NOT FOR PUBLICATION

In the
United States Court of Appeals
For the Eleventh Circuit

No. 23-13537

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

versus

CHARLES C. ADAMS,
CHARLES C. ADAMS, M.D., P.C.,
d.b.a. Full Circle Medical Center,

Defendants-Appellants.

Appeal from the United States District Court
for the Northern District of Georgia
D.C. Docket No. 4:18-cv-00191-WMR

Before NEWSOM, GRANT, and ABUDU, Circuit Judges.

PER CURIAM:

A jury found Dr. Charles C. Adams and his business, Dr. Adams M.D., P.C., (collectively "Adams") liable for violating the False

Claims Act ("FCA") by submitting 4,407 false claims to Medicare. Ultimately, the district court imposed $27,567,729 in damages. Adams now appeals. After a thorough review of the record and the parties' briefs, and with the benefit of oral argument, we affirm.

I. BACKGROUND

Medicare is a federal insurance program that provides coverage for individuals aged 65 or older or those who have end-stage renal disease. 42 U.S.C. § 1395c. It is administered by the Secretary of Health and Human Services through the Centers for Medicare and Medicaid Services ("CMS"). *Id.* § 1395kk. Medicare has a number of coverage rules that a provider must comply with for reimbursement. Applicable here, Medicare only covers items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." *Id.* § 1395y(a)(1)(A).

The Secretary has provided guidelines for determining when treatment is reasonable and necessary: it must be (1) safe and effective, (2) not experimental or investigational, and (3) appropriate given the prevailing standards of medical practice and the patient's medical needs and condition. CMS, Medicare Program Integrity Manual, Pub. 100-08, ch. 3, § 3.6.2.2. To determine whether a drug is safe and effective, CMS considers whether the drug has been approved by the Food and Drug Administration for the purpose for which it is being used. *See* CMS, Medicare Benefit Policy Manual, Pub. 100-02, ch. 15, §§ 50.4.1, 50.4.2. A drug is safe and effective when used for the indicated purposes on the drug's FDA label. *Id.* § 50.4.1. For an off-label use to be considered safe and

effective, it must be medically accepted according to medical literature and accepted standards of medical practice. *Id.* § 50.4.2.

From 2008 to 2015, Adams offered chelation therapy to various patients for heart conditions and atherosclerosis (the building of plaque inside the arteries). Chelation therapy is a treatment in which a provider infuses ethylenediaminetetraacetic acid ("EDTA") into a patient's bloodstream with an IV line. EDTA binds with heavy metals, such as lead, and is eventually excreted through urine. EDTA treatments traditionally have been used to remove heavy metal toxins from the body, particularly in cases of lead poisoning or lead encephalopathy. Adams himself described his use of chelation therapy for heart conditions and atherosclerosis as "experimental."

To aid in determining what services are reasonable and necessary, CMS issues national coverage determinations ("NCD") and local coverage determinations ("LCD"). 42 U.S.C. § 1395ff(f)(1)–(2). CMS has issued two NCDs on EDTA chelation therapy. The first states, "Chelation therapy is the application of chelation techniques [to] remov[e] unwanted metal ions from the body," and that "[t]he application of [EDTA chelation therapy] for the treatment and prevention of atherosclerosis is controversial." CMS, National Coverage Determination for Chelation Therapy for Treatment of Atherosclerosis, Pub. 100-03, ch. 1, pt. 1, § 20.21. Accordingly, the NCD determined that "EDTA chelation therapy for the treatment or prevention of atherosclerosis is not covered" by Medicare because "[t]here is no widely accepted rationale to explain the

beneficial effects attributed to this therapy," "[i]ts safety is questioned," and its use "is not widely accepted and practiced by American physicians." *Id.* The second NCD expanded the list of uncovered conditions for EDTA chelation therapy due to its "experimental" status, such that "atherosclerosis, arteriosclerosis, calcinosis, or [any] similar generalized condition not listed by the FDA as an approved use is not covered." CMS, National Coverage Determination for Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis, Pub. 100-03, ch. 1, pt. 1, § 20.22. The FDA label for EDTA states that the drug is labeled for the treatment of acute and chronic lead poisoning and lead encephalopathy.

Though Adams treated patients with atherosclerosis, to get reimbursed by Medicare, Adams submitted claims for these treatments under the guise of diagnosing metal-related problems, such as "poisoning by heavy metal" or "toxic effect of lead." He submitted 4,407 of these claims to Medicare and received over $1.1 million in return.

The government discovered this scheme and sued Adams and his practice under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, and for common law claims of payment by mistake and unjust enrichment. It sought civil penalties, including actual and treble damages. Following a trial, a jury found Adams liable for violating the FCA by knowingly presenting, or causing to be presented, 4,407 materially false claims for payment to Medicare, worth $1,109,743 in damages. The district court denied Adams's motions

for judgment as a matter of law and for a new trial and entered judgment for $27,567,729 after applying statutory treble damages under the FCA. Adams timely appealed.

II. STANDARDS OF REVIEW

We review evidentiary rulings by the district court, including a district court's exclusion of expert testimony, for abuse of discretion. *Knepfle v. J-Tech Corp.*, 48 F.4th 1282, 1293 (11th Cir. 2022). The abuse of discretion standard is deferential, as it "allows for a 'range of choice for the district court,' as long as that choice is not a 'clear error of judgment.'" *United States v. Beaufils*, 160 F.4th 1147, 1163 (11th Cir. 2025) (quoting *Rasbury v. IRS* (*In re Rasbury*), 24 F.3d 159, 168 (11th Cir. 1994)). We will also not vacate a district court's evidentiary ruling unless it impacted a party's substantial rights. *United States v. Kendrick*, 682 F.3d 974, 981 (11th Cir. 2012).

We review *de novo* a district court's denial of a Federal Rule of Civil Procedure 50(b) renewed motion for judgment as a matter of law, applying the same standards as the district court. *Skye v. Maersk Line Corp.*, 751 F.3d 1262, 1265 (11th Cir. 2014); *McGinnis v. Am. Home Mortg. Servicing, Inc.*, 817 F.3d 1241, 1254 (11th Cir. 2016). We will only reverse the denial of such a motion if the facts and inferences are so in favor of the losing party that a reasonable person could not arrive at the result the jury did. *Skye*, 751 F.3d at 1265. We evaluate the evidence and draw all logical inferences in favor of the non-moving party. *McGinnis*, 817 F.3d at 1254.

We review a ruling on a Federal Rule of Civil Procedure 59 motion for a new trial for abuse of discretion. *Id.* at 1255. "A

district court abuses its discretion if it applies an incorrect legal standard, follows improper procedures in making the determination, or makes findings of fact that are clearly erroneous." *Guevara v. Lafise Corp.*, 127 F.4th 824, 829 (11th Cir. 2025) (quoting *Chi. Trib. Co. v. Bridgestone/Firestone, Inc.*, 263 F.3d 1304, 1309 (11th Cir. 2001)). To grant a new trial, the district court must "find the verdict contrary to the great, and not merely the greater, weight of the evidence." *Williams v. City of Valdosta*, 689 F.2d 964, 973 (11th Cir. 1982).[1] We are particularly deferential when the district court does not upset the jury's verdict. *McGinnis*, 817 F.3d at 1255.

We review the limitations the district court places on a defendant's closing arguments for abuse of discretion. *United States v. Gaines*, 690 F.2d 849, 858 (11th Cir. 1982). Additionally, we review the refusal to give a particular instruction for abuse of discretion. *United States v. Morales*, 978 F.2d 650, 652 (11th Cir. 1992).

III. DISCUSSION

A. Exclusion of Expert Testimony

Before trial, the district court excluded the expert testimony of Dr. Eric Born, Adams's proffered medical expert, who was going to defend the medical necessity of Adams's treatments. Adams challenges Dr. Born's exclusion, arguing that the district court inappropriately weighed the evidence and prohibited Dr. Born from

[1] Adams misstates this standard throughout his briefing, which frequently argues that we should rule in his favor because he presented the "*greater* weight of the evidence." That is an incorrect recitation of our standard of review.

testifying because it found him unpersuasive after adopting the government's position.

Adams misrepresents the district court's ruling on this issue. The district court excluded Dr. Born's testimony because it found the testimony was not based on reliable principles and methods. *See* FED. R. EVID. 702; *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993); *United States v. Frazier*, 387 F.3d 1244, 1296 (11th Cir. 2004) (*en banc*). Indeed, while Dr. Born did not believe there was an established standard of care for when a provider should perform chelation therapy, he failed to identify any support for that position, and he acknowledged that major medical organizations disagreed with him. Not one of Dr. Born's ten references from his four-page expert report supported the use of chelation therapy in the manner he discussed. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.").

Further, Dr. Born expressed blind faith in Adams's judgment. Despite indicating that it was important to identify a patient's lead levels before starting chelation therapy, Dr. Born stated that he would still think Adams acted appropriately if he chelated a patient without measuring the amount of lead because he "trust[ed] Dr. Adams has the patient's best interest in his clinical decisions." In Dr. Born's expert opinion, "if Dr. Adams thought it was appropriate, it was." In this way, Dr. Born's testimony failed to identify supporting materials and relied, instead, on his trust in

Dr. Adams's intentions. The district court did not abuse its discretion in excluding his testimony for a lack of reliable methodology. *See Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1341 (11th Cir. 2010) (holding that it was not an abuse of its discretion for a district court to exclude expert testimony when the expert "had ample opportunity to identify all of the bases for his conclusions and to explain his methodology in reaching those conclusions" but did not do so); *Carrizosa v. Chiquita Brands Int'l, Inc.*, 47 F.4th 1278, 1322 (11th Cir. 2022) (same). At bottom, Adams falls far short of showing that the district court made "a clear error of judgment," so we affirm on this issue. *Beaufils*, 160 F.4th at 1163; *Rasbury*, 24 F.3d at 168.

B. Sufficiency of the Evidence on FCA Claim

Adams next challenges the sufficiency of the evidence on his FCA violations.[2] To prove liability under the FCA, the government must prove the defendant (1) made a false statement, (2) with scienter, (3) that was material, (4) causing the government to pay money. *United States ex rel. Bibby v. Mortg. Invs. Corp.*, 987 F.3d 1340, 1346 (11th Cir. 2021); 31 U.S.C. § 3729(a)(1)(A). All of these elements are easily met here.

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[2] Here and in the district court, Adams has made identical sufficiency of the evidence arguments for both his Rule 50(b) and Rule 59 motions. In denying the motions, the district court outlined the applicable facts and then applied each Rules' standards to them. Adams asserts that this was error. It was not. The district court did not apply the wrong standard, and it did not have to regurgitate the relevant evidence. We have reviewed both motions under the same factual account before, *see, e.g.*, *Thomas v. Broward County Sheriff's Office*, 71 F.4th 1305, 1312 (11th Cir. 2023), and we do so here.

A claim is false when it misrepresents the services provided or when a person fails to comply with statutory or regulatory requirements but nonetheless certifies they did. *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1299 (11th Cir. 2021). Adams falsely told CMS that his patients were suffering from the poisoning of heavy metals and lead, when in reality, he admitted that he "[n]ever treated anyone for heavy metal toxicity." The government's witness, Dr. Travis Olives, corroborated this after he reviewed 67 of the disputed claims and testified that no patients had acute or chronic lead poisoning, lead encephalopathy, or other heavy metal poisoning. In fact, while Adams would often order blood tests to see the lead levels of his patients, he would still give the patients chelation therapy when they had low levels or zero lead, and he would even begin chelation therapy before the results were available. Adams acknowledged that his use of chelation therapy was not FDA-approved. Contrary to Medicare's regulations, which Adams certified he was complying with, Adams used EDTA chelation therapy for experimental purposes—to treat atherosclerosis—and administered it for off-label uses. In submitting more than four thousand claims to Medicare for heavy-metal-related problems when the treatment was not for that purpose, a jury could reasonably conclude that Adams made false statements.

The "scienter" or knowledge requirement is satisfied when a person "has actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 749–50

(2023); 31 U.S.C. § 3729(b)(1). Before he began submitting claims to Medicare, Adams said on a recorded tape that Medicare "does not pay for chelation therapy." After he started submitting the claims as being related to the exposure to heavy metals, moreover, an internal auditor that Adams hired to review his records told him that the patients' medical records did not support their therapy. At a minimum, this evidence shows that Adams was "conscious of a substantial and unjustifiable risk that [his] claims [were] false, but submit[ed] the claims anyway," which is sufficient to establish the knowledge, or "scienter," requirement. *SuperValu*, 598 U.S. at 751.

Whether the claim was "material" depends on whether it had "a natural tendency to influence, or be capable of influencing, the payment or receipt of money." 31 U.S.C. § 3729(b)(4); *see Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 192–96 (2016). As discussed, Adams violated numerous rules—all of which proscribe coverage if not followed—in submitting his claims, because he used chelation therapy for experimental and off-label purposes. *See* National Coverage Determination for Chelation Therapy for Treatment of Atherosclerosis § 20.21 (proscribing coverage for chelation therapy used to treat atherosclerosis); National Coverage Determination for Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis § 20.22; (excluding coverage for chelation therapy used to treat other conditions); Medicare Program Integrity Manual § 3.6.2.2 (requiring that a drug's use be reasonable and necessary, meaning its use is not experimental); Medicare Benefit Policy Manual §§ 50.4.1, 50.4.2 (mandating that a drug be used for the purpose indicated on its

FDA-approved label). A federal contractor charged with identifying Medicare fraud testified that CMS would not have covered Adams's claims if it knew how Adams was actually using EDTA, which, again, violated the established standards. Because CMS would have denied coverage had it known the truth, the jury's conclusion that the government had presented sufficient proof of materiality is also well supported.

Considering the facts above, we hold that the evidence was sufficient for the jury to find Adams liable. Under Rule 50(b), the evidence is not so in favor of Adams that a reasonable person could not arrive at this result. *See Skye*, 751 F.3d at 1265. Therefore, Adams was not entitled to judgment as a matter of law. For the same reasons, under Rule 59, the verdict was not against the great weight of the evidence, so the district court did not abuse its discretion in denying Adams's motion for a new trial. *See Williams*, 689 F.2d at 973.

C. Sufficiency of the Evidence on Calculating Damages

Next, Adams challenges the sufficiency of the evidence to support the jury's finding of $1,109,743 in damages because, he asserts, the government did not prove that all 4,407 claims were false. However, there was sufficient evidence to support the jury's calculation of this award.

As noted, Adams submitted 4,407 claims for EDTA chelation therapy on patients he alleged had "poisoning by heavy metal" or were suffering from the "toxic effect of lead." During his

testimony, Adams himself admitted that he had never treated anyone for heavy metal toxicity, acute lead poisoning, or lead encephalopathy, and expert testimony supported that he also never treated anyone for chronic lead poisoning.[3] This testimony supports the finding that every one of his submitted claims was false.[4]

Adams also challenges the jury's inclusion of the cost of administering IVs in the damages award because, even though IVs are necessary for chelation therapy, those IVs could have been used for the administration of other drugs. However, Adams fails to put

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[3] While Adams argued that he thought everyone could benefit from chelation therapy because minor exposures to lead could slowly develop into chronic poisoning, his definition of chronic lead poisoning is not medically accepted. Chronic poisoning is more than just casual interactions with heavy metals. A medical toxicologist reviewed the files for 67 of Adams's patients and found that none had chronic poisoning. There certainly is no evidence in the record to suggest that Adams treated anyone for chronic lead poisoning as understood by the medical community.

[4] Adams contends that the government erroneously established damages by extrapolating the expert's statistical sampling of 67 (fraudulent) claims to all 4,407 of his claims. As discussed, the government relied on Adams's own testimony and accepted medical classifications, not extrapolation. Therefore, even though the right to recover in FCA cases may be established by circumstantial evidence, *United States v. Hangar One, Inc.*, 563 F.2d 1155, 1158 (5th Cir. 1977); *see infra* note 5, and other circuits have held that sampling and extrapolation are recognized methods of proof, *see, e.g.*, *United States v. Lahey Clinic Hospital, Inc.*, 399 F.3d 1, 18 n.19 (1st Cir. 2005); *United States ex rel. Absher v. Momence Meadows Nursing Center, Inc.*, 764 F.3d 699, 714 (7th Cir. 2014), we need not make a broad pronouncement about when such evidence is sufficient and when it might not be, as Adams has not shown the jury erred given the evidence presented.

forth any evidence establishing that those IVs *were* used for those purposes, or that he even presented this argument to the jury. In the only instance Adams points to when a patient received two IV infusions, he billed Medicare for two different IV lines. Given that Adams presented no evidence to the contrary at trial, and setting aside the question of whether Adams abandoned this argument, the jury could have reasonably found that the billed IVs were necessary for the chelation therapy. *See* 31 U.S.C. § 3731(d); *see generally Finnegan v. Comm'r*, 926 F.3d 1261, 1271 (11th Cir. 2019) ("The general rule is that we will not consider an issue raised for the first time on appeal.").

The evidence was sufficient for the jury to find that every one of his 4,407 statements to Medicare was false. Accordingly, under both Rule 50(b)'s and Rule 59's standards, we affirm the district court's decision. *See Skye*, 751 F.3d at 1265; *Williams*, 689 F.2d at 973.

D. Treble Damages

Finally, Adams argues that he should have been allowed to explain treble damages to the jury after the government said that Adams needed to "pay . . . back" the money he had obtained through his false claims. According to Adams, the government misled the jury into thinking that the damages award would be the $1.1 million he had fraudulently received, not treble damages as provided by the FCA.

However, the jury's role is to "return a verdict for actual damages, for which the court alone then determines any

multiplier, just as the court alone sets any separate penalty." *Cook Cnty., Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 132 (2003). Thus, the government did not "open the door" to a correction on damages, as Adams asserts. Additionally, as the Supreme Court noted, the court *alone* sets the treble damages. *Id.* We have held that "a judge has no general duty to inform the jury of the legal consequences of its verdict [because] the giving of such information might interfere with the jury's appraisal of the facts." *Ermini v. Scott*, 937 F.3d 1329, 1336 (11th Cir. 2019) (alterations accepted) (quoting *Beul v. ASSE Int'l, Inc.*, 233 F.3d 441, 450 (7th Cir. 2000)). For instance, we have held that, in the antitrust context, a district court should not advise the jury of the mandatory treble damages. *Pollock & Riley, Inc. v. Pearl Brewing Co.*, 498 F.2d 1240, 1242 (5th Cir. 1974).[5] Otherwise, informing the jury of such could influence the jury to adjust the damage award downward or find no liability, thwarting Congress's aim of deterring violations by imposing treble damages in the first place. *Id.* at 1242–43; *see also Lehrman v. Gulf Oil Corp.*, 500 F.2d 659, 667 (5th Cir. 1974) (holding that "the failure to give an instruction on treble damages [was] not reversible error" in an antitrust trial). In light of this authority, it was not an abuse of discretion for the district court to refuse to advise the jury about treble damages here. *See Beaufils*, 160 F.4th at 1163.

[5] Decisions issued by the former Fifth Circuit prior to October 1, 1981, are binding upon this Court. *Bonner v. City of Prichard, Ala.*, 661 F.2d 1206, 1210 (11th Cir. 1981) (*en banc*).

IV. CONCLUSION

For the foregoing reasons, we affirm the district court's judgment.

AFFIRMED.