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UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA

GARY SIEBERT,

Plaintiff,

v.

GENE SECURITY NETWORK, INC,

Defendant.

Case No. 11-cv-01987-JST

ORDER GRANTING IN PART AND DENYING IN PART MOTION FOR SUMMARY JUDGMENT AND DENYING MOTION FOR PARTIAL SUMMARY JUDGMENT

Re: ECF Nos. 109, 110

Before the Court are Plaintiff Gary Siebert's Motion for Summary Judgment or, in the alternative, for summary adjudication, and Defendant Gene Security Network's Motion for Partial Summary Judgment. ECF Nos. 109, 110. For the reasons set forth below, Siebert's Motion for Summary Judgment is GRANTED IN PART and DENIED IN PART, and Defendant's Motion for Partial Summary Judgment is DENIED.

I. BACKGROUND

On April 22, 2011, Plaintiff-relator Gary Siebert filed this False Claims Act ("FCA") case, alleging that Defendant Gene Security Network ("GSN")¹ falsely certified its compliance with accounting regulations and thereby unlawfully secured at least three grants from the National Institutes of Health ("NIH"). ECF No. 1. Specifically, Siebert alleges that GSN "knowingly submitted a false or fraudulent claim for payment or approval, and knowingly presented false records or statements to get a false or fraudulent claim paid or approved, in violation of 31 U.S.C. § 3729(a)(1) and (2)." ECF No. 22, ¶ 6. Siebert served as GSN's Chief Operating Officer and

¹ GSN is now known as "Natera, Inc." ECF No. 110 at 2. Because the case was filed against the company when it was known as "Gene Security Network," the relevant documents in evidence use that name, and the caption still reflects that name, the Court uses "GSN" rather than "Natera."

Vice President of Research from July 12, 2010 until GSN terminated his employment on February 11, 2011. <u>Id.</u> ¶ 12.

GSN is a private biotechnology company that studies and conducts minimally invasive embryonic tests for the presence of genetic disorders. ECF No. 110 at 2. Matthew Rabinowitz, the company's CEO, founded the company in 2003. <u>Id.</u> at 1. Rabinowitz has testified that he managed financial matters and accounting for GSN from "the very early days," but that later on, the company hired "other people to manage that" ECF No. 110 at 2-3. Rabinowitz also participated in research and helped prepare and submit the grant proposals at issue here. ECF No. 110-3 at 6-7, 10.

Three NIH grants totaling \$5,293,373 form the basis of Siebert's claims: \$1,689,902 from the "Novel Informatics" grant, \$1,799,814 from the "Array Informatics" grant, and \$1,803,657 from the "Non-Invasive Aneuploidy" grant. ECF No. 109 at 1-2. GSN applied for the grants on December 12, 2007, April 7, 2008, and August 5, 2009, respectively. <u>Id.</u> at 2. GSN drew funds from those grants on nine separate occasions. ECF No. 109-40, Exs. 1-9. ²

GSN hired various employees as it expanded over the years. The employees most pertinent to this motion – in addition to Rabinowitz – are John Croswell, whom GSN hired before applying for any of the NIH grants, Robin McElroy, whom GSN hired in 2007, and Venkata Peddada-West, who replaced McElroy after McElroy suffered a stroke in 2010. John Croswell held general management responsibilities, including those related to accounting, the "handling of grant funds," and interacting with the NIH grant office. ECF No. 110 at 3. McElroy was hired to

² Siebert asks the Court to take judicial notice of nine Project Information Reports from the NIH's "Project Reporter" website. ECF No. 109-40; see id., Exs. 1-9. The Court will take judicial notice of these reports, as they are publicly available government records. See Fed. R. Evid. 201 (providing that courts may take judicial notice of matters that are "not subject to reasonable dispute" and "can be accurately and readily determined from sources whose accuracy cannot be reasonably questioned."); Lee v. City of L.A., 250 F.3d 668, 689 (9th Cir. 2001) (holding that, under Rule 201, "a court may take judicial notice of matters of public record.") (quotation omitted). Furthermore, they are relevant here because they reflect the NIH grants awarded to GSN. See Fed. R. Evid. 401 (defining relevance); id. 402 (providing for the admission of relevant evidence).

handle administrative tasks, her responsibilities including "accounting manager, HR manager, facilities manager and office manager." <u>Id.</u> at 3-4. She input accounting data into Quickbooks and maintained accounting records for the company. <u>Id.</u> at 4. When McElroy became ill, various employees took over her responsibilities until West was hired and became accountant and office manager. <u>Id.</u>

At the time GSN applied for the three NIH grants, no GSN employee had experience with NIH grants. ECF No. 110 at 4-5. Rabinowitz, Croswell, McElroy, White, and several other employees have testified that they were not familiar with the specifics of the accounting regulations contained in 45 C.F.R. Part 74, and Rabinowitz has testified that he believed the only requirement in these regulations was the requirement that grant funds be used for the research NIH intended the grant to fund. <u>Id.</u> at 5-6.

Nonetheless, as part of the application process, GSN employees signed certifications that they were in compliance with the requirements of 45 C.F.R. Part 74.³ The certifications were located in the "NIH Small Business Innovation Research Program Small Business Concern Verification Statement," and read:

It is understood that if this project is funded, drawing NIH award funds from the HHS Payment Management System serves as a certification that the above-named organization has in place written policies and procedures for financial and business management systems that comply with 45 CFR 74 and the NIH Grants Policy Statement (12/03) and will follow these policies and procedures.

ECF No. 109-15. This statement indicates that each drawdown of grant funds constitutes a

Recipients' financial management systems shall provide for the following: (1) Accurate, current and complete disclosure of the financial results of each HHS-sponsored project or program . . . (2) records that identify adequately the source and application for funds for HHS-sponsored activities. . . . (3) Effective control over and accountability for all funds, property and other assets. Recipients shall adequately safeguard all such assets and assure they are used solely for authorized purposes. . . . (7) Accounting records, including cost accounting records, that are supported by source documentation.

³ The regulations at issue are found in 45 C.F.R. § 74.21(b) and provide, in relevant part:

discrete certification of compliance with 45 C.F.R. Part 74.

In August 2008, McElroy filled out a questionnaire from NIH. ECF No. 118 at 3-4; see ECF No. 109, Ex. D. That questionnaire was titled "Financial Questionnaire: Evaluation of Financial Management Systems," and contained the following pertinent language:

Financial management system requirements for grantee organizations of the National Institutes of Health (NIH) are addressed in the NIH Grants Policy Statement (NIHGPS) and Title 45 Code of Federal Regulations (CFR) Part 74.21. Grantee organizations are expected to have certain systems, policies, and procedures in place for managing their own funds, equipment, and personnel.

ECF No. 118 at 4 (citations omitted).

Like the certifications and questionnaire, the NIH Grants Policy Statement ("Statement") required compliance with 45 C.F.R. Part 74. ECF No. 109 at 4. Section 8.3.1 of the Statement provides:

Grantees are required to meet the standards and requirements for financial management systems set forth or referenced in 45 CFR part 74.21 or 92.20, as applicable. The standards and requirements for a financial management system are essential to the grant relationship. NIH cannot support the research unless it has assurance that its funds will be used appropriately, adequate documentation of transactions will be maintained, and assets will be safeguarded.

Grantees must have in place accounting and internal control systems that provide for appropriate monitoring of grant accounts to ensure that obligations and expenditures are reasonable, allocable, and allowable. . . .

A grantee's failure to establish adequate control systems constitutes a material violation of the terms of the award. Under these circumstances, NIH may include special conditions on awards or take any of the range of actions specified in Administrative Requirements—Enforcement Actions, as necessary and appropriate.

<u>Id.</u> The Statement was incorporated by reference into each verification of compliance that GSN submitted to NIH in conjunction with GSN's applications for grant awards. <u>Id.</u> at 2.

Finally, award notices that NIH sent out for each drawdown of the grants contained a

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statement regarding the terms and conditions of the grants that referred to "45 CFR Part 74" and the "NIH Grants Policy Statement." ECF No. 118 at 4; see ECF No. 109-40, Exs. 1-9.

REQUESTS TO EXCLUDE EVIDENCE II.

GSN asks the Court to exclude two items of evidence in support of Siebert's motion for summary judgment. First, GSN seeks to exclude the testimony of Michelle Bulls, the director of the Office of Policy for Extramural Research Administration at the NIH. ECF No. 119 at 18-24. Second, GSN seeks to exclude the 2010 audit report prepared by Newman Associates. Id. at 11-12.

Testimony of Michelle Bulls A.

Bulls submitted a declaration in support of Siebert's motion for summary judgment, describing the application and certification process for grants like those received by GSN. Although she works at the NIH, she did not personally participate in the review of GSN's applications or the award of any money to GSN.

GSN contends that Bulls provides improper expert opinion because (1) Siebert failed to disclose Bulls as an expert witness, (2) Bulls' testimony is not helpful or reliable under Federal Rule of Evidence 702, and (3) in her testimony, Bulls renders impermissible legal conclusions. Id. at 18-23. GSN also contends that Bulls' testimony as a fact witness is inadmissible because Bulls does not have personal knowledge of GSN's grant applications and awards. Id. at 23-24.

The Court finds that Bulls' testimony does not constitute improper expert testimony. A lay witness is entitled to give testimony in the form of an opinion if the testimony is "(a) rationally based on the witness's perception; (b) helpful to clearly understanding the witness's testimony or to determining a fact in issue; and (c) not based on scientific, technical, or other specialized knowledge within the scope of [Federal] Rule [of Evidence] 702." Fed. R. Evid. 701. The third element was added in 2000 "to prevent litigants from skirting the Daubert standard or the expert disclosure guidelines by introducing expert opinion testimony as lay opinion testimony." Hynix Semiconductor Inc. v. Rambus Inc., No. C-05-00334 RMW, 2008 WL 504098, at *3 (N.D. Cal. Feb. 19, 2008) (citing FRE 701, adv. committee note (2000)).

The matters to which Bulls testifies are not matters that require "scientific, technical, or specialized knowledge." They are observations about the ordinary inner workings of the NIH, derived from her personal experience. As the drafters of the Evidence Code recognized in an advisory note to Rule 701,

courts have permitted the owner or officer of a business to testify to the value or projected profits of the business, without the necessity of qualifying the witness as an accountant, appraiser, or similar expert. See, e.g., Lightning Lube, Inc. v. Witco Corp., 4 F.3d 1153 (3d Cir.1993) (no abuse of discretion in permitting the plaintiff's owner to give lay opinion testimony as to damages, as it was based on his knowledge and participation in the day-to-day affairs of the business). Such opinion testimony is admitted not because of experience, training or specialized knowledge within the realm of an expert, but because of the particularized knowledge that the witness has by virtue of his or her position in the business. The amendment does not purport to change this analysis.

FRE 701, adv. committee note (2000); see also Hynix, supra, at *4 (citing advisory committee note). Where, as here, a witness is testifying as to institutional operations and practices based on personal knowledge that the witness has accrued over the course of several years of employment, the witness is providing lay testimony not subject to Rule 702. See, e.g., United States v. Munoz-Franco, 487 F.3d 25, 35-36 (1st Cir. 2007) (permitting opinion testimony by a lay witness where the witness had personal knowledge of bank operations and banking practices that derived from his employment); In re Google AdWords Litig., No. 5:08-CV-3369 EJD, 2012 WL 28068, at *5-7 (N.D. Cal. Jan. 5, 2012) (permitting two different Google employees to testify about how that company's AdWords and AdSense systems worked and how advertisers responded to them, based on the witnesses' personal experiences at the company).

The only case GSN cites to the contrary, <u>United States ex rel. Jones v. Brigham & Women's Hospital</u>, 678 F.3d 72 (1st Cir. 2012), is not helpful. The issue in <u>Jones</u> was that the district court had not determined whether to admit or exclude the expert testimony of Dr. Daniel Teitelbaum, who was proffered as an expert statistician by the relator in an FCA lawsuit. 678 F.3d at 84. The question was not whether Teitelbaum was an expert – a fact that neither side disputed – but whether he was qualified to render specific opinions about the statistical analysis he had performed. Id. Thus, the court in Jones never reached the question presented here. Moreover,

there was no suggestion that Teitelbaum had ever worked at the National Institute on Aging, which was the agency at issue in <u>Jones</u>. Thus, unlike the witness in <u>Munoz-Franco</u>, and unlike Bulls in this case, Teitelbaum was not testifying from a base of personal experience. <u>Jones</u> simply is not relevant to the Court's determination.

The final basis on which GSN argues that Bulls should have testified as an expert is Bulls' response to a deposition question indicating that her testimony might fall under Rule 702. ECF No. 119 at 19 (citing Bulls' deposition testimony). Whether Bulls is an expert is a question of law for the Court, not an issue of fact for the witness. See Munoz-Franco, 487 F.3d at 34 ("Interpretation of the Federal Rules of Evidence is a question of law"). The Court concludes that Bulls did not offer expert testimony; that Siebert was not in error by not disclosing her as such; and that the standards for admissibility under Rule 702 do not apply.

The Court is also not persuaded by GSN's objection that Bulls lacks personal knowledge of GSN's applications and awards. As discussed above, Bulls may testify as a fact witness because she has personal knowledge of the general NIH grant procedures she discusses. See Fed. R. Evid. 602 (permitting testimony of witnesses with personal knowledge of the matters regarding which they testify). As part of her employment, she is required to be aware of NIH grant regulations and policies, and various documents outlining the same. ECF No. 109-35, ¶ 3. She can testify from personal knowledge as to these matters. And to the extent she testified as to GSN's grant applications, she relied on the grant applications that are in evidence. See id. ¶¶ 10-15.

Bulls' testimony, except for her legal conclusions, is admissible.⁴

2. Newman Associates Audit Report

GSN also seeks to exclude the Newman Associates audit report, ECF No. 109-28, because

⁴ GSN also objects to stray remarks in Bulls' declaration, which it contends constitute legal conclusions concerning GSN's applications. The objection is well-taken, and the Court will not consider any of Bulls' legal conclusions. <u>See, e.g.</u>, ECF No. 109-35, ¶ 9 ("Compliance with 45 C.F.R. §§ 74.20-74.28 is a critical and material condition precedent to the awarding of NIH research grant funds.") (emphasis added).

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it was not properly authenticated under Federal Rule of Evidence 901, and because it is inadmissible hearsay under Rules 801 and 802, and not an admissible business record under Rule 803. ECF No. 119 at 11-12. Siebert contends that the report "is properly authenticated because GSN produced the audit report and bates labeled it." ECF No. 120 at 1. Further, Siebert argues the report is not inadmissible hearsay because the report constitutes a party admission, and GSN has adopted the report and its contents as true under Federal Rule of Evidence 801(d)(2)(A) and (B), respectively. Id. at 2. Finally, Siebert contends the report is admissible as a business record under Rule 803. Id.

As to authentication, which serves to determine the genuineness of an item of evidence, GSN argues that Siebert cannot authenticate the report because Siebert has no personal knowledge of the report. ECF No. 119 at 11-12 (citing Orr v. Bank of Am., NT & SA, 285 F.3d 764, 775-76 (9th Cir. 2002)). But Siebert is not required to have personal knowledge of the document, because GSN produced the document to Siebert in discovery, thereby authenticating it. Maljack Prods., Inc. v. GoodTimes Home Video Corp., 81 F.3d 881, 889 n. 12 (9th Cir.1996) (holding that documents produced by a party in discovery were deemed authentic when offered by the partyopponent); 31 Fed. Practice & Procedure: Evidence § 7105, at 39 ("Authentication can also be accomplished through judicial admissions such as ... production of items in response to ... [a] discovery request.").

As for the document's admissibility under Rule 801(d)(2), the Court finds that GSN adopted or believed the information in the report was true, as indicated by its letter to the NIH, wherein it responded to the information contained in the report as accurate and true. See Fed. R. Evid. 802(d)(2)(B); ECF No. 109-31.

The Court will admit the Newman Associates audit report.

III. LEGAL STANDARD

Summary judgment is proper when the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P.

56(c). An issue is "genuine" only if there is sufficient evidence for a reasonable factfinder to find for the non-moving party, and "material" only if the fact may affect the outcome of the case.

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-49 (1986). All reasonable inferences must be drawn in the light most favorable to the non-moving party. Olsen v. Idaho State Bd. of Med., 363 F.3d 916, 922 (9th Cir. 2004). Unsupported conjecture or conclusory statements, however, do not create a genuine dispute of material fact and will not defeat summary judgment. Surrell v. Cal. Water Serv. Co., 518 F.3d 1097, 1103 (9th Cir. 2008). The Court may grant summary judgment as to a "part of each claim or defense" provided no genuine dispute of material fact exists and the movant is entitled to judgment as a matter of law as to that part of the claim or defense. Fed. R. Civ. P. 56(a).

Under 31 U.S.C. § 3729(a)(1)(A) and (B), the charged FCA provisions, liability attaches where one "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." The elements of an FCA violation under § 3729 are: (1) a false statement or fraudulent course of conduct; (2) that is material, and (3) made with knowledge of that falsity, that causes (4) the government to pay out money. <u>United States v. Corinthian Colls.</u>, 655 F.3d 984, 992 (9th Cir. 2011).

IV. ANALYSIS

A. GSN's Motion for Partial Summary Judgment

GSN contends that the Court should grant summary judgment in its favor because Siebert has provided no colorable evidence to show that an FCA violation occurred before August 2010. ECF No. 110. Specifically, GSN contends that Siebert has supplied scant and insufficient evidence to show GSN's "knowledge" that it supplied false claims to the United States prior to August 2010 and that the information it submitted to the NIH for funding was material to the grant decision. <u>Id.</u> at 9-11. Siebert counters that it is entitled to summary judgment as to the pre-August-2010 period as well as later periods because all elements of an FCA violation—including knowledge—have been conclusively shown. ECF No. 118.

1. Legal Standard

The element "knowingly" under the FCA can be satisfied by one of three possible levels of scienter: actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the statement at issue. 31 U.S.C. § 3729(b)(1)(A). No specific intent to defraud is required on the part of the alleged violator. <u>Id.</u> subsection (B). Deliberate indifference and reckless disregard can be means of inferring actual knowledge in the absence of direct evidence. <u>See, e.g., United States v. Krizek</u>, 111 F.3d 934, 941 (D.C. Cir. 1997) ("In some cases, recklessness serves as a proxy for forbidden intent."). Innocent mistakes and negligence, however, do not lead to FCA liability. <u>Wang v. FMC Corp.</u>, 975 F.2d 1412, 1420 (9th Cir. 1992).

In other contexts, the Ninth Circuit has defined deliberate ignorance to incorporate two components: (1) a subjective belief in a high probability that a fact exists, and (2) deliberate actions taken to avoid learning the truth. United States v. Yi, 704 F.3d 800, 805 (9th Cir. 2013) (citation omitted) (interpreting "deliberate ignorance" in relation to an alleged violation of the Clean Air Act). Similarly, the Ninth Circuit has defined "reckless disregard" in other circumstances to require proof of (1) a high degree of awareness of probable falsity or that (2) the defendant in fact entertained serious doubts as to a statement's truth. Phx. Trading, Inc. v. Loops, LLC, 732 F.3d 936, 944 (9th Cir. 2013) (citations omitted) (defining "reckless disregard" for the purposes of a defamation claim). Krizek provides a thorough discussion of the meaning of reckless disregard in the FCA context. 111 F.3d at 941-42 (defining "reckless disregard" to be something akin to aggravated gross negligence—i.e., "an extreme version of ordinary negligence" or "gross negligence-plus").

2. GSN's Pre-August-2010 "Knowledge"

a. Actual knowledge and deliberate ignorance

Siebert has not provided evidence from which a reasonable jury could find that GSN acted with either actual knowledge or deliberate indifference prior to August 2010. Rabinowitz testified, without contradiction, that he had no actual knowledge of the specific accounting requirements contained in 45 C.F.R. Part 74 before August 2010. ECF No. 110 at 10 (explaining that he was aware of "the fundamental regulation that [a grantee] needed to spend the money on

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the research that [the grantee] was doing," but that he only "became aware of the more specific regulations later on."). Rabinowitz clearly knew there were some requirements under those regulations, id., but the only evidence on the subject suggests he was not aware of the specific requirements with which Siebert has alleged he failed to comply. Siebert cites no evidence to the contrary.

Siebert also has not produced evidence of deliberate ignorance by GSN. Deliberate ignorance requires a willful or deliberate act by the defendant taken to avoid learning the truth, Yi, 704 F.3d at 805, but Siebert points to no evidence of a deliberate act by GSN or its responsible employees to avoid learning the requirements contained in 45 C.F.R. Part 74. Instead, Siebert's opposition to GSN's motion for partial summary judgment focuses on the allegation that GSN failed to investigate whether it complied, or to learn whether it was in compliance, with 45 C.F.R. Part 74, despite its various certifications of compliance with those regulations. See, e.g., ECF No. 118 at 3 ("Despite not having anyone with previous experience or knowledge of NIH grant application and funding procedures and requirements, no one at GSN bothered to familiarize themselves with the NIH regulations governing the award of those grants."). While this may support a finding of reckless disregard, see infra, it will not support a finding of deliberate indifference.

b. Reckless disregard

Viewing the evidence in the light most favorable to Siebert, he has provided sufficient evidence of reckless disregard to survive GSN's motion for partial summary judgment.

Most on point are the "false certification" cases in the Ninth Circuit. See, e.g., United States ex rel. Hopper v. Anton, 91 F.3d 1261 (9th Cir. 1996), and United States ex rel. Hendow v. Univ. of Phoenix, 461 F.3d 1166 (9th Cir. 2006).

In Anton, a relator brought an FCA suit against the Los Angeles Unified School District, alleging the District submitted false claims for federal funds while in knowing violation of a federal statute regarding funding for special education programs. 91 F.3d at 1263-64. Among other things, the District submitted regular certifications averring that it would "meet all applicable

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requirements of state and federal law and regulations, including general compliance with the [Individuals with Disabilities Education Act]." Id. at 1265 (internal quotations omitted). The court held that mere regulatory violations did not give rise to FCA liability under the false certification theory; rather, "the false certification of compliance . . . creates liability when certification is a prerequisite to obtaining a government benefit." <u>Id.</u> at 1266-67. In that case, however, because the claim forms submitted to the government did "not contain any certification regarding regulatory compliance," and "the IDEA does not require funding recipients to certify their compliance with federal laws and regulations," no actionable FCA claim existed. Id. at 1267. Nonetheless, the rule stated in **Anton** applies here.

In Hendow, two enrollment counselors employed by the University of Phoenix alleged "that the University falsely certifies each year that it is in compliance with the incentive compensation ban" – a statutory ban that prohibits universities from paying recruiters on a perstudent basis – "while intentionally and knowingly violating that requirement." Id. 461 F.3d at 1169. The relators alleged a number of flagrant attempts to cover up the lack of compliance, including statements by the University's head of enrollment that "we need to show the Department of Education what they want to see," real and fake files containing performance reviews of recruiters, and policy changes designed to obscure the violations. Id. The court found that plaintiff adequately alleged an FCA claim, including scienter. Id. at 1177-78. The court reaffirmed Anton and the general rule that certifications of compliance with statutory or regulatory requirements, and subsequent failure to comply with those requirements, can serve as the basis for a reckless disregard finding under the FCA. <u>Id.</u> at 1170-72. <u>Anton</u> and <u>Hendow</u> confirm that where an FCA defendant has certified compliance with statutory or regulatory criteria, and then fails to familiarize itself with those criteria, the defendant acts in reckless disregard of the truth or falsity of the statement of compliance with those criteria.

In other cases not involving false certifications, courts have found FCA defendants liable for reckless disregard where they have failed to familiarize themselves with applicable statutes or regulations. For example, in United States v. Mackby, 261 F.3d 821 (9th Cir. 2001), the owner of

a physical therapy clinic instructed clinic employees to use his physician father's PIN number on claim forms to bill Medicare for physical therapy services provided at the clinic. But his father "never referred provided medical services at or for the [clinic], never referred any patients to the clinic and was never involved with the care or treatment of its patients." <u>Id.</u> at 825. The PIN was provided on forms submitted to Medicare, and checks were made payable to Mackby's father. <u>Id.</u> Various communications from Medicare were addressed to Mackby's father but sent to the clinic. <u>Id.</u> The communications contained statements informing recipients that the PIN for the performing physician or supplier had to be used on claim forms submitted to Medicare. <u>Id.</u> at 826-27.

The Mackby court concluded that "[p]articipants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment." Id. at 828 (relying on Heckler v. Cmty. Health Servs. of Crawford Cnty., Inc., 467 U.S. 51 (1984). Specifically, "[b]y failing to inform himself of [Medicare] requirements, particularly when twenty percent of Asher Clinic's patients were Medicare beneficiaries, [Mackby] acted in reckless disregard or in deliberate ignorance of those requirements, either of which was sufficient to charge him with knowledge of the falsity of the claims in question." Id. (citing Krizek, 111 F.3d at 942).

Similarly, in Krizek, the D.C. Circuit Court of Appeals found that, despite a lack of certification, a psychiatrist and his wife acted in reckless disregard of the falsity of their Medicare billings where they submitted claims for reimbursement based on "seriously deficient" billing records. 111 F.3d at 936. "Mrs. Krizek completed the submissions with little or no factual basis; she made no effort to establish how much time Dr. Krizek spent with any particular patient; and Dr. Krizek 'failed utterly' to review bills submitted on his behalf." Id. at 937. The court found most telling that "there were a number of days . . . when even the shoddiest recordkeeping would have revealed that false submissions were being made—those days on which the Krizeks' billing approached twenty-four hours in a single day." Id. Moreover, Dr. Krizek was just as liable as his wife because he "delegated to his wife authority to submit claims on his behalf. In failing 'utterly' to review the false submissions, he acted with reckless disregard." Id.

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And in United States v. Stevens, the court found an FCA defendant acted in reckless disregard of regulatory requirements, despite not certifying compliance with those requirements. 605 F. Supp. 2d 863 (W.D. Ky. 2008). Stevens involved an FCA claim against a doctor, his pain management clinic, and clinic employees. Id. The court cited Krizek as holding that "in the healthcare setting, a physician demonstrates 'reckless disregard' when he fails to take reasonable steps to ensure that his clinic's claims for governmental reimbursement are accurate." <u>Id.</u> at 867. The court found the doctor acted in reckless disregard of Medicare requirements when he "did not properly oversee the billing" for services he provided and used a Medicare code for services that he did not provide in his billing submissions. <u>Id.</u> at 867-68.

These cases support the general principle that those who submit claims to the government for reimbursement may be acting in reckless disregard as to the truth or falsity of their submissions if they fail to take steps to confirm the accuracy of those submissions. Applying this principle to the record before the Court, it is clear that there is a jury issue as to scienter before August 2010.

GSN argues this case is like those in which courts found that FCA defendants did not act in reckless disregard of legal requirements, because the requirements were not clear to the defendants and the defendants failed to secure a legal opinion interpreting them. See, e.g., Hagood v. Sonoma Cnty. Water Agency, 81 F.3d 1465 (9th Cir. 1996); United States ex rel. Quirk v. Madonna Towers, Inc., 278 F.3d 765, 768 (8th Cir. 2002); Hochman v. Nackman, 145 F.3d 1069, 1079 (9th Cir. 1998). These cases are factually distinguishable, however, because the defendants in them formed a reasonable belief concerning a disputed legal question. GSN does not contend that it or its employees formed such a belief – to the contrary, GSN contends that its employees never even read the regulations and had no knowledge of them. See ECF No. 121 at 13 ("Natera admits that it was unfamiliar with these technical accounting regulations"). The "disputed legal question" cases do not have any bearing here.

GSN also attempts to construct a "red flag" requirement in the case law, arguing that "in the absence of some 'red flag' or aggravating circumstance, the mere failure to review a regulation

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that is applicable to a government grant, contract or program does not constitute 'reckless disregard' " ECF No. 121 at 2. But the cases GSN cites in support of this argument are either inapposite or do not identify a bright-line red-flag requirement. In <u>United States ex rel. Burlbaw</u> v. Orenduff, 548 F.3d 931, 949-50 (10th Cir. 2008), for example, there was no "red flag" warning defendants that they were submitting false claims. There was the opposite – a governmentpublished list stating affirmatively that defendants' educational institution was eligible for the government funds it applied for. Likewise, in Quirk, 278 F.3d 765 (8th Cir. 2002), the court also did not impose a "red flag" requirement. It noted that the defendants' employees had a good-faith understanding of federal nursing home billing requirements based on prior practice and industry custom, such that their submission of a false claim could not be characterized as "knowing." 278 F.3d at 768. Both Burlbaw and Quirk involved defendants who had an objectively reasonable, good-faith basis for their claims. In this case, defendants had no understanding of the relevant accounting regulations, because they did not read them and had no prior experience with NIH grants.

And even if there were a "red flag" requirement, the Court notes that a certification requirement, like the one presented here, could serve as a red flag to an applicant that compliance with certain regulations is required.

GSN has failed to show that it is entitled to partial summary judgment as to the issue of whether, prior to August 2010, GSN had "knowledge" that it was not in compliance with 45 C.F.R. Part 74. The cases suggest that, in similar circumstances to those alleged here, FCA defendants have been found to have acted in reckless disregard as to the truth or falsity of their statements to the government. At a minimum, the question of knowledge presents a factual issue rife with credibility determinations, all of which are suited to a jury determination. GSN's motion for partial summary judgment fails.

3. Knowing the submitted information was material to the grant decision

GSN alleges that Siebert must not only prove that GSN "knowingly" submitted a false claim, but also that GSN had knowledge that the false information was material to NIH's decision

to approve GSN's grant application. ECF No. 110 at 11 (citing <u>United States v. Sci. Applications Int'l Corp.</u>, 626 F.3d 1257, 1272 (D.C. Cir. 2010), and <u>United States v. DRC, Inc.</u>, 856 F. Supp. 2d 159, 172 (D.D.C. 2012)). While the D.C. Circuit has identified knowledge of materiality as an element of an FCA violation, the Ninth Circuit has not, despite having had ample opportunity to do so. <u>See, e.g., Anton</u>, 91 F.3d 1261. In the absence of controlling Ninth Circuit precedent, this Court will not impose this requirement.

Even if knowledge of materiality were an issue, however, there is sufficient evidence here for a jury to find it. GSN was required to certify compliance with the accounting regulations found at 45 C.F.R. Part 74, and those certifications incorporated the Grants Policy Statement, which provided that compliance was "essential to the grant relationship," and "that NIH cannot support the research unless it has assurances that its funds will be used appropriately, adequate documentation of transactions will be maintained, and assets will be safeguarded." ECF No. 109 at 20. Further, the 2008 questionnaire GSN submitted to NIH provided that "Demonstration of a grantee's management capabilities is one of the evaluative criteria used in the administrative review process prior to issuance of an award." Id. Thus, Siebert has pointed to evidence showing GSN was aware of the materiality of compliance with these regulations for receiving NIH grants.

For the foregoing reasons, the Court concludes that GSN's motion for summary judgment must be denied.

B. Siebert's Motion for Summary Judgment

Siebert also moves for summary judgment in his favor, as to the entire period encompassed by the three NIH grants to GSN. GSN argues that there are triable issues of material fact concerning three elements of the FCA: the falsity of statements made to the NIH; the materiality of the alleged statements; and GSN's knowledge of the falsity of those statements, or scienter.

1. Falsity

Siebert alleges three separate actions, or failures to act, that render false GSN's statements that it was in compliance with NIH accounting regulations. First, Siebert alleges that GSN "certified the existence of accounting systems which met the standards required by the NIH" in

each "grant application, Financial Questionnaire, and NIH SBIR Verification." ECF No. 109 at 15. In particular, Siebert alleges that GSN was required by NIH regulations to use project-based accounting, but failed to do so. GSN argues that its accounting system complied with NIH regulations. Second, Siebert alleges that GSN violated NIH regulations by failing to require employees to maintain time-sheets. Lastly, Siebert alleges that GSN commingled NIH grant funds with other funds. GSN acknowledges that it was required to "maintain[] adequate records to track its grant income and expenses for each of its grants," ECF No. 119 at 6, but denies that time-sheets or segregated bank accounts were required.

To evaluate Plaintiff's arguments, it is useful to look at each of these three categories separately: project-based accounting, commingling of funds, and time sheets.

a. Project-based accounting

The evidence regarding whether GSN used project-based accounting is in conflict. On the one hand, in 2010, the NIH required GSN to conduct a compliance audit for calendar year 2009. ECF No. 109-16 (West Depo.) 106:5-7. GSN hired a third party auditing firm, Newman Associates, to conduct the required audit. In its report, Newman Associates scrutinized all three of the relevant grants. See ECF No. 109-28 (Newman Report). With regard to the Non-Invasive Aneuploidy grant, Newman noted that under 45 C.F.R. § 74.21(b), GSN was required to maintain a reporting system that includes "[r]ecords that identify adequately the source and application of funds for HHS-sponsored activities. These records shall contain information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, outlays, income and interest," and "[c]omparison of outlays with budget amounts for each award." Id. at 8 (quoting regulation). Newman concluded that

[GSN]'s accounting system is not adequately set up to meet these requirements. We noted that many allocated costs are not clearly documented and many purchase orders are not clearly noted with the appropriate grant. There is not a clear reconciliation between the grant costs and funds and the general ledger. There is not a reconciled budget vs. actual schedule to monitor the financial progress of the grants.

Northern District of California

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On the other hand, GSN argues that it actually did use project-based accounting, incorporating a combination of "initial employment letters which established schedules, payroll records, the NIH budget which allocated employee time to projects, progress reports that [GSN] submitted to the NIH, reviews of the Excel spreadsheets that tracked grant expenditures (including payroll), and monthly board meetings which reviewed the business and research plans." ECF No. 119 at 3-4, 9. This argument is supported by the testimony of Grant Lam, the lead manager of Armanino LLP's auditing practice, and a member of a team that audited GSN for the year ending December 31, 2009. ECF No. 119-1 (Lam Declaration).⁵ According to Lam, Armanino considered [GSN]'s internal control over compliance requirements with, but not limited to, allowability of costs and activities, cost principles and cash management, which included examining and comparing the drawing down of funds against the expenditures incurred. As a result of our audit procedures surrounding [GSN]'s internal control over compliance, we did not identify any deficiencies in internal control over compliance that we consider to be a material weakness.

Id. at 2-3. This conflicting testimony and evidence raises a genuine dispute of material fact as to whether GSN adequately used project-based accounting, and therefore truthfully certified its compliance with 45 C.F.R. § 74.21(b).

b. Commingling of funds

The Court also finds that, viewing the evidence in the light most favorable to GSN, as it must do, there is a dispute of material fact regarding whether GSN's certifications were false with regard to its commingling of funds.

The dispute takes two forms: first, it is not clear that the regulation prohibits commingling⁶; and second, Siebert has not established as a matter of law that GSN commingled.

1985). The Court will decide this question, and other questions of regulatory interpretation, at

Siebert argues that Lam's testimony is inadmissible because Lam lacks personal knowledge of the matter to which he testifies and thus his testimony relies on hearsay. ECF No. 120 at 4-5. The Court finds that Lam has adequate personal knowledge of the Armanino audit, as he "was an integral part of the Armanino team that prepared the 2009 audit," and therefore his testimony does not rely on inadmissible hearsay, but rather on his personal experience. ECF No. 119-1, ¶ 3. ⁶ The interpretation of the NIH accounting regulations is a question of law for the Court to decide, not an issue of fact for the jury. Mathes v. The Clipper Fleet, 774 F.2d 980, 983-84 (9th Cir.

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The regulatory provision Siebert cites as a basis for the asserted prohibition on commingling provides that grantees must have "[e]ffective control over and accountability for all funds, property and other assets. Recipients shall adequately safeguard all such assets and assure they are used solely for authorized purposes." 45 C.F.R. §74.21(b)(3). But the regulation on its face does not, for example, prohibit the placing of grant funds in the same account with other funds.

Regarding GSN's compliance with the regulation, GSN employees did acknowledge that GSN deposited grant funds into, and withdrew them from, the same accounts used for other funds. They did not create separate accounts for the NIH grants. See, e.g., ECF No. 109-16 (Venkata West Depo.) 114:12-21. But GSN employees also testified that GSN was tracking funds and otherwise complying with 45 C.F.R. § 74.21(b)(3). See, e.g., ECF No. 119-9 (Robin McElroy Depo.) at 43. Moreover, Plaintiff's counsel has been clear that Siebert does not allege that GSN ever misused NIH funds, i.e., spent them for purposes that were not authorized by the terms of the grants. ECF No. 119-3 (Rabinowitz Depo.) at 93-94. Thus, viewed in the light most favorable to GSN, it had adequate procedures to maintain effective control over the funds and property associated with its NIH grants. Summary judgment is not appropriate on this issue.

GSN's failure to use timesheets c.

Siebert also argues that GSN's failure to use timesheets made its certifications false. He points out that the regulations require grantees to maintain "[a]ccounting records, including cost accounting records that are supported by source documentation." ECF No. 109 at 16 (citing 45 C.F.R. § 74.21(b)(7)). Siebert argues that GSN's failure to use timesheets for its employees violates this regulation and therefore that its certification of compliance with § 74.21 is false. Siebert also points to the statement in the 2008 questionnaire that indicates employees were submitting semi-monthly time sheets when no evidence shows that they were. ECF No. 109 at 7.

Once again, there is a dispute of material fact as to the interpretation of the NIH accounting regulations. Siebert cites no text from the regulations themselves requiring timesheets, and it is

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not clear that they require timesheets. The Newman audit, however, concluded that GSN's accounting was deficient for failing to keep timesheets. ECF No. 109-28 (Newman Audit) at 8.

Factually, while it is undisputed that GSN's employees did not keep task-based timesheets, there is also evidence that GSN hired individual employees to work solely on specified grant projects, such that any time spent by an individual employee could only relate to one grant, and GSN maintained other records relating to the time spent by employees on grant-related work. ECF No. 119 at 8-9. Thus, there is a dispute of material fact that is not subject to resolution on the instant motion for summary judgment.⁷

2. **Materiality**

Under the FCA, a "material" statement is one that has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). Siebert argues that the language of the 2008 questionnaire, and the verification statements GSN submitted to the NIH, as well as the testimony of Michelle Bulls, all demonstrate that GSN's certifications were material. GSN provides no contrary evidence on the issue of materiality, but instead contends the Court should not summarily decide this issue because: (1) Bulls' testimony should be excluded, (2) materiality is generally a question of fact for the jury, and (3) the language in the regulations and questionnaire, verifications, and Grants Policy Statement are ambiguous as to materiality. ECF No. 119 at 18-25. None of GSN's arguments on this issue is persuasive.

As previously noted, Bulls' testimony is admissible. Moreover, the Court finds that the regulations are not ambiguous.⁸ Finally, while materiality is often a question of fact for the jury, here it is established as a matter of law, because the NIH regulations explicitly condition receipt of

⁷ GSN did make one indisputably false statement. In 2008, it submitted a questionnaire to the NIH in which it affirmatively represented that its employees submitted semi-monthly timesheets. ECF No. 109-39 (Michelle Bulls Decl., Exh. D) at 1. GSN has provided no evidence that its employees were actually submitting such timesheets, and other evidence shows they were not doing so. Consequently, the Court finds no genuine dispute of material fact as to the falsity of this statement. It is not, however, possible for the Court conclude that this statement in isolation was sufficiently material to trigger FCA liability as a matter of law.

⁸ As previously noted, the interpretation of the regulations is a question of law for the Court.

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grant funds on certification with NIH accounting regulations. See Hendow, 461 F.3d at 1175-77 (discussed at greater length supra, section IV.A.2.b.).

In Hendow, the Ninth Circuit held that in FCA cases where funding is "explicitly conditioned" on compliance with certain requirements, the materiality standard is met. 461 F.3d 1166. In that case, certification came in three forms. <u>Id.</u> at 1175. First, the relevant statute provided that the program participation agreement "shall condition" eligibility "upon compliance" with a statutory incentive-compensation ban. Id. Further, under applicable regulations, a program could participate "only if" a program participation agreement is entered into, and such agreements "condition[]the initial and continued participation of an eligible institution upon compliance" with statutory requirements, including the ban. Id. The agreement itself also provided that compliance with the ban was a "prerequisite" to the institution's initial or continued participation in the program. Id. at 1175-76. Thus, the Court found, the conditional statements in the statute, regulation, and agreement "demonstrate that compliance with the [ban] is a necessary condition of continued eligibility and participation" in the program. <u>Id.</u> at 1176.

As in Hendow, the Grants Policy Statement, as discussed more fully in section IV.A.3., stated that compliance with the accounting regulations was "essential" to grant funding, and that grant funds would not be awarded without such a certification. GSN's certification of compliance was material because, by incorporating the Grants Policy Statement, the verifications GSN provided to NIH in conjunction with its applications for grant funds explicitly conditioned awards on compliance with 45 C.F.R. Part 74. The Court finds that GSN's allegedly false statements to the NIH were material to the NIH's decision to award GSN all three grants.

3. Knowledge—Post August 2010

In support of its allegations that GSN, and Rabinowitz in particular⁹, had actual knowledge of the falsity of the certifications submitted to the NIH after August 2010, Siebert points to email

⁹ GSN argues that FCA liability cannot be premised on the "collective knowledge" of GSN employees. ECF No. 119 at 12. Siebert rejects the notion that it is relying on a collective knowledge theory. ECF No. 120 at 8. Thus, the Court does not address this issue.

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chains between Rabinowitz and GSN employees, as well as to preparations for an audit that indicated GSN's accounting protocols were inadequate. ECF No. 109 at 17-18. In its opposition, GSN cites Rabinowitz and other employees' testimony that they had no knowledge of the falsity of any of their certifications to the NIH in grant applications. ECF No. 119 at 14-15. This evidence tends to show a genuine dispute of material fact as to whether Rabinowitz had actual knowledge of the falsity of GSN's certifications of compliance with 45 C.F.R. Part 74. This is not, however, the end of the scienter inquiry. Siebert can also prove knowledge indirectly by demonstrating that GSN acted in deliberate ignorance or reckless disregard of the truth or falsity of its statements to the government. 31 U.S.C. § 3729(b)(1)(A).

As to whether GSN acted in deliberate ignorance and/or reckless disregard of the truth or falsity of its certifications of compliance with 45 C.F.R. Part 74, Siebert points to Mackby and Anton as indicating that individuals or institutions receiving funds from the government act in reckless disregard of restrictions on that funding if they fail to inform themselves of those restrictions. ECF No. 109 at 18-19. GSN counters that the fact that it "disclosed complete and accurate information about its accounting system to the auditor that conducted the required grant audit tends to show that [GSN] did not intend to deceive the government." ECF No. 119 at 16.

The Court finds that Siebert has established as a matter of law that GSN acted at least with reckless disregard as to the truth or falsity of its statements of compliance with 45 C.F.R. Part 74 in the period following August 2010.¹⁰ The emails Siebert cites indicating GSN's non-compliance with regulatory requirements were sent in August and September 2010. Moreover, preparations for the Armanino audit began in September 2010. Id. It was at this time, therefore, that key GSN employees became aware that their accounting procedures might not comply with the NIH accounting regulations. After this date, GSN can be charged with at least constructive knowledge that its accounting procedures did not meet the requirements of 45 C.F.R. Part 74. Its failure to review and ensure its compliance with those regulations after that date demonstrates that it acted

 $^{^{10}}$ The Court finds that Siebert has not established the knowledge element of a False Claims Act action, as a matter of law, for actions taken before August 2010.

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in reckless disregard of those requirements.¹¹

The fact that GSN submitted its accounting information to Armanino for an audit, despite knowing that the information could be disclosed to the government, does not negate the fact that GSN acted in reckless disregard of the requirements of 45 C.F.R. Part 74. It only tends to prove that either: (1) GSN employees did not have actual knowledge of their failure to comply with those regulations, or (2) GSN employees did not attempt to cover up potential violations by falsifying documents or withholding information from the auditor.

In sum, the Court finds that Siebert has carried its burden to prove the scienter element of an FCA violation for the post-August-2010 period.

4. **Damages**

Because the Court finds that there is a dispute of material fact as to the issue of falsity at all relevant times, the Court does not address the issue of damages.

CONCLUSION

For the foregoing reasons, GSN's Motion for Partial Summary Judgment is DENIED, and Siebert's Motion for Summary Judgment is GRANTED IN PART and DENIED IN PART, as set forth above.

IT IS SO ORDERED.

Dated: December 1, 2014

nited States District Judge

¹¹ The Court notes that only two allegedly false statements or certifications of compliances occurred after August 2010: the implied certifications that accompanied the drawdowns of grant funds on May 26, 2011 and May 15, 2012, in the amounts of \$800,745 and \$802,079, respectively. ECF No. 109 at 15. Two drawdowns also occurred during August 2010: \$799,036 on August 19, 2010, and \$200,833 on August 12, 2010. Id.