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United States Court of Appeals
Tenth Circuit

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Elisabeth A. Shumaker
Clerk of Court

PUBLISH

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff - Appellee,

v.

GEORGE JOHN SCHULTE, a/k/a John Schulte,

Defendant - Appellant.

No. 12-1239

Appeal from the United States District Court
for the District of Colorado
(D.C. No. 1:10-CR-00455-WYD-1)

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James C. Murphy, Assistant U.S. Attorney, (John F. Walsh, United States Attorney, Jaime A. Pena, Tim R. Neff, Assistant U.S. Attorneys, with him on the brief) U.S. Attorney's Office, District of Colorado, Denver, Colorado, for Plaintiff - Appellee

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Before **KELLY**, **McKAY**, and **O'BRIEN**, Circuit Judges.

O'BRIEN, Circuit Judge.

John Schulte appeals from his conviction on one charge of making a false statement to the government. *See* 18 U.S.C. § 1001(a). The charge alleged he made five

false statements during a voluntary interview with a United States Food and Drug Administration (FDA) agent while a search warrant was being executed at the offices of Schulte's employer, Spectranetics. Schulte claims two of the charged statements were not false, and therefore, cannot support the verdict as a matter of law. As to all five statements, he contends the government failed to prove both his intent to supply false information and the materiality of the statements to the government's investigation. We find no error and affirm.

BACKGROUND

Because the jury found Schulte guilty, we draw the facts from the evidence presented at trial in the light most favorable to the government. *United States v. Rufai*, 732 F.3d 1175, 1188 (10th Cir. 2013). Schulte was the Chief Executive Officer of Spectranetics, located in Colorado Springs, Colorado. The company primarily developed, manufactured, and marketed laser-based medical devices for use in procedures to remove blockage in coronary (heart) arteries and peripheral arteries (usually located in the patient's leg). Schulte was CEO from January 2003 through October 2008. During this time, Spectranetics sought to expand its product line to include devices made by other manufacturers which would provide a good fit with Spectranetics' products. To that end, Schulte and various other Spectranetics employees engaged in discussions with manufacturing companies in the United States and abroad.

Schulte's statements concerned two potential product expansions. The first was a guidewire designed to puncture through a severe artery blockage known as chronic total

occlusion.[1] The guidewire was designed and manufactured by a Japanese company, Future Medical Design, Ltd. (FMD). The second product was a balloon angioplasty catheter which was placed into an artery to expand its circumference to remove blockage. This product was designed and manufactured by Bavarian Medizin Technologie (BMT) in Germany.

A. FMD Guidewire

The negotiations between Spectranetics and FMD began in early 2005 and continued through the end of 2007. On at least three occasions, Schulte travelled to Japan to meet with FMD President, Tsuyoshi Terashi, and was given guidewire samples to bring back to the United States. The first visit occurred in July 2005, when Schulte received a prototype coronary wire. In late September/early October 2005, FMD shipped 50 guidewires of various specifications to Spectranetics. Although FMD's facilities and products were approved by Japanese authorities, they had not been approved by the FDA. Spectranetics planned to file the necessary information for such approval. Prior to filing for approval, however, Schulte asked Dr. Bruce Murphy, one of Spectranetics' advising physicians, to evaluate the guidewires after he had used them in patients. Spectranetics received a second shipment of ten peripheral guidewires in November 2005. These wires were also sent to Dr. Murphy for evaluation. It is undisputed Murphy placed FMD's wires in five patients in November 2005, although the parties dispute whether he knew

[1] A total occlusion of the artery is a blockage so severe that there is almost no blood flow beyond the blockage.

the product was not FDA-approved at that time. As reported to Schulte, the evaluation of the guidewire was very positive.

Schulte again visited FMD in August 2006. At that time, he was given samples of new peripheral guidewires to bring back with him for bench evaluation. Schulte's third visit to FMD's facilities occurred in the summer of 2007; he returned with samples of the newest design. Disagreements over pricing stalled negotiations, but even so, Spectranetics submitted a 510(k) request for approval of the guidewires with the FDA under the market name "Quick-Cross" guidewires.[2] (Appellant's App'x. Vol. V at 1920-21.) The FDA requested additional information to complete the approval process. When Spectranetics did not respond, the FDA considered the 510(k) application withdrawn. In October 2007, Spectranetics notified FMD it was cancelling further business dealings as of January 1, 2008.

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[2] As Ashley Boam, branch chief for the FDA's regulatory oversight of medical devices, explained, "[m]edical devices are usually classified as Class I, Class II or Class III, depending upon the level or risk that they pose to a patient." (Appellant's App'x Vol. III at 1066.) Class I is the lowest risk and would include "bandages, gauze [and] tongue depressors." (*Id.*) While Class I devices do not need FDA approval before they can be sold in the United States, Class II, moderate risk devices, and Class III, high risk devices require FDA approval prior to being sold in the United States. The devices at issue here are Class II. The common name of the FDA marketing application for Class II devices is "called a 510(k), which is taken from the section of the statute that describes that type of application." (*Id.* at 1068.) If a manufacturer wants to study a Class II device in human subjects and that device presents a significant risk to the patient, an investigational device exemption (IDE) . . . approved by FDA is needed before that device can be used in human patients." (*Id.*) Spectranetics did not apply for an IDE before Murphy used the wires in humans.

B. BMT Balloon Catheter

BMT manufactured medical devices for customers worldwide. Each device was made to the customer's specifications and then distributed under the customer's label. In 2007, Schulte began negotiations with Knut Sauerteig, BMT's managing director, regarding a line of BMT balloon catheters. These catheters were not distributed in the United States and the balloons under discussion were not approved in Europe or by the FDA. In October 2007, BMT sent Spectranetics a shipment to be used in clinical studies (used on human patients) prior to FDA approval. A Spectranetics employee developed a one-page form entitled "BMT PTA Catheter Product Evaluation" to record the physician's comments. (Appellant's App'x Vol. VIII at 3290.) By e-mail, Schulte approved the form stating, "[O]n the money. I look forward to the results." (Appellant's App'x Vol. III at 1282.)

At the end of October, Schulte and others met with Sauerteig in Washington D.C. They discussed the positive clinical evaluations from two physicians, Dr. Craig Walker and Dr. Robert Gallino. Again, there was contradicting testimony as to whether the doctors knew the devices were not approved in the United States. Negotiations between the two companies continued into 2008, but were formally terminated in January 2009.

C. Internal Investigation

On April 1, 2008, a former employee contacted the Spectranetics' employee hotline. He complained of unethical practices, including the use of unapproved German and Japanese devices in patients. Emile Geisenheimer, chairman of Spectranetics Board

of Directors, telephoned Schulte and told him about the allegations. Schulte denied any use of the devices in humans and stated he had ordered the devices only for bench testing in the United States. Spectranetics' Board hired an outside law firm to conduct an internal investigation to determine the truth of the allegations. Lawyers from the firm interviewed Schulte and other Spectranetics employees over the next few months and Schulte and Geisenheimer spoke frequently during the investigation. Schulte steadfastly maintained the devices had not been used in human patients. In August 2008, Spectranetics' general counsel ended the Board's investigation.

D. FDA Search Warrant

In July 2008, three former employees and one current employee brought their allegations to the FDA. The employees provided internal company e-mails and the BMT evaluation forms as proof of Spectranetics' illegal conduct under Schulte's direction. FDA investigator Dan Burke was assigned to lead the investigation. The employees' information led to a search warrant which FDA executed on September 8, 2008.

Burke, along with 30-40 officers from the FDA and other federal agents, arrived unannounced at Spectranetics offices at approximately 9:15 a.m. The first hour was "chaotic." (Appellant's App'x Vol. V at 2257.) After immediate business concerns were addressed, Schulte and other key employees agreed to be interviewed. Burke conducted Schulte's interview in the presence of Special Agent Rob Cruz and Spectranetics' corporate counsel. Although Cruz and general counsel were both called out of the interview at certain times, they were present for much of the questioning. According to

Burke's testimony, Schulte said: he was never supplied FMD guidewires while in Japan and did not physically carry guidewires with him when he returned to the United States; he was not aware his staff or consultants provided FMD guidewires to Bruce Murphy for use in human patients; he never physically provided BMT balloons to Dr. Robert Gallino or Dr. Craig Walker for use in human patients; and when asked if "this testing [was] done by rogue employees," Schulte said, "I don't know." (Appellant's App'x Vol. V at 2221, 2223-24, 2225, 2227.) When shown the BMT evaluation forms with the testing results, Schulte said "he had never seen the forms before." (*Id*. at 2225-26.)

Because Burke did not feel Schulte was being truthful, he provided Schulte an advisement form containing the language of 18 U.S.C. § 1001(a) which states, in relevant part:

> [W]hoever, 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 [and] imprisoned not more than 5 years. . . .

This was followed by a sentence reading: "I have read and understand the provisions and penalties of this law." (Appellant's App'x Vol. VIII at 3281.) Schulte read the form and signed it. He told Burke he did not want to change any of his statements.

Later that day, Schulte called Chairman Geisenheimer. Schulte was "distraught" and said he had been reviewing his e-mails and realized his statements to the FDA agents were not accurate. (Appellant's App'x Vol. VI at 2341.) Geisenheimer told him to immediately contact the federal agents to correct the record and to get his own lawyer.

Geisenheimer testified "it was incredible to me that one needs to review their e-mails to know whether they were knowledgeable of facts." (*Id*. at 2341.) According to Geisenheimer:

> Schulte's statements about those balloons and wires changed from not having any knowledge of it to certainly believing that they were never used in humans, to acknowledging that they were imported, and if anything, this was a misdemeanor, that the doctors knew about it, that . . . senior colleagues, executives of the company knew about it, and it's common in the industry because these were low technology devices, et cetera.

(*Id*. at 2358-59.) Geisenheimer, however, said the use of unapproved devices was not common in the industry; he had "never encountered it before in [his] 40 years in the medical device industry." (*Id*. at 2359.)

E. Schulte's Corrections

Schulte, through his attorneys, provided three letters correcting his interview statements. On September 9, 2008, his attorneys faxed a letter to Burke. It said, in part: "In thinking about the questions you asked concerning guidewires, Mr. Schulte promptly went back to check his records. This further review has refreshed Mr. Schulte's recollection that in early July[] 2005, Mr. Schulte returned from FMD with a single demonstration sample." (Appellant's App'x Vol. VIII at 3304.) The second letter, sent on September 22, 2008, attached an e-mail chain showing Schulte's knowledge of the proposed BMT evaluation form. The letter said:

> Mr. Schulte believes Special Agent Burke showed Mr. Schulte the same or similar versions of this form, which had handwriting as though the forms had been filled out in whole or in part.

> To clarify, Mr. Schulte still does not believe he had ever seen the completed forms before the interview. . . . Based on Mr. Schulte's subsequent review of this matter, however, it appears he had seen an earlier version of the form which did not bear the handwriting on the forms Special Agent Burke displayed.

(*Id*. at 3305-06.) The third letter, dated January 16, 2009, was sent to the Assistant United States Attorney. It explained Schulte's files "suggest[ed] that Mr. Schulte brought a small number of FMD guidewires into the United States on two additional occasions," in August 2006 and early July 2007. (*Id*. at 3308.)

PROCEDURAL HISTORY

Schulte and others were charged in a twelve-count indictment alleging: (1) conspiracy to defraud the United States; (2) false statements; (3) introduction and receipt of adulterated and misbranded devices into interstate commerce; and (4) aiding and abetting. After 15 days of trial, the jury acquitted him on all counts except Count II, false statements. On that charge, the jury unanimously agreed Schulte knew at least one of the following statements he made was false:

> Statement One, Schulte told Special Agent Burke that he was never given FMD guidewires while in Japan and did not physically carry any with him when returning to the United States.
>
> Statement Two, Schulte told Special Agent Burke that the FMD guidewires provided to physicians were not provided for use in human patients.
>
> Statement Three, Schulte told Special Agent Burke that he was not aware that FMD guidewires were provided to [Dr. Bruce Murphy] by members of his staff or by [a consultant] for use inside human patients.
>
> Statement Four, Schulte told Special Agent Burke that he did not know that [Dr. Craig Walker] or [Dr. Robert Gallino] [was] supplied BMT balloons

> by employees to use inside human patients.
>
> Statement Five, Special Agent Burke showed Schulte a copy of the evaluation forms entitled "BMT PTA Catheter Product Evaluation," and Schulte told Special Agent Burke that he had never seen the forms.

(Appellant's App'x Vol. I at 101-02 (capitalization modified and numbering added).) Because neither party requested a special verdict form, the jury did not specify which statement or statements it unanimously found to be false.

Schulte filed a post-trial motion seeking a judgment of acquittal or a new trial. He claimed there was insufficient evidence to prove Statements Four and Five were false. He further argued there was insufficient evidence to show any statement was material to the investigation or that he knowingly made a false statement. The motion was denied.

DISCUSSION

Schulte contends the government failed to prove his intent to supply false information and the materiality of the information to the government's investigation. We disagree.

To convict Schulte under § 1001, the government must prove:

> First, the defendant made a false statement or representation to the government, specifically as detailed in Count Two of the Indictment.
>
> Second, the defendant made the statement knowing it was false.
>
> Third, the defendant made the statement willfully, that is deliberately, voluntarily and intentionally.
>
> Fourth, the statement was made in a matter within the jurisdiction of the Executive Branch of the United States.

> And [F]ifth, the statement was material to the United States Food and Drug Administration.

(Appellant's App'x Vol. VII at 3043-44.)

A. False Statement

1. Preservation

On appeal, Schulte argues Statements Four and Five were based "on a legally deficient theory of liability—one that violates both § 1001 and the First Amendment." (Appellant's Br. at 16.) The government claims Schulte did not raise this error below. Instead, he merely claimed there was insufficient evidence to prove these statements were false. Therefore, according to the government, our review must be for plain error. *United States v. DeChristopher*, 695 F.3d 1082, 1091 (10th Cir. 2012) ("Defendant did not raise this specific argument in his Rule 29 motion, meaning we review it only for plain error.").

We agree with the government. In his motion for acquittal or a new trial, Schulte argued the government *failed to prove* his statements were false. Regarding Statement Five, Schulte's argument to the district court consisted of the following sentence: "Because there is absolutely no evidence that Schulte had ever seen the completed, handwritten BMT Evaluation Forms, Statement Five was not false." (Appellant's App'x Vol. I at 249.) He made no mention of the First Amendment or any other constitutional argument. As to Statement Four, Schulte claimed, "Burke's subjective interpretation of what Schulte's responses to other questions meant cannot support proof of falsity beyond

a reasonable doubt." (*Id*. at 248). He never argued Statements Four and Five should not have gone to the jury because of a legal error.

The legal analysis of his argument to the district court varies significantly from his argument on appeal—and has significant consequences. If Statements Four or Five were merely unsupported by the evidence, Schulte's conviction will stand if there was sufficient evidence demonstrating any one of his remaining statements were false (and otherwise within the requirements of the statute). *See Griffin v. United States*, 502 U.S. 46, 56-57 (1991) (quoting *Turner v. United States*, 396 U.S. 398, 420 (1970) ("[W]hen a jury returns a guilty verdict on an indictment charging several acts in the conjunctive . . . the verdict stands if the evidence is sufficient with respect to any one of the acts charged."). On the other hand, if it was legal error to submit Statements Four or Five to the jury, then Schulte's conviction must be vacated as it could be based on a statement which did not qualify under the statute. *Griffin*, 502 U.S. at 59.

As the Supreme Court explained:

> Jurors are not generally equipped to determine whether a particular theory of conviction submitted to them is contrary to law – whether, for example, the action in question is protected by the Constitution, is time barred, or fails to come within the statutory definition of the crime. When, therefore, jurors have been left the option of relying upon a legally inadequate theory, there is no reason to think that their own intelligence and expertise will save them from that error. Quite the opposite is true, however, when they have been left the option of relying upon a factually inadequate theory, since jurors *are* well equipped to analyze the evidence.

Id.[3]

In his reply brief, Schulte argues he alerted the court to the "essential issue," and therefore, his failure to specifically define the error does not result in forfeiture. (Appellant's Reply Br. at 4.) However, we see nothing in Schulte's district court brief which would put either the district court or the government on notice of a claim of "legal error," as described by the Supreme Court in *Griffin*, as opposed to the failure to adduce sufficient evidence of falsity. Therefore, we review Schulte's claim of legal error for plain error. He must "demonstrate (1) error that is (2) plain, (3) affects substantial rights, and (4) seriously affects the fairness, integrity, or public reputation of judicial proceedings." *DeChristopher*, 696 F.3d at 1091.

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[3] The Supreme Court also distinguished legal error from insufficiency of the evidence as follows:

> In one sense "legal error" includes inadequacy of evidence – namely, when the phrase is used as a term of art to designate those mistakes that it is the business of judges (in jury cases) and of appellate courts to identify and correct. In this sense "legal error" occurs when a jury, properly instructed as to the law, convicts on the basis of evidence that no reasonable person could regard as sufficient. But in another sense – a more natural and less artful sense – the term "legal error" means a mistake about the law, as opposed to a mistake concerning the weight or the factual import of the evidence. . . . [W]e are using "legal error" in the latter sense.

Griffin, 502 U.S. at 59.

2. Legal Error – Fundamental Ambiguity

Whether the question itself is unable to legally support a perjury or false statement conviction depends on whether it contains a "fundamental ambiguity." *United States v. Strohm*, 671 F.3d 1173, 1178 (10th Cir. 2011). "We review claims that a question is fundamentally ambiguous de novo." *Id.* at 1179.[4]

> A question is fundamentally ambiguous in narrow circumstances. To qualify, the question must lack 'a meaning about which men of ordinary intellect could agree, nor one which could be used with mutual understanding by a questioner and answerer unless it were defined at the time it were sought and offered as testimony.' That is, the question itself is excessively vague, making it impossible to know—without guessing—the meaning of the question and whether a witness intended to make a false response.

Id. at 1179 (quoting *United States v. Farmer*, 137 F.3d 1265, 1269 (10th Cir. 1998)). "The purpose of the rule of fundamental ambiguity is three-fold, namely, to (1) preclude convictions grounded on surmise or conjecture; (2) prevent witnesses from unfairly bearing the risks of inadequate examination; and (3) encourage witnesses to testify (or at least not discourage them from doing so)." *Farmer*, 137 F.3d at 1269. "Fundamental ambiguity is the exception, not the rule. *Id.* "Given the nature of language, in hindsight,

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[4] While our precedent addresses perjury convictions, courts routinely apply the fundamental ambiguity analysis to analogous charges for various types of false statements. *See, e.g., United States v. Brooks*, 681 F.3d 678, 706 (5th Cir. 2012) (false natural gas price reporting), *cert. denied*, 133 S. Ct. 839 (2013); *United States v. Sarwari*, 669 F.3d 401, 407 (4th Cir. 2012) (false statement on passport application); *United States v. Mubayyid*, 658 F.3d 35, 61 (1st Cir. 2011) (false statement to FBI agent), *cert. denied*, 132 S. Ct. 2378 (2012); *United States v. Ahmed*, 472 F.3d 427, 433 (6th Cir. 2006) (false statement of federal employment application).

many questions could be susceptible to differing interpretations. Simply plumbing a question for *post hoc* ambiguity will not defeat a perjury conviction where the evidence demonstrates the defendant understood the question in context and gave a knowingly false answer." *Strohm*, 671 F.3d at 1178.

In other words, a fundamental ambiguity cannot be the basis for a false statement conviction because a person cannot knowingly give a false reply to a question that defies interpretation despite its context. Thus, the context of the question is "critically important." *Farmer*, 137 F.3d at 1269. The situation in *Farmer* is instructive. There, the defendant, while a witness at a pretrial hearing, had the following exchange with the prosecutor:

> Q. Prior to your coming to testify *here today*, *did you speak to anyone about your testimony here today*?
>
> A. No, just the attorney asked me if I would-you know, verifying that I would come.
>
> Q. When was that?
>
> A. Well, *I called the office this morning, which I didn't speak with him. Oh, I did too.* I spoke with an investigator, a federal investigator.
>
> * * * *
>
> Q. Have you talked to Mr. McMahon, the Defendant about your testimony *here today*?
>
> A. No.
>
> Q. When is the last time you talked to Mr. McMahon?
>
> A. I talked to him-well, *I believe it was yesterday*. I am not real sure. It was

> yesterday or the day before. He called and I talked to him briefly on the phone.

Id. at 1266-67 (emphasis added). In a later interview, she told an investigator she had spoken with McMahon about her testimony on the day prior to the pretrial hearing. She was charged and convicted of perjury based on her testimony at the pretrial hearing.

The defendant challenged her conviction based on the ambiguity of the prosecutor's questions. She claimed she understood the prosecutor's use of the phrase "here today" to refer to whether she had spoken with McMahon on the day of the pretrial hearing, and thus answered the question truthfully. *Id*. at 1267. Although we did not decide whether the question was fundamentally ambiguous or merely arguably ambiguous, we found it impossible to discern whether "here today" referred to either when she "talked" to the defendant or to her "testimony." *Id*. at 1270. The context of the exchange was the key to our decision to reverse her conviction. Read in its entirety, the context of the questions and answers was consistent with her understanding of the question, not the government's interpretation. *See id*. at 1270.

Considering Burke's questions "in light of the testimony as a whole," the questions leading to Statements Four and Five were not fundamentally ambiguous. *Id*. at 1269. Agent Burke testified as follows: after he and Schulte covered Schulte's background, they discussed the FMD project. Schulte said the FMD guidewires were not provided to physicians for use in human patients by members of his staff or by a consultant. Turning to the BMT project, Schulte said he was currently in negotiations

with a company in Germany. Burke asked Schulte if there were any BMT balloons on site. He replied there may have been at one time for "use in glass models." (Appellant's App'x Vol. V at 2224.) Burke continued:

> I asked him if he ever physically provided BMT balloons to Dr. Robert Gallino or Dr. Craig Walker for use in human patients, and he said that he had not. But he added that he recalled that they were possibly, those doctors were possibly at Spectranetics on site for use in glass models, to use those in glass models.
> . . . .
> I showed him the forms, and we went over the forms. He said he had never seen the forms before.
> . . . .
> I asked him . . . does this look like . . . these products were used in humans, and he said, yes, it did. He acknowledged that based on the responses, it looked like the balloons were in fact used in humans.
> . . . .
> He . . . again said he had never seen the forms before.
> . . . .
> He said that . . . other personnel were in charge of the BMT project. And then I asked him, well, then, was this testing done by rogue employees? And I remember him very distinctly saying I don't know.

(*Id.* at 2225-27.)

Burke explained he "didn't differentiate if [the form] was filled out or not filled out. It was the form. . . . [Schulte] said he had never seen it before." (*Id*. at 2234.) When again asked about the use of BMT balloons in human patients, Burke said:

> [B]ased on my questioning, particularly involving the BMT PTA catheter evaluation forms, . . . I asked him if the testing was done by rogue employees. And he said, I don't know. And so what was conveyed to me was that he did not know that Craig Walker and Rob Gallino were supplied these . . . BMT balloons by employees for use in human patients.

(*Id*. at 2237-38.)

Burke's testimony was not the only evidence establishing the context of the interview. Memorandums and notes of the interview were also presented. These notes reflect, prior to the questions about the evaluation forms, Schulte had affirmatively stated he had not provided the BMT balloons for use in patients. According to Cruz's notes:[5]

> Schulte was asked if BMT balloons were provided to doctors, and he claimed "No."
> Schulte was shown a[n] evaluation form used by SPECTRANETICS for doctors to fill out *and asked if he was aware of the form. He claimed "No he was not.*"

(Appellant's App'x Vol. VIII at 3288) (emphasis added).

Schulte claims Burke's testimony shows, as to Statement Four, he was never asked directly whether any employees had supplied balloons to Drs. Gallino or Walker. He was asked whether "rogue" employees had done the testing. Therefore, he truthfully replied he did not know. As to Statement Five, Schulte maintains because Burke did not distinguish between the completed and uncompleted forms, he truthfully stated he had never seen the completed forms. But this ignores the contextual evidence.

If the jury accepted Cruz's notes, whether Schulte had seen that particular form before was not the question. While Schulte's interpretation of the question may not be unreasonable, it changes the actual question from whether he was aware of "the form" to whether he was aware of "this completed form." And even accepting this interpretation, the evidence showing he had approved the form, and the later conversations discussing

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[5] Burke did not testify as to the specific question he asked Schulte when he produced the evaluation form.

the reactions of the doctors after using the BMT balloon shows he was "aware" of the completed form. Similarly, given Schulte's denials of any knowledge of the clinical use of the BMT balloons, Burke's use of the term "rogue" employee does not obfuscate the meaning of his question. In light of Schulte's previous statements, if an employee had initiated the testing it would necessarily have been a "rogue" employee.

Thus, the questions could be mutually understood by Burke and Schulte within the context in which they were asked. We do not diminish the importance of "clear, precise questioning" as a foundation for a false statement or perjury charge. *Strohm*, 761 F.3d at 1178. In this case, however, it was a question for the jury whether Schulte interpreted the questions as he claimed. *See Farmer*, 137 F.3d at 1269 ("[I]n most instances, the meaning of a prosecutor's question and the truthfulness of a defendant's answer are best left to the jury."). There was no error, let alone plain error in the district court's denial of Schulte's motions for acquittal and for a new trial based on fundamental ambiguity.

B. Sufficiency of the Evidence

Even if there was no legal error, Schulte argues the government failed: (1) to present sufficient evidence Statements Four and Five were false; (2) to prove any of his statements were made with intention of providing false information; and (3) to prove any statement was material to the FDA investigation. To determine whether evidence is sufficient to support a conviction, we review all the evidence in the light most favorable to the government to determine whether a reasonable jury might find the defendant guilty beyond a reasonable doubt. *United States v. Migliaccio*, 34 F.3d 1517, 1521 (10th Cir.

1994). Because his conviction will be affirmed if any one of Schulte's statements meets each element of the charge, for the sake of brevity we address only Statement Four.

1. Sufficient Evidence Schulte Knew Statement Four Was False.

Schulte maintains the government did not negate his reasonable interpretation of Burke's question. An arguably ambiguous question is one which contains more than one reasonable interpretation. *Strohm*, 671 F.3d at 1181. When a question is arguably ambiguous, "a witness can still intend, and in fact give, a response that was literally false." *Strohm*, 671 F.3d at 1181. We review a conviction based on an arguably ambiguous question to determine whether the government presented evidence sufficient to negate the defendant's alleged understanding of the question. *Id*.

Schulte relies on *United States v. Migliaccio*, where the government accused a doctor of "using incorrect medical terminology" in order to mislead a government agency to receive payment. 34 F.3d at 1523. The doctor argued the relevant medical terms and the reporting requirements were ambiguous, that his interpretations were reasonable, and his reasonable compliance therefore negated his intent to deceive. We said:

> In cases arising under 18 U.S.C. § 1001, which criminalizes making false statements to a government agency, the government bears the burden to negate any reasonable interpretations that would make a defendant's statement factually correct where reporting requirements are ambiguous. . . . It necessarily follows that, where the evidence supports a defendant's position, the jury must be instructed concerning reasonable interpretations of ambiguous requirements and the government's ensuing burden.

Id. at 1325 (citations omitted). We reversed and remanded for a new trial.

Schulte does not claim the jury instructions were flawed, but challenges the sufficiency of the evidence negating his reasonable interpretation of Burke's question. Burke asked if Schulte did not provide the balloons, was it done by rogue employees? Schulte said he didn't know. Schulte claims he answered truthfully because Burke only used the term "rogue employees" and Schulte did not remember any of his employees providing the BMT balloons to doctors at the time he answered the question. We find the evidence is sufficient for the jury to conclude he knew his answer was false.

As discussed above, there was an abundance of evidence contradicting Schulte's faulty memory. Numerous witnesses testified about their conversations with Schulte regarding the clinical use of the BMT balloons, including Sauerteig, who testified the shipment of balloons was sent because Schulte wanted to test them in clinical studies before reaching a supply agreement. Moreover, Schulte had been specifically questioned about the same issues during the recent internal investigation and had several conversations with Spectranetics' Board Chairman Geisenheimer on this subject. Finally, he had approved an evaluation form to assess physicians' reactions to the product. Geisenheimer testified that he found Schulte's forgetfulness incredible. It appears the jury agreed.

In addition, the term "rogue employees" was used only after Schulte stated he did not provide the balloons for clinical use. In the context of Burke's questions and Schulte's previous answers, "rogue" could only be understood to mean employees who

had acted without Schulte's permission and against the company's policies. Thus, unlike *Migliaccio*, the evidence sufficiently negated Schulte's explanation.

Schulte also claims his "prompt and voluntary recantations," precluded a finding he knowingly and willingly provided false statements to the FDA. (Appellant's Br. at 42 n.9.) According to Schulte, as he became aware of the inaccuracies in his statements to Burke, he corrected and clarified his statements. He asserts "[i]t is not plausible that Schulte would willfully give false information to the Government, only to turn around and correct those errors only days later." (*Id*. at 42.) However, even though Schulte testified he remembered the clinical use of the devices when he "corrected" his statements in September 2008, none of his "prompt recantations" included an admission he knew his employees gave the BMT balloons to the doctors at his direction. In sum, the record contains sufficient evidence to support the jury's determination that, beyond a reasonable doubt, Statement Four was deliberately false.[6]

2. Whether Statement Four Was Material to the Investigation

Schulte also maintains the government's evidence was insufficient to show his statements were material to the investigation. "[T]o establish 'materiality' under § 1001, the government must show that the statement had 'a natural tendency to influence, or [be] capable of influencing, the decision of the decisionmaking body to which it was addressed.'" *United States v. Gordon*, 710 F.3d 1124, 1144-45 (10th Cir.), (quoting

[6] Because we find the evidence sufficient to support his conviction, we need not address Schulte's lenity argument.

United States v. Gaudin, 515 U.S. 506, 509 (1995)) *cert. denied*, 134 S. Ct. 617 (2013). Materiality is a mixed question of law and fact. *Gaudin*, 515 U.S. at 511-12.

"Deciding whether a statement is 'material' requires the determination of at least two subsidiary questions of purely historical fact: (a) 'what statement was made?' and (b) 'what decision was the agency trying to make?'" *Id*. at 512. Schulte contends his statements were not material because Burke had already reviewed the e-mails and the decision to investigate Spectranetics had already been made. In addition, Burke had already decided who he wanted to interview. Thus, in Schulte's view, his statements did not have the capacity to influence any government decision.

This argument fails to account for the nascent quality of the investigation. As Burke testified, he had received information from the whistleblowers and was trying to confirm the information he received and learn the "scope" of the questionable activities. (Appellant's App'x Vol. V at 2229.) The FDA, charged with protecting citizens' health, was trying to ascertain the number and type of unapproved devices placed into human patients. Schulte's statements misdirected the focus of the investigation from a company policy soliciting clinical trials to the possible, but unknown activities of individual employees. *See Gordon*, 710 F.3d at 1145 (statement by attorney that he had no knowledge of potentially illegal conduct "could have influenced the agency's decision on how to craft its investigative focus"); *see also United States v. Oldbear*, 568 F.3d 814, 825 (10th Cir.2009) (holding that a false statement made to an FBI agent that the defendant had "no information" regarding the matter under investigation was "material"

under § 1001(a)(2) because the statement related to an issue important to the underlying investigation). "[F]or testimony to be material, it need not have an actual effect; it merely must be capable of influenc[e]." *See United States v. Hasan*, 609 F.3d 1121, 1140 (10th Cir. 2010) (quotation marks omitted). Given Schulte's position in the company and his ability to explain the purpose and use of the devices prior to FDA approval, the jury was provided sufficient evidence to find, beyond a reasonable doubt, Schulte's statements could have influenced the agency.

AFFIRMED.