir. 1997) ("It is, therefore, apparent that testimony offering nothing more than a legal conclusion—i.e., testimony that does little more than tell the jury what result to reach—is properly excluded under the Rules."); Weinstein's Federal Evidence § 704.04[2][a] (2d ed. 2001) ("The most common reason for excluding opinion testimony that gives legal conclusion is lack of helpfulness The testimony supplies the jury with no information other than the witness's view of how the verdict should read."). The role of the district court, therefore, is to distinguish opinion testimony that embraces an ultimate issue of fact from opinion testimony that states a legal conclusion. This task, however, is not an easy one. See *Owen v. Kerr-McGee Corp.*, 698 F.2d 236, 240 (5th Cir. 1983) ("[S]eparating impermissible questions which call for overbroad or legal responses from permissible questions is not a facile one.").

The best way to determine whether opinion testimony contains legal conclusions, "is to determine whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular." *Torres*, 758 F.2d at 151; *Lecureux*, 110 F.3d at 1220 ("It is also appropriate to exclude 'ultimate issue' testimony on the ground that it would not be helpful to

⁷We note, however, that "in some circumstances, opinion testimony that arguably states a legal conclusion is helpful to the jury, and thus, admissible." Weinstein's Federal Evidence § 704.04[2][a] (2d ed. 2001) ("For example, the testimony may be helpful if the case involves a specialized industry such as insurance.") (citing *Peckham v. Continental Casualty Ins. Co.*, 895 F.2d 830, 837 (1st Cir. 1990)).

the trier of fact when the terms used by the witness have a separate, distinct and specialized meaning in the law . . .") (emphasis and citation omitted). To determine when a question posed to an expert witness calls for an improper legal conclusion, the district court should consider first whether the question tracks the language of the legal principle at issue or of the applicable statute, and second, whether any terms employed have specialized legal meaning. *See Torres*, 758 F.2d at 151 (concluding that "discrimination" has a specialized legal meaning in a Title VII case). In many circumstances, a problematic question can be more carefully phrased to elicit similar information yet avoid a response that constitutes a mere legal conclusion. *See id.* (explaining that a question asking whether an expert believed that an employer "discriminated" against the defendant could be rephrased to ask whether the expert believed the defendant's national origin "motivated" certain treatment). An example of a question that should be excluded is: "Did T have capacity to make a will?" Fed. R. Evid. 704, advisory committee's notes. This question, because it is phrased in broad terms and uses a word with a specialized legal meaning, "could readily elicit a legal as well as a fact based response." *Cf. Owen*, 698 F.2d at 240 ("A direct response, whether it be negative or affirmative, would supply the jury with no information other than the expert's view of how its verdict should read."). Some examples, on the other hand, of questions that need not be excluded are: "Did T have sufficient mental capacity to know the nature and extent of his property?" or "Did T have sufficient mental capacity to know the natural objects of his bounty?" or "Did T have sufficient mental capacity to formulate a rational scheme of distribution?" *See Fed. R. Evid. 704*, advisory committee's notes. The latter questions are more specific, do not invade the judge's province of instructing the jury regarding the meaning of specialized legal terms, and would elicit responses that give the jury insight into the bases for the expert's conclusion.

Sheridan was prepared to testify that "while there was a lack of clarity in the three 510(k) submissions in question, the submissions were not unreasonable and did not contain materially misleading statements." (J.A. at 811.) Sheridan's conclusion that the 510(k) submissions did not contain "materially misleading statements" arguably constitutes a legal conclusion because materiality has a specialized legal meaning, and it is therefore within the district court's discretion to exclude such testimony. *See United States v. David*, 83 F.3d 638,

640 n.2 (4th Cir. 1996) (defining materiality as having "a natural tendency to influence agency action or [capability] of influencing agency action.") (internal quotation omitted). In an attempt to elicit testimony on the materiality of statements in the 510(k) submissions without merely stating a legal conclusion, Barile's counsel attempted to ask Sheridan whether the submissions were "reasonable." (J.A. at 611.) Specifically, Sheridan was prepared to testify that "combining actual test data for the Passport device along with actual test data for the ST Segment, was unclear but not unreasonable." (J.A. at 811.) Opinion testimony on whether the data submitted in a 510(k) submission were reasonable would not merely state a legal conclusion and therefore is not excludable on the ground that it invades the province of the jury. Therefore, if the other rules of evidence have been met, including the requisites of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny, an expert opinion on whether various aspects of the 510(k) submissions on which Barile was indicted were reasonable is precisely the type of expert testimony that could assist the trier of fact in its determination.⁸ Fed. R. Evid. 702 ("If . . . specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert . . . may testify thereto in the form of an opinion or otherwise."). Assuming a retrial⁹ and absent any other basis for exclusion, the district court must exercise its discretion in considering the admissibility of Sheridan's testimony according to the framework established by Rules 403, 701, 702, and 704.

IV.

For the foregoing reasons, we conclude that the district court's stated ground for excluding the prior statements that Barile attributes to Kroen was incorrect and that, if the proper foundation can be laid, the erroneous exclusion of the statement affected Barile's substantial

⁸The district court ruled that Sheridan was qualified as an expert on the 510(k) submission process. We therefore reject the Government's contention that Sheridan is not qualified to give opinion testimony on ultimate issues of fact. There is no separate category of experts qualified to give "ultimate issue" opinions. See *Garret v. Desa Industries, Inc.*, 705 F.2d 721, 725 (4th Cir. 1983).

⁹We express no opinion on whether a new trial is required.

rights. If the district court determines that the statements are attributable to Kroen, it must grant Barile a new trial on count two. We must remand, however, to allow the district court to determine whether Barile can lay the foundation to demonstrate that the prior inconsistent statements are attributable to Kroen. We affirm the district court's exclusion of Sheridan's expert testimony under Federal Rule of Criminal Procedure 16(d)(2) but, in an analysis that is of potential relevance on remand, we find that the district court's limitation on the scope of his testimony on the ground that his testimony would not be helpful to the jury was overbroad.

REMANDED WITH INSTRUCTIONS