UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNITED STATES ex rel., TRACEY GEORGE,	)	
Plaintiff / Relator,	)	Civil Action Number
vs.	)	**2:12-cv-00877-AKK**
FRESENIUS MEDICAL CARE HOLDINGS, INC.,	)	
Defendant.	)	

MEMORANDUM OPINION

Relator Tracey George brings this *qui tam* action against Fresenius Medical Care Holdings, Inc. ("Fresenius") for alleged violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq*. Doc. 47. Presently before this court and ripe for review are: (1) Fresenius's Motion for Summary Judgment, docs. 102, 118, 119, 122, 127; (2) Fresenius's Motion to Exclude the Testimony of Dr. Thomas McGuire, docs. 104, 115, 125; (3) Fresenius's Motion to Exclude the Testimony of Dr. Arif Asif, docs. 108, 114, 124; and (4) Fresenius's Motion to Strike Relator's Opposition Briefs and Exhibits to Fresenius's Motion to Exclude Expert Testimony,[1] docs. 117, 123, 126. For the reasons stated more fully below, the

[1] Also pending are George's unopposed Motion for a Briefing Schedule on the Motions to Exclude Testimony, doc. 113, which is **GRANTED**, and her unopposed Motion for Oral Argument on the Summary Judgment Pleadings, doc. 132, which is **DENIED AS MOOT**.

Motions to Strike, to Exclude Drs. McGuire and Asif, and for Summary Judgment are due to be granted in part.

I. RELEVANT BACKGROUND

A. Factual

i. The Parties

Fresenius operates approximately 2,200 outpatient dialysis clinics across the United States. Doc. 102-12 at 4. Dialysis treatment—which attempts to mimic kidney function and entails cycling a patient's blood from the patient's body, through a dialyzer (during which the blood is cleansed and necessary fluids and electrolytes are replaced), and back into the body—assists people suffering from End-Stage Renal Disease ("ESRD"). *Id.* Typically, Fresenius administers these treatments to each patient three times per week, and each treatment generally lasts several hours. *Id.* As will be discussed at length below, at the time of the patient's treatment, Fresenius's nurses also routinely administer certain relevant medications prescribed by the patient's physician. *Id.*

George began working at Fresenius's Birmingham West office as a staff nurse in 2006 and was eventually promoted in 2010 to the position of Operations Manager for the Birmingham West area. Doc. 110-4 at 6, 20–22 *SEALED*.

Fresenius's Motion for Leave to File Notice of Supplemental Authority, doc. 133, is **GRANTED**.

ii. Fresenius's Internal Structure

Although Fresenius treats patients suffering from kidney failure, the patients' attending physicians—whom Fresenius does not employ, but who are credentialed to admit patients for treatment at Fresenius clinics—make each patient's treatment decisions (such as, for instance, prescribing the patient's dialysis treatment). Doc. 102-12 at 8. Additionally, the attending physician prescribes the type, dosage, and interval of drugs a patient receives during treatment. Doc. 102-12 at 8. Fresenius employs the staff at its clinics, including the nurses who administer the prescribed dialysis treatments. Doc. 102-12 at 8. As such, Fresenius nurses execute the treating physician's orders for each patient, which requires administering a patient's prescribed drugs and setting the dialysis machine to the prescribed treatment. Doc. 102-12 at 8.

Each Fresenius clinic also has a Medical Director, a licensed nephrologist who contracts with Fresenius to provide administrative duties and to effectuate federal regulations related to the operation of the clinic. Doc. 201-12 at 9. Under the contract with Fresenius, the Medical Director participates in the adoption of clinic policies and reviews patient outcomes but is not responsible for individual patient care decisions.[2] Doc. 102-12 at 9. Additionally, Fresenius has a Corporate

[2] The Medical Director may also act as an attending physician for patients at the clinic. Doc. 102-12 at 9. However, when making decisions regarding individual patient care, the individual is acting in her capacity as an attending physician and not in her capacity as Medical Director. *Id.*

Medical Office ("CMO"), which consists of various physicians who facilitate and monitor the quality of care at the clinics, and who "provide clinical counsel and partnership to the business and operational leaders" at Fresenius. Doc. 102-12 at 9. Important here, the CMO, *inter alia*, approves policies related to the delivery of care at Fresenius clinics and occasionally publishes memoranda designed to assist physicians and staff with guidance on clinical issues relevant to patient care at the clinics. Doc. 102-12 at 10.

According to Fresenius, company policy prohibits staff from substituting Fresenius's treatment judgment for that prescribed by the patient's physician. Doc. 102-12 at 10. Put differently, patients' physicians are entitled to disagree with Fresenius's CMO publications and guidance regarding patient care. Doc. 102-12 at 10. Moreover, Fresenius policy mandates that, as long as a patient's physician's judgment on a particular treatment decision is within the range of "reasoned medical judgment," Fresenius nurses must follow that physician's direction—even if that direction runs contrary to a CMO publication or Fresenius policy. Doc. 102-12 at 10.

iii. Administration and Billing of Venofer and Zemplar

Two of George's claims involve two intravenous drugs administered during dialysis treatments: Venofer, an iron supplement, and Zemplar, a Vitamin D replacement. *See* docs. 102; 102-12 at 28; 118; 122-1 at 11–12 *SEALED.* Prior

to January 2011, Medicare billing rules permitted Fresenius to bill the Government for dialysis treatment and to bill *separately* (i.e., additionally) for the administration of Venofer and Zemplar. Docs. 102-12 at 12; 119-7 at 19.[3]

a. Vial Reentry and Double Billing Claim

During the relevant time period, both Venofer and Zemplar were "single-entry" drugs. Docs. 102-12 at 31. That is, the nurse administering these drugs could only enter the vials once to draw a dose and could not reenter the same vial to draw an additional dosage, even if the additional dosage was for the same patient. Doc. 122-1 at 15, 18–19 *SEALED.* According to Fresenius and FDA policy, a nurse was required to discard, or "waste," the additional medication left in the vials after that single administration. Doc. 122-1 at 19 *SEALED.* To ensure that nurses were not reentering single-dose vials, Fresenius claims to have educated employees about appropriate wastage policies and procedures and to have performed periodic audits to review medication administration. Doc. 122-1 at 20 *SEALED.*

George testifies that throughout the relevant time period, she witnessed nurses reenter and double bill for Venofer. Doc. 122-26 at 10–11, 16 *SEALED.* Specifically, she saw nurses administer a partial vial of Venofer with one patient,

[3] After January 1, 2011, Medicare no longer permitted clinics to bill separately for the use of these two drugs; instead, Fresenius had to "bundle" bill—that is, Fresenius received a flat rate for dialysis regardless of the drugs used. *See* docs. 102-12 at 12; 119-7 at 19.

enter into the patient's file (and to Medicare) that the medication was wasted, and then, contrary to Fresenius and Medicare policy, reenter the vial, administer the remaining content, and bill Medicare again for this wasted content. Doc. 122-26 at 10–11 *SEALED.* George testifies that, notwithstanding her direction as their direct supervisor to cease reentry and double billing, "all" her nurses refused to comply because the nurses "were trying to save [Fresenius] money." Doc. 122-26 at 12–13 *SEALED.* George informed her three supervisors about these ongoing violations multiple times in her capacity as Clinical Manager, but none of George's supervisors (each of whom George approached about this issue on multiple occasions) gave George permission to discipline the nurses for this behavior and simply told her to "educate the nurses" about the various policies.[4] Doc. 122-26 at 10–14 *SEALED.*

Moreover, Fresenius's records present discrepancies in the numbers of vials "used" and the clinics' physical inventory. *See* doc. 122-23 at 2 *SEALED.* Specifically, Fresenius's so-called "pharmacy usage documents" ("PUA") include, *inter alia*, the number of Venofer vials administered during a given time period and the inventory of those vials. *See* doc. 119-17 at 52; 122-1 at 21–22 *SEALED.* As will be discussed at length below, during many months at issue,

[4] Clinical managers are not permitted to take corrective action against a subordinate without permission from a direct supervisor. Doc. 122-26 at 10–11 *SEALED.* According to George, her supervisors gave her the same "educate the nurses" directive for three years. *Id.* at 13.

the Fresenius clinics' internal records indicated that they had administered a higher number of Venofer vials than their physical inventory records reflected. *See* docs. 119-17 at 48–50; 122-23 at 2 *SEALED.*

b. Unnecessary Waste Claim

At Fresenius and elsewhere, Venofer and Zemplar prescriptions did not always allocate dosages such that an administration of the drug perfectly used the entire quantity of Venofer or Zemplar vial. Therefore, in addition to the Venofer and Zemplar dosages actually administered to patients, Medicare billing rubrics permit the billing of "waste"—i.e., the amount of a drug that remained in the vial after the prescribed dose or doses were administered—for these two drugs. Doc. 102-12 at 12; *see Chapter 17 - Drugs and Biologicals*, Medicare Claims Processing Manual, at 27, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf (last visited Aug. 2, 2016) ("When a . . . provider . . . must discard the remainder of a single use vial . . . after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered"). However, the billing of waste was not without its limits; indeed, Medicare only provides for reimbursement when the provider "*must* discard" the remainder of the vial, *see* Medicare Claims Processing Manual at 27 (emphasis added), and, in 2003, Medicare released the following bulletin, which

George asserts Fresenius received: "[Medicare] expects ESRD clinics to plan drug administration responsibly to ensure prudent, efficient utilization of medications. Only in those circumstances when wastage is **absolutely unavoidable** would we expect to see wastage billed on a claim." Doc. 119-6 at 2 (emphasis in original).

Relevant here, prior to January 2011, Venofer was available only in 100 mg vials. Doc. 102-12 at 15. Therefore, any dosage other than 100 mgs resulted in waste because Fresenius nurses would administer the prescribed amount, "waste" the remainder up to 100 mgs, and bill Medicare for both the dosed amount and the waste. Doc. 102-12 at 15–16. Likewise, Zemplar's manufacturers only packaged the drug in 2 mg and 5 mg vials. Docs. 201-12 at 14. According to Fresenius, its internal policies required that nurses minimize Zemplar waste by using a combination of vial sizes that would permit the prescribed dose to be administered efficiently and, therefore, generate the least amount of waste possible.[5] Doc. 102-12 at 14.

Fresenius maintains that it made efforts during the relevant time period to reduce Venofer and Zemplar waste by encouraging attending physicians to dose efficiently. Docs. 102-3 at 57–58; 102-12 at 16. Fresenius's official position was that the drugs were just as effective for patients if the frequency of doses was

[5] For example, a nurse would use one 5 mg dose and one 2 mg dose to fill a 7 mg order and therefore only charge Medicare for 7 units as opposed to using two 5 mg vials and charging Medicare for 10 units. *See* doc. 102-12 at 14.

reduced and the amount of each individual dose was increased. Docs. 102-3 at 57–58; 102-12 at 16. For example, in August 2009, Fresenius's CMO issued the following recommendation to Fresenius Medical Directors:

> We recommend that you strongly consider ordering the labeled contents of a vial of intravenous [Zemplar] and/or intravenous [Venofer] and adjusting the dosing interval as necessary when considering therapy with these pharmaceuticals. . . . The single-use vial size of a drug is usually determined based on the usual or average dose indicated by available scientific literature and the FDA approval process. *There is little scientific or medical rationale for using a partial-vial dose for these medications.* We believe that the duration of action for vitamin D products and iron products is not critical, and have concluded that *one reasonable approach to eliminating wastage of these products is to use a full vial dose over a longer dosing interval to achieve the same total dose over time.*

Doc. 102-3 at 57–58 (emphasis added). This recommendation notwithstanding, however, Fresenius maintains that dosing frequency and amount are a matter of physician judgment. Doc. 201-12 at 16. Indeed, George testifies that Fresenius's nurses administered the dosages prescribed by the patients' treating physicians. *See* doc. 110-4 at 27 (George testifying, "[W]hat you're asking me is were [Fresenius's nurses] giving dosages different from what the doctor prescribed? . . . No, they were giving what the doctor prescribed.").

iv. Dialysis Run Times

Fresenius closely tracks the amount of time its nurses and support staff spend administering care to patients, and the company has specific ratios (called the "Total Area Productivity" or "TAP") that employees must meet to maximize

efficiency. *See generally* doc. 122-22 *SEALED.* Essentially, through the TAP system, Fresenius monitored the amount of time patients spent in the clinics, and Fresenius staff were incentivized by, for instance, increased bonuses to move patients through the clinic quickly. Docs. 122-1 at 48 *SEALED;* 122-26 at 16–17 *SEALED.* According to George, in an effort to reduce a clinic's TAP, clinic nurses shortened patient "run time" (i.e., the amount of time a patient received treatment) to more quickly advance patients through the clinic. *See* doc. 122-26 at 16–17. George purportedly "saw shortened treatments." Doc. 110-4 at 36–37 *SEALED* ("You go to the machine, you look at the treatment sheet compared to the settings of the machine, and then you would see that it wasn't per prescription."). She testifies that the "majority" of treatments were shorter than prescribed.[6] *Id.* Then, Fresenius nurses apparently increased run times on "lab days"—when patients' labs were tested for reporting to Medicare—to ensure that patients met their bloodwork and reporting goals.[7] Docs. 122-2 at 31–32

[6] George has also submitted what appear to be the run times of a patient who, according to Fresenius's records, did not receive his prescribed 210 minutes of run time during seven treatments. Doc. 122-21 at 2 *SEALED.* Indeed, the record reflects that his run times were short by eleven minutes on February 24, 2009, thirty minutes on April 28, 2009, and sixty minutes on April 18, 2009. *See id.* However, because it seems as though George has included no further context about this patient—for example, whether he was a Medicare patient—the court cannot rely upon this spreadsheet in its analysis. *See* docs. 118 at 30; 122-21 at 2 *SEALED.*

[7] If a clinic failed to meet these treatment statistics, Medicare reduced the clinic's reimbursements by two percent for the entire year following. Doc. 102-3 at 37; 122-1 at 38–39 *SEALED.* A patient's statistics were taken on specific "lab days." Doc. 122-1 at 40 *SEALED.* As will be discussed at length below, average dialysis length was longer on lab days, *see, e.g.*, doc. 122-13 at 85–86 *SEALED,* and longer run time is associated with a higher

SEALED; 122-26 at 36–38 *SEALED.* According to Fresenius's expert Dr. Franklin Maddux, systematic shortening of treatments in any material amount ultimately manifests in diminished patient outcomes, the most extreme of which are hospitalization and mortality. Doc. 102-12 at 20.

George claims that she raised these concerns about shortened run times and the potential for submitting false claims with her three supervisors. Doc. 122-26 at 18 *SEALED.* However, none of the three supervisors authorized George to discipline the offending nurses, instead instructing George to "educate the nurses" on the run time policy and reiterating that "there was no way to meet TAP goals [without shortening run times]." Doc. 122-26 at 18 *SEALED.* Notwithstanding George's attempts to dissuade Fresenius nurses from shortening run times, every one of George's nurses continued the practice, and Fresenius continued to submit claims for reimbursement for these shortened treatments. Doc. 122-26 at 20 *SEALED.*

Fresenius, not surprisingly, denies systematic shortening of run times and counters this evidence by noting that a patient's run time could run short or long for any number of reasons. *See* doc. 102-12 at 19–20. In fact, according to Fresenius, the most common reason for a shortened run time is a patient's

URR score, doc. 119-7 at 10–11. As such, George claims in her complaint that Fresenius staff, who had shortened run times to meet TAP goals so as to receive higher pay, were then able to avoid a two percent reimbursement reduction by making up for the shortened run times by having longer run times on lab days in order to meet their reportable statistics. *See* docs. 47 at 34–37; 188 at 40.

voluntary decision to terminate treatment early.[8] *Id.* at 35–36. Additionally, a patient could have a sudden change in blood pressure, experience hypotension or nausea, or otherwise feel ill. *Id.* at 19–20, 36–37. Fresenius's expert also notes that Fresenius's treatment completion rates are not unusual, as "[s]tudies have identified the rate of patient non-compliance with dialysis duration at 20% and higher." *Id.* at 36. Pursuant to Fresenius policy, nurses should report material deviations in treatment time in the patient's record. Docs. 102-12 at 19; 119-34 at 54. Conversely, a run time may also last longer than prescribed for any number of reasons. Doc. 102-12 at 38. For example, a nurse may be occupied with another medical issue when a patient's treatment time ends, or sometimes a few minutes elapse between the end of treatment and the nurse's availability to disconnect a patient. *Id.* at 38–39. Moreover, Fresenius recognizes that lab days in particular run long, which the company attributes to the added amount of time it takes for a nurse to draw the patient's labs while the dialysis machine runs. *Id.* at 38. Additionally, sometimes the dialysis machine does not accurately track the amount of time a patient actually undergoes treatment, resulting in a misrepresentation of treatment duration. *Id.* at 39.

[8] Fresenius is legally obligated to honor a patient's choice to end treatment early, even if that decision is contrary to medical advice. Doc. 102-12 at 19. When a patient chooses to shorten treatment time by a "material" amount (i.e., a treatment cut ten to fifteen minutes short, according to Fresenius's expert), Fresenius requires that the patient sign an Against Medical Advice ("AMA") form. Docs. 102-12 at 19; 119-34 at 54.

v. George's Employment at Fresenius After November 2011

In November 2011, George transferred to an Inpatient Case Manager position—a move that in an email at the time George stated she was "happy to accept." Docs. 102-5 at 2, 56–57; 122-26 at 56 *SEALED.* The Inpatient Case Manager reported to the same person as the Operations Manager, and George's pay remained the same. Docs. 102-3 at 7; 102-5 at 10; 102-16 at 18. However, as a result of this transfer, George purportedly lost a portion of her bonus for her work as the Operations Manager, became ineligible for future bonuses (the Inpatient Care Manager position cannot earn a bonus), and could no longer collect mileage checks for her travel. Docs. 102-5 at 14; 102-10 at 3; 122-1 at 49 *SEALED;* 122-20 at 2 *SEALED.* Moreover, although George's email indicated that she had accepted the position voluntarily,[9] doc. 102-16 at 17, George testifies that she accepted the position "under duress" because Fresenius had indicated that it would terminate her if she declined the position. Doc. 122-26 at 56 *SEALED.*

George maintains that Fresenius forced her to change positions in retaliation for George's report of what she believed were false claims made by certain Fresenius employees, including the systematic vial reentry and shortened run times to all three of her supervisors during her time at Fresenius. Doc. 122-26 at 12–14,

[9] Fresenius also purportedly offered George the option of remaining in the Operation Manager position on the condition that she complete a performance training. Doc. 122-1 at 49 *SEALED.* However, George testifies that Fresenius only offered her two options: take the Inpatient Care Manager position or termination. Doc. 122-26 at 56.

18, 64–65 *SEALED.* In support of her retaliation claim, George points to emails from July and December of 2011 and January of 2012 in which she recounts a report she supposedly made in July 2011 regarding a doctor's use of a billing form printed on Fresenius stationery that the clinic's governing body had adopted and that was not in the master forms manual. Docs. 102-5 at 14; 102-10 at 20–25; 119-37 at 2; 122-26 at 64 *SEALED.* George testifies that she was concerned that, because the doctor was using stationery the clinic had not adopted, Fresenius might have been liable in some way for improper billing under the FCA. Doc. 119-37 at 2. Also, in emails from September and December 2011 and January 2012, George supposedly reported a doctor in September 2011 who had not placed standing orders or algorithms in patients' charts. Docs. 102-5 at 14; 102-10 at 26–42; 119-37 at 2.

In April 2012, George resigned from Fresenius after a leave of absence due to stress and anxiety. Doc. 122-26 at 57 *SEALED.*

B. Procedural History

George originally filed this action in March 2012, doc. 1, and in November 2012 the United States declined to intervene, doc. 10. After George amended her complaint, docs. 18 and 47, and this court granted in part Fresenius's motion to dismiss the second amended complaint, docs. 50; 54; 55; 56, only the claims for knowingly submitting false claims to the Government in violation of 31 U.S.C. §

729(a)(1)(A) (Count I) and knowingly submitting false records in violation of 31 U.S.C. § 729(a)(1)(B) (Count II) remain as they relate to George's allegations regarding Fresenius's: (1) alleged billing for unnecessary waste; (2) purported double billing for administered waste; (3) supposed inadequate treatment in the form of reduced run times; and (4) apparent billing for free Epogen medication. *See* doc. 56. Additionally, George's claim for retaliation under the FCA (Count V) also survived. *See id.* Fresenius has moved for summary judgment on all remaining claims, doc. 102, and to exclude in its entirety the testimony of Thomas McGuire, doc. 104, and Dr. Asif, doc. 108. Then, based on the timing, length, and content of George's opposition to the motions to exclude, docs. 114 and 115, Fresenius filed a Motion to Strike George's Opposition Briefs and Exhibits related to these motions to exclude, doc. 117. Because the motions related to George's experts bear on this court's decision at summary judgment, the court must now wade into *Daubert*.

II. MOTIONS TO EXCLUDE EXPERT TESTIMONY

A. Standard of Review

Federal Rule of Evidence 702 governs the admission of expert testimony and provides that:

> [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.

Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, district court judges are responsible for acting as "gatekeep[ers]," *see* 509 U.S. 579, 597, 597 n.13 (1993), to keep "speculative, unreliable expert testimony" from the jury, *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1335 (11th Cir. 2010). The district court's gatekeeping role is "especially significant" because an expert's testimony "can be both powerful and quite misleading because of the difficulty in evaluating it." *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (*en banc*) (internal quotations and citation omitted). Therefore, "[t]he trial court must 'make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Kilpatrick*, 613 F.3d at 1335 (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)).

Applying these principles, the Eleventh Circuit has previously held that expert testimony may be admitted if three "rigorous" requirements are met. *See Frazier*, 387 F.3d at 1260. First, "the expert must be qualified to testify competently regarding the matter he or she intends to address." *Kilpatrick*, 613 F.3d at 1335. Second, "the methodology used must be reliable as determined by a *Daubert* inquiry." *Id.* Third, "the testimony must assist the trier of fact through the application of expertise to understand the evidence or determine a fact in issue." *Id.*

(citation omitted). When determining the admissibility of proffered expert testimony, a district court remembers that "[t]he burden of establishing qualification, reliability, and helpfulness rests on the proponent of the expert opinion," *Frazier*, 387 F.3d at 1260, and these factors "must be shown by a preponderance of the evidence," *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1256 (11th Cir. 2002) (quoting *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1306 (11th Cir. 1999)). As such, "[t]he *Daubert* requirement that the expert testify to scientific knowledge—conclusions supported by good grounds for each step in the analysis—means that *any* step that renders the analysis unreliable under the *Daubert factors renders the expert's testimony inadmissible*." *See McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1245 (11th Cir. 2005) (emphasis in original) (internal quotations and citation omitted).[10] Importantly, the district court has "considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Kumho Tire*, 526 U.S. at 152.

With these principles in mind, the court now turns to Fresenius's contentions related to their *Daubert* motions. Docs. 104, 108, 117.

[10] The non-exhaustive list of *Daubert* factors for trial judges to consider include: (1) whether the expert's theory or technique can be or has been tested; (2) whether the expert's theory or technique has been subjected to peer review and publication; (3) the theory or technique's known or potential rate of error; and (4) whether the theory or technique has been "generally accepted" by the community. *Daubert*, 509 U.S. at 593–94.

B. Motion to Strike (Doc. 117)

Before addressing the merits of Fresenius's motion to exclude Dr. McGuire's testimony, the court must first address Fresenius's pending Motion to Strike Relator's Opposition Briefs and Exhibits to Fresenius's Motion to Exclude Expert Testimony, doc. 117, which the court **GRANTS IN PART**. First, because of the conflicting page limitations indicated in Appendix II of the scheduling order issued in this case, doc. 64 at 15 (requiring 10 pages for non-dispositive motions), and the limitations indicated on the Northern District of Alabama's website, Site for Judge Kallon's Non-Summary Judgment Submissions Guidelines, at 3, http://www.alnd.uscourts.gov/forms/appendix-iii-non-summary-judgment-motion-scheduling-order-and-submissions-guidelines (last visited June 30, 2016) (allowing 20 pages for non-dispositive motions), the court **DENIES** the motion to the extent that Fresenius argues that George's opposition to its motions to strike Drs. McGuire and Asif should be stricken for failure to comply with the page limitations. Additionally, the court **DENIES** the motion insofar as Fresenius seeks to have the entire motion stricken for failure to timely respond, as the court, *supra* at footnote 1, granted George's unopposed motion for an extension.

However, the court **GRANTS** the motion insofar as it relates to Exhibit U of George's opposition to the motion to exclude Dr. McGuire, doc. 115-29 at 1, and Exhibit G of George's opposition to the motion to exclude Dr. Asif, doc. 114-8 at

2, and insofar as any of George's arguments are based upon these exhibits. George advances these exhibits—which are identical tables titled, "Frequency of Uncompleted Treatment"—to substantiate Dr. McGuire's opinion that Fresenius billed for more than 33,000 treatments that were ten or more minutes shorter than their prescribed time. *See* docs. 115 at 19–22; 117 at 3, 5–7. Important here, George's arguments and these exhibits portray a table displaying treatments that purportedly did not run their prescribed length. The new tables break this data into two columns: the first showing the number of treatments that were between zero and ten minutes short of the prescribed time, and the second showing treatments that were more than ten minutes short. *See* docs. 115-29 at 1; 114-8 at 2. In contrast, Dr. McGuire's expert report included a table that outlined the frequency of purportedly uncompleted treatment and sorted the data into increments of fifteen minutes (for example, it stated that in 2010, apparently 5,483 treatments had run between zero and fifteen minutes short of the prescribed time). Doc. 102-20 at 44.

Under Federal Rule of Civil Procedure 26(a)(2)(B), a party is required to disclose a putative expert witness and written report that, *inter alia*, "must" include:

> (i) a complete statement of all opinions the witness will express and the basis and reasons for them;
> (ii) the facts or data considered by the witness in forming them;
> (iii) any exhibits that will be used to summarize or support them[.]

George's failure to disclose this table—or to have Drs. McGuire or Asif assert any testimony related to this table—prior to her opposition to Fresenius' motion to exclude, constitutes a violation of Rule 26(a)(2)(B)'s disclosure requirements. Namely, in her opposition to Fresenius's motion to exclude Dr. McGuire's findings, George suddenly argues that his findings are relevant because run times that are shorter than the prescribed time by ten minutes are material to the court's finding of Fresenius's noncompliance. *See* doc. 115 at 19–22, 21 n.13. Assuming that Dr. McGuire considered these "facts or data . . . in forming" his opinion that Fresenius under-dialyzed patients and used this "exhibit[] . . . to summarize or support" the same finding, *see* Fed. R. Civ. P. 26(a)(2)(B), George should have disclosed this chart during discovery. To get around the discovery issue, George argues that she in fact disclosed this evidence previously because: (1) Dr. McGuire testified at his deposition about an article discussing the impacts of run times shortened by more than 10 minutes; (2) Fresenius's expert agreed that a run time of greater than ten minutes short was "material;" and (3) these exhibits simply sort Dr. McGuire's data according to a different time interval than the fifteen-minute interval in his report. *See* doc. 123 at 5–6. However, none of these arguments satisfy the court that George's purported "disclosures" of the ten-minute interval comport with one of the main goals of Rule 26(a)(2)(B)—namely, to give Fresenius a fair opportunity "to prepare an effective and efficient response to

[George's] expert[s'] opinions, which is one of the goals for requiring disclosure of a Rule 26(a)(2) report." *See Current v. Atochem N. Am., Inc.*, No. CIV. A. W-00-CA-332, 2001 WL 36101282, at *4 (W.D. Tex. Sept. 18, 2001) (noting that the plaintiff's expert's opinion had become "a moving target," and placed the defendants "at a distinct disadvantage" because they "have already expended significant time, effort, and resources in their attempt to rebut [the plaintiff's expert's] opinions"). Therefore, because George failed to disclose these exhibits on October 30, 2015, *see* doc. 97, and because George fails to establish or even plead that the omission is substantially justified or harmless under Federal Rule of Civil Procedure 37(c)(1), the court finds that Exhibits U (Dr. McGuire) and G (Dr. Asif), as well as the opinions and arguments based on these exhibits, are hereby **STRICKEN** as untimely.

C. Testimony of Thomas McGuire (Doc. 104)

George offers the expert testimony of Dr. McGuire to support her claim that Fresenius artificially inflated its profitability by: (1) wasting Venofer and Zemplar; (2) reentering Venofer vials; and (3) manipulating therapy run times to give a misleading impression of the care patients received at Fresenius clinics. *See generally* doc. 102-20 at 3–4, 26–49, 79–115. Fresenius argues that the court should exclude this testimony because Dr. McGuire's work is unreliable and his

opinions will not assist the trier of fact. *See* docs. 104 at 3–10; 125 at 1–5. For the reasons outlined below, this motion is due to be granted in part.

i. Qualification

An expert may be "qualified" in various ways. For instance, Federal Rule of Evidence 702 notes that an expert may be qualified "by knowledge, skill, experience, training, or education." Important here, however, "[e]xpertise in one field does not qualify a witness to testify about others." *Lebron v. Sec'y of Fla. Dep't of Children & Families*, 772 F.3d 1352, 1369 (11th Cir. 2014) (citations omitted). Although Fresenius does not dispute that Dr. McGuire is qualified to testify as an expert, the court will briefly discuss his credentials. Dr. McGuire is a Professor of Health Economics in the Department of Health Care Policy at Harvard Medical School and he teaches health economics in Harvard University's Health Policy Ph.D. program. Doc. 102-70 at 5. He holds a Ph.D. in economics from Yale University and, for forty years, has conducted research in the following areas: "the economics of managed care, health insurance and health care payment systems including Medicare, drug pricing and procurement, the economics of quality reporting, the economics of health care disparities by race and ethnicity, and the economics of mental health policy." *Id.* at 5–6. He has received awards for and published various books and papers on health economics topics, including those

such as the effects of Medicare payment quality reporting policies on the functioning of healthcare markets. *Id.* In short, he is qualified.

ii. Reliability

Federal Rule of Evidence 702 and *Daubert* both inform the court's consideration of reliability. "[T]he trial judge must assess 'whether the reasoning or methodology underlying the testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue.'" *Frazier*, 387 F.3d at 1261–62 (quoting *Daubert*, 509 U.S. at 592–93). A witness may testify as an expert if: "1) the testimony is based upon sufficient facts or data, 2) the testimony is the product of reliable principles and methods, and 3) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702. Important here, "[t]hese factors are illustrative, not exhaustive" because "not all of them will apply in every case, and in some cases other factors will be equally important in evaluating the reliability of proffered expert opinion." *Frazier*, 387 F.3d at 1262.

Dr. McGuire advances three important opinions in this case, all of which are based substantially on Fresenius's records. *See generally* doc. 102-20 at 26–49. Fresenius challenges Dr. McGuire's opinion as unreliable because he purportedly ignores undisputed alternative explanations and bases his opinions, in part, on an unreliable Fresenius document. *See generally* doc. 104.

a. Reentry

Dr. McGuire seeks to testify that a comparison of Fresenius's administration records with its inventory records reveals that, during the relevant time period, the nine clinics at issue administered 48,067 vials of Venofer but pulled only 40,933 vials from inventory, which, Dr. McGuire states, supports a finding of Venofer reentry. *See* doc. 102-20 at 35–40. Fresenius objects as to the foundation of Dr. McGuire's opinion—namely, that his opinion is not based upon sufficient facts or data because he relied upon Fresenius's inventory and administration records (records that Dr. McGuire did not explicitly review himself but that were compiled by George's data analyst for Dr. McGuire to review in aggregate). *See* docs. 104 at 7–10; 125 at 4–5.

Specifically, Fresenius argues that the pharmacy use of inventory forms "might help clinics understand if they had sufficient medication supply for the patients (or if more might need to be ordered)[, but] they are not reliable for an economic or accounting analysis." *Id*. at 9. Indeed, the calculations lead to some strange outcomes some months. For instance, sometimes Dr. McGuire shows negative vials used (i.e., more administered than in inventory), and other times the inventory logs list no vials used despite the fact that Fresenius's records indicate the drugs being administered during that shift. Additionally, Fresenius had no pharmacy inventory data for seven facility months (i.e., there were seven instances

where one of the clinics' monthly inventory was missing). *See generally* docs. 102-17 at 50; 102-18 at 1–2. Still, although Fresenius may maintain that these forms have underlying inaccuracies (such as missing or inconsistent data points), the underlying accuracy of the data in these documents goes to the weight of Dr. McGuire's testimony, not to its admissibility. *See Advanced Bodycare Sols., LLC v. Thione Int'l, Inc.*, 615 F.3d 1352, 1363–64 (11th Cir. 2010) (finding, in a case in which the putative expert relied upon a party's records "without verifying beforehand the accuracy of the . . . underlying data," that the plaintiff "was free to challenge—on cross-examination and on rebuttal—the reliability of the . . . data on which [the expert] grounded his opinions and thus the weight the jury should ascribe to those opinions"). Moreover, these forms are the only documentation Fresenius uses to track physical inventory and are, therefore, the only data Dr. McGuire has to compare the number of vials physically present in the clinics with the number of vials supposedly administered (and wasted). *See* doc. 110-3 at 30–31 *SEALED*; *see also United States v. Ala. Power Co.*, 730 F.3d 1278, 1287 (11th Cir. 2013) (noting that an expert's opinion had sufficient evidentiary basis because, *inter alia*, he relied upon the defendant's own records). Needless to say, it would encourage duplicity—and certainly invade the province of the jury—if this court were to find, as a matter of law, that a company can avoid unpleasant adverse testimony regarding its own records simply by arguing that the records are

inaccurate or that it keeps incomplete records. As such, Fresenius's argument—that Dr. McGuire's testimony is unreliable simply because he relied on Fresenius's own internal documents that are, apparently, inaccurate—fails to persuade the court.

Fresenius's arguments regarding the compilation of the pharmacy use records similarly fail to persuade the court. Fresenius argues that Dr. McGuire's opinion is rendered unreliable because Alden Snow, who compiled the pharmacy use data, "admitted in his deposition that inconsistencies in the data forced him to make 'judgment calls' . . . and that he had serious doubts about the reliability of the data." *See* doc. 104 at 9–10. However, a review of Snow's testimony paints a slightly different story. Snow was responsible both for manually transferring the pharmacy use data from the form in which Fresenius produced it (a PDF) into a spreadsheet that could be sorted along different variables and for verifying that the data transfer was accurate. *See* doc. 110-9 at 15 *SEALED.* Because Fresenius's monthly inventory forms were at times unclear about the month to which they were ascribed (for instance, sometimes the forms were simply labeled "April" as opposed to "April 2009"), Snow used context clues on the forms to determine to which date and year the inventory forms applied. For example, Snow looked to the date the form was prepared, the month's beginning Venofer inventory, and the month's ending Venofer inventory to determine where chronologically the month

fell and compared the physical inventory at the end of a month with the physical inventory at the beginning of another month to ensure that the physical inventory aligned. *See* doc. 110-9 at 31–36 *SEALED.* This methodology seems reasonable to the court, especially when faced with what appears to be Fresenius's poorly maintained inventory forms. Although Snow's approach may be vulnerable to criticism, the court finds that such attacks are fodder for cross examination, not for a finding that the foundation of Dr. McGuire's testimony is unreliable. *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000) (explaining that "[t]he soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact") (internal quotations omitted).

b. Waste

Fresenius also seeks to exclude as unreliable Dr. McGuire's opinions as to the creation of unnecessary waste. *See* docs. 104 at 3–5; 102 at 1–2. Dr. McGuire outlines Medicare's reimbursement regimen for Venofer and Zemplar to show the purportedly significant financial incentive to create unnecessary waste. Doc. 102-20 at 28–30. Critical to the court's analysis here, Dr. McGuire relied on Dr. Asif's opinion that "there is no scientific or medical justification supporting smaller and more frequent doses" of Venofer, doc. 102-14 at 15, and therefore Dr. McGuire "assume[d] that *all* wastage of Venofer was unnecessary," doc. 102-20 at 33

(emphasis added). Based on this assumption, Dr. McGuire found that, among Medicare patients during the years 2008-2010, there were 13,206 instances of wasteful administration (or $486,453 in additional Medicare payments) at Fresenius. Doc. 102-20 at 30–31. However, Dr. McGuire's assumption that *all* Venofer wastage is unnecessary because apparently no justification exists for a partial dose falls prey to the same problems that Dr. Asif's opinion, *see infra* Part III(B)(i)(b), does. That is, this assumption that all wastage is unnecessary fails to consider other potentially compelling reasons to explain the high number of partial vials. Namely, Dr. McGuire fails to account for the fact that Fresenius nurses may have administered partial doses pursuant to a physician's order—a consideration especially important because the parties agree that Fresenius's nurses must administer medication as directed by a patient's treating physician. *See, e.g.*, *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1253 (11th Cir. 2010) ("[A]n expert must provide some explanation of why other potential causes were not the sole cause.") (internal citations omitted); *Borum v. Werner Co.*, No. 5:11-CV-997-AKK, 2012 WL 2047678, at *13 (N.D. Ala. June 6, 2012) (excluding a putative expert because he "neglect[ed] to account for other possible, if not probable, causes of the . . . failure"). Therefore, Dr. McGuire's categorical determination that all Venofer administrations of fewer than 100 mg constituted unnecessary waste, without consideration of other competing reasons (namely, whether a physician

had prescribed the partial dose), falls short of the *Daubert* standard of reliability. *See Kumho Tire*, 526 U.S. at 157 ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.") (internal quotations and citation omitted).

Dr. McGuire also opined that, between 2008-2010, Fresenius was responsible for 6,518 instances of unnecessary Zemplar wastage. Doc. 102-20 at 34–35. Dr. McGuire compared the wastage patterns for the clinics at issue here and determined that some clinics were "high-waste" clinics while others were "low-waste" clinics. *Id.* Then, deciding that the low-waste clinics had engaged only in reasonable Zemplar waste (an opinion the bases of which Dr. McGuire does not outline to the court), Dr. McGuire applied the rate of "reasonable" waste in the low-waste clinics to the wastage in the high-waste clinics and determined that the high-wastage clinic numbers in excess of the low-waste clinic rates constituted "unnecessary waste." *Id.* Fresenius moves to exclude this finding, arguing again that Dr. McGuire failed to consider other proper explanations for Zemplar wastage, such as a physician's prescription. The court agrees. George's complaint alleges that Fresenius's nurses generated waste by failing to adhere to a treating physician's prescription, and so, to assist the jury in the determination of this claim, Dr. McGuire should have considered whether adhering to a physician's

prescription—a "possible, if not probable" explanation for the Zemplar wastage—explained the clinics' Zemplar statistics. *See* doc. 47 at 17, 33; *Borum*, 2012 WL 2047678, at *13. Therefore, because "an expert must provide some explanation of why other potential causes were not the sole cause," *see Guinn*, 602 F.3d at 1253; *see also Kumho Tire*, 526 U.S. at 157, Dr. McGuire's opinion as to Zemplar wastage is due to be excluded.

c. Run Time

Fresenius also moves to exclude as unreliable Dr. McGuire's opinions regarding Fresenius's run time claims. *See* doc. 104 at 5–7. In support of George's allegation that Fresenius systematically shortens dialysis run times and fraudulently sought reimbursement for these treatments, Dr. McGuire purports to present evidence that Fresenius shortened its run time claims by an average of 4.15 minutes below a patient's prescribed run time on so-called "non-lab" days and increased a patient's run time by an average of 3.17 minutes on so-called "lab" days. *See* doc. 102-20 at 42–44. Additionally, Dr. McGuire presents a chart that purports to represent the frequency of uncompleted dialysis treatments at the Fresenius clinics at issue, *see id.* at 44–45, which asserts that during the relevant time period, Fresenius shortened nearly 29,000 treatments by more than fifteen minutes. For the reasons outlined more fully below, however, the court agrees with Fresenius that this evidence should be excluded as unreliable, because Dr.

McGuire failed to consider a number of valid reasons that treatment times might run shorter than prescribed. *See* doc. 104 at 5.

The parties do not dispute that a treatment may run short for any number of reasons beyond purported fraud on the Government. For example, a dialysis treatment may run short because of patient choice or medical concerns, among others. *See* docs. 102-12 at 19–20, 36–37; 102-24 at 8. Critical here, Dr. McGuire failed to account for any of these reasons in his statistical analysis. *See* doc. 102-24 at 6–7, 28 ("I didn't examine the reasons why a treatment would be cut short other than the factors I identified in my report [of decreasing costs and saving staff time]."). As a result, Dr. McGuire's "statistical analysis" presents the impression that every variance from a patient's prescribed treatment time is fraudulent (or at least motivated by a desire to save expense and staff time), a finding particularly troublesome because treatment can be cut short for any number of non-fraudulent reasons (for instance, according to Fresenius's expert, research shows that the most common reason a patient fails to complete treatment is due to the patient's decision to terminate early). Doc. 102-12 at 35. Therefore, because Dr. McGuire has failed to incorporate research or present modeling that accounts for other perfectly reasonable explanations for early termination of run times, the court finds that his opinion is not based on reliable principles and methods. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too

great an analytical gap between the data and the opinion proffered.") (citation omitted); *Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 152 F.3d 588, 593 (7th Cir. 1998) ("Statistical studies that fail to correct for salient factors, not attributable to the defendant's misconduct, that may have caused the harm of which the plaintiff is complaining do not provide a rational basis for judgment."). As such, Dr. McGuire's opinions as to dialysis run times are due to be excluded.

iii. Conclusion

To summarize, Fresenius's motion to exclude Dr. McGuire's testimony, doc. 104, is due to be granted in part. Specifically, Dr. McGuire's opinions regarding Venofer and Zemplar wastage and his opinions regarding dialysis run times are unreliable. However, Fresenius's motion is due to be denied insofar as it applies to Dr. McGuire's reentry opinion.

D. Testimony of Dr. Arif Asif (Doc. 108)

Relevant to George's claims at summary judgment, Dr. Asif opines the following: (1) shorter dialysis treatment times negatively affect a patient's clearance of toxins from the body, doc. 102-14 at 8–13; (2) increased dialysis times on so-called "lab days" increases a patient's URR, *id.* at 13–14; and (3) there is no scientific or medical justification supporting smaller and more frequent doses of Venofer, *id.* at 14–15. Fresenius objects to these opinions because Dr. Asif is

purportedly not qualified and because his opinions would not be helpful to the jury. *See generally* docs. 108 and 124. The court agrees in part.

i. Qualification[11]

Fresenius first argues that the court should exclude Dr. Asif's expert testimony because he is purportedly not qualified to issue an opinion on Venofer and Zemplar dosing practices and because he evidently relied inappropriately on George's and Dr. McGuire's testimony. Docs. 108 at 1–5; 124 at 2–3. Dr. Asif is a nephrologist who currently serves as the Chief of Nephrology and Hypertension at Albany Medical College in Albany, New York. Doc. 102-14 at 4, 29. Board certified in internal medicine since 1999 and nephrology since 2000, Dr. Asif completed his residency in internal medicine at Mercy Hospital and Medical Center, University of Illinois College of Medicine and a fellowship in nephrology at the University of Miami Miller School of Medicine in Florida. *Id.* Dr. Asif also taught nephrology at the Miller School of Medicine from 2000 to 2012. *Id.* at 32. Additionally, from 2001-2012 Dr. Asif taught the nephrology fellows the core curriculum at Miller School of Medicine. *Id.* at 34. He has also chaired, led, or moderated numerous national nephrology meetings and conferences with a specialization in interventional nephrology and, from 2008-2010, was the President

[11] To the extent that Fresenius objects to Dr. Asif's qualifications as to Zemplar reentry, doc. 108 at 2–3, the court will not address these arguments because George has abandoned that claim at summary judgment, *see* doc. 102 at 16–23; *see also infra* note 14.

of the American Society of Diagnostic and Interventional Nephrology. *Id.* at 34–38.

Fresenius attacks Dr. Asif's qualification to opine on Venofer and Zemplar dosing because he purportedly did not begin prescribing dialysis treatments to patients until July 2012. Docs. 108 at 2–3; 124 at 2–3. Fresenius claims that this timing is important because George's allegations relate to Fresenius's actions prior to January 2011; at that time, Venofer was only manufactured in 100 mg vials, and Medicare allowed separate billing for Venofer and Zemplar waste. *See* doc. 108 at 2–3. Therefore, according to Fresenius, Dr. Asif is unqualified to opine at all regarding Venofer and Zemplar dosing. Doc. 102-14 at 15. The court disagrees insofar as Fresenius argues that Dr. Asif is not qualified to offer testimony regarding the medical outcomes of different Venofer and Zemplar treatment protocols. First, the record belies Fresenius's claim that, prior to 2012, Dr. Asif had not treated dialysis patients. *See* doc. 102-24 at 108 (describing the number of outpatient dialysis patients he treated at Albany Medical Center and at the University of Miami). Additionally, Dr. Asif's curriculum vitae indicates that he is a specialist in nephrology and that he taught nephrology—teaching which includes Venofer and Zemplar—during the relevant time period. *See* docs. 102-14 at 32; 102-24 at 106 ("Venofer, Zemplar, that's regular teaching that we all do as nephrologists, as academic nephrologists."). Moreover, even if Fresenius was

correct and Dr. Asif only began treating patients in 2012, the court's analysis would not change because the medical outcomes of different dosing protocols should not vary by the prescribed drug's vial size. *See Grindstaff v. Coleman*, 681 F.2d 740, 743 (11th Cir. 1982) ("A rule which would require an expert witness to have been an expert at the time of the questioned event would prevent proof based upon knowledge of historical events."). Dr. Asif's curriculum vitae and experiences satisfy the court of his qualifications in the field of nephrology, and, accordingly, the court finds that he is qualified to opine on the medical benefits of different Venofer and Zemplar protocols.

Fresenius also objects to Dr. Asif's qualifications on the grounds that he reiterates Dr. McGuire's opinions as his own. The court agrees. Dr. Asif's report ventures into territory that is outside his area of expertise when he testifies: (1) "giv[ing] lower doses of Venofer is not scientifically and medically justified" because the higher frequency of lower doses creates additional waste, doc. 102-14 at 15; (2) Fresenius benefitted from policies and practices that resulted in Venofer and Zemplar wastage, *id.* at 16–17; (3) Fresenius manipulated run times, thus negatively affecting patients, *id.* at 12–13; and (4) Fresenius provided "shorter dialysis sessions to a significant number of patients," *id.* at 14. These opinions lie outside Dr. Asif's expertise. Indeed, while Dr. Asif presents a curriculum vitae that asserts formidable qualifications in the area of nephrology treatment and research,

his resume does not indicate an expertise in analyzing or understanding behavioral patterns in the face of Medicare payment incentives. In fact, a review of Dr. Asif's report makes clear that he relied upon Dr. McGuire's testimony (which the court has excluded) regarding unnecessary waste or deliberately increased run times. *See* doc. 102-14 at 8–15. Moreover, Dr. Asif has no personal knowledge of the policies or practices motivating Fresenius employees, so he cannot testify to such behaviors on that basis either. Therefore, to the extent that Dr. Asif intends to opine about Fresenius's purported creation of waste or the manipulation of run times, his testimony is due to be excluded on the grounds that he is not a qualified expert in these topics. However, with respect to appropriate Venofer or Zemplar dosing or to the impact of run time on dialysis outcomes, the court finds that he is an appropriately qualified expert on these topics.

ii. Relevance

Fresenius also argues that Dr. Asif's testimony regarding both the wastage of Venofer and Zemplar and the impact a shortened run time has on patients is not relevant because it does not advance George's claims. *See* doc. 108 at 6–8. The court disagrees, because testimony that partial and full vial dosages of Venofer and Zemplar show equal patient results is relevant to George's claim regarding the necessity of wastage. Such testimony bears on the court's finding that a prescription cannot result in wastage where reasonable minds could differ as to the

treatment approach.[12] *See infra* at Part III(B)(i)(b). As to Fresenius's claim that Dr. Asif's testimony regarding shortened run times is not relevant to George's claim that Fresenius under-dialyzed patients and then billed Medicare for completed—and, presumably, insufficient—treatments, *see* docs. 108 at 6–8, the court finds otherwise. Indeed, as outlined below in the court's discussion of the implied false certification theory, whether the quality of treatment would materially affect Medicare's decision to reimburse Fresenius is at issue in this case. As such, Dr. Asif's medical opinion regarding the impact of a shortened run time is relevant to George's claim here.

iii. ***Conclusion***

For the reasons outlined above, the court finds that Fresenius's motion to exclude Dr. Asif's testimony is due to be granted in part. Specifically, Dr. Asif's testimony regarding Fresenius's supposed Venofer and Zemplar dosing as it relates to the creation of waste and his testimony as to Fresenius's supposed policy and practice of shortening run times to decrease costs are due to be excluded. However, Fresenius's motion is due to be denied insofar as it relates to the medical outcomes of prescribing partial and full vials of Venofer and Zemplar as well as the medical impact of shortened run times.

[12] In light of the court's exclusion of Dr. Asif's opinion insofar as he believes that "no justification" exists for a variation in prescriptions in light of the waste such prescriptions create, Dr. Asif's testimony can only relate to his research, experience, and knowledge as to the effectiveness of prescribing partial and full vials of Venofer and Zemplar.

III. MOTION FOR SUMMARY JUDGMENT

A. Standard of Review

Under Rule 56(a) of the Federal Rules of Civil Procedure, summary judgment is proper "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." To support a summary judgment motion, the parties must cite to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials." Fed. R. Civ. P. 56(c)(1)(A). Moreover, "Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The moving party bears the initial burden of proving the absence of a genuine issue of material fact. *Id*. at 323. The burden then shifts to the nonmoving party, who is required to "go beyond the pleadings" to establish that there is a "genuine issue for trial." *Id*. at 324 (citation and internal quotation marks omitted). A dispute about a material fact is genuine "if 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).

The court must construe the evidence and all reasonable inferences arising from it in the light most favorable to the non-moving party. *Adickes v. S. H. Kress & Co.*, 398 U.S. 144, 157 (1970); *see also Anderson*, 477 U.S. at 255 (all justifiable inferences must be drawn in the non-moving party's favor). Any factual disputes will be resolved in the non-moving party's favor when sufficient competent evidence supports the non-moving party's version of the disputed facts. *See Pace v. Capobianco*, 283 F.3d 1275, 1276 (11th Cir. 2002) (a court is not required to resolve disputes in the non-moving party's favor when that party's version of events is supported by insufficient evidence). However, "mere conclusions and unsupported factual allegations are legally insufficient to defeat a summary judgment motion." *Ellis v. England*, 432 F.3d 1321, 1326 (11th Cir. 2005) (*per curiam*) (citing *Bald Mountain Park, Ltd. v. Oliver*, 863 F.2d 1560, 1563 (11th Cir. 1989)). Furthermore, "[a] mere 'scintilla' of evidence supporting the opposing party's position will not suffice; there must be enough of a showing that the jury could reasonably find for that party." *Walker v. Darby*, 911 F.2d 1573, 1577 (11th Cir. 1990) (citing *Anderson*, 477 U.S. at 252).

B. Analysis

The only claims presently before this court are George's retaliation claim under § 3730(h) and her claims that Fresenius knowingly submitted false claims to the Government in violation of 31 U.S.C. § 3729(a)(1)(A) (Count I) and knowingly

submitted false records in violation of 31 U.S.C. § 3729(a)(1)(B) as they relate to: (1) alleged billing for unnecessary waste; (2) purported double billing for administered waste; and (3) supposed inadequate treatment in the form of reduced run times.[13] *See* docs. 56; 102; 118; 127. For the reasons more fully laid out below, the court finds that Fresenius' motion for summary judgment is due to be granted in part.

i. Claims Under § 3729

The FCA subjects to civil liability any person who "knowingly presents, or causes to be presented" to the Government "a false or fraudulent claim for payment or approval," § 3729(a)(1)(A), or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," § 3729(a)(1)(B). The purpose of the FCA is to encourage private persons who become aware of fraud against the Government to come forward. *Ragsdale v. Rubbermaid, Inc.*, 193 F.3d 1235, 1236 n.1 (11th Cir. 1999). Important here,

[13] This court has previously dismissed allegations under § 3729 related to a scheme to bill for extra syringes and to allegations of a nationwide fraudulent scheme, *see* doc. 5, and dismissed with prejudice plaintiff Dawn Simmons from this case, *see* doc. 99. Although George's claim regarding alleged billing as to the Epogen Fresenius received for free for uninsured patients survived Fresenius's motion to dismiss, *see* doc. 56, she does not assert any argument in opposition to the motion for summary judgment as to this claim, *see generally* doc. 118. As such, summary judgment is appropriate for her Epogen claim. *See, e.g.*, *Fischer v. Fed. Bureau of Prisons*, 349 F. App'x 372, 375 n.2 (11th Cir. 2009) (finding that the plaintiff waived claims he did not address in his response to the defendant's motion for summary judgment) (citing *Transamerica Leasing, Inc. v. Inst. of London Underwriters*, 267 F.3d 1303, 1308 n.1 (11th Cir. 2001)); *Resolution Tr. Corp. v. Dunmar Corp.*, 43 F.3d 587, 599 (11th Cir. 1995) ("[T]he onus is upon the parties to formulate arguments; grounds alleged in the complaint but not relied upon in summary judgment are deemed abandoned.") (citations omitted).

"[l]iability under the [FCA] arises from the submission of a fraudulent claim to the government, not the disregard of government regulations or the failure to maintain proper internal procedures." *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005). "Simply put, the '*sine qua non* of a[n FCA] violation' is the submission of a false claim to the government." *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1045 (11th Cir. 2015) (quoting *Corsello*, 428 F.3d at 1012). Therefore, to establish a cause of action under the FCA, a relator must prove three elements: "(1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with knowledge that the claim was false." *United States v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1355 (11th Cir. 2005) (relying on § 3729(a)).

With these principles in mind, the court now turns to George's false claims allegations against Fresenius.

a. Double Billing of Venofer Due to Vial Reentry[14]

George alleges that Fresenius nurses, in violation of Fresenius and Medicare policy, administered and billed Medicare for reentered Venofer vials. *See* doc. 47 at 26–27. Fresenius moves for summary judgment on George's double billing claim because, supposedly, George has failed to present any evidence that

[14] Because George fails to respond to Fresenius's motion for summary judgment as to Zemplar reentry, doc. 102 at 16–23, summary judgment is due to be granted as to the reentry claims for that drug, *see, e.g.*, *Resolution Trust Corp.*, 43 F.3d at 599. The claim also fails because George has not established that Fresenius presented a false claim for payment to the Government.

Fresenius submitted reimbursement claims for administered waste and cannot prove that Fresenius knowingly submitted a false claim to the Government. *See* doc. 102 at 15–23; 127 at 5–8. In response, George advances that she has sufficient evidence regarding reentry and double billing and that Fresenius knew it was submitting false claims for administered waste. *See* doc. 188 at 20–27, 29. After reviewing the record, the court finds that summary judgment is due to be granted as to this claim.

i. *False Claim*

Because "the *sine qua non* of a[n FCA] violation is the submission of a false claim to the government," *see Urquilla-Diaz*, 780 F.3d at 1045 (internal quotation and citation omitted), Fresenius argues that George must point to a specific false claim to survive summary judgment, *see* docs. 102 at 16–18; 127 at 5–8. Indeed, the FCA "attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the '*claim for payment*.' Therefore, a central question in [FCA] cases is whether the defendant ever presented a 'false or fraudulent claim' to the government." *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (citations omitted). Here, while George's testimony that she witnessed reentry as well as McGuire's calculations may imply a "disregard of government regulations or a failure to maintain proper internal policies," she is still unable to specifically show "[t]he act of submitting a

fraudulent claim to the government." *Corsello*, 428 F.3d at 1012 (internal citation omitted); *see also Clausen*, 290 F.3d at 1311 ("Without the *presentment* of such a claim, while the practices of an entity that provides services to the Government may be unwise or improper, there is simply no actionable damage to the public fisc as required under the [FCA.]") (emphasis in original). Indeed, if McGuire is correct and Fresenius is reentering Venofer vials, this fact still—notwithstanding that, as Dr. McGuire points out, sixty percent of Fresenius's patients are on Medicare—does not satisfy the requisite showing of a false claim. Discovery is designed to afford the plaintiff an opportunity to collect evidence to support a claim. George has received this opportunity and conducted significant discovery. Therefore, at this stage in the proceedings, her speculation that Fresenius submitted a false claim is not enough to show that Fresenius has "ask[ed] the Government to pay amounts it does not owe." *See Clausen*, 290 F.3d at 1311.

Even under *United States v. Krizek*, the out-of-circuit case upon which George relies, her arguments fail. 192 F.3d 1024 (D.C. Cir. 1999); *see also* doc. 118 at 22–24. *Krizek* involved an action the Government filed under the FCA against a psychiatrist for submitting reimbursement to Medicare for services allegedly performed. *See* 192 F.3d at 1025–26. Significantly, the issue in front of the D.C. Circuit was not whether the defendant had submitted a false claim—as the district court found that on some days the psychiatrist had billed for more than

twenty-four hours of work—but, rather, whether the judge's calculation of the specific number of false claims and, therefore damages, was appropriate. *Id.* at 1031. Here, by contrast, liability is not a foregone conclusion. Even construing the facts in the light most reasonable to George, there is no material dispute of fact where George cannot identify a single false claim that Fresenius submitted to the Government.

b. Waste

George also claims that Fresenius "purposefully created and sought reimbursement for intentional, unnecessary and unreasonable waste of Venofer and Zemplar" through the administration of partial-vial doses, purportedly resulting in a fraudulent increase of revenue and discounts from manufacturers. *See* doc. 47 at 22–29.

Under 42 U.S.C. § 1395y(a)(1)(A), Medicare funds cannot reimburse a dialysis clinic for "items and services . . . [that] are not reasonable and necessary for the diagnosis or treatment" of ESRD. At issue here is whether George has offered any evidence that Fresenius nurses billed for unnecessary or avoidable Venofer and Zemplar wastage. In that respect, even allowing for George's argument that Medicare limits reimbursements for waste to "those circumstances when wastage is **absolutely unavoidable**," docs. 118 at 6–7, 17–20; 119-6 at 2 (emphasis in original), George's claim still fails because she ignores that the record

indicates that Fresenius's nurses merely administered the dosages prescribed by the patients' treating physicians—a fact to which George herself testified, *see* doc. 110-4 at 27. George has failed to direct the court to any evidence to substantiate the allegations in her complaint that Fresenius nurses administered dosages inefficiently or manipulated doses to create waste. *See* doc. 47 at 25–27. While George is correct that Fresenius publicly encouraged physicians to dose in order to avoid waste, the physicians' failure to comply with this internal policy does not itself constitute a false claim because partial vials are medically reasonable. In fact, George's own expert testified that frequent administration of partial vials was just as medically effective as less frequent administration of whole vials. In short, the court declines to find that a difference in medical judgment—in absence of evidence that a doctor's independent medical judgment was compromised, for instance, through the writing of inefficient prescriptions—constitutes a false claim. *See United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980, 983 (10th Cir. 2005) ("Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false.") (internal quotations and citation omitted); *see also United States v. AseraCare, Inc.*, 153 F. Supp. 3d 1372, 1387 (N.D. Ala. 2015) ("An expert's opinion disagreeing with the clinical judgments of the certifying physicians, without more, is not enough to prove falsity under the FCA."); *cf. Urquilla-Diaz*, 780 F.3d at 1045 (noting that in

order to advance a claim under the FCA, the relator must show "the submission of a *false* claim to the government.") (emphasis added). As such, George's claim cannot survive the fact that Fresenius's nurses merely administered as written the treating physicians' prescriptions.

In her opposition brief, George asserts for the first time that Fresenius is liable under the FCA due to its use of corporate algorithms. *See* doc. 118 at 7–11. In essence, George asserts that, notwithstanding the official statements by Fresenius's leadership that dosing should be efficient so as to reduce waste (i.e., higher dosages at less frequent intervals instead of lower doses at more frequent intervals), Fresenius was in fact propagating treatment algorithms and protocols that used wasteful dosing amounts and intervals. *See id.* Allegedly, relying on the fact that treating physicians purportedly adopted the suggested Fresenius treatment protocols on a clinic-wide basis and did not revisit them until a year later, Fresenius could then inflate profits while hiding behind its public statements regarding the need for waste-free administrations of medication and the fact that nurses merely effectuated physician orders. *See id.* These allegations differ significantly from the wastage claims George asserts in her complaint, where she alleges that "[c]linic staff and clinical managers ignored [the Fresenius leadership's] medical direction to use full vial dosing and instead intentionally wasted [medication] . . . in order to increase Fresenius'[s] profits" and that "[c]linic

managers pressured nurses to manipulate medication dosing" to inflate wastage. *See* doc. 47 at 26–27. Indeed, based on the allegations in the complaint, George seems to assert that the Fresenius *nurses*—due either to pressure from superiors or the nurses' own recognition that increased proceeds for the company resulted in larger salaries—manipulated dosing to create waste. *See id.* Nowhere in George's complaint does she allege that *Fresenius leadership* propagated treatment algorithms that institutionalized unnecessary waste.[15] As such, George failed to put Fresenius on notice of this theory of liability through the amendment of her complaint. *See Sams v. United Food & Commercial Workers Int'l Union*, 866 F.2d 1380, 1384 (11th Cir. 1989) ("A complaint need not specify in detail the precise theory giving rise to recovery. All that is required is that the defendant be on notice as to the claim being asserted against him and the grounds on which it rests."). The court declines to consider George's algorithm arguments because "[a] plaintiff may not amend her complaint through argument in a brief opposing summary judgment." *Gilmour v. Gates, McDonald & Co.*, 382 F.3d 1312, 1315 (11th Cir. 2004) (citation omitted). Instead, "the proper procedure for plaintiffs to assert a new claim is to amend the complaint in accordance with Fed.R.Civ.P. 15(a)." *Id.*

[15] Indeed, the term "algorithm" does not appear in George's complaint. *See generally* doc. 47. To the extent that the complaint discusses treatment "protocols," it mentions them only in the general sense of Fresenius's corporate protocol and best practices, *see id.* at 11, 29, or in the context of George's and Simmons's job descriptions, *see id.* at 21 (George and Simmons are "responsible for reviewing . . . protocols . . . associated with these clinics").

Therefore, in light of the evidence advanced at summary judgment, the court finds that summary judgment is due to be granted as to George's wastage claim.

c. Dialysis Run Times

George asserts a claim alleging that Fresenius purposefully shortened run times to save costs and then billed Medicare for the full treatment notwithstanding the negative health risks to Fresenius's patients. *See* docs. 47 at 31–37; 118 at 25–40. Fresenius argues that George cannot show the presence of a "false claim" because she purportedly advances no evidence that Fresenius systematically shortened dialysis treatments and fails to show that Fresenius actually submitted a "false" claim that affected Medicare's reimbursement decisions. *See* docs. 102 at 24–41; 127 at 8–11. The court agrees generally with Fresenius.

Turning first to Fresenius's argument that George can advance no showing of systematically decreased run times, the court notes that the decision to exclude aspects of the opinions of Drs. McGuire and Asif, *see supra* Parts II(C)(ii)(c) and (D)(i), hinders George's case. Indeed, in light of the fact that the court has excluded Dr. McGuire's testimony regarding the frequency of shortened run times and Dr. Asif's opinion that Fresenius engaged in a practice of shortening run times, the court may rely only on lay witnesses when deciding whether this claim survives summary judgment. Although George failed to point the court toward lay testimony supporting her claim that Fresenius shortened run times, the court did

endeavor to examine George's testimony, and notes that George purportedly "saw shortened treatments" during her employment at Fresenius. Doc. 110-4 at 36–37 *SEALED* ("You go to the machine, you look at the treatment sheet compared to the settings of the machine, and then you would see that it wasn't per prescription."). Therefore, because George has testified that the "majority" of treatments were shorter than prescribed, *id.* at 37, and because she presents one person whose treatment times fell below their prescribed time, doc. 122-21 at 2 *SEALED,* she has met her burden on this issue.

Fresenius also argues that, even if run times were shortened to cut costs, the company still did not submit a "false" claim for reimbursement.[16] *See* doc. 102 at 28–29. In essence, Fresenius's argument asserts that because Medicare does not explicitly request reporting as to the duration of treatment (and Medicare pays the

[16] Fresenius argues here that George has "pivot[ed]" her theory of liability at summary judgment. *See* doc. 127 at 8. According to Fresenius, George's complaint only alleged that patient treatments were shortened during "non-lab" days and then extended on "lab days" so that patient numbers were sufficiently strong to avoid a reduction in Fresenius's "composite rate reimbursement." *See id.* at 8–9; doc. 47 at 29–37. Therefore, according to Fresenius, George cannot assert that Fresenius shortened run times and then fraudulently sought reimbursement for those purportedly inadequate treatments under an implied certification theory. *See* docs. 35-36; 127 at 8–9. However, a review of George's complaint belies Fresenius's contention. Indeed, George's complaint included a section entitled, "Quality Assurance Requirements Imposed by CMB," and also included the following allegations: "By under-dialyzing patients, Fresenius was able to bill Medicare for treatment that was not the same as the physician prescriptions," "Fresenius would bill Medicare for the full treatment, yet would not complete the full treatment," and "Fresenius billed Medicare for reimbursements for dialysis treatment that does not match physician prescriptions and does not correspond to the actual treatment given to patients." Doc. 47 at 29–33. Given these statements in George's complaint, the court disagrees with Fresenius that George failed to place it on notice as to her theory that Medicare was reimbursing Fresenius for incomplete treatments. *See Sams*, 866 F.2d at 1384 ("A complaint need not specify in detail the precise theory giving rise to recovery. All that is required is that the defendant be on notice as to the claim being asserted against him and the grounds on which it rests.").

reimbursement regardless of the duration of treatment), Fresenius's claim cannot be false—regardless of patient treatment time. *See* doc. 102 at 29. However, since the parties completed briefing on this motion for summary judgment, the Supreme Court in *University Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), provided guidance on this issue. In *Escobar*, the Supreme Court held that liability under the so-called "implied false certification theory" can "attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement." *Id.* at 1995. Importantly, the "misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be *material* to the Government's payment decision" for liability under the FCA. *Id.* at 1996 (emphasis added). Indeed, "half-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information—can be actionable misrepresentations." *Id.* at 2000. This opinion directs the court's holding on Fresenius's argument.

Applying this new guidance to the case here, the court finds that George cannot show that Fresenius submitted a false claim under the implied false certification theory. That said, the court does find that, although Medicare does not ask dialysis providers to submit information on the duration of its dialysis

treatments, it is an inherent assumption underpinning the dialysis reimbursement scheme that a patient receive treatment of a sufficient duration so that the significant benefits of dialysis are realized. However, not all deviations from treatment are "material" under *Escobar*. That is, even taking George's facts in the light most favorable to George and finding that Fresenius did shorten run times, the claim still fails because George has not identified by how many minutes these run times were cut short. Instead, George has left the court only to speculate as to the number of minutes—or, perhaps, hours—that dialysis was incomplete. Without additional facts, the court cannot determine whether reimbursements on these treatments omitted "critical qualifying information" that would have been "material to the Government's payment decision" under the FCA. *See Escobar*, 136 S. Ct. at 2000. Therefore, in light of the fact that George has failed to satisfy the showing that Fresenius submitted false claims for shortened run times, Fresenius's motion for summary judgment on this claim is due to be granted.

ii. Retaliation Under § 3730(h)

George also asserts Fresenius violated § 3730(h) by demoting her to the position of Inpatient Case Manager in retaliation for her reporting potentially fraudulent conduct. *See* docs. 47 at 41–42; 118 at 40–43. Pursuant to § 3730(h), an employee is entitled to "whistle blower" protection when:

> [the employee] is discharged [or] demoted . . . because of lawful acts done by the employee or others in furtherance of an action under [the

> FCA], including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under [the FCA], shall be entitled to all relief necessary to make the employee whole.

To find relief under this statute, a plaintiff must show "that she engaged in protected conduct and that the defendant retaliated against her because of that protected conduct." *Mann v. Olsten Certified Healthcare Corp.*, 49 F. Supp. 2d 1307, 1313 (M.D. Ala. 1999) (citations omitted). Moreover, an employee is only protected under § 3730(h) when there was at least "a distinct possibility" of litigation under the FCA at the time of the employee's actions. *See Childree v. UAP/GA AG Chem., Inc.*, 92 F.3d 1140, 1146 (11th Cir. 1996); *United States ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d 1300, 1303 (11th Cir. 2010) (same).

The Eleventh Circuit has held that "a distinct possibility" of litigation under the False Claims Act exists at the time of an employee's actions "[i]f an employee's actions . . . are sufficient to support a reasonable conclusion that the employer could have feared being reported to the government for fraud or sued in a *qui tam* action by the employee." *Lymphatx, Inc.*, 596 F.3d at 1304. In *Lymphatx, Inc.*, the plaintiff (a former employee) alleged that she complained "again and again" about the defendants' (her former employer and its owners) "unlawful actions" and warned them that they were "incurring significant criminal and civil liability." *Id.* at 1303–04. The court held that the plaintiff's actions "would be

sufficient, if proven, to support a reasonable conclusion that the defendants were aware of the possibility of litigation under the False Claims Act." *Id.*

In order for a plaintiff to demonstrate that the defendant retaliated against her because of her protected conduct, the plaintiff must show a causal link between her protected activity and the alleged retaliatory action. To do this, the employee must establish that the employer had knowledge of the protected expression at the time it took the adverse employment action. *Goldsmith v. City of Atmore*, 996 F.2d 1155, 1163 (11th Cir. 1993). The employee can establish this by circumstantial evidence, *id.* (internal citations omitted), and the employee does not need to show that she threatened to file a lawsuit against the employer. *U.S. ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 742 (D.C. Cir. 1998) (stating that while "[m]erely grumbling to the employer about job dissatisfaction or regulatory violations does not satisfy the requirement[,] . . . [t]hreatening to file a qui tam suit or to make a report to the government . . . is not the only way" to make an employer aware of one's protected activity).

Here, neither party objects to the fact that Fresenius, as a recipient of funding from Medicare, is an employer covered by the FCA. Fresenius seems to challenge George's ability to advance a *prima facie* case. Specifically, Fresenius argues that George's claim fails because her purported FCA complaints did not reference the conduct alleged in the complaint or any other purported FCA

violations. Also, Fresenius asserts that George transferred voluntarily to Inpatient Case Manager, and, regardless, the change was not actually a demotion. Finally, Fresenius contends that George apparently has no proof that she reported her FCA concerns prior to her position change. *See* docs. 102 at 41–43; 127 at 15. The court disagrees and finds that summary judgment is due to be denied.

The court begins with Fresenius's argument that George's purported FCA complaints did not reference the conduct complained of in the lawsuit and so, presumably, could not constitute protected conduct. *See* docs. 102 at 42–43; 127 at 15. Indeed, to support an FCA retaliation claim, an employee's actions must be "sufficient to support a reasonable conclusion that the employer could have feared being reported to the government for fraud or sued in a *qui tam* action by the employee." *Lymphatx, Inc.*, 596 F.3d at 1304. Fresenius seems to focus exclusively on George's emails from 2011 and 2012 in which she describes allegedly improper conduct that George asserts constitutes protected conduct. *See* doc. 102 at 42 n.8. However, the court need not examine the emails (or, relatedly, whether a relator may receive protection under § 3730(h) for complaining of conduct that did not ultimately form the basis of her lawsuit) because Fresenius ignores that George has testified that, while she was Operations Manager, she informed her supervisors on multiple occasions that she was concerned about purported double billing and run time activities. Given the nature of George's complaints and the fact that her

supervisors understood the Fresenius billing structure, George's multiple reports of double billing and shortened run times constitute "internal reports that alert the employer to fraudulent or illegal conduct." *Lymphatx, Inc.*, 596 F.3d at 1304 (citation omitted). Moreover, Fresenius would be hard-pressed to argue that these supposed reports did not constitute the foundation of George's allegations against it or to argue that it had no "reasonable" fear that such activity (especially the complaint regarding double billing Medicare) would lead to a lawsuit. Therefore, taking the facts in the light most favorable to George, the court finds that she engaged in protected conduct by reporting her concerns of fraud to her supervisors. *See Yesudian*, 153 F.3d at 741 n.9 ("[I]nternal reporting of false claims is itself an example of a protected activity.").

As to the requirement of an adverse action, the record belies Fresenius's argument that George changed positions voluntarily and that the position change did not constitute a demotion. Indeed, George's testimony that she felt pressured to accept the new position and that she feared termination if she did not, creates a material dispute as to whether her position change was, in fact, voluntary. The court also finds that a material dispute of fact exists as to whether George's ineligibility for the additional perquisites of the Operations Manager position—namely, the eligibility for bonuses and the ability to earn mileage

reimbursements—constitutes the loss of a material aspect of her job that made the transfer a demotion. As such, summary judgment is improper on this ground.

Fresenius seems to object to an inference that Fresenius took this employment action "because of" George's protected conduct by arguing that George only alerted Fresenius about her FCA concerns subsequent to her position change. *See* doc. 118 at 42–43. However, again, Fresenius disregards George's testimony of the complaints to her supervisors and instead focuses on George's emailed complaints from the latter half of 2011 and early 2012.[17] As the court stated previously, it need not address these emails (and whether they can support an inference of causation) in light of George's testimony that she reported the purported double billing and run time allegations at different times to three different supervisors. *See Mann*, 49 F. Supp. 2d at 1317 (relying on *Holifield v. Reno*, 115 F.3d 1555, 1566 (11th Cir. 1997)), to note that to show causation under § 3730(h), a plaintiff "must at least establish that the employer was actually aware of the protected expression at the time the employer took adverse employment action against the plaintiff") (internal quotations omitted). Therefore, because George has asserted a showing that she reported this activity to her supervisors prior to her position change, the court will infer causation here.

[17] Fresenius argues that George sent these emails after her position change. *See* doc. 118 at 42–43. Fresenius is correct with respect to the December 2011 and January 2012 emails. However, in July and September 2011 George also sent emails related to complaints that she now asserts put Fresenius on notice of fraudulent activity—well before her position change. *See* doc. 102-10 at 20–46.

Having found that George has advanced a *prima facie* case "raises a presumption that the employer is liable to the employee." *See id.* at 1317 (citations omitted); *see also McDonnell Douglas Corp. v. Green*, 411 U.S. 792 (1973). Therefore, when faced with a retaliation action under § 3730(h), courts in this circuit have applied the *McDonnell Douglas* approach, whereby "the burden then shifts to the employer to rebut the presumption by producing sufficient evidence to raise a genuine issue of fact as to whether the employer took unlawful actions against the employee." *See Mann*, 49 F. Supp. 2d at 1317. An employer may satisfy this burden by presenting evidence of a "legitimate, nonretaliatory reason for the employment decision, a reason which is clear, reasonably specific, and worthy of credence." *Id.* (applying *Tex. Dep't of Cmty. Affairs v. Burdine*, 450 U.S. 248, 253–55 (1981)). Here, Fresenius has stated that the company offered George the option of either the performance improvement plan (therefore allowing her to remain in the Operations Manager role) or the role of the Renal Inpatient Case Manager because she was having "some difficulty in th[e Operations Manager] role" and she was "not being successful in establishing productive communications with the physicians and the Clinic Managers and our team as a whole." Docs. 110-1 at 49 *SEALED;* 110-3 at 59–60. Such vague reasons—that George was having "difficulty" in the role and that she was not maintaining "productive communications" with her team—fail to satisfy the requirement that Fresenius

advance "clear, reasonably specific" reasons for the purported adverse action. Therefore, on this showing, Fresenius fails to rebut George's *prima facie* case, and summary judgment is due to be denied as to George's retaliation claim.

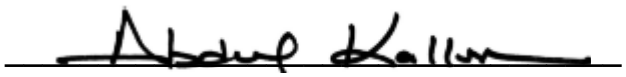
CONCLUSION

For the reasons outlined above, Fresenius's Motion to Exclude the Testimony of Dr. McGuire, doc. 104, is due to be granted in part. As to his opinions regarding Venofer and Zemplar wastage as well as Fresenius's dialysis run times, the motion is granted. It is denied in all other respects. The court also grants in part Fresenius's Motion to Exclude the Testimony of Dr. Asif, doc. 108. Specifically, as it relates to Dr. Asif's testimony regarding the justification of Venofer and Zemplar dosing as it relates to the creation of waste and as to Fresenius's supposed policy and practice of shortening run times, the motion is granted. The motion is due to be denied as to the remainder of his testimony. Moreover, Fresenius's motion to strike George's opposition to Fresenius's motions to exclude Drs. McGuire and Asif, doc. 117, is also due to be granted in part; that is, except for the witnesses' opinions, exhibits, and arguments related to analysis of deviation from prescribed treatment time across ten-minute intervals, the motion is due to be denied.

Fresenius's Motion for Summary Judgment, doc. 102, is due to be granted except as to George's retaliation claim (Count V). The court will issue a separate

order granting in part and denying in part the motions to exclude Drs. McGuire and Asif and the motion for summary judgment.

DONE the 26th day of September, 2016.



ABDUL K. KALLON
UNITED STATES DISTRICT JUDGE