

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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United States of America, ex rel. Kipp  
Fesenmaier,

Case No. 13-cv-3003 (WMW/DTS)

Plaintiffs,

**ORDER**

v.

The Cameron-Ehlen Group, Inc., and Paul  
Ehlen,

Defendants.

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This matter is before the Court on the parties' cross-motions for summary judgment and to exclude expert testimony. (Dkts. 624, 630, 639, 641.) In addition, the parties cross-appeal the magistrate judge's July 10, 2020 Order, which granted in part the parties' cross-motions for sanctions and denied Plaintiffs' motion to compel discovery. (Dkts. 699, 701.) For the reasons addressed below, the parties' motions for summary judgment are denied, the parties' motions to exclude expert testimony are granted in part and denied in part, and the magistrate judge's July 10, 2020 Order is affirmed in part and reversed in part.

**BACKGROUND**

Defendant The Cameron-Ehlen Group, Inc., doing business as Precision Lens (Precision Lens), is a distributor of intraocular lenses (IOLs) and other products related to ophthalmic surgeries. Defendant Paul Ehlen is the founder and majority owner of Precision Lens. Precision Lens provides ophthalmic supplies and equipment to ophthalmologists and facilities for use in ophthalmology procedures, including cataract surgeries. Relator

Kipp Fesenmaier worked for Sightpath Medical, Inc. (Sightpath), a corporate partner of Precision Lens, for approximately 15 years, including several years as a vice president of Sightpath.

Fesenmaier filed a qui tam complaint in November 2013 against Precision Lens and Ehlen.<sup>1</sup> Plaintiff United States of America filed an intervenor complaint against Precision Lens and Ehlen in February 2018. The intervenor complaint alleges that Precision Lens and Ehlen offered unlawful kickbacks and that, as a result of those kickbacks, false and fraudulent claims for payment were made to federal health care programs, including Medicare, in violation of the False Claims Act (FCA), 31 U.S.C. § 3729(a)(1), (a)(2).<sup>2</sup>

The parties now cross-move for summary judgment and to exclude expert testimony. Specifically, Plaintiffs move for partial summary judgment as to a subset of their FCA claims and to exclude the testimony of three of Defendants' proposed experts. Defendants move for summary judgment as to all of Plaintiffs' FCA claims and to exclude the expert testimony of two of Plaintiffs' proposed experts. The parties also cross-appeal the magistrate judge's July 10, 2020 Order, which granted in part the parties' cross-motions for sanctions and denied Plaintiffs' motion to compel discovery.

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<sup>1</sup> The Court subsequently dismissed Fesenmaier's claims against Sightpath and TLC Vision Corporation based on those parties' stipulation for dismissal pursuant to a settlement agreement.

<sup>2</sup> In an October 22, 2018 Order, the Court granted Defendants' motion to dismiss Plaintiffs' common-law claims for unjust enrichment and payment by mistake but denied Defendants' motion to dismiss Plaintiffs' FCA claims.

## ANALYSIS

### I. Cross-Motions for Summary Judgment

Plaintiffs move for partial summary judgment as to a subset of the alleged false claims at issue in this case, arguing that the undisputed facts establish FCA violations as to Medicare claims resulting from kickbacks Defendants provided to 18 physicians. Defendants move for summary judgment as to all of Plaintiffs' claims, arguing that Plaintiffs cannot prove falsity or causation—essential elements of their FCA claims.

Summary judgment is proper when, viewing the evidence in the light most favorable to the nonmoving party and drawing all reasonable inferences in that party's favor, there is "no genuine dispute as to any material fact" and the moving party is "entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Windstream Corp. v. Da Gragnano*, 757 F.3d 798, 802–03 (8th Cir. 2014). A genuine dispute as to a material fact exists when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). To defeat a motion for summary judgment, the opposing party must cite with particularity those aspects of the record that support any assertion that a fact is genuinely disputed. Fed. R. Civ. P. 56(c)(1)(A); *accord Krenik v. County of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995).

#### A. Plaintiffs' Motion for Summary Judgment

Plaintiffs move for partial summary judgment, arguing that the undisputed facts establish FCA violations as to Medicare claims resulting from kickbacks that Defendants provided to 18 physicians. Because Plaintiffs bear the burden of proving their claims, they

are entitled to summary judgment only if they establish every essential element of those claims based on undisputed facts in the record.

The FCA imposes liability on anyone who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval” to the United States. *United States ex rel. Strubbe v. Crawford Cnty. Mem’l Hosp.*, 915 F.3d 1158, 1163 (8th Cir. 2019) (quoting 31 U.S.C. § 3729(a)(1)(A)). “The FCA attaches liability, not to the underlying fraudulent activity, but to the claim for payment.” *Id.* (quoting *Olson v. Fairview Health Servs. of Minn.*, 831 F.3d 1063, 1070 (8th Cir. 2016)). The elements of an FCA claim are (1) the defendant presented a claim for payment to the United States, (2) the claim was false or fraudulent, and (3) the defendant knew the claim was false or fraudulent. *Olson*, 831 F.3d at 1070; *see also* 31 U.S.C. § 3729(a)(1)(A).

Here, Plaintiffs’ FCA claims are premised on Defendants’ alleged violations of the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b). An unlawful kickback in violation of the AKS may result in a violation of the FCA if a Medicare claim submitted to the United States “includes items or services resulting from a violation of” the AKS. 42 U.S.C. § 1320a-7b(g). Four elements comprise a violation of the AKS: (1) the defendant acted knowingly and willfully; (2) the defendant offered or paid any remuneration—including a kickback, bribe, or rebate—directly or indirectly, overtly or covertly, in cash or in kind, to any person; (3) the remuneration was offered or paid to induce such person to purchase, lease, order—or arrange for or recommend purchasing, leasing, or ordering—any good, facility, service, or item, or to refer an individual to a person for the furnishing of any item or service; and (4) such good, facility, service, or item

was one for which payment may be made in whole or in part under a federal healthcare program. *See* 42 U.S.C. § 1320a-7b(b)(2); *see also United States v. Nerey*, 877 F.3d 956, 968 (11th Cir. 2017); *United States v. St. Junius*, 739 F.3d 193, 210 n.18 (5th Cir. 2013).

There is no dispute that the fourth element of an AKS violation is satisfied here—namely, that the products Defendants sold to physicians are goods for which payment may be made under Medicare.<sup>3</sup> But the parties disagree as to whether undisputed facts establish the other three elements of an AKS violation: knowledge and willfulness, remuneration, and inducement. The Court addresses each element in turn.

### **1. Knowledge and Willfulness**

The “knowingly and willfully” element of an AKS violation requires a defendant to know that the conduct at issue was wrongful. *United States v. Jain*, 93 F.3d 436, 440–41 (8th Cir. 1996). A defendant need not have acted with the specific intent to violate the AKS. *Id.* In both civil and criminal contexts, “circumstantial evidence can demonstrate willfulness” and is “just as probative as direct evidence.” *United States v. Hirani*, 824 F.3d 741, 747 (8th Cir. 2016); *accord United States v. Starks*, 157 F.3d 833, 839 n.8 (11th Cir. 1998) (recognizing that the “furtive methods” by which remuneration had been paid were sufficient evidence “from which the jury could reasonably have inferred” that defendants acted willfully).

Plaintiffs contend that there is no genuine dispute that Defendants knew their conduct was wrongful. The alleged AKS violations occurred between 2006 and 2015.

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<sup>3</sup> The AKS defines “[f]ederal health care program” to include Medicare. 42 U.S.C. § 1320a-7b(f).

Ehlen testified that, as of 2006, “I don’t believe that I felt I could take [physicians] on trips and pay for them.” He also testified that, at all times between 2005 and 2015, he understood that it was wrongful to subsidize physicians’ travel and entertainment. The record reflects that, in 2007, Ehlen understood that Precision Lens was required to split travel costs with physicians or ask physicians to reimburse Precision Lens for the cost of any trip. During the relevant time period, Precision Lens maintained an account that it referred to as a “slush fund” or “secret fund” from which Precision Lens paid for travel involving physicians. And the record includes evidence that, on multiple occasions between 2002 and 2013, Precision Lens employees researched and sought legal advice about the AKS and other ethical guidelines that prohibit providing remuneration to physicians.

Defendants do not directly address the knowledge and willfulness element of an AKS violation or dispute the accuracy of the foregoing evidence. Instead, Defendants argue and cite evidence suggesting that they followed the advice they received regarding AKS compliance. But even accepting this evidence as true, the fact that Defendants may have sought and followed legal advice on certain occasions does not negate the undisputed evidence that Defendants knew, during the relevant time period, that providing remuneration to physicians was wrongful. Significantly, Defendants make no effort to refute Plaintiffs’ evidence of furtive conduct, such as Defendants’ express efforts to put “distance” between Precision Lens and the alleged misconduct and Defendants’ use of a “slush fund” or “secret fund” to pay for physicians’ travel.

For these reasons, if any violation of the AKS occurred, the undisputed evidence reflects that such conduct was committed knowingly and willfully.

## 2. Remuneration

To prove an AKS violation, Plaintiffs also must establish that Defendants “offer[ed] or pa[id] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person.” 42 U.S.C. § 1320a-7b(b)(2). “[A] remuneration is virtually anything of value.” *Shoemaker v. Cardiovascular Sys., Inc.*, 300 F. Supp. 3d 1046, 1049 (D. Minn. 2018) (internal quotation marks omitted). Although the relevant section of the AKS does not define “remuneration,” courts have concluded that a remuneration is the transfer of anything of value for less than its fair market value. *See, e.g., Bingham v. HCA, Inc.*, 783 F. App’x 868, 873 (11th Cir. 2019); *Miller v. Abbott Labs.*, 648 F. App’x 555, 561 (6th Cir. 2016).

Plaintiffs seek summary judgment as to remuneration Defendants allegedly provided to 18 physicians. Because the allegations are specific as to each physician, the Court evaluates the evidence of remuneration as to the alleged recipients either individually or in closely related groups of physicians.

### a. Dr. John Bormes and Dr. Curt Wischmeier

Plaintiffs present evidence that Defendants took Dr. John Bormes, Dr. Curt Wischmeier, and Dr. Wischmeier’s wife on a trip by private airplane to Napa Valley in September 2007. Precision Lens was invoiced \$15,506.82 for the flight and, in turn, invoiced each doctor \$500. Precision Lens also paid for a \$1,900 meal and did not seek reimbursement from either doctor. In total, Defendants incurred \$33,422.50 in expenses for the trip and billed the two doctors \$3,356 each.

Defendants do not dispute that the Napa Valley trip occurred. But Defendants counter by citing Dr. Wischmeier’s testimony that he and Dr. Bormes had “to pay our share of the trip.” Such vague testimony, however, is insufficient to demonstrate a genuine dispute of fact. *See Gannon Int’l v. Blocker*, 684 F.3d 785, 794 (8th Cir. 2012) (“Speculation and conjecture are insufficient to defeat summary judgment.”); *Moody v. St. Charles County*, 23 F.3d 1410, 1412 (8th Cir. 1994) (“A mere scintilla of evidence is insufficient to avoid summary judgment.”). Aside from Dr. Wischmeier’s vague testimony, Defendants cite no specific evidence contrary to the record evidence that these doctors each were billed less than 5 percent of the cost of a private flight, or that each doctor was billed \$3,356 for a trip that cost Defendants \$33,422.50. On this record, there is no genuine dispute that Dr. Bormes and Dr. Wischmeier each received something of value at a significant discount. As such, Plaintiffs have established that these doctors received remuneration.

**b. Dr. Timothy Cavanaugh, Dr. Scott McKnight, and Dr. Stephen Wiles**

Plaintiffs present evidence that Defendants flew Dr. Timothy Cavanaugh, Dr. Scott McKnight, and Dr. Stephen Wiles to a golf tournament in Georgia in April 2011 by private plane. Although Precision Lens paid \$19,632.20 for the flight, Precision Lens invoiced each doctor \$500.

Defendants do not dispute any of these facts, but instead argue that Ehlen thought charging each doctor \$500 “was fair, as he would have incurred the cost anyway, and [each doctor] could have flown commercial for \$300.” Defendants provide no legal basis, nor is the Court aware of any, for concluding that Ehlen’s subjective belief that he charged a



“fair” amount is relevant to whether a remuneration was paid. The undisputed evidence is that each doctor paid less than 3 percent of the total cost of a private flight, which demonstrates that these doctors received something of value at a significant discount. As such, Plaintiffs have established that Dr. Cavanaugh, Dr. McKnight, and Dr. Wiles each received remuneration.

**c. Dr. Elizabeth Davis**

Plaintiffs present evidence that, in February 2007, Defendants flew Dr. Elizabeth Davis by private plane to New York City for a three-day trip that included dining at two restaurants and attending a Broadway show. Precision Lens invoiced Dr. Davis \$750 for the entire trip. Dr. Davis does not recall who paid for what portions of the trip and thought Ehlen may have “treated” her to the Broadway show. In addition, in December 2012, Defendants paid more than \$1,800 for Dr. Davis’s birthday celebration at a steakhouse in Minneapolis.

Defendants do not dispute any of the foregoing facts. Instead, they counter with evidence that Dr. Davis socializes with Ehen often and they sometimes pay for each other. Although this evidence of Ehlen’s social relationship with Dr. Davis might be relevant to Defendants’ *intent* with respect to these payments, such evidence has no bearing on whether Dr. Davis received something of value for free or at a discount. It is undisputed that she did. As such, Plaintiffs have established that Dr. Davis received remuneration.

**d. Dr. Richard DeChamplain**

Plaintiffs present evidence that Defendants have flown Dr. Richard DeChamplain by private plane to South Dakota for hunting trips every December between 2006 and at

least 2018. According to Plaintiffs, there is no record of Defendants charging Dr. DeChamplain for any portion of these hunting trips until 2011, and Defendants did not charge Dr. DeChamplain for the private flights until 2012.

Defendants do not specifically dispute any of the foregoing facts. Instead, Defendants present evidence of Ehlen's social relationship with Dr. DeChamplain that involves the reciprocal exchange of gifts. Although this evidence of Ehlen's social relationship with Dr. DeChamplain might be relevant to Defendants' *intent*, such evidence has no bearing on whether Dr. DeChamplain received something of value for free or at a discount. It is undisputed that he did. As such, Plaintiffs have established that Dr. DeChamplain received remuneration.

**e. Dr. Kevin Flaherty and Dr. Matthew Hattenhauer**

Plaintiffs present evidence that Defendants flew Dr. Kevin Flaherty and Dr. Matthew Hattenhauer by private plane to ski in Colorado in January 2007 and January 2010. For the 2010 flight, Defendants were charged \$10,097. The doctors recall paying the cost of fuel for both flights, but there is no documentary evidence of what they paid or that they were invoiced by Defendants.

According to Defendants, these doctors testified that they paid Ehlen a "fair" amount for any flight and that they "split up, evenly, all the expenses," taking turns paying for items, and would "square up" at the end of the trip. Although Defendants' evidence that these doctors paid a fair portion for these trips is vague, Plaintiffs' evidence as to these trips is equally vague. Because neither party has presented specific evidence as to what proportion of these trips were paid for by Defendants without reimbursement from these

doctors, there are genuine disputes of material fact as to whether these doctors received remuneration.

**f. Dr. Michel Gelin**

Plaintiffs present evidence that Defendants flew Dr. Michel Gelin by private plane to South Dakota for hunting trips on multiple occasions between 2006 and 2011. Defendants did not invoice Dr. Gelin for the hunting trips until 2010 and did not invoice him for the private flights until 2011. Defendants invoiced Dr. Gelin \$316.77 for the round-trip private flights in 2011. On two occasions, including once in March 2006, Defendants also flew Dr. Gelin and a companion by private plane to attend Minnesota Wild hockey games in club-level seats and did not charge Dr. Gelin for the hockey tickets or flights.

Defendants' only response regarding Dr. Gelin is that he had hunted with Ehlen for many years and that Precision Lens had a "general practice" of charging physicians for tickets to sporting events. Neither of these assertions, even if true, refutes Plaintiffs' evidence that Defendants provided Dr. Gelin valuable trips and entertainment at little or no cost. As such, Plaintiffs have established that Dr. Gelin received remuneration.

**g. Dr. David Hardten and Dr. Patrick Riedel**

Plaintiffs present evidence that, in December 2007, Defendants flew Dr. David Hardten and Dr. Patrick Riedel, together with their wives, by private plane to Chicago. In connection with this trip, Precision Lens was charged \$5,862.44 for the flights, \$2,516.73 in hotel expenses, and \$575.18 for a limousine. The doctors testified that they did not pay for this trip. Within the following year, Defendants flew Dr. Riedel and his wife by private

plane to New York City for dinner and a show and flew Dr. Riedel by private plane to South Dakota for a three-day trip. Defendants charged Dr. Riedel nothing for the New York trip and \$200 for the South Dakota trip.

As to the Chicago trip, Defendants cite testimony that Dr. Hardten contributed \$2,400-worth of wine to the six traveling companions. But Defendants undisputedly paid more than \$10,000 in expenses for this trip. Thus, the testimony on which Defendants rely establishes that, on a pro-rata basis, Dr. Hardten and his wife *contributed* \$800 in value but *received* more than \$3,000 in value. And Defendants present no evidence that Dr. Riedel paid for any aspect of the trip. Nor do Defendants present any evidence or argument disputing that Dr. Riedel paid nothing for the New York trip and only \$200 for the South Dakota trip. As such, Plaintiffs have established that Dr. Hardten and Dr. Riedel received remuneration.

#### **h. Dr. Richard Lindstrom**

Plaintiffs present evidence that Defendants flew Dr. Richard Lindstrom and his son by private plane to South Dakota in September 2009. Precision Lens generated a \$4,008.16 invoice for Dr. Lindstrom in connection with this trip. But a contemporaneous internal Precision Lens email from Ehlen's assistant to Sightpath's CEO states that "[Ehlen] said you may want to pay for [Lindstrom's] invoice since he is the Medical Director for [Sightpath]" and asks whether Lindstrom's invoice should be "pa[id] out of the 'secret

fund.’ ” Plaintiffs contend that Precision Lens has no record of Dr. Lindstrom paying for the South Dakota trip.<sup>4</sup>

Defendants cite Dr. Lindstrom’s deposition testimony, in which he did not specifically recall receiving the \$4,008.16 invoice for the South Dakota trip but recognized the invoice as a type that he would have received and paid. On this record, there are genuine disputes of material fact as to whether Dr. Lindstrom received remuneration.

**i. Dr. Lorne Schlecht**

Plaintiffs present evidence that, in February 2007, Defendants flew Dr. Lorne Schlecht and his wife by private plane to New York City for a three-day trip that included dining at two restaurants and attending a Broadway show. Defendants present no evidence or argument in response. As such, Plaintiffs have established that Dr. Schlecht received remuneration.

**j. Dr. Jitendra Swarup**

Plaintiffs present evidence that Defendants flew Dr. Jitendra Swarup by private plane on four hunting trips between 2007 and 2012. In connection with these trips, Defendants paid for meals, hotel expenses, and both private and commercial flights. Some of these expenses were paid for out of Defendants’ “slush fund,” and an invoice pertaining to one of these trips includes the following notation made by Ehlen or at Ehlen’s direction: “VOID. Not paying invoice, taking out of slush fund instead[.]”

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<sup>4</sup> Plaintiffs also contend that Defendants paid for hunting trips for Dr. Lindstrom on four occasions but appear to cite no evidence to support these contentions. Although Defendants do not dispute that such hunting trips occurred, the record is insufficient to demonstrate undisputedly that these hunting trips constitute remuneration.

Defendants do not dispute that these hunting trips occurred or that Dr. Swarup did not pay for these trips. Instead, Defendants dispute Plaintiffs' characterization of the "slush fund." According to Defendants, this account was a "rebate" account that Precision Lens held on behalf of Sightpath and, therefore, it was Sightpath, not Defendants, that paid for Dr. Swarup's trips. Because there is evidence in the record to support each of the conflicting characterizations of this "slush fund" or "rebate" account, there are genuine disputes of material fact as to whether Dr. Swarup received remuneration from Defendants.

**k. Dr. Vance Thompson**

Plaintiffs contend that Defendants flew Dr. Vance Thompson and a guest by private plane to Green Bay for a football game in November 2009. But, as addressed below in Part III.A.1. of this Order, the magistrate judge properly excluded evidence pertaining to this trip as a sanction because the evidence was not timely disclosed during fact discovery. Because Plaintiffs rely solely on evidence that has been excluded, they have not established that Dr. Thompson received remuneration.

**l. Dr. Kurt Weir**

Plaintiffs present evidence that Defendants flew Dr. Kurt Weir and his guests by private plane to a club in Montana in 2006 and 2008. Plaintiffs contend that there is no record that Dr. Weir was invoiced for the 2006 trip. Defendants did not charge Dr. Weir for the 2008 trip, which included Dr. Weir's wife. In January 2009, Defendants flew Dr. Weir and his wife by private plane to a football game in Miami. Precision Lens was charged \$24,650.34 for the flight and did not invoice Dr. Weir. Defendants also flew

Dr. Weir and three other doctors to a golf tournament in Georgia in April 2011 by private plane. Precision Lens paid \$19,632.20 for the flight and invoiced each doctor \$500.

With respect to the 2006 Montana trip, deposition testimony indicates that expenses were shared among those who attended the trip. Similarly, deposition testimony from Ehlen and Dr. Weir suggests that Dr. Weir may have paid for his portion of the flight to Miami notwithstanding the lack of an invoice. Although this counter evidence is vague, so is Plaintiffs' affirmative evidence as to these trips. As such, there are genuine disputes of material fact as to whether the 2006 Montana trip or the January 2009 Miami trip were remuneration to Dr. Weir.

Defendants provide no evidence or argument as to the 2008 Montana trip, however. And as to the golf tournament, Defendants do not dispute any of the material facts. Instead, Defendants argue that Ehlen thought charging each doctor \$500 "was fair, as he would have incurred the cost anyway, and they could have flown commercial for \$300." Defendants provide no legal basis for concluding that Ehlen's subjective belief that he charged a "fair" amount is relevant to whether a remuneration was paid. The undisputed evidence is that Dr. Weir paid less than 3 percent of the total cost of a private flight, which demonstrates that he received something of value at a significant discount.

As such, Plaintiffs have established that Dr. Weir received remuneration.

**m. Dr. David West**

Plaintiffs present evidence that Defendants flew Dr. West by private plane to a club in Montana in 2006. Defendants paid for lodging, meals, and entertainment at no charge to Dr. West, and Dr. West could not recall whether he was charged for airfare. In

November 2009, Defendant flew Dr. West by private plane to Green Bay for a football game and did not invoice Dr. West for the flight. In February 2011, Defendants flew Dr. West and his son to the Super Bowl in Dallas. Precision Lens was charged \$13,886.83 for the flight to Dallas and did not invoice Dr. West for the flight.

With respect to the 2006 Montana trip, deposition testimony indicates that expenses were shared among those who attended the trip. And with respect to the trips to football games, Dr. West testified that he cannot remember whether he reimbursed Ehlen for those flights, but he thinks that he might have attempted to do so. Ehlen also testified that he thought Dr. West might have been invoiced. Although this counter evidence is vague, so is Plaintiffs' affirmative evidence as to these trips, which does not necessarily establish that unreimbursed remuneration was provided. Consequently, there are genuine disputes of material fact as to whether Dr. West received remuneration.

#### **n. Summary of Remuneration Evidence**

In summary, Plaintiffs have established that Defendants provided remuneration to 12 doctors: Drs. Bormes, Wischmeier, Cavanaugh, Davis, DeChamplain, Gelinas, Hardten, Riedel, McKnight, Schlecht, Weir, and Wiles. However, genuine disputes of material fact exist as to whether Defendants provided remuneration to Drs. Flaherty, Hattenhauer, Lindstrom, Swarup, Thompson, or West.

### **3. Inducement**

To prove an AKS violation, Plaintiffs also must establish that the remuneration that Defendants offered or paid to a physician was intended “to induce such person” to purchase, lease, order—or arrange for or recommend purchasing, leasing, or ordering—



any good, facility, service, or item, or to refer an individual to a person for the furnishing of any item or service. *See* 42 U.S.C. § 1320a-7b(b)(2). “The AKS’s plain language thus makes it unlawful for a defendant to pay a kickback with the intent to induce a referral, whether or not a particular referral results.” *United States ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 665 (S.D. Tex. 2013). As such, courts treat the AKS’s inducement element as an intent requirement. *Id.* (collecting cases).

At least five federal appellate courts have held that an AKS violation exists if *one* purpose of the remuneration was to induce Medicare purchases, even if other legitimate purposes for the remuneration existed. *See, e.g., United States v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011) (collecting cases from the Third, Fifth, Ninth, and Tenth Circuits). In *Borrasi*, the Seventh Circuit rejected the defendant’s argument that inducement must be “the primary motivation behind the remuneration” because nothing in the text of the AKS supports such a requirement. *Id.* at 781–82. The United States Court of Appeals for the Eighth Circuit has not directly addressed this issue. But the weight of persuasive authority reflects that Plaintiffs need only prove that *one* of the purposes of the remuneration Defendants offered or paid was to induce Medicare purchases. And Defendants do not expressly dispute the applicability of this “one purpose” standard.

Plaintiffs cite evidence from which a factfinder *could* infer that one of the purposes of the remunerations Defendants provided to physicians was to induce improper referrals. Testimony reflects that Defendants provided trips and entertainment to physicians to develop important business relationships as part of their business model, and that Defendants knew that most of their business involved Medicare. Internal meeting minutes

from March 2009 reflect that Defendants intended to put “restrictions on marketing . . . including no: . . . Trips – will cancel hunting, fishing, etc. . . . Golf, sports tickets . . . Extravagant meals and meals for spouses,” but that Defendants would “monitor to see if this has an effect on sales.” Defendants’ sales representatives were directed to cancel trips “if you don’t have docs lined up or they drop out” and to ensure that certain benefits were going to “good customers.” And testimony from some physicians suggests that they perceived Defendants’ conduct as an attempt to gain or maintain business. Plaintiffs also contend that the timing of providing remunerations coincided with Defendants’ attempts to persuade physicians to purchase Defendants’ products, creating an inference that improper inducement was one purpose of the remuneration.

Even under the “one purpose” standard, however, there are genuine disputes of material fact that preclude summary judgment in Plaintiffs’ favor as to the inducement element. Ehlen testified that inducement was *not* his intent when inviting physicians to social events and on trips. It is undisputed that Defendants sought legal and ethical advice as to kickbacks, which could suggest an intent to comply with the AKS rather than to violate it. Defendants also cite evidence that, on at least some occasions, Defendants charged physicians for trips and other entertainment and believed that the rates they charged were fair. Some physicians complained that the amounts Defendants charged for trips were too high. Significantly, it is undisputed that many of the physicians who allegedly received remunerations had social relationships with Ehlen and his wife and that some of those relationships spanned years or even decades. Moreover, as described above, several physicians testified that they informally split costs for trips and entertainment, or

took turns paying for such expenses, and these physicians believed those costs had been evenly split.

In summary, the record includes evidence from which a factfinder reasonably could conclude that social courtesies and gift-giving among friends were the only purposes for the remunerations at issue, and that Defendants had no intent to induce improper Medicare referrals. Notwithstanding Plaintiffs' evidence to the contrary, a jury could disbelieve Plaintiffs' evidence and believe Defendants' evidence, especially given that much of the evidence of Defendants' intent depends on witness credibility and inferences. Because genuine disputes of material fact exist as to Defendants' intent with respect to their payment of remunerations, Plaintiffs' motion for summary judgment must be denied.

#### **B. Defendants' Motion for Summary Judgment**

Defendants move for summary judgment as to all of Plaintiffs' FCA claims. Because Plaintiffs have the burden to prove their claims, summary judgment in Defendants' favor is appropriate if Defendants can either (1) produce undisputed evidence negating an essential element of Plaintiffs' FCA claims or (2) establish that Plaintiffs lack evidence to prove an essential element of their FCA claims. *See Bedford v. Doe*, 880 F.3d 993, 996 (8th Cir. 2018). Here, Defendants argue that Plaintiffs lack evidence to prove two essential elements of their FCA claims: falsity and causation.

Whereas Plaintiffs' motion for summary judgment focused on the elements of the alleged underlying AKS violations, Defendants' motion focuses on the essential elements of an FCA claim. As addressed above, the FCA imposes liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or

approval” to the United States. *Strubbe*, 915 F.3d at 1163 (quoting 31 U.S.C. § 3729(a)(1)(A)). “The FCA attaches liability, not to the underlying fraudulent activity, but to the claim for payment.” *Id.* (quoting *Olson*, 831 F.3d at 1070). The elements of an FCA claim are (1) the defendant presented, or caused to be presented, a claim for payment to the United States; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent. *Olson*, 831 F.3d at 1070; *see also* 31 U.S.C. § 3729(a)(1)(A). Because a defendant can be liable either for submitting a false claim or for causing a false claim to be submitted, a plaintiff need not prove that the individual or entity that provided the kickback is the same individual or entity that submitted the false claim for payment. *See* 31 U.S.C. § 3729(a)(1)(A) (imposing liability on anyone who “causes to be presented” a false claim); *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 390 (1st Cir. 2011) (“The Supreme Court has long held that a non-submitting entity may be liable under the FCA for knowingly causing a submitting entity to submit a false or fraudulent claim . . .”).

The 93,032 Medicare claims at issue in this case fall into two categories: 47,122 “Professional Fee” Medicare claims and 45,910 “Facility Fee” Medicare claims. The nature of these two categories is undisputed. Professional Fee Medicare claims reimburse a physician for the physician’s services in completing a Medicare-covered medical procedure—here, cataract surgery. In contrast, Facility Fee Medicare claims reimburse costs incurred by the facility where the procedure was performed including, among other things, the costs of non-physician staff and surgical supplies such as those sold by Defendants. Defendants advance separate arguments as to the Professional Fee Medicare

claims and the Facility Fee Medicare claims, and the Court addresses each argument in turn.

### **1. Professional Fee Medicare Claims**

Defendants first assert that Plaintiffs lack evidence to prove that the 47,122 Professional Fee Medicare claims in this case resulted from any allegedly false or fraudulent conduct (*i.e.*, kickback). According to Defendants, because Professional Fee Medicare claims reimburse the cost of a physician's services rather than the cost of Defendants' products, Plaintiffs cannot prove that the Professional Fee Medicare claims were either false or caused by Defendants' conduct because these claims did not result from the sale of Defendants' products. For the reasons that follow, the law does not support Defendants' position.

In relevant part, the FCA requires Plaintiffs to prove that the Professional Fee Medicare claims at issue were "false or fraudulent." 31 U.S.C. § 3729(a)(1)(A). And the AKS statute, in turn, provides that "a claim that *includes items or services resulting from* a violation of this section constitutes a false or fraudulent claim for purposes of" the FCA. 42 U.S.C. § 1320a-7b(g) (emphasis added). It is undisputed that the Professional Fee Medicare claims in this case included services—namely, cataract surgeries. What *is* disputed is whether, assuming an AKS violation occurred, the cataract surgeries "result[ed] from" the AKS violation. The alleged AKS violations involve the sale of surgical supplies—namely, cataract lenses—used to perform cataract surgeries. Defendants do not dispute that cataract lenses are necessary components of a cataract surgery. If the sale of Defendants' surgical supplies is proved to have been the result of an AKS violation, it

defies logic to conclude that a Medicare claim seeking reimbursement for the related surgery did not also result from the AKS violation.

Defendants contend that Plaintiffs must prove that any kickbacks were the but-for cause of the false claims, namely, that the cataract surgeries would not have occurred—or Defendants’ products would not have been used in those surgeries—*but for* the alleged kickbacks. Relatedly, Defendants assert that Plaintiffs cannot prevail as to the Professional Fee Medicare claims unless they prove that the cataract surgeries were not medically necessary, because a medically necessary surgery would have occurred irrespective of any kickbacks.<sup>5</sup> As addressed below, Defendants provide no legal authority to support a but-for causation requirement, and the weight of persuasive authority belies Defendants’ argument.

The Eighth Circuit does not appear to have addressed this precise issue. But multiple courts, including at least one court within this Circuit, have rejected Defendants’ but-for causation argument in the context of FCA claims predicated on alleged AKS

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<sup>5</sup> To prove an FCA claim, a plaintiff also must prove that the claim for reimbursement at issue was *materially* false, in that the falsity was material to the government’s payment decision. *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002–03 (2016). Defendants do not expressly argue that proof of materiality is lacking here, but their arguments that the cataract surgeries underlying the Professional Fee Medicare claims “would have occurred anyway” implicate materiality. Any such argument would be unavailing, however. Multiple courts have persuasively concluded that an AKS violation, at least with respect to claims submitted after the 2010 amendments to the AKS, is *per se* materially false for purposes of an FCA claim. *See, e.g., United States ex rel. Goodman v. Arriva Med., LLC*, 471 F. Supp. 3d 830, 840 (M.D. Tenn. 2020) (collecting cases and concluding that “because 42 U.S.C. § 1320a-7b(g) states that a claim caused by an AKS violation ‘constitutes a false or fraudulent claim’ as a matter of law, it requires the courts to treat the question of materiality—just one element of that term—as resolved”).

violations. *E.g.*, *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 96–98 (3d Cir. 2018) (rejecting application of but-for causation to FCA claims predicated on AKS violation); *United States v. Teva Pharms. USA, Inc.*, No. 13 Civ. 3702 (CM), 2019 WL 1245656, at \*23 (S.D.N.Y. Feb. 27, 2019) (observing that “the FCA does not require the kickback to be the ‘but for’ cause”); *United States ex rel. Cairns v. D.S. Med., L.L.C.*, No. 1:12CV00004 AGF, 2017 WL 3781807, at \*4 (E.D. Mo. Aug. 31, 2017) (concluding that defendant’s but-for causation argument was “without merit”); *United States ex rel. Kester v. Novartis Pharms. Corp.*, 41 F. Supp. 3d 323, 332 (S.D.N.Y. 2014) (rejecting argument that FCA claims based on AKS violations include “a strict ‘but for’ causation requirement”); *see also Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) (favorably citing Third Circuit’s discussion of causation in *Greenfield*). In contrast, Defendants cite *no* case in which a court has held that an AKS violation must be the but-for cause of a false claim.

The cases on which Defendants rely are inapposite. Although the basis for Defendants’ causation argument is the statutory text of the AKS, only one of the cases on which Defendants rely for this argument involved the AKS. *See United States ex rel. King v. Solvay Pharm., Inc.*, 871 F.3d 318, 331–32 (5th Cir 2017). The *King* decision did not address causation, however, because the Fifth Circuit concluded that the plaintiffs lacked proof that a kickback had even occurred. *Id.* And none of the other cases on which Defendants rely for their causation argument involved the AKS. *See Burrage v. United States*, 571 U.S. 204, 210 (2014) (involving Controlled Substances Act, not AKS or FCA); *United States v. Luce*, 873 F.3d 999, 1014 (7th Cir. 2017) (involving FCA claims that did

not arise from an AKS violation, and nonetheless rejecting a but-for causation requirement, observing that “an increasing number of our sister circuits have adopted expressly proximate causation as a rule more compatible with the [FCA’s] language and purpose”); *Cimino v. Int’l Bus. Machines Corp.*, No. 13-CV-00907 (APM), 2019 WL 4750259 (D.D.C. Sept. 30, 2019) (involving FCA claims that did not arise from an AKS violation). Defendants’ inapposite legal authority does not provide a sufficient basis for rejecting the weight of persuasive authority to the contrary. As such, Plaintiffs need not prove that a kickback was the but-for cause of a false claim submitted in violation of the FCA. The fact that cataract surgeries might have been medically necessary or might have occurred irrespective of any alleged kickback is insufficient to defeat Plaintiffs’ FCA claims predicated on Professional Fee Medicare claims.

In summary, Defendants have not demonstrated that the Professional Fee Medicare claims at issue in this case are categorically insulated from liability merely because these claims involved medical services provided by physicians as opposed to medical supplies provided by Defendants, or because these claims involved services that “would have occurred anyway.” Neither fact, even if true, precludes Plaintiffs from proving FCA liability as to the Professional Fee Medicare claims. Because Defendants’ arguments as to the Professional Fee Medicare claims are based solely on Defendants’ legally incorrect application of a but-for causation requirement, Defendants’ motion for summary judgment as to the Professional Fees Medicare claims is denied.



## **2. Facility Fee Medicare Claims**

Defendants also contend that Plaintiffs lack evidence to prove that the 45,910 Facility Fee Medicare claims in this case were caused by Defendants. Defendants concede that the allegedly false Facility Fee Medicare claims include reimbursement for products sold by Defendants. But according to Defendants, Plaintiffs nonetheless lack sufficient evidence to prove a causal connection between the alleged kickbacks and the Facility Fee Medicare claims. In addition, Defendants contend that Plaintiffs' use of a "taint" period to link alleged kickbacks to the Facility Fee Medicare claims is improper because it has no basis in the law and attempts to establish causation based on temporal proximity. The AKS and the FCA each contain language that courts have interpreted as a causation element that a plaintiff must prove, and the Court addresses each in turn.

### **a. Causation Under the AKS**

Because the AKS provides that a claim is false or fraudulent if it "includes items or services *resulting from*" an AKS violation, 42 U.S.C. § 1320a-7b(g) (emphasis added), a plaintiff must have "some record evidence that shows a link between the alleged kickbacks and the medical care received," *Greenfield*, 880 F.3d at 100. Defendants have not established that Plaintiffs lack evidence of such a link. To the contrary, Plaintiffs have presented evidence that the physicians who allegedly received kickbacks were responsible for choosing or recommending which lenses would be used in cataract surgeries. This evidence demonstrates a link between the alleged kickbacks and the medical care received.

Defendants argue that many of the physicians testified that the alleged kickbacks had no bearing on their purchase of Defendants' products because those physicians had a

“long-standing preference” for the products they purchased. This essentially is a but-for causation argument—namely, that these physicians would have purchased Defendants’ products anyway. Such evidence does not defeat Plaintiffs’ claims because, as addressed above, but-for causation is not a requirement of the AKS. If Plaintiffs prove that Defendants provided kickbacks to physicians in violation of the AKS, and those physicians subsequently performed cataract surgeries using products purchased from Defendants, there is a “link between the alleged kickbacks and the medical care received.” *See id.* This is true regardless of whether the physicians would have purchased Defendants’ products even without the kickbacks.

Defendants also argue that there is no evidence of increased utilization of Defendants’ products after the alleged kickbacks occurred. According to Defendants, the evidence “demonstrates the alleged kickbacks did not result in a statistically significant change in utilization of Precision Lens products.” But even if that were true, it is not relevant to whether a causal link exists between the alleged kickbacks and the cataract surgeries. Defendants provide no legal authority suggesting that a kickback must result in an overall increase in sales to the recipient of the kickback in order to establish a violation of the AKS. To the contrary, the AKS is violated whenever a remuneration is knowingly and willfully offered or paid with the intent to induce a purchase. 42 U.S.C. § 1320a-7b(b). A *resulting sale* is not an element of an AKS violation, nor is the kickback recipient’s subjective belief that he or she has been influenced. The AKS may be violated even if *no* sale occurs. *See, e.g., Parikh*, 977 F. Supp. 2d at 665 (“The AKS’s plain language thus makes it unlawful for a defendant to pay a kickback with the intent to induce a referral,

whether or not a particular referral results.”). And if a subsequent purchase does occur—even if *overall* sales of Defendants’ products stay the same or even *decrease*—any Medicare claim linked to that purchase is “false or fraudulent” as a matter of law under the FCA. *See* 42 U.S.C. § 1320a-7b(g). Although fluctuations in the purchase or utilization of Defendants’ products might be relevant as circumstantial evidence of Defendants’ intent to induce purchases (or lack thereof), it is not relevant to whether there is a link between the alleged kickback and the cataract surgeries. As such, Defendants’ arguments as to changes in utilization do not entitle Defendants to summary judgment.

Finally, Defendants challenge Plaintiffs’ reliance on a “taint” period to link alleged kickbacks to Medicare claims submitted within one year after a kickback was provided. Temporal proximity between a kickback and a Medicare claim, without more, is insufficient to establish the requisite causal link under the AKS. *Greenfield*, 880 F.3d at 99 (concluding that a plaintiff “may not prevail on summary judgment simply by demonstrating that [a defendant] submitted federal claims while allegedly paying kickbacks”). But here, Plaintiffs’ one-year “taint” period is not the sole evidentiary basis that Plaintiffs rely on to demonstrate a causal link between the alleged kickbacks and the Medicare claims.<sup>6</sup> Plaintiffs also rely on evidence that Defendants’ alleged kickbacks went to specific physicians who then purchased products from Defendants, performed cataract surgeries using Defendants’ products, and submitted claims to Medicare for reimbursement

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<sup>6</sup> Notably, the Third Circuit in *Greenfield* did not conclude that temporal proximity is irrelevant to causation under the AKS; rather, the court concluded only that temporal proximity, *without more*, is insufficient to prove causation. *See id.*

related to those surgeries. This evidence is sufficient to create a fact issue for a jury as to whether Plaintiffs have proven the requisite causal link.

For these reasons, Defendants have not demonstrated that summary judgment is warranted as to the AKS's causation element.

#### **b. Causation Under the FCA**

Independent of the AKS's "resulting from" causation requirement, the FCA separately requires a plaintiff to prove causation. The parties appear to agree, and this Court concludes, that the FCA requires Plaintiffs to prove proximate cause.

Under the FCA, a defendant may be liable either for directly submitting a false claim or for *causing* a false claim to be submitted. *See* 31 U.S.C. § 3729(a)(1)(A) (imposing liability on anyone who "causes to be presented" a false claim); *Hutcheson*, 647 F.3d at 390 ("The Supreme Court has long held that a non-submitting entity may be liable under the FCA for knowingly causing a submitting entity to submit a false or fraudulent claim . . ."). Here, Plaintiffs do not allege that Defendants submitted false claims to Medicare; rather, they allege that Defendants caused third parties to submit false claims to Medicare. Although the Eighth Circuit does not appear to have squarely addressed this causation element of an FCA claim, multiple circuits have applied a proximate-cause standard. *E.g.*, *Ruckh v. Salus Rehab., LLC*, 963 F.3d 1089, 1106–07 (11th Cir. 2020); *United States ex rel. Sikkenga v. Regence BlueCross BlueShield of Utah*, 472 F.3d 702, 714–15 (10th Cir. 2006), *abrogated on other grounds by Cochise Consultancy, Inc. v. United States ex rel.*

*Hunt*, 139 S. Ct. 1507 (2019).<sup>7</sup> “Under this analysis, a defendant’s conduct may be found to have caused the submission of a claim for Medicare reimbursement if the conduct was (1) a substantial factor in inducing providers to submit claims for reimbursement, and (2) if the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of defendants’ conduct.” *Ruckh*, 963 F.3d at 1107 (internal quotation marks omitted).

With respect to proximate causation, Defendants again argue that a mere temporal connection is insufficient. But as addressed above, Plaintiffs do not rely solely on a temporal connection. Rather, Plaintiffs rely on evidence from which a jury could conclude that proximate causation has been proven. There is evidence in the record that Defendants’ alleged kickbacks went to specific physicians who then purchased products from Defendants, performed cataract surgeries using Defendants’ products, and submitted claims to Medicare for reimbursement related to those surgeries. The record also contains evidence that the majority of Defendants’ products are used by ophthalmologists in cataract surgeries and that cataract surgery generally is a Medicare-reimbursed procedure. Indeed, Ehlen testified that “cataract lenses are used in cataract surgeries” and “those cataract surgeries are paid for, in large part, by Medicare.” Based on this and other similar evidence

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<sup>7</sup> In addition, the FCA provides for the recovery of “damages which the Government sustains *because of*” a defendant’s conduct. 31 U.S.C. § 3729(a)(1) (emphasis added). Courts similarly have interpreted this language to require a plaintiff to prove proximate causation with respect to damages. *Luce*, 873 F.3d at 1012–14. Although Defendants advance arguments as to damages in response to Plaintiffs’ motion for summary judgment, Defendants do not affirmatively seek summary judgment based on these arguments. As such, the Court does not address proximate causation as it pertains to damages.

in the record, a jury reasonably could conclude that Defendants’ alleged conduct—namely, the sale of its products in violation of the AKS—was both a substantial factor in inducing providers to submit Medicare claims for reimbursement and that the submission of Medicare claims was reasonably foreseeable as a natural consequence of Defendants’ conduct. *See, e.g., Teva Pharms.*, 2019 WL 1245656, at \*26 (explaining that a jury could find that fraudulent conduct was a substantial factor in inducing the submission of false claims when a physician submitted claims for reimbursement for surgeries involving defendant’s products while receiving illegal kickbacks from the defendant). As such, there is sufficient evidence to create a fact issue for a jury as to proximate causation.

Defendants also challenge Plaintiffs’ use of a one-year “taint” period following the payment of a kickback as an arbitrary “made-up time period” that precludes Plaintiffs from establishing proximate causation. Implicit in Defendants’ argument is that a one-year taint period is too long and, thus, too attenuated to demonstrate proximate cause. But Defendants offer no specific factual or legal basis for this argument. Nothing in the FCA or the AKS imposes a strict temporal cutoff such that a false claim ceases to be false if a certain amount of time has passed between the fraudulent conduct and the submission of the claim. Nor have Defendants demonstrated any factual basis for it being categorically unforeseeable that Defendants’ customers would submit Medicare claims for cataract surgeries involving Defendants’ products up to a year after the alleged kickbacks occurred. Moreover, Plaintiffs have presented evidence that substantiates their use of a one-year taint period, including evidence that physicians tend to stick with a lens choice for a long period of time, that Defendants tracked and compared sales on a year-to-year basis, and that many

of Defendants' alleged kickbacks were provided on an annual basis. As such, Defendants have not established that Plaintiffs' one-year "taint" period renders Plaintiffs' causation evidence insufficient as a matter of law.

In summary, Defendants have not demonstrated that Plaintiffs lack sufficient evidence to prove causation as to either the Professional Fee Medicare claims or the Facility Fee Medicare claims at issue in this case. As this is the only basis for Defendants' motion for summary judgment, Defendants' motion for summary judgment is denied.

## **II. Cross-Motions to Exclude Expert Testimony**

The parties also move to exclude the opinions and testimony of certain experts. The admissibility of expert testimony is an issue of law for the district court to decide and is governed by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. "An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." Fed. R. Evid. 703. "If experts in

the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted.” *Id.*

The proponent of expert testimony must prove its admissibility by a preponderance of the evidence. *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). “Rule 702 reflects an attempt to liberalize the rules governing the admission of expert testimony” and favors admissibility over exclusion. *Id.* (internal quotation marks omitted). Determinations as to the admissibility of expert testimony are within the district court’s discretion. *See Arkwright Mut. Ins. Co. v. Gwinner Oil, Inc.*, 125 F.3d 1176, 1182 (8th Cir. 1997).

A district court must ensure that testimony admitted under Rule 702 “is not only relevant, but reliable.” *Daubert*, 509 U.S. at 589. When making this reliability determination, district courts may evaluate whether the expert’s method has been tested or subjected to peer review and publication, the method’s known or potential rate of error, and the method’s general acceptance. *Presley v. Lakewood Eng’g & Mfg. Co.*, 553 F.3d 638, 643 (8th Cir. 2009) (citing *Daubert*, 509 U.S. at 593–94). These factors are not exhaustive, and a court must evaluate the reliability of expert testimony based on the facts of the case. *Id.* A district court also may consider “whether the expertise was developed for litigation or naturally flowed from the expert’s research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case.” *Sappington v. Skyjack, Inc.*, 512 F.3d 440, 449 (8th Cir. 2008) (internal quotation marks omitted). When weighing these factors, the district court must function as a gatekeeper to separate “expert opinion



evidence based on ‘good grounds’ from subjective speculation that masquerades as scientific knowledge.” *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001).

Expert testimony is not admissible if it is “speculative, unsupported by sufficient facts, or contrary to the facts of the case,” *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757 (8th Cir. 2006), such that it is “so fundamentally unsupported that it can offer no assistance to the jury,” *Minn. Supply Co. v. Raymond Corp.*, 472 F.3d 524, 544 (8th Cir. 2006) (internal quotation marks omitted). But disputes about the factual basis of an expert’s testimony ordinarily are issues of credibility—not admissibility—of the expert’s testimony. *Sappington*, 512 F.3d at 450; *see also Minn. Supply Co.*, 472 F.3d at 544. “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 509 U.S. at 596.

#### **A. Plaintiffs’ Motion to Exclude Expert Testimony**

Plaintiffs move to exclude the opinions and testimony of Defendants’ causation expert Scott Van Meter, Medicare program expert David Gregory, and rebuttal valuation expert David Duffus. According to Plaintiffs, these experts improperly intend to opine about issues of law and their opinions are not based on sufficient facts, data, or reliable principles or methods. The Court addresses each expert in turn.

##### **1. Van Meter**

Plaintiffs first move to exclude the opinions and testimony of Defendants’ causation expert, Scott Van Meter. Defendants intend to offer Van Meter to opine about causation,

using a “statistical regression analysis to determine whether the alleged kickbacks affected utilization” by comparing physicians’ use of Defendants’ products before and after the alleged kickbacks occurred. Plaintiffs argue that Van Meter’s opinions involve impermissible legal conclusions as to Defendants’ state of mind and that his regression analysis is unreliable and unhelpful.

Evidence is relevant if “it has any tendency to make a fact more or less probable than it would be without the evidence” and that fact “is of consequence in determining the action.” Fed. R. Evid. 401. Van Meter’s opinions pertain to the causation and intent elements of the AKS and the FCA. As addressed above, an increase in the purchase or utilization of Defendants’ products after a kickback was paid is not relevant to causation, nor is but-for causation an element of Plaintiffs’ claims. Even if a jury were to believe Van Meter’s opinions that physicians did not buy *more* of Defendants’ products after receiving a kickback, that fact does not make it any less likely that the products physicians *did* purchase from Defendants resulted from a kickback. Nor does that fact make it any less likely that Defendants’ products were used in a surgery for which reimbursement was sought from Medicare. In short, Van Meter’s regression analysis has no relevance to causation.

The foregoing conclusion does not necessarily render Van Meter’s opinions inadmissible, however. The AKS “makes it unlawful for a defendant to pay a kickback with the intent to induce a referral.” *Parikh*, 977 F. Supp. 2d at 665. Van Meter’s regression analysis purports to demonstrate whether Defendants’ alleged kickbacks were intended to induce a referral. Van Meter examined patterns in physicians’ use of

Defendants’ products before and after the alleged kickbacks occurred to determine whether the alleged kickbacks affected utilization of Defendants’ products. Van Meter concluded that the alleged kickbacks did not increase physician utilization of Defendants’ products. In doing so, Van Meter also concluded that the data do not suggest a pattern of Defendants targeting physicians that, based on market share, might be more likely to generate business for Defendants. This evidence could suggest that the remunerations Defendants allegedly provided to physicians were not provided with the requisite intent to generate business but instead were provided for innocuous reasons, such as gift-giving between friends. Thus, although irrelevant as to causation, this evidence *is* relevant as to Defendants’ intent.

Plaintiffs argue, however, that Van Meter may not opine as to intent. It is true that expert testimony as to a party’s “intent, motives, or states of mind . . . have no basis in any relevant body of knowledge or expertise.” *Kruszka v. Novartis Pharms. Corp.*, 28 F. Supp. 3d 920, 931 (D. Minn. 2014) (internal quotation marks omitted). Expert testimony that *directly* opines about Defendants’ intent would be pure speculation because Van Meter has no personal knowledge of Defendants’ intent and has no expertise that would assist a jury in determining Defendants’ intent. As such, to the extent that Van Meter seeks to opine *directly* as to whether Defendants intended to induce referrals in violation of the AKS, such opinions must be excluded.

An expert may, however, testify about observable underlying facts that could be relevant to determining an individual or entity’s intent. *See, e.g., In re ResCap Liquidating Tr. Litig.*, 432 F. Supp. 3d 902, 930 (D. Minn. 2020) (acknowledging that “fact-based testimony as to what an entity actually did—as opposed to what it was motivated by,

thought, or intended— . . . does not cross the line into inadmissible testimony”); *Metro Sales, Inc. v. Core Consulting Grp., LLC*, 275 F. Supp. 3d 1023, 1058 n.13 (D. Minn. 2017) (observing that an expert may testify about underlying conduct that is indicative of the plaintiff’s intent if such testimony will “assist the factfinder in evaluating [the plaintiff’s] actions”). Thus, although Van Meter cannot directly opine that Defendants lacked the requisite intent, he *can* opine as to underlying facts that may be indicative of Defendants’ intent.

Plaintiffs correctly argue that they need not prove an increase in utilization of Defendants’ products by physicians to prevail on their FCA claims. But just because a change in utilization is not *necessary* for Plaintiffs to prove intent does not mean that a change in utilization is not *relevant* to intent.<sup>8</sup> The parties’ disagreements as to the significance of such evidence implicates the weight and credibility of the evidence, not its admissibility. Similarly, to the extent that Plaintiffs believe Van Meter’s opinions are flawed or incomplete, the appropriate method of challenging his opinions is through cross-examination, not exclusion. Plaintiffs have not demonstrated that any gap between the evidence and Van Meter’s opinions is so great as to render his opinions unreliable.

For these reasons, Plaintiffs’ motion to exclude the opinions and testimony of Van Meter is granted in part and denied in part. Van Meter is precluded from testifying as to causation, because his opinions are irrelevant to causation. Van Meter also is precluded

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<sup>8</sup> To the extent that any of Van Meter’s opinions suggest that Plaintiffs must prove an increase in utilization to prevail on their FCA claims, such opinions would be improper because they are contrary to law.

from directly testifying as to Defendants’ intent. But his opinions about changes in physicians’ utilization of Defendants’ products and whether Defendants targeted physicians that were more likely to generate business are relevant to Defendants’ intent and, therefore, admissible.

## **2. David Gregory**

Plaintiffs also move to exclude the opinions and testimony of Defendants’ Medicare program expert, David Gregory. Defendants intend to offer Gregory to opine that “Medicare would have paid the same amount regardless of the source of the surgical products.” In addition, Defendants intend to offer Gregory to rebut the testimony of Plaintiffs’ Medicare claims expert, Ian Dew. Plaintiffs argue that Gregory’s opinions are impermissible because they are based on an incorrect legal standard—namely, a but-for causation standard that does not apply in this case.

As addressed above, Plaintiffs are not required to prove but-for causation. Gregory’s opinions about the medical necessity of cataract surgeries, and whether Medicare would have reimbursed the same amount for the cataract surgeries even if Defendants’ products had not been used, are irrelevant and based on an incorrect legal standard. Indeed, under the AKS, any Medicare claim “resulting from” an AKS violation is materially false as a matter of law. *See, e.g., United States ex rel. Goodman v. Arriva Med., LLC*, 471 F. Supp. 3d 830, 840 (M.D. Tenn. 2020) (collecting cases and concluding that “because 42 U.S.C. § 1320a-7b(g) states that a claim caused by an AKS violation ‘constitutes a false or fraudulent claim’ as a matter of law, it requires the courts to treat the question of materiality—just one element of that term—as resolved”).

Moreover, because the AKS provides that a claim is false or fraudulent if it “includes items or services *resulting from*” an AKS violation, 42 U.S.C. § 1320a-7b(g) (emphasis added), a plaintiff may prove that a claim is false with “record evidence that shows a link between the alleged kickbacks and the medical care received,” *Greenfield*, 880 F.3d at 100. As such, Gregory’s opinion that Medicare reimbursements for Professional Fee Medicare claims are not recoverable because “these claims reimburse only the physician’s services and do not implicate surgical supplies” is incorrect as a matter of law. As is Gregory’s opinion that Plaintiffs may recover only the portion of Facility Fee Medicare claims that represents the cost of Defendants’ products.<sup>9</sup> To the contrary, Medicare claims as to services and other costs associated with cataract surgeries may result from Defendants’ conduct even if those services and costs are not limited to the cost of Defendants’ products.

Defendants purport to offer Gregory’s opinions to help the jury understand the financial impact of Defendants’ conduct on the Medicare program and the difference between the value the government actually received and the value the government would

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<sup>9</sup> Defendants assert that the FCA limits Plaintiffs’ recovery to actual damages. Defendants rely on the FCA’s language providing for the recovery of “damages which the Government sustains *because of*” an FCA violation. 31 U.S.C. § 3729(a) (emphasis added). But courts have interpreted this language as a proximate-cause requirement with respect to damages. *Luce*, 873 F.3d at 1012–14. As such, Plaintiffs may recover damages that are the foreseeable result of Defendants’ conduct. *Id.* Significantly, “[t]he FCA attaches liability, not to the underlying fraudulent activity, but to the claim for payment.” *Strubbe*, 915 F.3d at 1163 (quoting *Olson*, 831 F.3d at 1070). Gregory’s opinions as to what proportion of the Medicare claims represent the actual cost of Defendants’ products have no relevance to whether the submission of the Medicare claims, as a whole, were the foreseeable result of Defendants’ alleged AKS violations.

have received but for the Defendants' conduct. These factors are irrelevant to the correct legal standard, however, which is *not* but-for causation. Because these aspects of Gregory's opinions are contrary to law and irrelevant to any element of Plaintiffs' FCA claims, they would not be helpful to a jury. Therefore, these aspects of Gregory's opinions must be excluded.

Defendants also offer Gregory's opinions to rebut the opinions of Plaintiffs' expert, Dew. "It is the proper role of rebuttal experts to critique [an opposing party's] expert's methodologies and point out potential flaws in the [opposing party's] experts' reports." *Aviva Sports, Inc. v. Fingerhut Direct Mktg., Inc.*, 829 F. Supp. 2d 802, 835 (D. Minn. 2011). Gregory opines that Dew's analysis of the Medicare claims at issue did not properly account for modifier codes in the claims data that reflect multiple procedures performed on the same day or postoperative management. As a result, according to Gregory, Dew's analysis improperly included reimbursements for procedures unrelated to cataract surgeries. Unlike Gregory's other opinions, his rebuttal opinions as to modifier codes may be relevant to whether Plaintiffs have demonstrated proximate causation as to particular Medicare claims at issue. Moreover, his explanations as to how to understand Medicare claims data, including modifiers, may be helpful to a jury in understanding the evidence. To the extent that Plaintiffs challenge the significance or accuracy of Gregory's rebuttal opinions as to these issues, their disagreement implicates the weight and credibility of the evidence, not its admissibility.

Accordingly, Plaintiffs' motion to exclude the opinions and testimony of Gregory is granted in part and denied in part. To the extent that Gregory's opinions rely on a but-

for causation standard or an analysis that categorically excludes Medicare claims (or portions thereof) that did not directly reimburse the costs of Defendants' products, such opinions must be excluded as irrelevant and contrary to the applicable legal standard. But Gregory's rebuttal opinions as to Dew's analysis of the Medicare claims data modifiers are admissible.

### **3. David Duffus**

Plaintiffs also move to exclude the opinions and testimony of Defendants' rebuttal valuation expert, David Duffus. Defendants intend to offer Duffus to rebut the opinions of Plaintiffs' valuation expert Michael Phillips, who opines that Defendants charged physicians less than fair market value for alleged remunerations. According to Duffus, Phillips's application of valuation standards is flawed and results in a significant overstatement of the fair market value of the trips and entertainment Defendants provided to physicians.

Plaintiffs contend that Duffus fails to "provide clarity about Defendants' alleged [fair market value] analyses." But the purpose of a rebuttal expert is to critique the opposing expert's theories and calculations, and a rebuttal expert need not offer alternatives. *See Aviva Sports*, 829 F. Supp. 2d at 834–35. It is Plaintiffs' burden to prove that the trips and entertainment that Defendants provided to physicians were provided at less than fair market value. Plaintiffs intend to do so, in part, with the testimony of Phillips. Duffus intends to identify flaws in Phillips's analysis and cast doubt on Phillips's conclusions based on Duffus's review and analysis of the evidence, including documents and deposition testimony. Plaintiffs do not contend that Duffus, who is a certified public



accountant, is unqualified to testify about valuation. Nor do Plaintiffs plausibly suggest that Duffus applied an incorrect legal standard or that any gap between the evidence and Duffus's opinions is so great as to render his opinions unreliable. To the extent that Plaintiffs disagree with Duffus's conclusions or believe his opinions are flawed or incomplete, this disagreement implicates the weight and credibility of the evidence, not its admissibility. And the appropriate method of challenging the opinions is through cross-examination, not exclusion.

For these reasons, Plaintiffs' motion to exclude the opinions and testimony of Duffus is denied.

## **B. Defendants' Motion to Exclude Expert Testimony**

Defendants move to exclude the opinions and testimony of Plaintiffs' rebuttal expert Dr. Adriane Fugh-Berman and Medicare claims expert Ian Dew. According to Defendants, Dr. Fugh-Berman lacks qualifications to serve as an expert and her opinions are unreliable, irrelevant, and unfairly prejudicial. And Defendants contend that Dew's opinions lack proper foundation. The Court addresses each expert in turn.

### **1. Dr. Adriane Fugh-Berman**

Plaintiffs intend to offer the opinions and testimony of Dr. Adriane Fugh-Berman to rebut the testimony of Defendants' causation expert Van Meter. Dr. Fugh-Berman intends to opine about marketing tactics used to target physicians to rebut Van Meter's opinions as to intent and causation. Defendants argue that Dr. Fugh-Berman is not qualified and that her opinions are unreliable, irrelevant, and unfairly prejudicial.

As an initial matter, because the Court has excluded Van Meter's causation opinions as irrelevant to the applicable legal standard, any dispute as to Dr. Fugh-Berman's anticipated rebuttal testimony that is specific to the issue of causation is moot. However, to the extent that Van Meter offers expert testimony pertaining to circumstantial evidence of Defendants' intent, the parties' disputes as to Dr. Fugh-Berman's rebuttal testimony are *not* moot.

Defendants first challenge Dr. Fugh-Berman's qualifications. A witness may be qualified as an expert based on knowledge, skill, experience, training, or education. Fed. R. Evid. 702. The witness's qualifications must, however, match the subject matter of the witness's testimony. *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1101 (8th Cir. 2006). Defendants contend that Dr. Fugh-Berman is not qualified to rebut Van Meter's statistical analysis because she lacks education, training, or experience in the subject matter of statistical analysis. But Plaintiffs do not purport to offer Dr. Fugh-Berman as a statistical expert or to criticize Van Meter's statistical analysis. Rather, Dr. Fugh-Berman's testimony is intended to identify flaws and gaps in the data and assumptions *underlying* Van Meter's statistical analysis and his conclusions about whether Defendants' conduct reflects an intent to induce physicians to purchase and use Defendants' products for Medicare-reimbursable procedures.

The record reflects that Dr. Fugh-Berman is a licensed physician with extensive medical experience. She is a medical professor who teaches courses and has written peer-reviewed articles addressing, among other things, the subject of marketing influence on doctors. In rebutting Van Meter's testimony, Dr. Fugh-Berman intends to testify about

industry marketing tactics used to target physicians and the efficacy of such tactics, including but not limited to the use of incentives to maintain sales rather than merely to initiate or increase sales. Defendants do not argue that Dr. Fugh-Berman is unqualified to present this marketing-related testimony, and the record demonstrates that she is qualified to do so. Therefore, Defendants' arguments as to Dr. Fugh-Berman's qualifications lack merit.

Defendants also argue that Dr. Fugh-Berman's opinions are unreliable. Specifically, Defendants contend that Dr. Fugh-Berman's opinions are too general and insufficiently particularized to the facts and allegations in this case because she relied on a "cherry-picked review of the record" and failed to consider certain evidence. But the record reflects that Dr. Fugh-Berman reviewed deposition testimony and documents when preparing her report and applied her industry marketing-related expertise to analyze this evidence. Disputes about the factual basis of an expert's testimony ordinarily are issues of credibility—not admissibility—of the expert's testimony. *Sappington*, 512 F.3d at 450; *see also Minn. Supply Co.*, 472 F.3d at 544. Defendants' arguments as to the reliability of Dr. Fugh-Berman's opinions and testimony do not warrant exclusion.

Defendants also contend that Dr. Fugh-Berman's opinions are irrelevant and unfairly prejudicial because they misleadingly suggest that lawful marketing activities are unlawful. To the contrary, her opinions identify marketing activities that, regardless of their lawfulness, might influence physicians, and she criticizes Van Meter for purportedly failing to take some of these variables into account in his analysis. The purpose of Dr. Fugh-Berman's opinions, therefore, is to cast doubt on Van Meter's conclusions. Such

opinion evidence is relevant to the issue of Defendants' intent to induce physicians to purchase products, which is an essential element of Plaintiffs' claims. In particular, consideration of Defendants' alleged kickback conduct in the broader context of Defendants' overall marketing tactics might assist a jury in determining whether Defendants provided remunerations to physicians with the requisite intent to influence those physicians' purchasing decisions.<sup>10</sup> Defendants' disputes with this evidence implicate the weight and credibility of Dr. Fugh-Berman's testimony rather than its admissibility. Defendants have not established that Dr. Fugh-Berman's opinions and testimony are either irrelevant or unfairly prejudicial.

For the foregoing reasons, Defendants' motion to exclude the opinions and testimony of Dr. Fugh-Berman is granted in part and denied in part. Dr. Fugh-Berman's opinions and testimony are excluded only to the extent that she intends to testify directly as to her conclusions about Defendants' intent.

## **2. Ian Dew**

Plaintiffs intend to offer the opinions and testimony of Ian Dew to identify claims for payment that Defendants allegedly caused to be submitted to Medicare. Dew is a data analyst and computer programmer with experience analyzing healthcare claims data. Dew began with a dataset of all Medicare claims that were submitted to the government for

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<sup>10</sup> As addressed above with respect to Van Meter's opinions, however, to the extent that Dr. Fugh-Berman seeks to opine directly as to her conclusions about Defendants' intent, motives, or state of mind, such testimony is inadmissible. *See In re ResCap*, 432 F. Supp. 3d at 930 (explaining that conclusions as to a defendant's intent, motive, or state of mind are not proper topics for expert testimony, but opinions as to a defendant's underlying conduct relevant to intent may be admissible).

cataract-related procedures during the relevant time period—more than 42 million total claims. He then isolated a subset of 138,556 claims that were submitted by the 53 physicians who allegedly received kickbacks from Defendants during a kickback-tainted time period. From within that subset, Dew matched Medicare claims to surgeries that allegedly involved Defendants’ products. This analysis resulted in two categories of Medicare claims: 76,493 claims that Dew cross-referenced with entries in a registry obtained from product manufacturer Johnson & Johnson that included Defendants’ customer number and relevant physician names, surgery dates, and patient names (J&J Registry Subset); and 16,539 claims that Dew cross-referenced with physicians’ tax identification numbers and lists provided to Dew by Plaintiffs’ counsel (Other Subsets).

Defendants contend that Dew’s opinions as to the “Other Subsets” lack foundation. According to Defendants, Dew “did not undertake the analysis to match these claims to Defendants’ products” but instead relied on lists provided by Plaintiffs’ counsel. Plaintiffs counter that the purpose of Dew’s “Other Subsets” analysis is not to determine which surgeries used Defendants’ products but instead to *assume* that particular surgeries used Defendants’ products and match those surgeries to Medicare claims data based on Dew’s experience and expertise with such data.

An expert witness “may express an opinion that is based on facts that the expert assumes, but does not know, to be true.” *Williams v. Illinois*, 567 U.S. 50, 57 (2012). “It is then up to the party who calls the expert to introduce other evidence establishing the facts assumed by the expert.” *Id.* Here, Plaintiffs do not dispute that they provided Dew with lists created by counsel, “based on information obtained during discovery,” that Dew

was instructed to assume were “associated with procedures that used interocular lenses or viscoelastic products distributed by the Defendants.” Plaintiffs contend that “Dew was not asked to determine what physicians were at issue, what time periods were relevant, or what surgeries used [Defendants’] products.” Instead, Dew was asked to assume this underlying information, which Plaintiffs intend to prove using other evidence.

Defendants correctly contend that Plaintiffs cannot prove an essential element of their claims based on unsupported assumptions relied on by an expert. *See In re James Wilson Assoc.*, 965 F.2d 160, 173 (7th Cir. 1992) (“If for example the expert witness (call him A) bases his opinion in part on a fact (call it X) that the party’s lawyer told him, the lawyer cannot in closing argument tell the jury, ‘See, we proved X through our expert witness, A.’ ”). But Plaintiffs are not purporting to prove their assumptions through Dew, and Plaintiffs acknowledge that they must prove those underlying assumptions through other evidence. Whether Plaintiffs have sufficient other admissible evidence to prove those underlying assumptions is outside the scope of the pending motion, which is limited to whether Dew’s opinions and testimony should be excluded. Because an expert is permitted to base his or her expert opinion on assumptions, Defendants have not demonstrated a basis for excluding Dew’s opinions and testimony.

Accordingly, Defendants’ motion to exclude the opinions and testimony of Dew is denied.

### III. Appeals of July 10, 2020 Order

Plaintiffs and Defendants, respectively, appeal aspects of the magistrate judge's July 10, 2020 Order, which granted in part the parties' cross motions for sanctions and denied Plaintiffs' motion to compel discovery.

A district court conducts an "extremely deferential" review of a magistrate judge's ruling on a nondispositive issue.<sup>11</sup> *Smith v. Bradley Pizza, Inc.*, 314 F. Supp. 3d 1017, 1026 (D. Minn. 2018) (internal quotation marks omitted), *aff'd*, 821 F. App'x 656 (8th Cir. 2020). Such a ruling will be modified or set aside only when the ruling is clearly erroneous or contrary to law. *Id.* (citing 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); LR 72.2(a)(3)). A ruling is clearly erroneous when the reviewing court "is left with the definite and firm conviction that a mistake has been committed." *Wells Fargo & Co. v. United States*, 750 F. Supp. 2d 1049, 1050 (D. Minn. 2010) (internal quotation marks omitted). A ruling is contrary to law when a court "fails to apply or misapplies relevant statutes, case law or rules of procedure." *Id.* (internal quotation marks omitted). Applying this standard, the Court addresses the parties' respective arguments in turn.

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<sup>11</sup> Plaintiffs contend that aspects of the magistrate judge's sanctions are dispositive rather than nondispositive, and therefore subject to *de novo* review, to the extent that the sanctions result in Plaintiffs' "claims" being "remove[d] from the case." But, as the magistrate judge correctly observed, Plaintiffs' argument confuses *legal* claims (namely, causes of action) with "false claims" (namely, kickback-induced Medicare claims for reimbursement). The sanctions ordered by the magistrate judge exclude evidence of kickbacks and false claims, they do not—either directly or indirectly—dispose of Plaintiffs' legal claims. As such, Plaintiffs' argument in favor of *de novo* review is mistaken.

## **A. Plaintiffs' Appeal**

Plaintiffs appeal the magistrate judge's July 10, 2020 Order to the extent that the magistrate judge (1) ordered discovery sanctions pertaining to Plaintiffs' untimely identification of false claims, (2) ordered discovery sanctions as to the testimony of Plaintiffs' to Rule 30(b)(6) witnesses, and (3) denied Plaintiffs' motion to compel discovery.

### **1. Sanctions as to Untimely Identification of False Claims**

The magistrate judge found that Plaintiffs, contrary to prior court orders, "identified thousands of new allegedly false claims after the close of discovery." As such, the magistrate judge sanctioned Plaintiffs by excluding from evidence the untimely identified false claims because they were disclosed "in violation of the Court's orders and prejudice Defendants."

A district court may impose sanctions on a party that fails to obey a discovery order, including "prohibiting the disobedient party . . . from introducing designated matters in evidence." Fed. R. Civ. P. 37(b)(2)(A)(ii). "District courts have inherent power, moreover, to impose sanctions short of dismissal for violations of court orders." *State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 137 S. Ct. 436, 444 (2016); accord *Nick v. Morgan's Foods, Inc.*, 270 F.3d 590, 594 n.2 (8th Cir. 2001). It is within a district court's "wide discretion" to select the appropriate sanction to impose. *Nick*, 270 F.3d at 595.

Plaintiffs do not dispute that they identified additional allegedly false claims two months after the close of fact discovery without seeking permission from the Court. By doing so, Plaintiffs blatantly violated the magistrate judge's prior orders, which required



any such disclosures to occur before the close of fact discovery. Therefore, it was well within the magistrate judge's discretion to exclude Plaintiffs' untimely evidence as a sanction.

Plaintiffs contend that their late supplementation was permissible under Rule 26(e), which requires a party to "supplement or correct" its discovery responses "if the party learns that in some material respect the disclosure or response is incomplete or incorrect." Fed. R. Civ. P. 26(e)(1)(A). But "district courts have broad discretion in maintaining compliance with discovery and pretrial orders." *Williams v. TESCO Servs., Inc.*, 719 F.3d 968, 976 (8th Cir. 2013) (rejecting contention that Rule 26(e) precluded district court from enforcing discovery deadlines by striking untimely disclosure). And because Rule 26(e) requires a party to supplement discovery responses "*in a timely manner*," a party's "failure to disclose in a timely manner is equivalent to a failure to disclose." *United States v. STABL, Inc.*, 800 F.3d 476, 487 (8th Cir. 2015) (emphasis added) (internal quotation marks omitted). Here, the supplemental disclosures at issue pertain to alleged kickbacks and false claims that occurred more than five years ago. And prior court orders made clear the deadline by which Plaintiffs were required to provide supplemental disclosures of alleged false claims. Plaintiffs admittedly failed to abide by that deadline. Consequently, in addition to violating the Court's prior discovery orders, Plaintiffs' disclosures also were not provided in a timely manner and, therefore, are not excused by Rule 26(e). As such, Plaintiffs have not established that Rule 26(e) renders the magistrate judge's sanctions clearly erroneous or contrary to law.

Plaintiffs argue that some of their untimely disclosures are justified because the untimeliness is attributable to Defendants' late discovery disclosures. But the magistrate judge rejected this argument, observing that Plaintiffs did not "bother to delineate which new claims they attribute to new discovery productions." Plaintiffs had the opportunity to fully present this argument to the magistrate judge in the first instance, and their failure to do so does not render the magistrate judge's decision clearly erroneous. Moreover, Plaintiffs could have sought an extension from the magistrate judge based on Defendants' late discovery disclosures, but Plaintiffs concede that they did not do so. Instead, Plaintiffs chose to disregard the deadline imposed by the magistrate judge without seeking the Court's permission. Plaintiffs have not established that Defendants' late discovery disclosures render the magistrate judge's sanctions clearly erroneous or contrary to law.

Plaintiffs also contend that the magistrate judge erred by failing to apply the requisite four-part balancing test before imposing sanctions. But Plaintiffs' argument confuses the standard applicable to Rule 37(c) sanctions with the standard applicable to Rule 37(b)(2) sanctions.

Rule 37(c) *requires* the imposition of sanctions when "a party fails to provide information or identify a witness as required by Rule 26(a) or (e) . . . unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1); *CMI Roadbuilding, Inc. v. Iowa Parts, Inc.*, 322 F.R.D. 350, 363 (N.D. Iowa 2017). Because Rule 37(c) sanctions are mandatory, the rule contains exceptions for "substantially justified" or "harmless" violations to "avoid unduly harsh penalties that may result from an inflexible application of the Rule." *Transclean Corp. v. Bridgewood Servs., Inc.*, 101 F. Supp. 2d 788, 795 (D.

Minn. 2000) (internal quotation marks omitted). As such, when determining whether a violation was substantially justified or harmless under Rule 37(c), district courts consider four factors: “[1] the importance of the excluded material; [2] the explanation of the party for its failure to comply with the required disclosure; [3] the potential prejudice that would arise from allowing the material to be used . . . ; and [4] the availability of a continuance to cure such prejudice.” *Id.* at 795–96 (citing *Citizens Bank of Batesville, Ark. v. Ford Motor Co.*, 16 F.3d 965, 966 (8th Cir. 1994)).

By contrast, Rule 37(b)(2) is permissive in nature and may be applied at a district court’s discretion to impose sanctions when a party “fails to obey an order to provide or permit discovery.” *CMI Roadbuilding*, 322 F.R.D. at 363 (quoting Fed. R. Civ. P. 37(b)(2)). Here, the magistrate judge imposed sanctions under Rule 37(b)(2) because Plaintiffs violated the Court’s orders setting discovery deadlines *and* requiring Plaintiffs to provide specific discovery by a specific date. Unlike an automatic Rule 37(c) sanction, which might arise from a harmless or inadvertent violation of general disclosure rules, Plaintiffs violated a *specific order* issued by the magistrate judge that was unambiguously affirmed on appeal. Because the disputed sanctions were imposed pursuant to Rule 37(b)(2), the magistrate judge did not err by concluding that the four-factor test on which Plaintiffs rely, which applies to Rule 37(c) sanctions, is inapplicable here.<sup>12</sup>

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<sup>12</sup> Even if the four-factor test applied here, the magistrate judge’s analysis effectively evaluates all four factors and concludes that each factor favors the imposition of sanctions. *Cf. Amplatz v. Country Mut. Ins. Co.*, 823 F.3d 1167, 1172 (8th Cir. 2016) (affirming district court’s imposition of sanctions when “[t]he district court considered the [four factors], though not in rote fashion as [appellant] argues it should have done”).

For these reasons, Plaintiffs have not established that the magistrate judge's July 10, 2020 Order is clearly erroneous or contrary to law as to the sanctions imposed on Plaintiffs for the untimely identification of false claims.

## **2. Sanctions as to Plaintiffs' Rule 30(b)(6) Witnesses**

The magistrate judge also "carefully reviewed the deposition transcripts" of Plaintiffs' three Rule 30(b)(6) witnesses and found that, although these witnesses generally were "sufficiently prepared, their testimony was deficient in two discrete areas." First, the magistrate judge found that Plaintiffs' witness who testified about the approximately 27,000 alleged false claims that Plaintiffs identified on November 7, 2019, "was wholly unprepared to answer general questions about the claims matching process." Second, the magistrate judge found that Plaintiffs' two Medicare Administrative Contractor witnesses could not "meaningfully answer questions about how Medicare claims are reviewed for medical necessity." Consequently, the magistrate judge sanctioned Plaintiffs by precluding them from introducing any evidence, beyond what their witnesses testified to during Rule 30(b)(6) depositions, as such evidence pertains to the following two topics: (1) how Plaintiffs determined that the allegedly false Medicare claims they identified on November 7, 2019, involved products sold by Defendants (Claims-Matching Sanction), and (2) whether any of these allegedly false Medicare claims involved services that were not medically necessary (Medical-Necessity Sanction). Plaintiffs challenge both sanctions.

### **a. Claims-Matching Sanction**

Plaintiffs first challenge the magistrate judge's Claims-Matching Sanction, which precludes them from introducing any evidence, beyond their witness's deposition

testimony, as to how Plaintiffs determined that the allegedly false Medicare claims they identified on November 7, 2019, involved products sold by Defendants. Central to this objection is whether Plaintiffs violated the magistrate judge's prior discovery orders by failing to prepare its Rule 30(b)(6) witness to testify about the methodology used to match approximately 27,000 allegedly false Medicare claims to Defendants' products. According to Plaintiffs, the magistrate judge's prior orders required their witness to be adequately prepared to testify only as to 25 representative claims, not all 27,000 claims. Resolving this dispute requires a brief overview of the magistrate judge's prior orders.

At a September 12, 2019 hearing, the magistrate judge addressed the parties' dispute over Plaintiffs' production of a Rule 30(b)(6) witness to "provide testimony on the topic of the factual basis and methodology by which the government asserts that the claims already identified by the government as . . . false claim[s] include[ ] items or services provided by [Defendants]." In doing so, the magistrate judge expressly limited the scope of this topic, in relevant part, as follows:

The defendants are not going to be entitled to ask about every single claim on the spreadsheet. If you wish to have the government answer information about a specific claim, you may identify up to 25 specific claims reasonably far in advance of the deposition.

The September 12, 2019 ruling does not appear to expressly require Plaintiffs to prepare their witness to address general questions about the claims-matching process for claims outside the scope of the 25 representative claims identified by Defendants.

Subsequently, on November 7, 2020, Plaintiffs identified approximately 27,000 additional allegedly false Medicare claims, which necessitated a supplemental deposition

to address the claims-matching process as to these newly identified claims. At a November 25, 2019 hearing, the parties stipulated to the scope of this supplemental deposition, which the magistrate judge memorialized on the record as follows:

On the designee who will testify regarding the process by which the Precision Lens products were identified as being involved in the 27,000 recently-disclosed claims . . . . It is only on the topic of the process by which the government took information, primarily in the form of clinic records or medical records, and used that information to identify whether the particular surgery that is the genesis of the claim lines involved a Precision Lens product.

The magistrate judge later observed, at a December 11, 2019 hearing, that this recitation into the record of the parties' stipulation was "binding" and "intended to be an order of this court." The magistrate judge also characterized the forthcoming supplemental deposition as a "deposition concerning 25 representative surgeries." At neither the November 25, 2019 hearing nor the December 11, 2019 hearing does it appear that Plaintiffs were expressly ordered to prepare their supplemental witness to address general questions about the claims-matching process for claims outside the scope of the 25 representative claims identified by Defendants.<sup>13</sup>

At the supplemental deposition on December 16, 2019, a dispute arose as to the scope of the deposition—namely, whether Plaintiffs' witness was required to answer general questions about all 27,000 allegedly false Medicare claims as opposed to only the

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<sup>13</sup> Defendants assert that, at the prior Rule 30(b)(6) deposition on this topic, "Defendants asked—without objection—general questions about the overall methodology used." But this fact does not expand or otherwise alter the scope of the magistrate judge's order, which did not expressly *require* Plaintiffs' witness to be prepared to answer such questions.

25 representative claims identified by Defendants. The parties contacted the magistrate judge to resolve the dispute. Although this telephone conversation is not in the record, the magistrate judge's July 10, 2020 Order represents that the magistrate judge "clarified that Defendants could ask general methodology question regarding the 27,000 claims, as well as questions about the 25 representative claims Defendants had identified." The deposition transcript reflects that, after the magistrate judge provided clarification, Plaintiffs' witness answered some of Defendants' general questions but was unprepared to answer others.

When sanctioning Plaintiffs based on the inadequacy of its witness's testimony, the magistrate judge made the following relevant findings based on his review of the deposition transcript:

When asked questions about the 25 representative claims, the witness generally answered ably. She was also able to answer several general questions about the 27,000 additional claims, such as why a given surgery may have multiple claims lines and which data Plaintiffs relied on when there were discrepancies between records. She also provided an estimate of 27,000 claims for which Plaintiffs lacked medical records specifying the product that was used.

However, the witness could not answer questions on many relevant topics. For example, she was unable to specify without speculating what led to the identification of the 27,000 new claims. Nor could she say whether Plaintiffs were including claims for pre- or post-operative treatment as potential false claims. The witness did not provide a reason why viscoelastic products were identified in some claims, but not others. In some instances, counsel for the Government instructed the witness not to answer questions regarding underlying records or changes in Ian Dews's process.

(Citations omitted). Based on these findings, the magistrate judge concluded that Plaintiffs' witness "was wholly unprepared to answer general questions about the claims

matching process,” a “fact [that] became clear early in the deposition and required a telephone conference with this Court to clarify that such questions were within the scope of the deposition.”

A district court may impose sanctions on a party that fails to obey a discovery order, including “prohibiting the disobedient party . . . from introducing designated matters in evidence.” Fed. R. Civ. P. 37(b)(2)(A)(ii). And it is within a district court’s “wide discretion” to select the appropriate sanction to impose. *Nick*, 270 F.3d at 595. Here, however, the record is unclear as to what precise discovery order Plaintiffs failed to obey. As detailed above, the Court has been unable to identify—nor have Defendants cited—a court order that expressly required Plaintiffs to prepare their witness to testify about the claims-matching process for claims outside the scope of the 25 representative claims identified by Defendants. To the contrary, in September 2019, the scope of this Rule 30(b)(6) topic was expressly limited to 25 representative claims, and Defendants were told they were “not going to be entitled to ask about every single claim.” When a supplemental deposition became necessary, the scope of that deposition again was described as a “deposition concerning 25 representative surgeries.” Based on the Court’s review of the record, the first time Plaintiffs were expressly ordered to require their witness to answer questions beyond the scope of the 25 representative claims was during the December 16, 2019 supplemental deposition. At that point it was too late for Plaintiffs to prepare their witness to answer such questions or designate an alternative witness who could. At best, the prior orders are ambiguous as to the extent to which Plaintiffs were required to prepare a witness for more general questions. Despite this ambiguity, as the magistrate judge



recognized, Plaintiffs' witness was prepared to answer some of Defendants' general questions, in addition to "ably" answering specific questions about the 25 representative claims.

Because the Court cannot identify from the record the violation of a discovery order warranting the imposition of the Claims-Matching Sanction, this aspect of the July 10, 2020 Order is clearly erroneous and, therefore, reversed.

**b. Medical-Necessity Sanction**

Plaintiffs also challenge the magistrate judge's sanction precluding them from introducing evidence as to medical necessity. But regardless of whether the magistrate judge's sanction is proper, medical necessity is irrelevant in this case. As addressed in Part I.B.1. of this Order, but-for causation is not the applicable legal standard and, therefore, an allegedly false claim submitted to Medicare does not cease to be false merely because the underlying medical procedure was medically necessary and would have occurred anyway. Neither party may introduce irrelevant evidence. Fed. R. Evid. 402 ("Irrelevant evidence is not admissible.") Because this aspect of the July 10, 2020 Order excludes evidence that is otherwise inadmissible due to its irrelevance, the Court need not address the merits of this sanction. Plaintiffs' objection to this sanction is moot.

**3. Plaintiffs' Motion to Compel**

Plaintiffs also challenge the magistrate judge's denial of their motion to compel. In particular, Plaintiffs sought to compel Defendants to produce all expense reports and other source documents for expenses on Precision Lens's general ledger for meals and entertainment during the relevant time period. The magistrate judge found that, although

Defendants may have missed some responsive documents in their production, “Defendants have produced tens of thousands of relevant and responsive documents at significant financial expense.” As such, the magistrate judge concluded that compelling Defendants to search for and produce documents that might have been missed “is extremely burdensome but offers only limited benefit.” For this reason, the magistrate judge denied the motion to compel.

A party “may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense and *proportional to the needs of the case.*” Fed. R. Civ. P. 26(b)(1) (emphasis added). Although “[b]road discovery is an important tool for the litigant,” *Chavis Van & Storage of Myrtle Beach, Inc. v. United Van Lines, LLC*, 784 F.3d 1183, 1198 (8th Cir. 2015) (internal quotation marks omitted), a district court has the discretion to limit discovery if the court determines that the burden of the discovery sought outweighs its benefit, *Roberts v. Shawnee Mission Ford, Inc.*, 352 F.3d 358, 361 (8th Cir. 2003). And courts have “considerable discretion in determining the need for, and form of, discovery.” *In re Nat’l Hockey League Players’ Concussion Injury Litig.*, 120 F. Supp. 3d 942, 949 (D. Minn. 2015).

Plaintiffs disagree with the magistrate judge’s findings and conclusions as to this issue. But Plaintiffs have failed to demonstrate that the magistrate judge’s ruling is either clearly erroneous or contrary to law. To the contrary, the magistrate judge’s ruling is well within the considerable discretion afforded to such discovery matters. As such, Plaintiffs’ appeal of this ruling lacks merit.

## **B. Defendants' Appeal**

Defendants appeal the magistrate judge's decision to grant, in part, Plaintiffs' motion for spoliation sanctions against Defendants and to deny Defendants' motion for spoliation sanctions against Plaintiffs.

“The obligation to preserve evidence begins when a party knows or should have known that the evidence is relevant to future or current litigation.” *E\*Trade Sec. LLC v. Deutsche Bank AG*, 230 F.R.D. 582, 588 (D. Minn. 2005). A district court has inherent authority to impose sanctions against a party when that party destroys evidence that it knew or should have known is relevant to potential litigation and, in doing so, prejudices the opposing party. *See Dillon v. Nissan Motor Co.*, 986 F.2d 263, 267 (8th Cir. 1993). Determining the appropriate sanction to impose, if any, is within the district court's discretion. *Id.* at 267–68. Before imposing certain severe sanctions, such as dismissal, the district court must find that the sanctioned party acted in bad faith. *See Stevenson v. Union Pac. R.R. Co.*, 354 F.3d 739, 746–47 (8th Cir. 2004). But a district court may impose other types of sanctions without a finding of bad faith. *See id.* at 745 (observing that “a finding of bad faith is not always necessary to the court's exercise of its inherent power to impose sanctions”).

Here, Defendants challenge the July 10, 2020 Order to the extent that the magistrate judge found that (1) Defendants spoliated evidence by failing to take reasonable steps to preserve relevant text messages and (2) Plaintiffs did *not* fail to preserve certain digital records. The Court addresses each spoliation issue in turn.

## **1. Defendants' Alleged Spoliation**

Defendants first challenge the magistrate judge's finding that Defendants failed to take reasonable steps to preserve certain relevant text messages after Defendants' duty to preserve relevant evidence arose. According to the magistrate judge's findings, this duty arose "no later than October 2014."

In October 2018, Plaintiffs requested the production of communications, including text messages, between Defendants and certain physicians. The magistrate judge found that Defendants produced some text messages in response to this request, but none from Ehlen. Moreover, Plaintiffs learned through third-party discovery that Precision Lens employees had communicated with physicians via text messages that Defendants did not produce. Defendants do not dispute that some responsive data was lost due to the passage of time, damage to Ehlen's cell phone, and technology upgrades. The magistrate judge concluded that Defendants did not take reasonable steps to preserve these text messages:

By the time Defendants issued the November 2014 preservation notice, they knew the investigation concerned the Anti-Kickback Statute and that communications relating to the trips and other remunerations were relevant. Logically, Defendants should have also known the "key players"—i.e., the custodians of such information—included Ehlen, the sales representatives who communicated directly with physicians, and any other employees who organized the trips. As to text messages specifically, Defendants communicated with physicians via text about business before October 2014, and so should have known text messages could be relevant.

(Citations omitted.) The magistrate judge determined that Defendants' sole step of issuing a litigation hold, without more, was insufficient to satisfy Defendants' preservation duties. The magistrate judge observed that Defendants' litigation hold notices "were few and far

between” and that Defendants failed to take even relatively inexpensive affirmative steps to ensure the preservation of text messages. Defendants did not, for example, “talk to individual custodians about ensuring messages were backed up” or “remind employees to either keep their old device when upgrading or otherwise ensure the data was preserved.”

The magistrate judge also concluded that Plaintiffs were prejudiced by the irretrievable loss of relevant evidence, but that Defendants were merely negligent and did not act with the intent to deprive Plaintiffs of the information’s use in litigation. Accordingly, as a sanction, the magistrate judge ordered Defendants to “produce all text messages they have or can obtain from employees or contractors that are relevant to the current litigation, irrespective of time period or custodian.”

Defendants do not dispute that relevant evidence was lost or that its duty to preserve arose at least as early as October 2014. According to Defendants, however, the magistrate judge clearly erred by finding that Defendants’ preservation efforts were unreasonable. Although Defendants contend that the magistrate judge disregarded Defendants’ “significant steps to preserve relevant evidence,” Defendants cite no such efforts specific to the preservation of *text messages*. Instead, Defendants describe their efforts to preserve, review, and produce emails and other documents, and observe that “none of these document productions included text messages, because the Government did not request text messages.” But none of these facts or arguments is germane to whether Defendants knew or should have known that the lost text messages likely would be relevant to this litigation. Defendants present no legal authority to establish that a court must excuse a party’s spoliation of some relevant evidence if that party took reasonable efforts to preserve

*other* relevant evidence. Nor does the fact that Plaintiffs did not initially request the production of text messages mean that Defendants were reasonable in assuming that text messages were irrelevant to this litigation. To the contrary, the magistrate judge specifically found that, in late 2014, Defendants had reason to know that “communications relating to . . . trips and other remunerations were relevant,” and that because Defendants communicated with physicians via text message before October 2014, Defendants “should have known text messages could be relevant.” Defendants cite nothing in the record, nor has the Court found anything, that would render these findings clearly erroneous.

Defendants also argue that the magistrate judge failed to consider the amount of financial resources necessary to preserve possible evidence and the proportionality of such expenditures to the needs of the case. This argument is blatantly contrary to the record. The magistrate judge expressly found that Defendants failed to undertake even inexpensive efforts to preserve text messages, such as advising employees to back up their data. And the magistrate judge’s ruling necessarily implies that such efforts would have been proportional to the needs of this case. Defendants present no evidence contrary to the magistrate judge’s findings. As such, Defendants’ argument is meritless.

Defendants also object to the sanction imposed by the magistrate judge to remedy Defendants’ spoliation, arguing that the sanction is disproportionate to the needs of this case. Determining the appropriate sanction to impose on a party for spoliation of evidence is within the district court’s discretion. *Dillon*, 986 F.2d at 267–68. Here, the magistrate judge ordered Defendants to “produce all text messages they have or can obtain from employees or contractors that are relevant to the current litigation, irrespective of time

period or custodian,” which the magistrate judge concluded “may help Plaintiffs fill in gaps and are a reasonable, though imperfect, replacement” for the irretrievable relevant evidence Defendants lost. According to Defendants, this sanction is overbroad because it requires them to produce evidence “highly unlikely to relate to the matters from the relevant time period: 2006-2015,” such as “communications [sent] via text in 2020.” Although the magistrate judge’s order does not include a temporal limitation, the order nonetheless is limited to the production of text messages “that are relevant to the current litigation.” Thus, Defendants’ arguments are unfounded and do not demonstrate that the magistrate judge abused his discretion.

For these reasons, Defendants have not demonstrated that the magistrate judge’s July 10, 2020 Order is clearly erroneous or contrary to law with respect to Defendants’ spoliation of evidence.

## **2. Plaintiffs’ Alleged Spoliation**

Defendants also challenge the magistrate judge’s finding that Plaintiffs did *not* fail to preserve certain digital records. In particular, Defendants requested production of all documents relating to complaints made to the Officer of the Inspector General concerning Defendants. Plaintiffs produced responsive documents but, according to Defendants, the files Plaintiffs produced did not contain several documents that Defendants expected to find. The magistrate judge found that Defendants failed to establish that Plaintiffs destroyed any discoverable material:

Defendants ask this Court to assume two facts from the absence of certain documents in the hotline files: (1) that the documents ever existed at all and (2) Plaintiffs destroyed the

documents, or at least allowed them to be destroyed. Both assumptions require too great an inferential leap unsupported by the record. There is no testimony or other evidence of specific documents that once existed but are now missing. . . . Defendants offer no evidence, even in the abstract, showing how Plaintiffs may have destroyed the documents. There is not enough evidence in the record to support a conclusion that it is more likely than not the documents ever existed.

The magistrate judge also found that, even if such documents existed and were lost, Defendants failed to demonstrate any prejudice resulting from the loss.

In challenging the magistrate judge’s findings as to this issue, Defendants rely on testimony from one of Plaintiffs’ witnesses who *expected* that the files would contain documents that were not present. But the magistrate judge did not clearly err by finding that a witness’s speculative expectations as to the existence of certain documents is insufficient to demonstrate that such documents both existed *and* were lost or destroyed by Plaintiffs. Nor did the magistrate judge clearly err by finding that Defendants’ spoliation argument is independently insufficient because Defendants failed to demonstrate prejudice.<sup>14</sup> Because the record supports the magistrate judge’s findings, Defendants’ arguments to the contrary lack merit.

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<sup>14</sup> Defendants contend that they suffered prejudice because the allegedly spoliated evidence is relevant to materiality. But as addressed above, multiple courts have persuasively concluded that an AKS violation, at least with respect to claims submitted after the 2010 amendments to the AKS, is *per se* materially false for purposes of an FCA claim. *See, e.g., Goodman*, 471 F. Supp. 3d at 840 (collecting cases and concluding that “because 42 U.S.C. § 1320a-7b(g) states that a claim caused by an AKS violation ‘constitutes a false or fraudulent claim’ as a matter of law, it requires the courts to treat the question of materiality—just one element of that term—as resolved”).



In summary, the July 10, 2020 Order is reversed to the extent that it sanctions Plaintiffs by precluding them from introducing any evidence, beyond their witness's deposition testimony, as to how Plaintiffs determined that the allegedly false Medicare claims they identified on November 7, 2019, involved products sold by Defendants. The July 10, 2020 Order is affirmed in all other respects.

### **ORDER**

Based on the foregoing analysis and all the files, records and proceedings herein, **IT IS HEREBY ORDERED:**

1. Plaintiffs' motion for partial summary judgment, (Dkt. 639), is **DENIED**.
2. Defendants' motion for summary judgment, (Dkt. 624), is **DENIED**.
3. Plaintiffs' motion to exclude expert testimony, (Dkt. 641), is **GRANTED IN**

**PART AND DENIED IN PART** as follows:

- a. Scott Van Meter's opinions and testimony are excluded to the extent that they involve opinions as to causation and direct conclusions as to Defendants' intent;
- b. David Gregory's opinions and testimony are excluded to the extent that his opinions rely on a but-for causation standard or an analysis that categorically excludes Medicare claims (or portions thereof) that did not directly reimburse the costs of Defendants' products; and
- c. Plaintiffs' motion to exclude the opinions and testimony of Defendants' experts is denied in all other respects.

4. Defendants' motion to exclude expert testimony, (Dkt. 630), is **GRANTED IN PART AND DENIED IN PART** as follows:

- a. Dr. Adriane Fugh-Berman's opinions and testimony are excluded to the extent that she intends to testify directly as to her conclusions about Defendants' intent; and
- b. Defendants' motion to exclude the opinions and testimony of Plaintiffs' experts is denied in all other respects.

5. The magistrate judge's July 10, 2020 Order, (Dkt. 691), is **AFFIRMED IN PART AND REVERSED IN PART** as follows:

- a. the July 10, 2020 Order is **REVERSED** to the extent that it sanctions Plaintiffs by precluding them from introducing any evidence, beyond their witness's deposition testimony, as to how Plaintiffs determined that the allegedly false Medicare claims they identified on November 7, 2019, involved products sold by Defendants; and
- b. the July 10, 2020 Order is **AFFIRMED** in all other respects.

Dated: January 12, 2021

s/Wilhelmina M. Wright  
Wilhelmina M. Wright  
United States District Judge