UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA *ex rel.* SHEILA EL-AMIN, *et al.*,	)	
Plaintiffs/Relators,	)	
v.	)	**Civil Action No. 95-2000 (CKK)**
THE GEORGE WASHINGTON UNIVERSITY,	)	
Defendant.	)	

MEMORANDUM OPINION
(February 4, 2008)

There are a number of evidentiary-related motions presently before the Court that will, when resolved, narrow the parties' focus as we move towards trial. The Court therefore resolves the following motions: (1) Relators' Motion *In Limine* [653], (2) Defendant GW's Motion *In Limine* No. 1: Motion to Limit Relator Testimony to Anesthesia Procedures in Which They Participated [655], (3) Defendant GW's Motion *In Limine* No. 2: Motion to Preclude Relators from Testifying Regarding GW's Billing Practices [656], (4) Defendant GW's Motion *In Limine* No. 3: Motion to Preclude Relators from Offering Irrelevant and Prejudicial Evidence [657], (5) Defendant GW's Motion *In Limine* No. 4: Motion to Preclude Relators from Offering Evidence Regarding the Locke Reports [700], (6) Defendant GW's Motion to Sequester Relator Witnesses During Trial [660], (7) Relators' Motion for Order Setting Trial by Representative Sample [687], and (8) Relators' Motion for Leave to Submit Relators' Filing Pursuant to the Court's March 1, 2007 Bench Order under Seal [705]. The Court will examine each motion in turn, after providing a brief factual summary.

BACKGROUND[1]

Plaintiffs, four certified registered nurse anesthetists ("CRNAs") who were formerly employed by the George Washington University Hospital, brought suit on behalf of the United States under the *qui tam* provision of the False Claims Act ("FCA"). *See* 31 U.S.C. §§ 3729-3733. The *qui tam* plaintiffs ("Relators") allege that from 1989 to 1995 George Washington University ("Defendant") bilked the federal treasury out of thousands, if not millions, of dollars by routinely submitting false claims for anesthesia services to Medicare. These claims were false, the Relators allege, because the Defendant sought reimbursement from Medicare under the guise that each anesthesia procedure had been wholly performed by a licensed anesthesiologist, when in fact portions of the procedure had been performed by residents or CRNAs.

Medicare regulations then in effect did not prohibit the Defendant from using residents or CRNAs in rendering anesthesia services; the regulations did, however, provide guidelines establishing the amount of reimbursement the Defendant was entitled to receive for anesthesia procedures rendered, even in part, by a resident or CRNA. At bottom then, this case tests the merits of the Defendant's billing practices for reimbursement under Medicare; it does not impeach the efficacy of the anesthesiologists' medical care or the Defendant's treatment of Medicare patients.

At trial, it will be incumbent upon the Relators to show, under 31 U.S.C. § 3729(a)(1), that "(1) the defendant submitted a claim to the government, (2) the claim was false, and (3) the

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[1] The facts and protracted history of this case have been detailed in multiple prior opinions. *See generally United States ex rel. El-Amin v. George Washington Univ.*, 2007 U.S. Dist. LEXIS 85327 (D.D.C. 2007); *United States ex rel. El-Amin v. George Washington Univ.*, 2005 U.S. Dist. LEXIS 18886 (D.D.C. 2005); *United States ex rel. El-Amin v. George Washington Univ.*, 2005 U.S. Dist. LEXIS 3563 (D.D.C. 2005); *United States ex rel. El-Amin v. George Washington Univ.*, 26 F. Supp. 2d 162 (D.D.C. 1998). The Court assumes the parties have a basic familiarity with these decisions and the factual background of this case.

defendant knew the claim was false," or alternatively, under section § 3729(a)(2), that "(1) the defendant created a record and used this record to get the government to pay its claim, (2) the record was false, and (3) the defendant knew the record was false." *United States ex rel. Harris v. Bernad*, 275 F. Supp. 2d 1, 6 (D.D.C. 2003) (citing *United States v. Southland Mgmt. Corp.*, 288 F.3d 665, 674-75 (5th Cir. 2002), *aff'd en banc*, 326 F.3d 669 (5th Cir. 2003)).

To demonstrate the Defendant submitted "false" claims to Medicare, the Relators will attempt to show that the Defendant's anesthesiologists failed to meet the requirements of a billing regulation commonly known as the "seven steps" regulation. *See* 42 C.F.R. § 405.552. The seven steps regulation required anesthesiologists to perform several specific tasks for each patient to be eligible to receive reimbursement from Medicare at the highest reimbursement level, *i.e.*, reasonable charge. *See El-Amin*, *supra*, 2005 U.S. Dist. LEXIS 18886 at *17. Under the seven steps regulation the anesthesiologist was required to:

> (i) Perform a pre-anesthetic examination and evaluation;
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> (ii) Prescribe the anesthesia plan;
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> (iii) Personally participate in the most demanding procedures in the anesthesia plan, including induction and emergence;
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> (iv) Ensure that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified individual. . . .;
>
> (v) Monitor the course of anesthesia administration at frequent intervals;
>
> (vi) Remain physically present and available for immediate diagnosis and treatment of emergencies; and
>
> (vii) Provide indicated [post-anesthesia] care.

See 42 C.F.R. § 405.552(a)(1)(i)-(vii) (1989-95). For each allegedly fraudulent claim, the Relators will attempt to show the attending anesthesiologist failed to satisfy one or more of the seven steps.

DISCUSSION

I. Introduction

Although the Court takes this opportunity to resolve the parties' outstanding pretrial motions, and certainly does not foresee a need to revisit these evidentiary issues, the Court nonetheless recognizes that it is not prescient and cannot predict with absolute certainty how events will unfold at trial. This opinion sets forth the Court's analysis based on the current record before the Court and the arguments articulated by the parties in their respective motions. As evidence and witness testimony are presented at trial, however, either party may find it desirable to revisit discrete evidentiary rulings addressed here. The parties are not foreclosed from doing so. A party desiring to revisit an evidentiary ruling should, conspicuously, bring the matter to the Court's attention and be prepared to summarize the Court's original ruling and explain why the original ruling should be modified in light of new evidence or testimony or a change in circumstances. The parties are cautioned that this is not an invitation to recycle old arguments.

A key purpose of motions *in limine* is to resolve specific evidentiary issues in advance of trial. To this end, each party was obligated to demonstrate why certain categories of evidence should (or should not) be introduced at trial and to direct the Court to specific evidence, by pointing to specific parts of the record, that would favor or disfavor the introduction of that particular category of evidence. The Court expected the Relators to respond to the Defendant's motions *in limine* with citations to the record linking evidence of the Defendant's conduct to specific allegedly fraudulent claims, so it could decide whether this evidence would be allowed at trial. As described more fully below, however, the Relators have failed in many instances to provide the Court with the essential link between their arguments and the evidence in the record that would support their arguments.

Too frequently the Relators make bald assertions or generalized arguments without directing the Court to the part of the record that would support their assertions or arguments. In some instances the Relators fail to even controvert the basic arguments raised by the Defendant, essentially conceding the point. For example, while the Relators assert they would like to introduce evidence of the routine practice of the Defendant's anesthesiologists, they do not identify the specific practice that is allegedly routine, provide the Court with any evidence that the anesthesiologists' conduct was habitual or uniform, or controvert the Defendant's argument that the anesthesiologists' conduct varied with each patient and procedure, and was therefore not routine. In these situations, which are painfully common, the Court has no choice but to conclude the Relators do not support their arguments with specific evidence and references to the record because they cannot – the evidentiary foundation is not there. It is not the Court's responsibility to formulate the Relators' arguments for them or to scour the record for evidence that will support their assertions, and it will not do so here. Nor will the Court delay the resolution of these important evidentiary issues until trial on the slim hope the Relators will be able to cobble together the evidentiary support necessary to make their case. Each party will go to trial with the evidence they have, not with the evidence they wish they had.

II. Evidentiary Standard: Relevance

Because the parties' motions test the basic relevancy of several categories of evidence that may be admitted at trial, a brief summary of the evidentiary standard for relevance is appropriate. Rule 401 of the Federal Rules of Evidence defines relevant evidence as "having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." FED. R. EVID. 401. "The Advisory

Committee Notes to [the] Rule . . . explain that 'relevant evidence' permits the use of evidence that is 'admitted as an aid to understanding.'" *United States v. Holton*, 325 U.S. App. D.C. 360, 116 F.3d 1536, 1542 (D.C. Cir. 1997) (quoting *Id*., advisory committee's note). "The basic concept is that an item of proof is relevant if it tends to prove or disprove any material issue of fact in a case." 2 WEINSTEIN'S FEDERAL EVIDENCE § 401.02. Because the rule is "silent as to what factors the court must consider in determining whether an item of evidence is relevant[,] . . .[c]ourts cannot employ a precise, technical, legalistic test for relevance; instead, they must apply logical standards applicable in every day life." *Id.* at § 401.04.

III. Relators' Motion *In Limine*

In Relators' Motion *In Limine* [653], the Relators move to preclude the Defendant from presenting any evidence at trial regarding three separate topics, each of which is addressed below. For the following reasons, this motion is granted in part and denied in part.

A. The Government's Investigation and Non-Intervention

First, the Relators move to preclude the Defendant "from presenting evidence or argument on the Government's investigation and decision not to intervene in this case." Rels.' Mot. at 2. The Relators argue that evidence of the government's non-intervention "fails the basic test of relevancy under [Federal Rules of Evidence] 401 and 402" because it is not probative of any of the "elements to be proved" at trial. *Id*. at 2 n.3. *See also* Rels.' Reply Br. at 3-4 (explaining how evidence of non-intervention "undermines" the FCA and "is irrelevant to any element of the [Relators'] case"). The Relators note the government may have had "numerous reasons" for electing not to intervene in this case; without knowing the actual reason the government elected not to intervene, however, this evidence has no probative value. Rels.' Reply at 2. The Court agrees.

Evidence showing the government decided not to intervene in the Relators' case is not relevant because there is no evidence linking the government's nonintervention with its actual motivation for doing so. Without knowing the actual motivation behind the government's nonintervention, evidence of its nonintervention is not probative of how the government appraised the merits of this case and is therefore not relevant. A brief summary of the FCA's *qui tam* provision demonstrates this point.

The FCA expressly authorizes private individuals to bring a civil action for alleged violations of the FCA. *See* 31 U.S.C. § 3730(b)(1). The action, while litigated by a private party, is brought on behalf and in the name of the United States. Subsection (b)(2) requires the complaint to be filed under seal. It also requires the private individuals bringing the action to furnish a "copy of the complaint" and a "written disclosure of substantially all material evidence and information" in their possession to the government. Once filed, the complaint remains under seal for 60 days, and is not served on the defendant during this period. Congress provided "numerous reasons for mandating that the complaint be filed initially under seal." John T. Boese, CIVIL FALSE CLAIMS AND *QUI TAM* ACTIONS § 4.04[B] (3rd ed. 2007 Suppl.). The "primary purpose" of the 60-day seal requirement "was to allow the government to ascertain privately 'whether it was already investigating the claims stated in the suit and then to consider whether it wished to intervene.'" *Id*. (quoting *Erickson ex rel. United States v. American Inst. of Biological Sciences*, 716 F. Supp. 908, 912 (D. Va. 1989)).

The government must respond to the *qui tam* complaint at the conclusion of the 60-day sealing period. Section 3730 of the FCA gives the government, expressly or impliedly, five options: (i) request an extension of the 60-day period, *see* § 3730(b)(3); (ii) intervene in the action, *see* §

3730(b)(4)(A); (iii) decline intervention[2] and allow the relators to conduct the action, *see* § 3730(b)(4)(B); (iv) move to dismiss the action, *see* § 3730(c)(2)(A); or (v) attempt to settle the action before formally intervening. *See generally* Boese, CIVIL FALSE CLAIMS AND *QUI TAM* ACTIONS § 4.05[A]. If the government elects to intervene, sections 3730(b) and (c) of the Act "clearly provide that the government controls the action." *Id*. So while a *qui tam* complaint is filed by a private citizen, the action may, at the government's election, ultimately be conducted by the United States. *See* 31 U.S.C. § 3730(b)(4) (" Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall . . . proceed with the action, in which case the action shall be conducted by the Government[.]"). It is only where the government notifies the court during the 60-day evaluation period or during an extension of that period that it is declining to intervene, that " the person bringing the action shall have the right to conduct the action." 31 U.S.C. § 3730(b)(4)(B).

As other courts have noted, the government " may have a host of reasons for not pursuing a claim." *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006). This is why the Court " do[es] not assume that in each instance in which the government declines intervention in an FCA case, it does so because it considers the evidence of wrong doing insufficient or the *qui tam* relator's allegations [of] fraud to be without merit." *Id*. *See also United States ex rel. DeCarlo v. Kiewit/AFC Enters.*, 937 F. Supp. 1039, 1047 (S.D.N.Y. 1996) (noting government's " [n]on-intervention does not necessarily signal governmental disinterest in an action"). Indeed, assuming the government looked unfavorably upon each *qui tam* action

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[2] The government may intervene at a later date upon a showing of good cause. 31 U.S.C. § 3730(c)(3).

in which it did not intervene would seem antithetical to the purpose of the *qui tam* provision – to encourage private parties to litigate on behalf of the government. *See United States ex rel. Berge v. Bd. of Trustees*, 104 F.3d 1453, 1458 (4th Cir. 1997), *cert denied*, 522 U.S. 916 (1997) (" [T]he plain language of the Act clearly anticipates that even after the Attorney General has 'diligently' investigated a violation [of the FCA], the Government will not necessarily pursue all meritorious claims; otherwise there is little purpose to the *qui tam* provision permitting private attorneys general."). Similarly, the Court will not presume that because the government did not move to dismiss the action, *see* § 3730(c)(2)(A), that it concluded the Relators' allegations were meritorious.

Simply put, the Court will not allow either party to use the government's investigation and/or inaction as evidence of how the government appraised the merits of the Relators' case. Without evidence tending to show the actual reason the government elected not to intervene in this case – and the Defendant has not offered any evidence other than speculation on this point – the simple fact that the government did not intervene has no probative value and is not relevant. As such, it is inadmissible at trial. *See* FED. R. EVID. 401 & 402.

The Defendant argues that the " government's investigation and subsequent . . . inaction are . . . relevant to the materiality of the allegedly false claims." Def.'s Opp'n at 2 (emphasis added). The Defendant reasons that the government's decision not " to reopen any claim determinations or to recoup as overpayments any Medicare monies already paid to GW[U]" suggests that even if some of these claims were false " the alleged falsity . . . was immaterial to the government's decision to pay." *Id.* at 3-4. " If the claims that relators allege to have been false were ineligible for Medicare payment," GWU explains, " one would reasonably expect the

government to take some [enforcement or protective] action." *Id.* at 3. The fact that the government " continued to pay [GWU' s] claims . . . and elected not to exercise even one of its various administrative remedies" shows that the falsity, if any, was immaterial. *Id.*

The Court is not swayed by this argument. The Defendant' s argument is implicitly based on the premise that the government would not have remained idle had the allegedly fraudulent claims been " materially" false. The Defendant offers no actual evidence that would support this premise however. It would have the Court assume that the government always takes action whenever a claim is materially false and, conversely, that the government takes no action when a claim is not materially false. This effectively transforms the legal definition of materiality into a simple question of whether the government took enforcement action. The record before the Court is too paltry to support this inference. As explained above, the government may have had any number of reasons for not exercising " one of its various administrative remedies" in this case.

B. Documentary Evidence of the Defendant's Performance of the Seven Steps

Second, the Relators move to preclude the Defendant "from presenting any other documentary evidence" that would show the Defendant's anesthesiologists performed the seven steps apart from "the OR Circulating Records and Surgical Anesthesia Records." Rels.' Mot. at 3. The Defendant's documentary evidence should be limited to these two types of records, the Relators reason, because these were the only records the Defendant identified in responding to the Relators' First Set of Interrogatories. A brief review of the actual language of the Relators' interrogatories shows the weakness in this argument.

"In their Interrogatory No. 2, the Relators sought the name of the anesthesiologist, if any, that performed the Seven Steps on every Medicare patient requiring anesthesia since September 30,

1986." Rels.' Mot. at 3 (citing Relators' First Set of Interrogatories at 1) (emphasis added).[3] In response, the Defendant noted that the identity of the attending anesthesiologist for these procedures could be found on either the OR Circulating record or the first page of the Surgical Anesthesia Record. *See* Rels.' Reply Br. at 5. This interrogatory, by its express language, was focused exclusively on the "name" of each anesthesiologist who "performed the seven steps on every Medicare patient" during the relevant time period. It is not surprising, then, that the Defendant's response was equally narrow, directing the Relators to the specific documents that indicated the names of the anesthesiologists who had participated in the relevant procedures.

Despite the narrow focus of the interrogatory, the Relators now ask the Court to use the Defendant's response as a justification for imposing a blanket prohibition on all other forms of documentary evidence at trial other than the OR Circulating Records and Surgical Anesthesia Records. The Relators provide no reason based on law or common sense, however, why the Court should implement such a draconian measure, and the Court can see none. It would be patently unfair and nonsensical to strip the Defendant of its ability to defend itself on a key issue at trial based on a narrow interrogatory that focused exclusively on the names of the Defendant's anesthesiologists. Moreover, the Relators' offer no legal basis, such as a relevant case or a rule of evidence, which would authorize the Court to exclude relevant, exculpatory evidence *en masse*, essentially depriving the Defendant of a defense.

C. Evidence that the Defendant's Anesthesiologists' Work Comported with Generally Accepted Medical Practices

Third, the Relators move to preclude "any evidence" that "the Defendant's anesthesiologists

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[3] In Interrogatory No. 3, the Relators asked the Defendant to identify all documents relating to its answer to Interrogatory No. 2. *See* Rels.' Reply Br. at 5.

conducted themselves in accordance with generally accepted or sound anesthesiology practices." *See* Rels.' Reply Br. at 5. This evidence "is entirely irrelevant to this action," the Relators explain, because it conflates the standard for reimbursement under the seven steps regulation, which is relevant to this case, with the anesthesiologist standard of care, which is not relevant to any issue at trial. *Id*. at 5-6. The Relators explain that whether the Defendant violated the FCA turns on whether the anesthesiologists complied with the seven steps regulation; whether the anesthesiologists adhered to generally accepted medical practices, by contrast, has no bearing on the seven steps regulation and may confuse the jury.

In opposition, the Defendant argues that generally accepted medical practices are "relevant" because they inform the "meaning of the seven steps regulation" and elucidate "the vocabulary the witnesses will use at trial." Def.'s Opp'n at 6-7. The Defendant asserts that granting the Relators' motion would lead to a "ludicrous result": "the jury would be required to assess allegations that [the Defendant's] anesthesiologists failed to perform anesthesia services without hearing evidence of what those anesthesia services were." *Id*. at 6. "To know what anesthesia services would be required by the seven steps regulation in any particular case," the Defendant explains, "the jury will have to hear from an anesthesiologist about the nature of the anesthesia services provided." *Id*.

The Relators have the stronger argument here. Judge Penn touched upon this issue in an earlier opinion when he rejected the Defendant's "theory" that the seven steps regulation "was intended to codify [] existing medical practices." *See El-Amin*, *supra*, 2005 U.S. Dist. LEXIS 18886 at *19. He explained:

> Defendant's theory is incorrect because it confuses reimbursement standards with medical standards. In brief, the [seven steps] regulation was intended to change reimbursement standards, not to address medical standards. Thus, medical standards were not incorporated as 'terms of art' and there is no reason to look to defendant's

experts to explain them.

Id. at *19-20 (emphasis added). Judge Penn also quoted then-president of the American Society of Anesthesiologists, who had clarified this distinction:

> It is imperative that all Medicare providers . . . realize that these federal regulations are legal requirements only for receiving *reimbursement* for services rendered. In spite of an often voiced complaint from many physicians that the government is telling us how to practice medicine, the simple truth is: you can practice as you please; just do not send them the bill for payment.

Id. (quoting Phillip O. Bridenbaugh, "Knowingly?" – Ignorance Is No Excuse!, ASA Newsletter, Vol. 61, No. 7, President's Page) (emphasis in original). This is why Judge Penn concluded that "the Seven Steps regulation was intended to change reimbursement practices, it was not composed of terms of art which simply codified existing medical standards." *Id*. at *21.

Given the distinction already drawn by the Court, the Defendant will be precluded from presenting evidence that its anesthesiologists adhered to generally accepted medical practices because such evidence is not relevant. FED. R. EVID. 401. For example, the Defendant may not demonstrate that it satisfied step one by presenting evidence that it was a generally accepted medical practice at the time for an anesthesiologist to review a pre-anesthesia examination prepared by another individual, when, in actuality, step one required the anesthesiologist to prepare the examination. *See El-Amin*, *supra*, 2005 U.S. Dist. LEXIS 18886 at *22 (finding "only an anesthesiologist, not a student or, by extension, a CRNA, could perform step one, or indeed, any step, if the procedure was to be eligible for charge reimbursement."). In other words, while it may have been an acceptable medical practice for an anesthesiologist to review a pre-anesthesia examination prepared by a resident or a CRNA, rather than prepare the examination himself or herself, this is not relevant to step one. To be eligible for charge reimbursement, step one required

the anesthesiologist to prepare the pre-anesthesia examination; reviewing a resident's plan was insufficient. Evidence of the generally accepted medical practice at the time is therefore not relevant to this issue. The Defendant effectively acknowledges as much in other filings. *See, e.g.*, Defendant GW's Motion *In Limine* No. 1, 11 n.7 ("The regulations on which relators rely do not establish standards of care for anesthesiology, but rather set forth Medicare billing standards."); Defendant GW's Reply In Support of its Motion *In Limine* No. 3, 4 (noting "the False Claims Act [] has nothing to say about standards of care [or] quality of care").

The Defendant's primary concern, that "the jury will be required to assess allegations that [its] anesthesiologists failed to perform anesthesia services without hearing evidence of what those anesthesia services were," is misplaced. *See* Def.'s Opp'n at 6-7. The Court is not precluding either party from educating the jury on the medical procedures that comprise the seven steps regulation. Indeed, the Court expects that the parties will want to describe some of the specific anesthesia procedures involved here, *e.g.*, performing a pre-anesthesia examination. What the Defendant may not do however, because it is not relevant, is present evidence demonstrating that its anesthesiologists comported with generally accepted anesthesiology practices. This case tests the merits of the Defendant's billing practices for reimbursement under Medicare; it does not test the adequacy the Defendant's medical care.

D. Conclusion

The Relators' Motion *In Limine* is granted in part and denied in part. At trial, the Defendant shall be precluded as described above from presenting testimony, documents, or other direct or demonstrative evidence regarding (1) the Government's investigation into the alleged false claims and its subsequent decision not to intervene in this case; and (2) the anesthesiologists' practice of

adhering to the generally accepted medical practices at the time, as opposed to testimony to educate the jury on the specific anesthesia procedures at issue through a description of the process. The Defendant shall, however, be permitted to present documentary evidence other than OR Circulating Records and Surgical Anesthesia Records to demonstrate that its anesthesiologists satisfied the seven steps regulation.

IV. Defendant GW's Motion *in Limine* No. 1: Motion to Limit Relator Testimony to Anesthesia Procedures in Which They Participated

In Defendant GW's Motion *In Limine* No. 1 [655], the Defendant moves to limit the scope of the Relators' testimony at trial in two material ways. First, it seeks to preclude the Relators "from offering testimony at trial regarding anesthesia procedures [in] which they were not involved." Def.'s Mot. at 4. This includes any evidence that its anesthesiologists acted according to habit or routine practice. *See* FED. R. EVID. 406. Second, it seeks to preclude the Relators "from testifying regarding procedures for which they cannot show that a claim for payment was presented to the government." *Id.* For the following reasons, the motion is granted.

A. Personal Knowledge & Evidence of Habit and Routine Practice

The Defendant moves to preclude the Relators from testifying about any anesthesia procedures in which they were not personally involved. The Relators' testimony should be limited to those procedures in which they were personally involved, the Defendant reasons, because Federal Rule of Evidence 602 limits lay witness testimony to those matters of which the witness has "personal knowledge." *Id.* at 5. The Defendant notes that its anesthesiologists were involved in "thousands" of anesthesia procedures during this time period and that "the Relators themselves participated in only a fraction of those procedures." *Id.* Allowing the Relators to testify about the vast number of procedures in which they were not personally involved would render their testimony

"speculative." *Id*. at 1. The Court agrees.

Federal Rule of Evidence 602 "requires that non-experts testify only as to matters of which they have personal knowledge; its purpose is to assure reliability." *United States v. Lemire*, 232 U.S. App. D.C. 100, 720 F.2d 1327, 1347 (D.C. Cir. 1983) (citing FED. R. EVID. 602 advisory committee's note).[4] "Additionally, under Rule 701(a), a lay witness's testimony must be 'rationally based on the perception of the witness.'" *Athridge v. Aetna Cas. & Sur. Co.*, 474 F. Supp. 2d 102, 105 (D.D.C. 2007) (quoting FED. R. EVID. 701(a)). Thus, the Relators' testimony must be limited to those anesthesia procedures that they participated in.

The Relators do not outright object to the notion that they must have personal knowledge of a procedure to testify about it. *See* Rels.' Opp'n at 3 ("[T]he Relators do not object to the principle that one can only testify to things of which one has personal knowledge . . . "). Rather, they object to the scope of the Defendant's proposed order. The Relators argue that the proposed order is "overbroad" because it will "impermissibly exclude" relevant evidence. *Id*. The Relators' primary concern is that they will be prevented from "testifying . . . about the Defendant's routine practices" "under Federal Rule of Evidence 406." *Id*. at 3, 4.[5] Based on their opposition brief and previous

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[4] Rule 602 provides in relevant part:

> A witness may not testify to a matter unless evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter. Evidence to prove personal knowledge may, but need not, consist of the witness' own testimony.

FED. R. EVID. 602.

[5] The Relators also claim the proposed order is overbroad because it will prevent them from "testifying . . . about facts relevant to the 'knowledge' element of the Defendant's violations of the False Claims Act . . . [and] about the Defendant's false records." The Relators do not elaborate on either point, however, apart from these general statements, and the Court is consequently unable to evaluate their merit.

filings, it appears the Relators would like to introduce evidence of the anesthesiologists' habit or routine practice of failing to perform one or more of the seven steps. The Defendant, on the other hand, seeks to exclude all habit and routine practice evidence. It rejects the idea that its "anesthesiologists were so formulaic in the practice of medicine that their conduct became reflexive and nonvolitional – a threshold showing under Rule 406." Def.'s Mot. at 4. The Defendant explains that its anesthesiologists' conduct "invariably depended on the specific circumstances of any given anesthesia procedure," which varied with, among other things, the type of procedure involved, the condition of the patient, and the skill and experience of the accompanying resident or CRNA.

Rule 406 deals with two similar types of evidence: habit and routine practice. Habit applies to individuals; routine practice applies to organizations. The rule authorizes the admission of evidence of a person's habit or an organization's routine practice to prove that the conduct of the individual or organization on a particular occasion was in conformity with that habit or routine practice. *See* FED. R. EVID. 406 ("Evidence of the habit of a person or of the routine practice of an organization . . . is relevant to prove that the conduct of the person or organization on a particular occasion was in conformity with the habit or routine practice.").

A habit is a regular response to a specific situation. *See* 2 WEINSTEIN'S FEDERAL EVIDENCE § 406.02. It "refers to the type of nonvolitional activity that occurs with invariable regularity." *Weil v. Seltzer*, 277 U.S. App. D.C. 196, 873 F.2d 1453, 1460 (D.C. Cir. 1989). A habit is considered to be probative because it is nonvolitional; it has "a reflexive, almost instinctive quality." *Id*. *See also United States v. Sampol*, 204 U.S. App. D.C. 349, 636 F.2d 621, 656 n.21 (D.C. Cir. 1980) ("It is the 'semi-automatic' character of the behavior which renders habit evidence trustworthy."). Habit is "a *consistent* method or manner of responding to a particular stimulus." *Weil*, 873 F.2d at 1460

(emphasis in original). Because the rule "is based principally upon the fact that habitual conduct is largely free from the complicating and confusing element of volition," the recognition that an action has a "volitional basis . . . raises serious questions as to its invariable nature, and hence its probative value." *Levin v. United States*, 119 U.S. App. D.C. 156, 338 F.2d 265, 272 (D.C. Cir. 1964), *cert. denied*, 379 U.S. 999 (1965) (holding individual's religious practice of observing the Sabbath does not constitute habit).[6]

The admissibility of habit or routine practice "evidence under Rule 406 does not hinge on the ability of the party seeking exclusion of the evidence to disprove the habitual [or routine] character of the evidence." *Weil*, 873 F.2d at 1461 (citation omitted). To the contrary, "the burden of establishing the habitual [or routine] nature of the evidence rests on the proponent of the evidence," which is the Relators. *Id*. To establish the existence of a habit, the Relators "must establish a degree of uniform response showing more than a mere tendency to act in a given manner." 2 WEINSTEIN'S FEDERAL EVIDENCE § 406.02. They must show "conduct that is semi-automatic in nature." *Id*. The D.C. Circuit has noted that at least two "significant factors" should guide the Court "in deciding whether particular conduct amounts to 'habit.'" The two factors are the "'adequacy of sampling and [the] uniformity of responses." *Weil*, 873 F.2d at 1460 (quoting FED. R. EVID. 406 advisory committee's note). To be a reliable gauge of habit, "the conduct at issue . . . [should] have occurred with sufficient regularity making it more probable than not that it would be carried out in every instance or in most instances." *Id*. (citing *Levin*, *supra*).[7]

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[6] *Levin v. United States* was decided before the enactment of Rule 406.

[7] Rule 406's foundational requirements for the admissibility of routine practice evidence are less stringent than those for habit. *Wetherill v. University of Chicago*, 570 F. Supp. 1124, 1129 (D. Ill. 1983). The Relators have failed to meet their burden under either standard.

Based on this record, the Court concludes the Relators have failed to meet their burden of establishing the habitual or routine character of the Defendant's anesthesiologists' conduct. As the following discussion illustrates, there are a number of reasons for this conclusion.

It is axiomatic that Rule 406 requires the proponent of habit or routine practice evidence to, at the very least, identify the conduct that is purportedly performed with such "invariable regularity" that it has "a reflexive, almost instinctive quality," making it a habit or routine practice. *Weil*, *supra*, 873 F.2d at 1460. *Cf. Babcock v. General Motors Corp.*, 299 F.3d 60, 66 (1st Cir. 2002) (evidence that decedent "always wore his seat belt, regardless of whether he was the driver or a passenger and regardless of the length of the trip" was properly admitted as habit evidence to prove the decedent was wearing a seatbelt at the time of the accident in question); *Rosenburg v. Lincoln American Life Ins. Co.*, 883 F.2d 1328, 1336 (7th Cir. 1989) (evidence that insurance company agents had previously waived standard, written conditions when issuing an insurance policy was admissible as evidence of a routine business practice). Here, however, the Relators never identify the habit or routine practice they attribute to the Defendant or its anesthesiologists. While they say they would like to introduce routine practice evidence pursuant to Rule 406, they never explain what action was supposedly performed routinely or, if admitted, what this evidence will prove. The Relators do not claim, for example, that it was a routine practice for all fifteen anesthesiologists to fail to perform a pre-anesthetic evaluation (step one) or, to use another example, that a particular anesthesiologist had a habit of never participating in the patient's induction and emergence (step three). Indeed, their opposition brief is completely silent on the specific type of routine practice evidence they would like to introduce at trial. Instead of indicating the precise routine practice they attribute to the Defendant, the Relators assert, without explanation or citation to the record, that they now, having "completed

discovery," have a "foundation" for this evidence. *See* Rels.' Opp'n Br. at 4. The Court has no idea what this foundation is or what it will purportedly show. Even more confusing, the Relators at one point in their opposition brief refer to the Defendant's "routine practices," suggesting the Defendant had several routine practices. And then, in the same brief, the Relators alter their approach and refer to the Defendant's "routine practice," suggesting the Defendant had only one routine practice. *See id*. at 3, 4. The Court has no idea how many routine practices are potentially implicated. The Relators' failure to identify the habit or routine practice involved in this case fatally complicates the Court's task of determining whether the anesthesiologists' conduct satisfies the requirements of Rule 406. It is impossible to determine whether the anesthesiologists acted with a reflexive, instinctive quality, without knowing what conduct the Relators ascribe as habit or routine practice.

The Court's Rule 406 assessment is further frustrated by a number of conspicuous omissions in the Relators' briefing on this issue. First, the Relators do not explain whether the habit or routine practice evidence they would like to introduce at trial applies to all 15 anesthesiologists as a group or whether it applies to the anesthesiologists on an individual basis. In other words, the Relators do not distinguish between habit evidence, which would presumably apply to each individual anesthesiologist, from routine practice evidence, which would apply to the 15 anesthesiologists as a group or to the Defendant as a single organization. Second, the Relators do not specify whether the alleged habit or routine practice lasted the entire six-year time period that is encompassed by this lawsuit or whether it was limited to shorter periods within this six-year span. Third, the Relators do not specify which of the seven steps the anesthesiologists routinely failed to perform. It is not clear, for example, whether the anesthesiologists routinely failed to perform just one of the steps, whether they failed to perform all seven steps, or whether they routinely performed some steps but not others.

Finally, the Relators do not specify whether the alleged habit or routine practice applies to all the anesthesia procedures the Defendant conducted during this time period, or whether it applied to some procedures, *e.g.* MAC anesthesia, but not others, *e.g.* local or regional anesthesia.

Even if the Court could comprehend what conduct was purportedly habitual, the Relators have provided no evidence that would warrant a finding of habit or routine practice under Rule 406. Although the Relators vaguely suggest in their opposition brief there is a "foundation" for admitting "routine practice evidence under Federal Rule of Evidence 406," they do not direct the Court to a single piece of evidence, like a deposition or declaration, that would support this claim. Instead, they assert that this "foundation" will be born (presumably at trial) from "the testimony of every deposed witness who routinely observed the inside of Defendant's operating rooms." This statement is too vague to be helpful; indeed, the Relators' entire brief contains a paucity of facts or arguments, making it impossible for the Court to "decid[e] whether particular conduct amounts to habit." *Weil*, 873 F.2d at 1460 (internal quotation marks omitted). It seems reasonable to expect, if "every deposed witness" will testify to the anesthesiologists' routine practice, that the Relators would have presented at least one supporting statement demonstrating the existence of a routine practice, such as the deposition testimony of an anesthesia resident, but they have not.[8]

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[8] The Relators appear to adopt a somewhat contradictory position in their opposition brief. On one hand, they argue the Court should not rely on an earlier opinion by Judge Flannery, *see United States ex rel. El-Amin v. George Washington Univ.*, No. 95-2000 (D.D.C. Sept. 13, 2000), in which Judge Flannery concluded the Relators had failed to establish the existence of habit or routine practice in their declarations. *See id*. at 5 ("Relators have failed to lay a proper foundation for admission of the contested evidence under federal Rule 406(a)."). On the other hand, the Relators, in a footnote, refer back to these very same declarations and incorporate them by reference in support of their claim that they should be allowed to introduce evidence of habit and routine practice at trial. *See* Rels.' Opp'n at 5 n.2. What is conspicuously absent from the Relators' analysis, however, is an explanation of why Judge Flannery's original conclusion is no longer sound, including a description of the additional evidence, to the extent any exists, which would support a finding of habit or routine practice.

Not only have the Relators failed to identify the purported routine practice, and likewise failed to put forth any evidence that would support such a finding, they have also failed to demonstrate that habit evidence, if admitted, would be reliable. The Court of Appeals has explained that "one of the concerns over the reliability of habit [evidence] is that the conduct at issue may not have occurred with sufficient regularity making it more probable than not that it would be carried out in every instance or in most instances." *Weil*, 873 F.2d at 1460 (citing *Levin*, *supra*, 338 F.2d at 272). To determine whether proffered habit evidence has "occurred with sufficient regularity" and is therefore reliable, the Court considers both the "adequacy of sampling and uniformity of responses." FED. R. EVID. 406, advisory committee's note. *See also* Stephen A. Saltzburg, 2 FEDERAL RULES OF EVIDENCE MANUAL § 406.02[5] (9th ed. 2006) ("Whatever the mode of proof, the touchstone of admissibility is to prove an 'adequacy of sampling and uniformity of responses' in specific circumstances."). The Court cannot properly evaluate the adequacy of sampling in this case for one important reason: The Relators have yet to define the total universe of claims that are encompassed by this lawsuit.

Before the Court can determine if a given sample is adequate, which is to say that the sample is representative of the whole, it must have some idea of the size and composition of the universe of claims. Here, however, the Relators have not been able to ascertain or enumerate the claims that are involved in this case; instead, they assert the Defendant submitted somewhere between 5,000 and 15,000 claims to Medicare during this time period. This figure is too imprecise to permit the Court to evaluate the adequacy of a proffered sample. *See United States v. Newman*, 982 F.2d 665, 669 (1st Cir. 1992) (evidence that "between 75 and 100 prisoners [were] handcuffed to the cell bars, but never to the first bar," was properly excluded because "[t]here was no evidence even approximating

the number of times prisoners were handcuffed to the cell bars").

In addition, even if the Court knew the number of claims involved in this lawsuit, the Relators do not say how many procedures they observed during this six-year time period. What the Court is missing, in other words, is a ratio comparing the number of claims the Relators observed versus the total universe of claims. *See Weil*, 873 F.2d at 1461 ("[W]hen considering evidence under Rule 406 as habit 'it has been held that it is necessary to critically examine the ratio of reactions to the situations and to show regularity of conduct by comparison of the number of instances in which any such conduct occurs with the number in which no such conduct takes place'" (quoting Annotation, *Admissibility of Evidence of Habit or Routine Practice Under Rule 406*, Federal Rules of Evidence, 53 A.L.R. Fed. 703, 705 (1981))). Here, the Relators have not identified, or even estimated, the number of anesthesia procedures they observed in which the anesthesiologists' conduct conformed to the Defendant's purported routine practice. They have not, in short, identified the size of their sample. Because the Relators have not identified the size of the sample on which they would base their Rule 406 testimony, the Court is unable to evaluate its adequacy. Moreover, there is contrary evidence, as the Defendant points out, that suggests the Relators did not participate in a large percentage of the Defendant's anesthesia procedures. *See* Berrigan Decl. ¶ 6 (noting the Relators "participated in fewer than 20 percent of all anesthesia procedures"). This renders routine practice testimony inherently unreliable.

The second aspect of the habit calculus the Court considers, *i.e.*, the "uniformity of responses," is just as troublesome. Habit evidence might be admissible (assuming the sample was adequate) if the anesthesiologists "reacted the same way each time [they were] presented with a new [anesthesia] patient." 873 F.2d at 1461. As explained above, however, the Court does not know

what conduct is allegedly habitual and consequentially cannot determine whether the anesthesiologists' conduct was uniform for each of the anesthesia procedures in which they were involved. In fact, what little evidence the Court can glean from the Relators' declarations suggests just the opposite – that the anesthesiologists' conduct was not uniform for all patients and procedures. *See* Linden Decl. ¶ 18 (noting an "anesthesiologist was present for induction no more than twenty percent of the time"); ¶ 11 (noting the "supervising anesthesiologist performed a pre-anesthesia examination and evaluation for a small fraction of the patients undergoing general anesthesia"). As the Defendant aptly notes in its motion, the Relators' declarations are frequently couched in conditional language, which implies the anesthesiologists' conduct was not reflexively uniform. Def.'s Mot. at 9-10. *See, e.g.*, El-Amin Decl. ¶ 6 ("I <u>often</u> had to perform the pre-evaluation and develop the anesthesia plan. . . . and only very <u>rarely</u> did I see a GWU anesthesiologist perform any of this work."); Lasley Decl. ¶ 7 (same).

Finally, although it is not the Defendant's burden to disprove the existence of a habit, *see Weil*, *supra*, the Defendant convincingly argues that evidence of habit or routine practice is not appropriate here. Specifically, the Defendant notes that its anesthesiologists' conduct was not uniform for all patients, but rather varied with the type of anesthesia procedure involved, the individual patient's condition, and the skill and experience of the accompanying resident or CRNA. *See, e.g.*, Berrigan Decl. ¶ 16. This variance, shaped by external stimuli, suggests that the anesthesiologists' conduct was the result of conscious decision-making, and was neither reflexive nor instinctive, the hallmarks of habit. *See Levin*, *supra*; *see also Simplex, Inc. v. Diversified Energy Systems, Inc.*, 847 F.2d 1290, 1293 (7th Cir. 1988) ("[B]efore a court may admit evidence of habit, the offering party must establish the degree of specificity and frequency of uniform response that

ensures more than a mere 'tendency' to act in a given manner, but rather, conduct that is 'semi-automatic' in nature.") (citations omitted). Moreover, the Relators do not, in their opposition brief, controvert the Defendant's basic arguments and evidence on this point. The Relators never explain how a complicated medical activity, such as an anesthesia procedure, can be reduced to semi-automatic behavior. *See* Stephen A. Saltzburg, 2 FEDERAL RULES OF EVIDENCE MANUAL § 406.02[2] (9th ed. 2006) ("[A]ctivity that is extremely complicated is unlikely to be considered habit, since such activity would ordinarily be dependent on a significant thought process, and a number of contingencies, and all of this is inconsistent with the notion of habit as reflexive and automatic."). To the contrary, given the volitional and complex nature of this conduct, evidence of the anesthesiologists' prior conduct is more appropriately deemed character evidence, which is generally inadmissible. *See* FED. R. EVID. 404(b). *Accord Weil*, *supra*, 873 F.2d at 1461 ("Evidence concerning Dr. Seltzer's treatment of five former patients is not of the nonvolitional, habitual type that ensures its probative value. . . .[but] is the type of character evidence contemplated under Rule 404(b).").

B. Claims Submitted to the Government

The Defendant also seeks to preclude the Relators "from testifying regarding procedures for which they cannot show that a claim for payment was presented to the government." Def.'s Mot. at 11. "Testimony regarding procedures for which no claim was submitted would be irrelevant," the Defendant explains, "[b]ecause presentment of a claim for payment is a requisite element of a cause of action under the False Claims Act." *Id*. This is essentially a corollary to the Defendant's argument that the Relators should be prevented from introducing habit evidence or evidence of prior bad acts. Subject to the exceptions contained in Rule 404(b), the Court agrees.

Evidence regarding claims that were not submitted to Medicare – or, more precisely, claims that were not *allegedly* submitted to Medicare, as this is ultimately a question left to the factfinder – is not relevant to whether the Defendant violated the False Claims Act. By its own admission, the Defendant performed thousands of anesthesia procedures during this time period, for Medicare and non-Medicare patients alike. For only a fraction of these procedures, however, did the Defendant submit a claim for reimbursement to Medicare. Those claims that were not allegedly submitted to Medicare are not relevant to this action and are properly excluded. *See* FED. R. EVID. 401 & 402.[9]

C. Conclusion

The Defendant's Motion *In Limine* No. 1 is granted. The Relators' testimony will be limited to those anesthesia procedures of which they have personal knowledge. Additionally, based on the present record the Relators are precluded from presenting evidence regarding (1) the habit or routine practice of the Defendant or its anesthesiologists; and (2) anesthesia procedures for which a claim was not allegedly submitted to Medicare.

V. Defendant GW's Motion *In Limine* No. 2: Motion to Preclude Relators from Testifying Regarding GW's Billing Practices

In Defendant GW's Motion *In Limine* No. 2 [656], the Defendant moves to preclude the Relators from testifying at trial regarding its billing practices. *See* Def.'s Mot. at 1. The Defendant contends that the Relators should not be allowed to testify regarding its billing practices because they

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[9] To date, the Relators have not provided the Court or the Defendant with a list, both comprehensive and exact, of the allegedly fraudulent claims submitted to Medicare. This is no longer acceptable. The Relators will be required, by the upcoming pretrial conference, to identify the exact Medicare claims that were allegedly false. For each claim, the Relators will be expected to provide, at a minimum, the date the claim was filed with Medicare, the name of the attending anesthesiologist, the type of medical procedure involved, and the amount of the claim. The Relators will also be expected to identify each document that they will seek to introduce at trial that corresponds to each allegedly fraudulent claim.

"had no involvement with GW's billing practices generally," and, as a result, "possess no personal knowledge" of the subject. *Id*. at 1, 2. Pointing to an earlier opinion by the Court, the Defendant notes that "Magistrate Judge Kay struck portions of relators' declarations insofar as they purported to describe the operations of GW's Billing Office or the bills themselves" because they had no personal knowledge of these issues. *Id*. at 2.

The Court need not address this motion in great detail, as the Relators concede they have no personal knowledge of the Defendant's billing practices and, moreover, that they will not testify at trial regarding the Defendant's billing practices. *See* Rels.' Opp'n at 1 ("The Relators were not involved in the actual submission of the Defendant's Medicare bills and therefore do not intend to testify about the actual submission of the Defendant's bills."). Given the Relators' concession and Magistrate Judge Kay's earlier opinion on the subject, *see United States ex rel. El-Amin v. George Wash. Univ.*, No. 95-2000 (D.D.C. May 9, 2000), the Defendant's motion is granted. The Relators are precluded from testifying at trial regarding the Defendant's billing practices because they, by their own admission, have no personal knowledge to support this testimony. *See* FED. R. EVID. 602.

VI. Defendant GW's Motion *In Limine* No. 3: Motion to Preclude Relators from Offering Irrelevant and Prejudicial Evidence

In Defendant GW's Motion *In Limine* No. 3 [657], the Defendant moves to limit the scope of the Relators' testimony and argument at trial in five material ways. Specifically, the Defendant seeks to preclude the Relators "from introducing at trial any evidence or argument" regarding: (1) the "anesthesiologists' care of non-Medicare patients," (2) "harm to patients, real or imagined," (3) "procedures performed by physicians other than the 15 GW anesthesiologists named in relators' Third Amended Complaint," (4) "anesthesiologists reading the newspaper, playing video games, looking out the window, having lunch, or engaging in other non-medical activities," and (5) the

"anesthesiologists' signing of medical records after the fact." Def.'s Mot. at 1-2. According to the Defendant, these five categories of evidence should be excluded because they are not relevant to the narrow issue at trial: whether the Defendant submitted false claims to Medicare. *Id*. at 4. Because the Court agrees in general that these topics are not relevant, at least not on this record, the motion will be granted.

A. The Anesthesiologists' Care of Non-Medicare Patients

The Relators will be precluded from presenting evidence regarding the anesthesiologists' care of non-Medicare patients because this evidence is not relevant. *See* FED. R. EVID. 401 & 402. To establish a violation of the FCA, the Relators must prove the Defendant knowingly presented a false claim to the Health Care Finance Administration for Medicare reimbursement. *See* 31 U.S.C. § 3729(a)(1). The Defendant's anesthesiologists' treatment of non-Medicare patients is not probative of whether the Defendant submitted a false claim to Medicare. *See Huddleston v. United States*, 485 U.S. 681, 687, 108 S. Ct. 1496 (1988) (noting "relevant evidence [is] evidence that makes the existence of any fact at issue more or less probable"). This case concerns the Defendant's billing practices with respect to Medicare patients only; how the Defendant provided anesthesia care or billed non-Medicare patients is not probative of how the Defendant provided services to Medicare patients because, as the Court explained above, the anesthesiologists did not treat all patients the same. Their care varied with each patient. Evidence regarding non-Medicare patients is therefore not relevant and not admissible. FED. R. EVID. 401 & 402.

The Relators argue, in opposition, that a court order is not "necessary" here because they will not try to "offer evidence to prove the conduct and billing of non-Medicare procedures." *See* Rels.' Opp'n at 1. If an order is issued, however, they exhort the Court to "be careful to preserve the

Relators' rights to offer . . . evidence of routine practice under [Rule] 406 [and] evidence of 'knowledge.'" *Id*. at 2.

Notwithstanding the Relators' assurance that they will not address non-Medicare patients at trial, the Court concludes that an order is appropriate here. This case is complex. The Relators' allegations involve thousands of Medicare claims, which were performed by 15 different anesthesiologists, for thousands of patients who received anesthesia services from the Defendant over a six-year period. An order setting specific parameters on the scope of the evidence that may be presented at trial, like this one, will help both parties prepare for trial. Moreover, as the Court has already found the Relators may not present evidence of habit or routine practice under Rule 406, the Relators' apprehension that the Court's order would be overbroad is moot.

B. Patient Harm

The Relators will be precluded from presenting evidence regarding harm to the Defendant's patients because this evidence is not relevant. *See* FED. R. EVID. 401 & 402. Evidence that a patient was harmed (or died) while receiving anesthesia services at the Defendant's hospital is not probative of whether the Defendant unlawfully billed Medicare for anesthesia procedures its anesthesiologists did not perform. *See* 31 U.S.C. § 3729(a)(1). The Relators essentially concede as much, noting in their opposition brief that "[w]hether a patient was harmed during [] a procedure is secondary to . . . the anesthesiologist's failure to perform the service." Rels.' Opp'n at 2 (emphasis added). Notably, the Relators do not explain how "secondary" evidence of patient harm has any probative value on the issues slated for trial; nor do they point the Court, with a citation to the record, with a single instance of a patient being harmed while undergoing an anesthesia procedure at the Defendant's hospital. Wholly divorced from an anesthesiologist's failure to satisfy the seven steps regulation,

evidence of patient harm is not probative and not admissible.

It is of course conceivable that a patient was harmed due to an anesthesiologist's failure to perform one or more of the seven steps. *See* 3d Am. Compl. ¶ 1 ("[T]he Defendant's false billing practices for anesthesiologists led to . . . several deaths, when an anesthesiologist required to personally participate in certain stages of a patient's anaesthesia failed to do so[.]") (emphasis in original). Evidence of this nature might arguably meet the relevancy requirements of Rules 401 and 402. The Court need not decide this issue, however, for two reasons. First, it is strictly hypothetical. The Relators have not provided the Court with a single, concrete instance of a patient suffering harm due to an anesthesiologist's failure to perform one of the seven steps. There is no evidence before the Court that this ever happened. Second, this situation would undoubtedly implicate Federal Rule of Evidence 403. The absence of an actual instance of this type of patient harm, however, coupled with the corresponding absence of a complete evidentiary record on which to balance the probative value against the potential prejudice to the Defendant, makes it impossible for the Court to conduct a Rule 403 assessment.[10]

C. Physicians Other Than the 15 Named Anesthesiologists

By Court order, this case has been confined to only those Medicare claims that are based on the conduct of the 15 anesthesiologists named in the Relators' complaint. *See El-Amin*, *supra*, 2005 U.S. Dist. LEXIS 3563 at *21 ("[O]nly claims based on the conduct of the fifteen anesthesiologists named in paragraph 34 survive; any claims based on the conduct of unnamed anesthesiologists are

[10] The Defendant agrees that the Relators will be able to testify based on personal knowledge that an anesthesiologist was absent when a particular service was performed which was billed to Medicare.

dismissed.").[11] Thus, as the Defendant points out, evidence relating to Medicare claims that were wholly performed by physicians other than the 15 named anesthesiologists will not be admissible at trial because it is not relevant. *See* FED. R. EVID. 401 & 402. Procedures that were wholly performed by the so-called unnamed anesthesiologists do not have any probative value on the procedures that were performed, in whole or in part, by the 15 named anesthesiologists.

While the Relators may not present evidence relating to Medicare claims that were wholly performed by physicians other than the 15 named anesthesiologists, the Court does not mean to suggest that all evidence relating to these unnamed anesthesiologists is always inadmissible. As the Relators explain in their opposition brief, there may have been instances where both a named and unnamed anesthesiologist worked together on the same anesthesia procedure. Indeed, this may be one of the Defendant's defenses at trial: that a licensed anesthesiologist always performed each of the seven steps, even if it was not always the same anesthesiologist performing each step. *See* Rels.' Opp'n at 3. In this type of hybrid situation, the conduct of the unnamed anesthesiologist would be relevant to whether the Defendant satisfied the seven steps regulation and would therefore be admissible. What the Court is precluding, however, is evidence relating to anesthesia procedures that were wholly performed (and billed) by physicians other than the 15 anesthesiologists named in the Relators' complaint. The distinction, for purposes of determining relevancy, turns on whether a named anesthesiologist was involved in the procedure. *See* Def.'s Reply Br. at 5 ("[O]nly procedures not performed – in whole or in part – by one of the 15 named anesthesiologists would be precluded under this *in limine* order.").

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[11] The 15 anesthesiologists named in the complaint are Richard Becker, Michael J. Berrigan, May L. Chin, Paul Diana, Michael Herzig, Charles Hickock, Christopher Junker, Don S. Lee, Phuc Luu Nguyen, Michael J. Peck, Jason D. Sankar, Herbert Weintraub, Manfred Lichtmann, George Morales, and John Huffman. *See* 3d Am. Compl. ¶ 34(a)-(o).

D. The Anesthesiologists' Non-Medical Activities

The Relators will be precluded from presenting evidence regarding the anesthesiologists' non-medical activities, *e.g.*, playing video games,[12] reading the newspaper,[13] and eating lunch,[14] unless the Relators demonstrate the anesthesiologists undertook these non-medical activities instead of performing an anesthesia procedures for which they later billed Medicare. It goes without saying that anesthesiologists, like most everyone else, will spend some time at work not working. Engaging in non-medical activity at work does not, however, prove the anesthesiologists failed to perform one or more of the seven steps. It merely shows that the anesthesiologists took breaks to read the newspaper and eat lunch. Thus, evidence that the anesthesiologists engaged in non-medical activities is not, by itself, probative. *See* FED. R. EVID. 401.

This type evidence would be probative, however, if the Relators were able to show that an anesthesiologist engaged in a non-medical activity in lieu of performing an anesthesia procedure. For example, the fact that an anesthesiologist ate lunch at the hospital cafeteria is not peculiar or probative. But this fact becomes probative if this same anesthesiologist was eating lunch in the hospital cafeteria while, at the same moment, a resident was prescribing the anesthesia plan (step two) for the anesthesiologist's Medicare patient. In the latter situation, evidence that the anesthesiologist was eating lunch is relevant because it tends to show the anesthesiologist did not perform step two of the seven steps regulation and was therefore not lawfully able to bill Medicare as if he or she had.

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[12] *See* Def.'s Mot., Ex. 3, El-Amin Decl. ¶ 3.

[13] *See* Def.'s Mot., Ex. 5, Roubik Decl. ¶ 7.

[14] *See* Def.'s Mot., Ex. 6, Lasley Decl. ¶ 4.

For evidence of non-medical activity to be relevant, then, the Relators would have to show the activity was undertaken instead of performing the anesthesia procedure (or part of the procedure) for which the Defendant later billed Medicare. However, on this record, the Relators have failed to establish this link for any specific claims submitted to Medicare. They cannot, even after many years of discovery, identify a single claim that was submitted to Medicare even though the attending physician was engaged in a non-medical activity during the underlying anesthesia procedure. The Relators will therefore be precluded from presenting evidence regarding the anesthesiologists' non-medical activities. FED. R. EVID. 401 & 402.

E. The Delayed Signing of Medical Records

Finally, the Relators will be precluded from presenting evidence that an anesthesiologist did not sign a medical record until after the anesthesia procedure was concluded. As the Defendant notes, the applicable Medicare regulation in effect at the time gave the physician 30 days, following the patient's discharge, to complete the medical record. *See* 42 C.F.R. § 482.24(c)(2) (1986) ("All records must document the . . . [f]inal diagnosis with completion of medical records within 30 days following discharge."). Thus, an anesthesiologist's failure to complete a medical record immediately following a procedure does not, by itself, have any probative value bearing on the likelihood the anesthesiologist performed the procedure. The timing of an anesthesiologist's signing of a medical record, as long as it was done within 30 days, does not make it any more or less likely that the Defendant falsified its billing records. There may be many reasons a physician does not immediately complete a medical record. The Relators do not explain why a delay that satisfies the applicable Medicare regulation is nonetheless probative of fraud.

There is one potential exception to this general rule. The Relators assert that the

anesthesiologists engaged in "signing parties," where a group of anesthesiologists would gather to blindly sign a pile of unsigned, uncoded anesthesia records. *See, e.g.*, Def.'s Mot., Ex. 3, El-Amin Decl. ¶ 71. The Relators maintain that "[e]vidence that the anesthesia records were signed . . . *en masse* long after the [procedure], is probative of the anesthesiologists' absence from the operating room during the performance of the [procedure]." Rel.'s Opp'n at 5. The Court agrees. Evidence that anesthesiologists indiscriminately signed medical records is potentially probative in two ways. First, it makes it more probable the anesthesiologist who signed the medical report did not perform the anesthesia procedure, which calls into question whether a licensed anesthesiologist actually performed the procedure. Second, it makes it more probable the Defendant used a false record – here, a medical report -- to get Medicare to pay a false claim. *See* 42 C.F.R. § 482.24(c)(1) ("All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided . . .") (emphasis added). Evidence that the anesthesiologists indiscriminately signed medical reports, irrespective of the delay involved, is therefore probative.

While evidence of signing parties is relevant in the abstract, before the Relators could introduce this evidence at trial they would first have to be able to tie it to the actual Medicare claims that are allegedly fraudulent. In other words, evidence that the anesthesiologists engaged in signing parties is relevant only to the extent that the anesthesiologists signed a medical record that was later used to file a claim for reimbursement with Medicare. General evidence that the anesthesiologists engaged in signing parties is not relevant standing alone. As noted above, the Defendant's anesthesiologists performed thousands of anesthesia procedures, for Medicare and non-Medicare patients alike, during this six year period. Only a fraction of these procedures are actually at issue

in this case. The Relators must be able to establish this link, between a signing party and a specific Medicare claim, for the evidence to be admissible at trial. To date, however, the Relators have not established this link and so the Court has no choice, on this record, but to preclude evidence of the signing parties.

F. Conclusion

The Defendant's Motion *In Limine* No. 3 is granted. At trial, the Relators shall be precluded from presenting evidence or argument, as described above, regarding: (1) the anesthesiologists' care of non-Medicare patients; (2) the physical harm suffered by anesthesia patients while at the Defendant's hospital; (3) those Medicare claims that were based, entirely, on the performance of a physician who is not one of the 15 anesthesiologists named in the third amended complaint; (4) the anesthesiologists' non-medical activities; and (5) the signing of medical records after the anesthesia procedure was complete.

VII. Defendant GW's Motion *In Limine* No. 4: Motion to Preclude Relators from Offering Evidence Regarding the Locke Reports

In Defendant GW's Motion *In Limine* No. 4 [700], the Defendant moves to "preclude relators from introducing at trial any evidence or argument regarding consulting reports prepared for the [GWU] anesthesia department by Joseph A. Locke in 1990." Def.'s Mot. at 1. The so-called "Locke Reports" should be excluded, the Defendant argues, because they "are not relevant to the narrow issue remaining in this case – whether . . . GW knowingly submitted false claims to Medicare for anesthesia procedures in which 15 GW anesthesiologists supposedly failed to comply with certain Medicare billing regulations by not doing the work for which GW billed Medicare." *Id*. "Allowing relators to introduce the Locke Reports would," the Defendant contends, "be confusing to the jury and unfairly prejudicial." *Id*. at 6. The Court agrees. In the following discussion, the Court provides

an overview of the Locke reports, explains why the reports are not relevant to this case, and explains why the reports, even if they were relevant, would nonetheless be excluded under Federal Rule of Evidence 403 because they are unfairly prejudicial and likely to confuse the jury.

A. The Locke Reports

In 1990, Dr. Burton Epstein, the former head of the Defendant's anesthesiology department, engaged an outside consulting agency, Joseph A. Locke & Associates, Ltd. ("Locke"), to investigate and evaluate the anesthesiology department's billing practices. Def.'s Mot., Ex. 4 at 1; Ex. 1., Dec. 17, 1999 Epstein Dep. at 288 (explaining the purpose of the investigation was "to determine whether there was anything wrong with the departmental responsibilities in the billing process"). The stated "objectives of the study" were to "determine the extent to which the Department of Anesthesiology was being under- or overpaid by Medicare" and "identify probable explanations for inconsistencies and errors in Medicare payments." The study also sought to "evaluate the [Anesthesiology] Department's exposure or risk as a result of accepting incorrect payments" from Medicare and "propose recommendations to reduce the department's risk in the future." Def.'s Mot., Ex. 4 at 1. The study was not designed, however, to evaluate the anesthesia department's treatment of Medicare patients or to determine whether the department's anesthesiologists were performing the procedures that were being billed to Medicare. Accordingly, Locke did not review the documentation prepared by members of the anesthesia department, *see* Def.'s Mot., Ex. 3, Locke Dep. at 113 ("I did not focus on the extent to which the documentation provided by the physicians, residents, and CRNAs at GW met or didn't meet Pennsylvania Blue Shield's requirements."), or the actual claims that were submitted to Medicare, *id.* at 124 ("I never saw either the tapes, a print-out of the tapes, or HCFA forms that went to [Pennsylvania Blue Shield]."). Instead of reviewing the actual claims the

Defendant submitted to Medicare, the "report was based on charge information [that Locke] gleaned from the Department of Anesthesia's computer database." Def.'s Mot., Ex. 6 at 1.

Locke's findings were released in two separate reports.[15] The first report, released on May 29, 1990, was based on Locke's examination of Medicare payments made to the Defendant during the six-month period beginning in September 1989.[16] To determine whether the anesthesia department was being properly reimbursed by Medicare, Locke first compiled a list of all the Medicare patients who had been treated by the department during this six-month period. Once Locke had compiled this list, it calculated the "expected payment" for each claim. S*ee* Def.'s Mot., Ex. 4 at 1. The term "expected payment," as used by Locke, did not refer to the amount of money the Defendant actually billed Medicare. Locke did not have this information. Rather, Locke arrived at this figure by multiplying the "total units" for a given anesthesia procedure by "the amount the Department should collect from Medicare per unit." Def.'s Mot., Ex. 4 at 10. Locke assumed that the department would collect $15.41 per unit, which was "80% of the department's charge rate." *Id*. Once an "expected payment" was assigned to each claim, Locke compared it to the "actual payment" the Defendant received from Medicare.[17] By comparing the expected payment against the actual payment, Locke was able to determine, on a claim-by-claim basis, whether Medicare had accurately reimbursed the Defendant.

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[15] The first report expanded on a "preliminary study," performed in April 1989, "which found a significant incidence of over- and underpayments from Medicare." Def.'s Mot., Ex. 4 at 1.

[16] The first Locke "report focused on all patients over the age of 65 with dates-of service between September 1, 1989 and February 28, 1990." Def.'s Mot., Ex. 6 at 1.

[17] Locke determined the "actual payment" by reviewing the payment vouchers received and saved by Financial Services. S*ee* Def.'s Mot., Ex. 4 at 1. This figure indicated "the exact amount Medicare paid for the service." *Id*. at 10.

Locke's findings were not rosy. Three of these findings bear repeating here. First, Locke determined the anesthesia department faced a "significant" "problem of unpaid [Medicare] claims," which "deserved the department's immediate attention." Def.'s Mot., Ex. 4 at 6. Specifically, Locke noted the Department was "carrying an excessive accounts receivable with Medicare," totaling nearly $200,000 for this six-month period, and that "almost half of all Medicare claims from September and October [were] still open."[18] *Id*. at 4, 6. Second, Locke determined that the "number of miscalculated payments accepted by the [anesthesia department's] billing agent without review or investigation [was] significant." Def.'s Mot., Ex. 4 at 4. Locke noted that, on the whole, these "over- and underpayments generally balance[d] each other out." *Id*. There were, however, "a disproportionate number of overpayments" for "mixed" cases – those anesthesia procedures "in which an anesthesiologist supervise[d] a CRNA and a resident concurrently." *Id*. at 5. Lastly, Locke noted that the anesthesiology department placed an "unusually heavy reliance on anesthesiologists working with two residents simultaneously." *Id*. at 4. Locke characterized the department's "use of residents" as "dramatic and exceptional," noting that it was "clear that residents [exercised] a major role in the provision of anesthesia" services. *Id*. at 7. The department's dependence on residents presented a major problem, according to Locke, because it placed the department "at risk" of facing "a nightmare in reviews and additional paperwork" should its fiscal intermediary,

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[18] The large "number of claims still outstanding" was, in Locke's opinion, indicative of "a major [breach] of the billing agent's responsibility to the Department." Def.'s Mot., Ex. 4 at 4. Locke theorized that the billing agent's inaction was "probably the result of the billing agent's own lack of understanding of how Medicare reimbursements are calculated." *Id*. Similarly, Locke noted that the department's "administrative staff [had] indicate[d] confusion" about the proper method of billing "mixed" cases – procedures involving both a resident and CRNA. *Id*. at 5.

Pennsylvania Blue Shield (PBS), "decide to enforce existing guidelines." *Id.*[19] Locke's second report, released on August 27, 1990, was intended to be a more detailed "follow-up" to the first. Def.'s Mot., Ex. 6 at 1. The report was more comprehensive than the first in that it focused on the entire billing process and Locke reviewed "payment information from Explanation of Medicare Benefits forms (EOMBs)." *Id*. at 2. Nonetheless, the second report was similar to the first in that Locke did not review the actual claims submitted to Medicare. Instead, as it had done for the first report, Locke calculated an "expected payment," based on "all applicable payment calculation rules and other payment guidelines," and compared this figure with the payment information contained in the EOMB form. *Id*. at 3. Locke did not, as it had not for the first report, examine whether the anesthesiologists were actually performing the procedures for which the department was billing Medicare.

According to Locke, the second report was "prepared . . . with three distinct objectives in mind." *Id*. at 1. Locke sought, first, to review and evaluate the method by which the anesthesiology department calculated the fee submitted to Medicare; second, to calculate the number of incorrect payments accepted by the department's billing agent; and third, to anticipate "the degree of exposure" the department could face "as a consequence of having accepted overpayments on Medicare claims." *Id*. at 2. To determine the appropriate "Medicare payment for each claim," Locke examined the factors that were used to calculate the charge to Medicare, including procedure codes, concurrency, time units, Gramm-Rudman reductions, and deductible requirements. *Id*. "Based on this analysis," Locke "categorized all Medicare accounts into four categories – overpayments,

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[19] Interestingly, while Locke expressed concern that the department's anesthesiologist-to-resident ratio was high, it also cited a letter from a Medicare representative that seemed to condone the Defendant's billing practice with respect to these procedures. *See* Def.'s Mot., Ex. 4 at BE0312.

underpayments, non-payments and correct payments." *Id*. at 2-3.

For the second time, Locke's findings were not rosy. Locke determined that between 30-35% of all Medicare accounts for this two-month period "represent[ed] payment problems" and a "majority" of the these payment problems were due to the department's "acceptance of overpayments." *Id*. at 5. Although Locke could not "clearly determine[] what the risk to the Department [was] of accepting these overpayments," there was "reason to believe the risk could be significant." *Id*. The department's acceptance of overpayments was due, Locke concluded, to a number of weaknesses in the billing process. There were "a number of internal inconsistencies and problems in the flow of case details from [the operating room] to PBS." *Id*. at 6. Locke "identified errors in coding, the calculation of time units and the determination of concurrency," and concluded the department's billing "system [was] cumbersome, time-consuming and without meaningful internal controls." *Id*. Locke found, for example, that the procedure codes generated by the department and reported to PBS were not subject to adequate quality control measures. *Id*. at 11 ("At no point does the system allow for meaningful review, edit or verification of the code ultimately to be submitted to Medicare against the original service."). Locked explained that "each miscoding involve[d] either lost revenue or a fraudulent overpayment, the sum of which [was] significant." *Id*. at 12.

The second report also identified errors made by Financial Services. Locke was "especially struck" by the "Financial Services policy of not dealing with over or under payments." *Id*. at 5. Financial Services exerted "very little effort . . . to identify payment errors at the time such payments [were] received . . . [and was] even less interest[ed] in reviewing claims which prove[d] to have been paid in error." *Id*. Locke "wonder[ed] if Financial Services [] understood the concurrency

guidelines, especially with regard to 'mixed' cases," as Locke "could determine no observable pattern determining which [mixed cases] were reported correctly." *Id*. at 25.

In addition to identifying errors in the billing process, Locke proposed a series of corrective measures the department could take to lower the number of incorrect payments.[20] Notably, Locke never suggested the Defendant needed to do a better job of ensuring that its anesthesiologists were comporting with the applicable Medicare billing regulations.

B. Rule 401: The Locke Reports are Not Relevant

The Defendant argues that evidence of Locke's study and the Locke reports should be excluded at trial because it is "not relevant to the narrow issue in this case," which is "whether GW knowingly sought Medicare reimbursement for anesthesia services for which the 15 named GW anesthesiologists did not comply with the 'seven steps' or 'personally performed' regulations." Def.'s Mot. at 1, 7. The Defendant points out the Locke reports "contain no analysis of whether the services rendered by any GW anesthesiologist at any time satisfied the 'seven steps' regulation . . . or other regulations governing Medicare billing for anesthesia services," and that they do not identify any of the 15 named anesthesiologists that are the subject of this lawsuit. *Id*. at 8. Thus, the Defendant concludes that Locke's study and the Locke reports do not satisfy the relevancy requirement of Federal Rule of Evidence 401. The Court agrees.

The Locke study and reports are not relevant, as the Defendant convincingly argues, because Locke did not examine whether the Defendant's anesthesiologists were performing the work for

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[20] For example, Locke encouraged the department to check all Medicare payments for accuracy at the time of receipt; to compare actual Medicare payments against expected payments; and to modify its "database program" to increase the accuracy of claim data. Def.'s Mot., Ex. 6 at 34. Locke also encouraged the department to examine a larger sample of claims to get "a true picture" of its billing practices.

which they billed Medicare. Locke examined the Defendant's billing process, not the medical care underlying that process. For example, in the first report Locke sought to determine the extent to which the anesthesia department was being underpaid or overpaid by Medicare. To do this, Locke compared the amount of money the department expected to receive for each anesthesia claim with the amount of money the department actually received from Medicare. In calculating the "expected payment," however, Locke did not independently evaluate whether the services billed to Medicare had actually been rendered by the anesthesiologists. Locke calculated the "expected payment" figure by multiplying the "total units" for each anesthesia procedure by "the amount the Department should collect from Medicare per unit," which was 80% of the department's charge rate. Def.'s Mot., Ex. 4 at 10. Although the second Locke report was designed to be more detailed than the first, Locke, again, did not examine the conduct of the anesthesiologists. Locke assumed, for the purposes of its analysis, the anesthesiologists had performed the work that was billed to Medicare. This is a crucial point to note because the Relators' allegations, as contained in the third amended complaint, concern the failure of the 15 named anesthesiologists to satisfy the relevant billing regulations. *See* 3d Am. Compl. ¶¶ 24-29. The Locke study and reports, which never examined the anesthesiologists' provision of services, have no probative value regarding this issue. FED. R. EVID. 401.

In addition to the fact the reports do not address whether the anesthesiologists performed the work for which they billed Medicare, the Relators have not been able to connect Locke's findings to any of the 15 anesthesiologists named in the complaint or to any of the specific claims the Relators allege are false. As the Defendant correctly points out, the reports do not identify which anesthesiologists performed the anesthesia procedures that were included in Locke's study sample. Consider the first Locke report, for example. While Locke analyzed hundreds of claims for this six-

month period, the report never identified which anesthesiologist performed each claim. It is possible (even if unlikely) none of the claims in Locke's study sample implicated the work of these 15 anesthesiologists. The Relators, moreover, have not connected, or even attempted to connect, any of these anesthesia claims to any of the 15 anesthesiologists. It is impossible to know with any reliability, on this record, whether Locke examined anesthesia claims that were performed by any of these 15 anesthesiologists.

Similarly, the Relators have not shown that any Medicare claims included in Locke's two reports are encompassed by this lawsuit. Consider, for example, the second Locke report, which was limited in scope to claims performed during a two-month period in 1989. For this report, Locke examined 190 Medicare claims for each of the months of September and October 1989. This lawsuit does not include anesthesia procedures performed in September, however, which immediately renders half of Locke's sample, and its accompanying findings, unquestionably irrelevant to this lawsuit. For the remaining procedures that were performed in October and are, temporally speaking, potentially encompassed by this lawsuit, there is no indication that any claims Locke examined are allegedly false. *See* Def.'s Mot. at 9 n.3 (noting "the temporal overlap between matters addressed in the [second] Locke Report and this case is limited to a matter of days"). It may be that none of the claims Locke examined for the month of October are encompassed by this lawsuit; the Court simply has no reliable way of knowing if there is any overlap because the Relators have not tied any claims in Locke's sample to this case. The first Locke report, although it was broader in scope than the second, suffers from the same weakness – the Relators are never able to connect any of the Medicare claims in Locke's sample with any of the allegedly fraudulent claims in this lawsuit. Without being able to make this connection, the Relators cannot demonstrate that the reports tend

to prove or disprove any material issue of fact, the basic test for relevancy. 2 WEINSTEIN'S FEDERAL EVIDENCE § 401.02.

In their opposition brief, the Relators do not claim the Locke reports are relevant to whether the anesthesiologists performed the work for any of the allegedly false claims they will present at trial. They essentially concede that the reports do not address the anesthesiologists' actual performance of specific procedures. *See* Rels.' Opp'n at 6 (noting the reports "do not state" whether any anesthesiologists failed to perform one or more of the seven steps). Rather, the Relators assert the reports are relevant "to show the Defendant's 'knowledge' of its false billing." *Id*. at 6. Specifically, the Relators argue the "Locke Reports are relevant to show the Defendant's actual knowledge of the falsity of its Medicare billing for anesthesia services[,] and separately to show that the Defendant acted with 'reckless disregard' of the veracity of its anesthesia billing[.]" *Id*. at 6-7. The Relators point to both the stated objectives of Locke's investigation and several of Locke's specific findings to demonstrate the Defendant had knowledge that it was falsely billing Medicare. The Court disagrees.

The Locke reports are not relevant to the knowledge element of the FCA for the same reasons they are not relevant to prove the substance of the Relators' case: Locke did not examine whether the anesthesiologists performed the work for which they billed Medicare.[21] The Relators attempt to sidestep this fact by cherry-picking a random selection of Locke's most inflammatory findings and presenting them to the Court as evidence that the Defendant knew it was defrauding Medicare. Upon

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[21] The FCA imposes liability on an individual who "knowingly presents" a "false or fraudulent claim." 31 U.S.C. § 3729(a). According to the Act a person acts "knowingly" with respect to information if he or she "(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required." 31 U.S.C. § 3729(b).

closer inspection, however, none of Locke's statements, inflammatory or not, are relevant to this case. The Court will briefly examine each statement to explain why.

The Relators claim that two of the five objectives in the first Locke report show the Defendant "was aware of problems with the Anesthesia Department's Medicare billing." Rels.' Opp'n at 7. Specifically, the Relators point to the fact that Locke was asked "to identify probable explanations for inconsistencies and errors in Medicare payments" and "to evaluate the Department's exposure or risk as a result of accepting incorrect payments." *Id*.

To an extent, the Relators are correct. The Defendant did retain Locke to examine the efficacy its Medicare billing system and, in particular, to determine why the department's revenues were declining. *See* Def.'s Mot., Ex. 2 at 17. This led Locke to compare the "expected payment" with the "actual payment" for a sample of Medicare claims, in an effort to determine why "the Department of Anesthesiology was being under- or overpaid by Medicare." *See* Def.'s Mot., Ex. 4 at 1. In essence, Locke was looking for a pattern that would explain why the department was not, on a consistent basis, receiving accurate payments from Medicare. In a very general sense, then, the anesthesia department did know, or at the very least it did have a reason to suspect, that something was amiss with the hospital's billing system. But this is a completely distinct issue from the focus of this case. This case concerns the work of the Defendant's anesthesiologists. The stated objectives of the Locke reports, as described above, show there is no overlap between the scope of Locke's study and the scope of this case. Hence, there is no reason to infer, as the Relators do, that the Defendant had knowledge that its anesthesiologists were not performing the work that was being billed to Medicare simply because the anesthesia department commissioned this study.

In addition to the study's stated objectives, the Relators also highlight two specific findings

contained in the first Locke report as evidence the Defendant had actual knowledge it was defrauding Medicare. Specifically, the Relators highlight the following findings:

> 1. Under the heading "Significant Findings," the Report states that there was an "identifiable pattern [of concurrency which] involved 'mixed' cases, in which an anesthesiologist supervises a CRNA and a resident concurrently. There are a disproportionate number of overpayments on these accounts."
>
> 2. "When we looked at the accuracy of Medicare payments a number of things became evident. First, there was no consistent pattern to the errors. We noticed some patterns but these don't seem to shed any meaningful light on the problem. For example, we noticed a disproportionate number of overpayments for cases involving both a resident and CRNA, but this makes no sense in light of the fact that both services were supposedly reported as personally rendered by the anesthesiologist."

See Rels.' Opp'n at 8.

The Court cannot comprehend how either of these two findings – which both deal with "mixed" cases – are at all relevant to knowledge in this case. Both of these findings address the issue of concurrency, which, as the Relators admit, "is no longer a part of this case." Rels.' Opp'n at 8 n.7; *see generally El-Amin*, *supra*, 2005 U.S. Dist. LEXIS 3563 at *21-34 (dismissing the "Relators' false concurrency claims [because they] fail[ed] to meet the requirements of Rule 9(b)"). There is nothing in either of these findings that relates to the anesthesiologists' performance of the seven steps. Much like the rest of Locke's study, these findings presume the anesthesiologists were performing the work that was being billed to Medicare. While the Relators vaguely intimate that the concurrency issue somehow relates to whether the "Defendant was entitled to receive the higher anesthesiologist rate for work performed by residents and/or CRNAs," they never explain how the two issues are connected. In short, the Court cannot understand how Locke's examination of "mixed" cases has any bearing on whether the anesthesiologists satisfied the seven steps regulation. Locke's analysis focused on how the anesthesia department's administrative staff determined the

appropriate "base and time units" to bill Medicare for "mixed" cases; Locke did not examine the anesthesiologists' interaction with residents and CRNAs to see if they actually performed the work. *See* Def.'s Mot., Ex. 4 at 5.

In regards to the second Locke report, the Relators highlight five specific findings that purportedly serve as evidence of the Defendant's actual knowledge. Specifically, the Relators highlight the following five findings:

1. "30-30% of all Medicare accounts for September and October represent payment problems. The majority of these problems involve the acceptance of overpayments. While it has not been clearly determined what the risk is to the Department of accepting these overpayments, there is reason to believe the risk could be significant."

2. "[In the audit sample, a]pproximately $5,012 was accepted in overpayments as a result of Financial Services' misrepresentation of concurrent services involving residents and/or CRNAs."

3. "Most of the 90 'Mixed' cases, i.e., those involving a resident and a CRNA, were paid as personally rendered service instead of as concurrent care."

4. "Payment patterns are not consistent with HCFA guidelines for payment of 'clean claims' for participating physicians."

5. "The sum total of these cases [in the audit sample] does not involve an aggregate loss to the Hospital and yet, each miscoding involves either lost revenue or a fraudulent overpayment, the sum of which is significant."

See Rels.' Opp'n at 8. According to the Relators, these findings "warn[ed] [the Defendant] of possible overpayments from Medicare" and "provide[d] [the] Defendant with knowledge of its false Medicare billing system." *Id*. at 8.

There is no question these five findings would have given the Defendant pause for concern. After all, Locke identified several problems in the hospital's billing process that were causing the Defendant, and the anesthesiology department in particular, to accept numerous incorrect payments

from Medicare. The Defendant was therefore on notice, as the Relators assert, that its billing system needed correction. This does not mean, however, that the Defendant had actual knowledge that its anesthesiologists were not performing the work for which they had billed Medicare. To the contrary, none of these findings, examined together or independently, identify any deficiencies in the anesthesiologists' performance of the seven steps. As the Defendant persuasively argues, "Locke's identification of specific alleged deficiencies [does not] somehow serve[] to impute to GW knowledge of all possible deficiencies." Def.'s Mot. at 9. A closer look at each of these five findings demonstrates why they are not relevant.

The first finding is not relevant because Locke never explains why these claims constitute overpayments; nor does Locke explain what the potential "risk" is to the department. Def.'s Mot., Ex. 6 at 5. There is no reason to infer, as the Relators apparently do, that these claims amount to overpayments because the anesthesiologists had failed to perform the seven steps for the underlying procedure. Looking at the chart that accompanies this finding, however, it appears that a majority of the claims were considered to be overpayments because of a problem relating to concurrency billing. *Id*. at 7. There is no evidence Locke concluded these claims constituted overpayments because the department's anesthesiologists had failed to perform the underlying anesthesia procedure. The second and third findings are not relevant because they strictly concern the issue of concurrency, which, as explained above, is no longer a part of this case. *Id*. at 6. The fourth finding is not relevant because it deals with the timeliness of Medicare's payment of claims. *Id*. at 6, 27. It does not address the Defendant's formulation of Medicare claims. Finally, the fifth finding is not relevant because it concerns coding problems that were due to the Defendant's arcane billing system – a system that was revamped shortly thereafter. *Id*. at 11-12. Like the other four findings

highlighted by the Relators, the fifth finding has nothing to say about the anesthesiologists' performance of the seven steps.

The Relators' secondary argument, that the Defendant acted in "reckless disregard" of the veracity of its anesthesia billing, suffers from the same weakness. *See* Rels.' Opp'n at 10-11. Although the Relators are able to cite to three inflammatory-sounding phrases, hand-picked from the Locke reports, none of these phrases actually addresses whether the anesthesiologists performed the work for which they billed Medicare. Indeed, these three selections are symptomatic of the Relators' entire opposition brief. The Relators are never able to connect Locke's specific findings, or the objectives of the study, to the subject matter of this case.[22] There is no question the department was on notice that it may have had deficiencies in its billing process during this six-month period. Nothing in the Locke reports, however, suggests the Defendant was on notice, or should have been on notice, that its anesthesiologists were not satisfying the seven steps regulation.

C. Rule 403: The Locke Reports are Unfairly Prejudicial and Confusing

Even assuming, *arguendo*, the Locke reports were relevant, the Court would still not allow the Relators to introduce them in their case-in-chief. Rule 403 of the Federal Rules of Evidence provides that relevant "evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." FED. R. EVID. 403. *See also United States v. Rezaq*, 328 U.S. App. D.C. 297, 134 F.3d 1121, 1137 (D.C. Cir. 1998) ("Federal Rule of Evidence 403 permits the district court to exclude evidence 'if its probative value

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[22] The Relators have not asserted that discrete portions of each Locke report could be admitted in lieu of the entire report, so the Court has had no occasion to consider whether the reports might be admitted in part or in redacted form.

is substantially outweighed by the danger of unfair prejudice.'") (quoting *id.*). Here, any probative value the Locke reports might have would be substantially outweighed by the danger of unfair prejudice to the Defendant and jury confusion.

For the reasons explained above, the Locke reports are devoid of probative value. Locke examined the Defendant's billing process and found a number of problems in the way the anesthesia department billed Medicare. While Locke may have determined the anesthesia department was accepting overpayments from Medicare due to deficiencies in the Defendant's "arcane" billing system, the reports did not examine the central issue in this case: whether the Defendant's anesthesiologists satisfied the Medicare regulations for charge reimbursement. *See* 42 C.F.R. §§ 405.552, 414.46. On this, the crucial issue, the Locke reports are silent. The reports therefore will be of no use to the factfinder in determining whether, on a claim-by-claim basis, the anesthesiologists inflated their Medicare claims. Moreover, Locke could not have commented on the accuracy of the Defendant's Medicare claims because it did not review the actual claim forms.

The risk of unfair prejudice that will flow to the Defendant as a result of the admission of the reports is, on the other hand, considerable. In the context of Rule 403, unfair prejudice "means an 'undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one.'" 2 WEINSTEIN'S FEDERAL EVIDENCE § 403.04 (quoting FED. R. EVID. 403 advisory committee's note). The Locke reports present a danger of unfair prejudice because they are replete with statistical and anecdotal evidence the Defendant's billing process was broken and the anesthesia department was, for this six-month period at least, accepting overpayments from Medicare. Although these statements are not relevant to this case, they are inflammatory and may encourage the jury to punish the Defendant for past wrongs. Consider just a few of Locke's more incendiary

observations:

1. The anesthesia department was accepting a disproportionately high number of overpayments for anesthesia procedures "in which an anesthesiologist supervise[d] a CRNA and a resident concurrently."

2. The anesthesiology department placed an "unusually heavy reliance on anesthesiologists working with two residents simultaneously" and that this "practice place[d] the Department at risk."

3. The anesthesia department's billing agent "probably" lacked an "understanding of how Medicare reimbursements are calculated."

4. The anesthesia department's "arcane" billing "system [was] cumbersome, time-consuming and without meaningful internal controls."

5. Financial Services made "very little effort . . . to identify payment errors" or correct improper payments from Medicare.

In short, the reports present a danger of unfair prejudice because they contain numerous inflammatory statements, such as Locke's conclusion that the department had accepted "overpayments" from Medicare that put it "at risk," which, while they do not address whether the anesthesiologists satisfied the seven steps regulation, are likely to cause the jury to be unfairly biased against the Defendant or to presume that it was predisposed to commit fraud. *See also* Def.'s Mot., Ex. 6 at 12 (noting each "miscoding involves . . . a fraudulent overpayment, the sum of which is significant"); Ex. 6 at 5 (noting "30-35% of all Medicare accounts for September and October represent payment problems").

Similarly, the reports also contain a number of findings that may engender significant jury confusion. The first example of such a finding is Locke's conclusion that the Defendant's "heavy reliance on anesthesiologists working with two residents simultaneously" placed "the Department at risk." Def.'s Mot., Ex. 4 at 4. This finding is potentially confusing for two reasons. First, as the Defendant explains in its motion, the Defendant's "Medicare carrier made it clear that the very

practice that Locke contended placed GW's anesthesia department "at risk" was perfectly acceptable. *See id.*, Ex. 4 at BE312. Thus, it is not clear what risk Locke was referring to. It appears that the first Locke report may be internally inconsistent on the point. Second, Locke's concern about the anesthesiologist-to-resident ratio is relevant to the issue of concurrency; it is not relevant to whether the anesthesiologists satisfied the seven steps regulation. Indeed, the Locke reports makes several derogatory references to the Defendant's heavy use of residents – but these statements are always tied to the issue of concurrency. It might, however, be tempting for the jury to infer that the department's heavy reliance on residents made it more likely that its anesthesiologists did not perform the work for which they had billed Medicare.[23] To draw this inference, however, would amount to an unwarranted extension of Locke's findings, pushing the study's conclusions far past their factual moorings. There is a real danger the jury may become unnecessarily tangled in the concurrency issue if the Locke reports are admitted.

The second example of a discrete finding that may engender significant jury confusion, which was highlighted by the Defendant in its reply brief, *see* Def.'s Reply Br. at 5-6, is Locke's conclusion that the department's "miscoding" of certain anesthesia procedures constituted "lost revenue or a fraudulent overpayment, the sum of which [was] significant." Def.'s Mot., Ex. 6 at 12. This statement is potentially confusing because it relates, not to intentional miscoding by the Defendant's anesthesiologists, which would be relevant, but to errors due to the Defendant's aging computer system used to process anesthesia charges. This same computer system was replaced in 1990 with a more sophisticated billing system designed for hospitals. *See* Def.'s Reply Br. at 6; Ex. 2, Sorrell

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[23] The same danger exists with respect to Locke's repeated discussion of "mixed" case billing. *See, e.g.*, Def.'s Mot., Ex. 6 at 6 (noting that most of the "90 "Mixed"cases, i.e. those involving a resident and a CRNA, were paid as personally rendered service instead of as concurrent care").

Dep. at 28; Ex. 3, Epstein Dep. at 92. This statement might lead the jury to conclude, wrongly, that the defendant was intentionally miscoding anesthesia claims to cover-up the fact that its anesthesiologists were not performing each procedure as they should.

In sum, evidence regarding the Locke study and the Locke reports will be excluded from the Relators' case-in-chief because the probative value of this evidence is substantially outweighed by the danger of unfair prejudice and jury confusion. *See* FED. R. EVID. 403.

D. Conclusion

The Defendant's Motion *In Limine* No. 4 is granted. The Relators shall be precluded at trial, in their case-in-chief, from presenting testimony, documents, or other direct or demonstrative evidence regarding the Locke reports or Locke's investigation.

VIII. Defendant GW's Motion to Sequester Relator Witnesses During Trial

In Defendant GW's Motion To Sequester Relator Witnesses During Trial [660], the Defendant "moves *in limine* under FED. R. EVID. 611(a) to sequester each relator from the courtroom during the testimony of any other surgical procedure witness – including other relators and third-parties – taken before that relator completes his or her own testimony." Def.'s Mot. at 1. "[S]equestration is necessary," the Defendant argues, to combat the "heightened risk . . . that the relators will consciously or unconsciously combine their testimony with that of other witnesses, or, worse, imagine or concoct testimony to contradict that of other witnesses, to create the appearance of sufficient proof of their claims." *Id*. at 4, 5. There is a "heightened risk" the Relators will "mold," "conform" or even "concoct" their testimony, according to the Defendant, because the "relators have already demonstrated a propensity to parrot other witness." *Id*. at 5, 6. The Court is not convinced.

The Defendant's motion raises a somewhat thorny legal issue. Although the Defendant

moves to sequester the Relators pursuant to Rule 611, it is actually Rule 615 of the Federal Rules of Evidence that "authorizes the [Court] to exclude witnesses from the courtroom so that they cannot hear the testimony of the other witnesses." 4 WEINSTEIN'S FEDERAL EVIDENCE § 615.02. Rule 615 "provides that, at the request of a party, the Court shall order witnesses excluded so they cannot hear the testimony of other witnesses." *Minebea Co. v. Papst*, 374 F. Supp. 2d 231, 233 (D.D.C. 2005). *See* FED. R. EVID. 615 ("At the request of a party the court shall order witnesses excluded so that they cannot hear the testimony of other witnesses, and it may make the order of its own motion."). Its use of the word "shall" makes the rule mandatory; a "court may not deny a request for the exclusion of witnesses, except as to a witness who fits into one of three exempted categories." 4 WEINSTEIN'S FEDERAL EVIDENCE § 615.03.

The reason the Defendant relies on Rule 611, rather than Rule 615, is that Rule 615 actually bars the precise relief the Defendant seeks. The first category of witnesses exempted from Rule 615 are natural parties. *See* 2 MOORE'S MANUAL--FEDERAL PRACTICE AND PROCEDURE § 15.12 ("Rule 615 governs sequestration of witnesses, generally allowing for automatic exclusion of trial witnesses, other than the parties or their designated agents, so that they cannot hear the testimony of other witnesses."). By its language, Rule 615 expressly withholds from the Court the authority to sequester a natural person who is a party to the action, providing: "This rule does not authorize exclusion of . . . a party who is a natural person." FED. R. EVID. 615(1); *accord Minebea*, 374 F. Supp. 2d at 234 ("Rule 615 does not authorize the exclusion of a party who is a natural person or a designated representative of a party that is not a natural person."). Because, as the Defendant concedes, each Relator is a natural person who is a party to the action, the Court lacks the express authority to exclude them from the courtroom pursuant to Rule 615. *See also* FED. R. EVID. 615

advisory committee's note ("Exclusion of persons who are parties would raise serious problems of confrontation and due process. Under accepted practice they are not subject to exclusion."). Rule 611, by contrast, does not by its language address party sequestration.

That the Court may lack the express authority under rule 615 to sequester the Relators does not end the Court's inquiry. For as the Defendant argues, Rule 615 does not bar the Court from excluding the Relators from the courtroom; it "merely withholds authorization for the[ir] exclusion." Wright & Gold, FEDERAL PRACTICE AND PROCEDURE: EVIDENCE § 6245. This is a subtle difference that suggests the Court may still "have discretion to exclude these individuals so long as that power derives from a source other than Rule 615, such as the court's general powers to manage the conduct of trial." *Id*. at § 6245 (citing *United States v. Phibbs*, 999 F.2d 1053, 1073 (6th Cir. 1993), *cert. denied*, 510 U.S. 1119 (1994)). *See, e.g.*, *United States v. Mosky*, 1990 WL 70819 (N.D. Ill. 1990) (court "exercise[d] its discretion" under Federal Rules of Evidence 102 and 611 to exclude the government's case agent from the courtroom until he had testified). The Court's inherent authority to manage trial is nonetheless subject "to a party's confrontation and due process rights to remain in the courtroom." FEDERAL PRACTICE AND PROCEDURE: EVIDENCE § 6245 n.27.

The Court need not resolve this thorny legal issue in this case. Irrespective of whether the Court has the authority to exclude the Relators from the courtroom, whether this authority is derived from Rules 102 & 611 or the Court's inherent authority to manage trial, it would not do so here.[24] The Defendant favors sequestration because it believes there is a heightened risk the Relators will alter their trial testimony based on the testimony of other witnesses. Granting the Defendant's request would, however, effectively exclude the Relators from being present in the courtroom for

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[24] The Court therefore expresses no opinion on whether it has the authority to sequester a natural person who is a party to the action.

the majority of their trial. This is a drastic measure that would prevent the Relators from, *inter alia*, assisting their trial counsel in preparing and presenting their case and responding to trial events as they unfold. The Court will not, in preemptive fashion, impose this type of sanction.

The Court does not dismiss the Defendant's position when it says there is a risk the Relators will parrot the testimony of one another. As Magistrate Judge Kay found, numerous paragraphs in their respective declarations were nearly identical to one another and not supported by personal knowledge. See *El-Amin*, *supra*, No. 95-2000 (D.D.C. May 9, 2000). Nevertheless, the Defendant has an effective corrective measure readily at its disposal should the Relators attempt to alter their testimony at trial. Specifically, the Defendant has the powerful tool of cross-examination. The Defendant will be able to cross-examine the Relators using their deposition testimony to highlight any discrepancies, perceived or real, in their in-court testimony compared with their earlier statements. The Defendant will also be able to pointedly ask each Relator, in front of the jury, whether that Relator was present in-court for the testimony of other witnesses. This will highlight for the jury the potential risk that a Relator's testimony has changed, consciously or not, because of the testimony of other witnesses.

In addition to the tool of cross-examination, the Court believes that it has, by this opinion, already curtailed, in two important ways, the Relators' ability to make overly-broad or perjurious statements at trial, similar to the overly-broad statements Magistrate Judge Kay struck from the Relators' declarations. First, the Court has ruled that the Relators may not present alleged habit or routine practice evidence regarding the anesthesiologists. FED. R. EVID. 406. This will preclude the Relators from claiming the anesthesiologists' conduct was uniform for all the anesthesia procedures at issue. Second, and relatedly, the Court has ruled the Relators must link their testimony to

anesthesia procedures for which the Defendant allegedly submitted a claim for reimbursement to Medicare. Based on these twin rulings, the Relators cannot broadly assert, as they attempted to in their declarations, that a particular anesthesiologist "virtually never performed the required pre-anesthetic examination" or "never prescribed the anesthesia plan." *See* El-Amin Decl. ¶ 32. Instead, their testimony will be tied to specific Medicare claims for specific patients.

In conclusion, the Defendant's motion to sequester the Relators is denied. Based on this record, the Court would not (regardless of its authority to do so) exercise its discretion to exclude the Relators from the courtroom. The Defendant's ability to cross-examine the Relators about their deposition testimony and the fact that they have attended trial and been present in the courtroom during the testimony of other witnesses, in combination with the specific ways in which the Court has already limited the Relators' ability to present generalized evidence of habit or routine practice, should provide adequate safeguards to prevent the Relators from parroting the testimony of each other and the testimony of other witnesses. The Court will not preemptively sequester the Relators because it is confident these safeguards will provide an adequate mechanism for containing the risk the Relators' testimony might prove malleable.

IX. Relators' Motion for Order Setting Trial by Representative Sample

In the Relators' Motion for Order Setting Trial by Representative Sample [687], the Relators "request that a representative sample of their claims relating to fraud allegations – for example, 300 – be set for trial." Rels.' Mot. at 5. Noting they "are ready, willing and able" to prove the falsity of each of the "approximately 5,000 to 15,000" Medicare claims submitted during this time period, the Relators nonetheless argue that the "extensive overlapping of the factual issues [for these claims] warrants a trial of liability and damages by representative sample." *Id*. at 2, 4. The jury's "verdict

as to the sample" would, they explain, then "be extrapolated to the total number of procedures billed to Medicare to find the total number of false claims and false records." *Id*. at 4-5.

The Defendant vigorously opposes statistical sampling, arguing, among other things, that this "eleventh-hour" motion is "totally at odds with the history and posture of this litigation" because the Relators have not "develop[ed] a record necessary to try a case by statistical sample." Def.'s Opp'n at 1, 7. Specifically, the Defendant asserts that the Relators have "produced no discovery on the subject," have "never designated a statistician as an expert witness," and cannot even "identify the sample on which they purport to rely." *Id*. at 7. The Relators' failure to raise this issue in the "eleven years" since this case was filed has, according to the Defendant, denied it an opportunity to "retain[] a statistical expert of its own to . . . [prepare its] defense." *Id*. at 7,8. The Defendant has the stronger argument here.

This case was filed in 1995; since then the parties have engaged in a protracted period of discovery too lengthy and complex to summarize here. At no point during this lengthy period, however, have the Relators taken the preparatory steps that would give them the proper foundation to try this case by statistical sample. *See generally* Carol C. Lam, *Assessing Loss in Health Care Fraud Cases*, 10 FED. SENT. R. 145 (Dec. 1997) (describing generic method of statistical sampling in medical fraud cases). Most glaringly, the Relators have not defined the total universe of Medicare claims from which their sample will be drawn. Nor have they consulted an expert statistician to assist them in defining this universe. This is a crucial first step because the sample that is ultimately presented to the jury should be randomly selected and representative of the universe of claims. The Relators' complete lack of preparation on this step is evident from their inability, even now, to pinpoint the exact number of claims involved. Instead, they estimate that there are between 5,000

and 15,000 claims. Perhaps even more tellingly, the Relators invite the Court, rather than a statistician or other expert, to select the appropriate sample size. With the Relators unable to define the universe of claims involved, the Court cannot be confident that a sample (regardless of the size selected) will adequately represent the allegedly thousands of claims that are spread out over a six-year period and which were submitted by 15 different anesthesiologists.

The Relators assert that they are not required to consult an expert statistician in order to present the case by representative sample. Maybe so. But this assertion misses the thrust of the Defendant's argument, which is as much practical as it is legal. The Defendant argues that this case cannot proceed to trial by representative sample because neither side has determined, with mathematical confidence, what a representative sample is in this case. Consulting an expert statistician, qualified to perform random samples, is one proven and judicially accepted method of determining that a proffered sample is mathmatically sound. *See United States v. Rosin*, 2008 U.S. App. LEXIS 1080 (11th Cir. 2008) ("The purpose of statistical sampling is to provide a means of determining the likelihood that a large sample shares characteristics of a smaller sample."); Laurens Walker & John Monahan, *Sampling Evidence at the Crossroads*, 80 S. CAL. L. REV. 969, 974 (2007) ("With its mathematical superiority . . . random sampling has, for the past sixty years, been a hallmark of the scientific method."). There may be another acceptable method of obtaining a reliable sample, besides consulting an expert statistician, but the Relators have not explained what it is and – most importantly – they have not done it. Instead, they betray their unpreparedness by claiming, without explanation, that the Court and the jury can perform the "basic arithmetic" of representative sampling. Rels.' Reply Br. at 5.

In short, the Relators' failure to take even the most basic steps in preparing for a trial by

representative sample proves fatal to the instant motion because, as the Defendant convincingly argues, the time for trial preparation is over. The discovery period, already lengthy, has closed; the time for selecting, consulting and deposing expert witnesses is likewise complete. The Relators' pretrial statement, filed nearly two months before this motion, did not address a trial by representative sample; nor did counsel for the Relators raise this issue during the first pretrial conference held before Judge Penn. It is not simply a matter of timing either. It would be unfair to the Defendant at this stage of the litigation and on the eve of trial to permit the Relators to convert this case to a trial by representative sample. The Defendant, like the Relators, has not consulted an expert statistician and, like both the Relators and this Court, cannot even identify the universe of allegedly fraudulent claims. In light of these practical considerations, the motion is denied.

X. Relators' Motion for Leave to Submit Relators' Filing Pursuant to the Court's March 1, 2007 Bench Order Under Seal

In the Relators' Motion for Leave to Submit Relators' Filing Pursuant to the Court's March 1, 2007 Bench Order Under Seal [705], the Relators seek leave to file their response to the Court's request for deposition testimony, which the Court made orally at the March 1, 2007 pretrial conference, under seal. Specifically, Judge Penn asked the Relators to file "a representative deposition" from a physician that would corroborate the Relators' counsel's claim that the physicians would admit that they did not always perform one or more of the seven steps. *See* Def.'s Resp. at 2. The Relators seek to have this material filed under seal because it contains confidential patient information subject to the Court's protective order. The Defendant does not oppose the motion to the extent that the material be kept under seal. However, it does urge the Court to "disregard" the filing, arguing that the material is not responsive to the Court's request.

Because there is apparently no disagreement between the parties that this patient information

is confidential and subject to the protective order, the Court will grant the Relators' motion and the material will be filed under seal.[25] Nevertheless, the Relators should not interpret the Court's decision to grant their motion as a sign that it considers their submission to be responsive to Judge Penn's request. To the contrary, the Court agrees with the Defendant that the Relators have submitted exactly what Judge Penn did not want – a self-serving patchwork of deposition testimony that is composed of random snippets and statements, often taken out of context. Judge Penn's request was uncomplicated. He asked the Relators to file the transcript of a single deposition, in its entirety, that would corroborate counsel's claim that the Defendant's physicians admitted they did not always perform all seven steps. Most of the Relators' filing is superfluous and is not responsive to this request; the sole deposition transcript the Relators did file in its entirety, which is seemingly responsive, does not actually corroborate counsel's claim. The deponent, Dr. Richard Becker, does not admit that he or any of the Defendant's anesthesiologists failed to perform one or more of the seven steps.

Judge Penn's request, while straightforward, has proven elusive for the Relators, which suggests the Relators do not have the evidence they say they have, want to have, and – as trial begins – need to have.

CONCLUSION

Appropriate orders accompany this Memorandum Opinion.

Date: February 4, 2008

/s/
COLLEEN KOLLAR-KOTELLY
United States District Judge

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[25] Where possible, the parties are instructed, for all future filings, to file redacted copies of material they consider to be confidential.