Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *ex rel.* WENDY A. BAHNSEN *et al.*, *Plaintiffs*, v. BOSTON SCEINTIFIC NEUORMODULATION CORPORATION, *Defendant.*	Civil Action No. 11-1210 **OPINION**

John Michael Vazquez, U.S.D.J.

This matter comes before the Court on motions to exclude the testimony of several expert witnesses. Plaintiffs Wendy Bahnsen and Carolina Fuentes (collectively "Plaintiffs") filed a motion to exclude the testimony of Defendants' four expert witnesses: Wayne Van Halem, Suzanne O'Shea, Gregory Russo, and Timothy Deer. D.E. 297. Defendant Boston Scientific Neuromodulation Corporation ("BSNC" or "Defendant") filed a brief in opposition, D.E. 310, to which Plaintiffs replied. D.E. 335. Defendant also filed a motion to exclude the testimony of Plaintiffs' expert witnesses, Richard Baer and Meredith Rosenthal. D.E. 300. Plaintiffs filed a brief in opposition, D.E. 312, to which Defendant replied. D.E 331.[1] The Court reviewed the submissions made in support and in opposition to the two motions and considered the motions without oral argument pursuant to Fed. R. Civ. P. 78(b) and L. Civ. R. 78.1(b). For the reasons

[1] In this Opinion, Plaintiffs' motion to exclude expert testimony with be referred to as "Pl. MEE." Defendant's brief in opposition will be referred to as "Def. Opp." Plaintiffs' reply brief will be referred to as "Pl. Rep." Likewise, Defendant's motion to exclude expert testimony will be referred to as "Def. MEE." Plaintiffs' brief in opposition will be referred to as "Pl. Opp." Defendant's reply brief will be referred to as "Def. Rep."

that follow, Plaintiffs' motion to exclude expert testimony is **GRANTED** in part and **DENIED** in part. Defendant's motion to exclude expert testimony is **DENIED**.[2]

I. FACTS AND PROCEDURAL HISTORY

For the purposes of the pending motions, the Court need not retrace this case's complex factual and procedural history. The Court is an issuing an opinion addressing Defendant's motion for summary judgment, D.E. 299, which includes a detailed recounting of the background of this matter. To the extent relevant to these motions, the Court incorporates the factual and procedural history into this Opinion.

Generally, during the relevant time period of 2006 to 2010, Defendant BSNC marketed, sold, supplied, and submitted claims for an implantable spinal cord stimulator, the Precision Plus™ SCS System ("SCS"). As a government supplier of medical equipment, BSNC fulfilled patient requests for replacement supplies of some external equipment ("Replacement Supplies") for a SCS. BSNC's Billing and Collections Department processed the necessary documentation for BSNC to be reimbursed when it supplied such equipment.

Plaintiffs are former BSNC employees, who worked in its Billing and Collections Department. Plaintiffs assert that through their work, they became aware that BSNC was knowingly submitting thousands of false claims to Medicare for reimbursement. Among other things, Plaintiffs claim that Defendant submitted claims for Replacement Supplies without written physician orders and/or with fabricated diagnosis codes. The present suit springs from these allegations. Following discovery, the parties now challenge their opponents' respective expert witnesses.

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[2] Plaintiffs have also filed a motion for summary judgment as to Defendant's counterclaims, while Defendant has moved for summary judgment on Plaintiffs' False Claims Act counts. Those motions are addressed in separate opinions.

II. LEGAL STANDARD

A. Federal Rule of Evidence 702

Federal Rule of Evidence 702 ("FRE 702") guides a court's determination as to the admissibility of expert testimony. "Under the Federal Rules of Evidence, it is the role of the trial judge to act as a 'gatekeeper' to ensure that any and all expert testimony or evidence is not only relevant, but also reliable." *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993)). To fulfill its role as gatekeeper, the court analyzes the admissibility of an expert's testimony pursuant to the following three requirements under FRE 702: "(1) the proffered witness must be an expert; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact."[3] *Kannankeril*, 128 F.3d at 806 (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-42 (3d Cir. 1994)).

Thus, "Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit." *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003) (citing *In re Paoli Railroad Yard PCB Litigation,* 35 F.3d at 741-43). Qualification requires a witness to have a specialized expertise. The Third Circuit has "interpreted this requirement

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[3] The full language of FRE 702 is as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

liberally, holding that 'a broad range of knowledge, skills, and training qualify an expert.'" *Schneider ex rel. Estate of Schneider*, 320 F.3d at 404 (citations omitted). Reliability requires that the testimony "be based on the methods and procedures of science rather than on subjective belief or unsupported speculation; the expert must have good grounds for his on her belief." *Id.* (citation and internal quotation marks omitted). Thus, guided by *Daubert*, the Third Circuit has found that reliability of scientific evidence requires assessing its scientific validity. *Id.* Finally, fit requires that the expert's testimony "be relevant for the purposes of the case and must assist the trier of fact." *Id.* Once again, guided by *Daubert*, the Third Circuit has found that to be helpful the testimony must have "a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id.* (citation omitted).

The Third Circuit has made clear that when a district court evaluates the admissibility of expert testimony it is not requiring perfection. The Circuit has held that under FRE 702, district courts should extend a "liberal policy of admissibility" to an expert's substantive and formal qualifications. *In re Paoli Railroad Yard PCB Litigation,* 35 F.3d at 741. Similarly, for reliability a district court must find "good grounds" for the expert's belief after conducting a "flexible" inquiry. *Id.* at 742. Finally, a district court applies the same standard to find fit as for finding reliability. The Circuit has "emphasize[d] that the standard is not that high." *Id.* at 745.

III. ANALYSIS

Both Plaintiffs and Defendant argue that the testimony of the other party's respective expert witnesses is inadmissible under FRE 702. The Court will first address the admissibility of Defendant's expert witnesses: Wayne Van Halem, Suzanne O'Shea, Gregory Russo, and Timothy Deer. Then, the Court will address the admissibility of Plaintiffs' expert witnesses: Richard Baer and Meredith Rosenthal.

Defendant's Experts:

A. Wayne Van Halem

Wayne Van Halem ("Mr. Van Halem") is a healthcare consultant, who would testify that BSNC's billing practices from 2006 through 2010 did not violate Medicare rules and regulations. Pl. MEE. at 5. Specifically, Mr. Van Halem would testify that Chapter Five of the relevant Medicare Program Integrity Manual ("PIM") did not require BSNC to submit a physician order with its claims for reimbursement of SCS Replacement Supplies.[4] Plaintiffs move to exclude the testimony of Mr. Van Halem on the bases that his opinions are unreliable and contradict the prior testimony of BSNC's 30(b)(6) witness, Wendy Chan. Pl. MEE. at 5-12.

BSNC hired Mr. Van Halem to analyze the report of Plaintiffs' expert witness, Dr. Richard Baer. Expert Report of Wayne Van Halem ("Van Halem Report"); D.E. 297-5. Mr. Van Halem reviewed thirty-nine documents and references to form his report. *Id.* Exhb. B. Several of these documents are Medicare guidance and regulations, such the PIM (Pub 100-8), Medicare Benefit Policy Manuel (Pub 100-2), Medicare Change Request 5917, Transmittal 1603, etc. *Id.* Plaintiffs contend that Mr. Van Halem's methodology is unreliable because he cannot point to a single Medicare regulation that says Chapter Five of the PIM does not apply to DME claims submitted to A/B MACs. Pl. Rep. at 1. Further, they argue that Mr. Van Halem has never advised anyone before that Chapter Five is inapplicable to DME claims submitted to A/B MACs. Pl. MEE. at 8.

[4] The PIM is a published document, through which the CMS communicates "program issuances, day-to-day operating instructions, policies, and procedures that are based on statutes, regulations, guidelines, models, and directives." *See* CENTERS FOR MEDICARE & MEDICAID SERVICES, *Manuals*, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html (last visited December 4, 2017).

At the outset, to the extent that Mr. Van Halem or Plaintiffs' expert witness Dr. Richard Baer, or any other expert witness in this case, will seek to testify about the governing law and regulations, the Court will not allow them do so. Interpreting the law (and instructing the jury accordingly) is solely within the province of the Court. *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006) (citing *United States v. Leo,* 941 F.2d 181, 195-96 (3d Cir. 1991)) (holding that under the Federal Rules of Evidence "an expert witness is prohibited from rendering a legal opinion"); *First National State Bank v. Reliance Elec. Co.,* 668 F.2d 725, 731 (3d Cir. 1981) (per curiam) (holding that FRE 702 supports excluding expert witnesses from explaining the law to the jury).

Generally, however, Mr. Van Halem's testimony is reliable enough for the Court to admit it under FRE 702. To be admissible the Court must find that the opinions in Mr. Van Halem's report were "based on the methods and procedures of science rather than on subjective belief or unsupported speculation." *Schneider ex rel. Estate of Schneider*, 320 F.3d at 404 (citations omitted). Mr. Van Halem relied on an array of information to support his opinions. Van Halem Report. These documents and references could provide a person with "21 years of experience specifically in the Medicare billing field" with good grounds for forming opinions on BSNC's Medicare billing practices. Def. Opp. at 9. Further, to the extent that Mr. Van Halem's opinions contradict those of BSNC's 30(b)(6) witness, this may impact the weight of those opinions but not their admissibility. Thus, Mr. Van Halem's testimony is admissible as long as he does not opine on the law.

B. Suzanne O'Shea

Suzanne O'Shea ("Ms. O'Shea") is a U.S. Food and Drug Administration ("FDA") lawyer, who would testify that after a patient receives a SCS, BSNC must make SCS

Replacement Supplies available to that patient. Pl. MEE. at 12; Def. Opp. at 16. Plaintiffs move to exclude Ms. O'Shea's testimony on the grounds that it is irrelevant and would confuse the jury.[5] In particular, Plaintiffs argue that Ms. O'Shea's testimony regarding FDA requirements does not relate to or impact Medicare's requirements that BSNC bill Medicare for SCS Replacement Supplies only when they are ordered by a physician. Pl. MEE. at 14. Because FDA requirements do not control Medicare's billing requirements, Plaintiffs further argue that Ms. O'Shea's testimony would unduly confuse the jury. *Id.* at 15-16. Defendant claims that "[w]hile Ms. O'Shea does not offer an opinion on whether Medicare requires specific physician orders or diagnosis codes for reimbursement decisions, her testimony will help the jury understand what the SCS System . . . is." Def. Opp. at 18. Defendant also claims that Ms. O'Shea's testimony will directly rebut Dr. Baer's opinions. *Id.*

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[5] To support their argument, Plaintiffs point to Ms. O'Shea's answers in her deposition:

> Q: That's not my question. You have said that there is a requirement from the FDA that Boston Scientific make adhesive patches available. That's your opinion, correct?
> A: Yes.
> Q: And when you say make them available, do you have any opinion at all about what sorts of requirements for a physician order or a diagnosis code or a prescription would be required in order for a patient to order new adhesive patches?
> A: I do not have an opinion on that, as the FDA did not address the process for that in the information I read, and FDA does not get involved in a lot of those things.
> Q: Do you have expertise in submitting claims to Medicare or the documentation requirements for supplier to submit such claims?
> A: I do not.
> Q: Do you have any expertise in Medicare or CMS regulations surrounding the submission of claims?
> A: I do not.

Pl. MEE.; Exhb. 6 (Deposition of Suzanne O' Shea at 28:21-29:17); D.E. 297-8.

The Court agrees with Plaintiffs that Ms. O'Shea's testimony would be unduly prejudicial and confusing for the jury while only tangentially relevant. Ms. O'Shea proposes to testify on FDA rules and regulations, not Medicare billing rules and regulations. Such testimony does not reach the "fit" requirement of FRE 702. While the Court recognizes that FDA requirements regarding the SCS and its Replacement Supplies relate to the case, such information will not help a trier of fact resolve the issues in this lawsuit, that is, whether Defendant violated Medicare's requirements when it submitted the relevant claims. Defendant has presented no evidence that FDA approval means, as a matter of law, that Medicare must pay for the approved product or that FDA approval overrides Medicare's claim requirements. The risk for confusion and undue prejudice is clear. The confusion and undue prejudice stems from the real risk that a jury will conclude that FDA approval trumps Medicare requirements. Healthcare, FDA approval, and Medicare reimbursement are complex areas of the law, and a jury could reasonably (though improperly) conclude that because the FDA approves an item, Medicare should pay for it. The FDA's approval of the SCS and the Replacement Supplies is not at issue in this case. Further, Ms. O'Shea's testimony does not directly contradict Dr. Baer's testimony. Ms. O'Shea did not reference Dr. Baer's reports or opinions in her report, O'Shea Report; Exhb. 5; D.E. 297-7, and Dr. Baer did not discuss FDA regulations in his report. Baer Report; Exhb. 42; D.E. 316-9. Thus, Ms. O'Shea's testimony is inadmissible.

C. Gregory Russo

Gregory Russo ("Mr. Russo") is a healthcare consultant, who would testify about his analysis of Plaintiffs' expert witnesses' opinions, Drs. Richard Baer and Meredith Rosenthal. Russo Report, Exhb. 7; D.E. 297-9. BSNC, in particular, asked Mr. Russo to provide an opinion regarding the claims BSNC submitted to Medicare for reimbursement of SCS Replacement

Supplies. *Id.* Plaintiffs move to exclude Mr. Russo's testimony on the bases that it is unreliable and impermissible. Pl. MEE. at 16. Plaintiffs argue that the definition of a claim is a legal question. *Id.* at 18. Further, they assert that the relevant statute, 31 U.S.C. § 3729, defines "claim" and, moreover, that Mr. Russo misinterprets that definition. *Id.* Defendant counters that Mr. Russo's testimony rebuts Dr. Baer's testimony concerning BSNC claims data and that his testimony only opines on factual conclusions. Def. Opp. at 18.

As stated above, to the extent that Mr. Russo, or Dr. Baer, or any other expert witness in this case will opine on what a "claim" is or offer another legal conclusion on what constitutes a false claim, such testimony is admissible. The Court will instruct the jury on this issue. 31 U.S.C. § 3729 (b)(2) already defines "claim" and the Court does not require either of the parties' assistance reading the statute.[6] However, to the extent that Mr. Russo will offer testimony on underlying factual issues, such testimony could assist the trier of fact. Similar to how Federal

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[6] 31 U.S.C. § 3729 (b)(2) provides that a "claim":

> (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that--
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> (i) is presented to an officer, employee, or agent of the United States; or
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> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--
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> (I) provides or has provided any portion of the money or property requested or demanded; or
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> (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and
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> (B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property[.]

Rule of Evidence 1006 allows summary witnesses to testify on the contents of voluminous writings, recordings, and photographs, the Court will allow Mr. Russo, Dr. Baer, and other experts in this case to testify to factual details based on the data available and explanations about claims. Thus, Mr. Russo's testimony is admissible as long as he does not stray into the province of the Court and give an improper legal opinion.

D. Timothy Deer

Dr. Timothy Deer ("Dr. Deer") is a pain doctor with experience treating patients who have implanted SCS systems. Pl. MEE. at 19. Plaintiffs' motion to exclude Dr. Deer's testimony concerns only Dr. Deer's opinions on the "standard of care" for patients with implanted SCS systems. *Id.* Dr. Deer would testify that since patients only receive SCS systems after a physician finds such a chronic pain treatment medically necessary, "there is no need to confirm medical necessity annually, each time a patients needs to replenish his or her supplies, or at any other arbitrary interval." Def. Opp. at 26.

Plaintiffs contend that this testimony is based on unreliable methods and irrelevant to the case. Plaintiffs assert that Dr. Deer cannot reliably speak for the medical community on the standard of care for SCS patients with regards to BSNC supplying them with SCS Replacement Supplies when he "has not reviewed any particular patient files," "has not reviewed any of the claims BSNC submitted for payment to the [G]overnment," "has not conferred with others [doctors] in the field", and seeks to testify "about an aspect of caring for SCS patients with which he has virtually no experience." Pl. MEE. at 23.[7] Further, Plaintiffs assert that the physician

[7] Plaintiffs point to Dr. Deer's deposition testimony for proof that he should not be able to testify as to the physician standard of care:

> Q: Has any physician ever told you affirmatively that they are not involved in ordering SCS supplies?

standard of care for treating patients with implanted SCS systems is irrelevant to the issue of whether BSNC violated Medicare rules and regulations when it billed Medicare for the Replacement Supplies. *Id.* at 20. Plaintiffs support their position by citing *U.S. ex rel. El-Amin v. George Washington University*, where the D.C. Circuit excluded evidence concerning anesthesiologists' generally accepted medical practices because it was irrelevant to the FCA Medicare billing dispute at bar. 533 F. Supp. 2d 12, 24.

Defendant argues that Dr. Deer's testimony is both reliable and relevant. BSNC asserts that Dr. Deer's testimony is reliable because his opinions come from "over twenty years experience treating SCS System patients, implanting thousands of such devices over that time in such patients, and following patients throughout their lifetimes with such devices." Def. Opp. at 28.[8] Further, Defendant argues that Dr. Deer's testimony concerning the physician standard of

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> Ms. Galant: Object to form.
> A: Well, I don't recall ever asking them that, because it's not been an issue of discussion when we've had extensive hours of discussion about reimbursement and requirements of medical necessity for the devise and no one's ever mentioned that out of hundreds and hundreds of physicians who I've talked to about these issues of medical necessity.
> Q: So you've never even asked another physician whether they order SCS supplies, correct?
> Ms. Galant: Object to form.
> A: Well since in my opinion, the medical necessity is documented up front, that would be a question that's improper because it's not needed and not medically necessary –
> Q: So you haven't asked that question, correct?
> Ms. Galant: Objection to form.
> A: I don't recall – I don't recall asking that specific question. Nor would I. And I wouldn't today either.

Pl. MEE.; Exhb. 10 (Deposition of Timothy Deer 96:17-97:18); D.E. 297-12.

[8] Defendant cites to *Heller v. Shaw Indus., Inc.,* for the proposition that an expert witness's conclusion may still be reliable if based on scientifically valid methods, even if not based on any published studies. 167 F.3d 146, 155 (3d Cir. 1999). *Heller*, however, did not involve testimony on a physician standard of care or even an industry custom. In *Heller*, the expert witness based

care is necessary to rebut, and correct, Dr. Baer's testimony on the physician standard of care. *Id.* at 23-26.

The Court agrees with Plaintiffs that Dr. Deer's testimony regarding the physician standard of care is, at most, tangentially relevant and outweighed by the risk of juror confusion and unfair prejudice. In short, the issue is not whether a physician believes that Replacement Supplies should be provided indefinitely as medically necessary. Instead, the critical question concerns what information Medicare required suppliers to obtain before submitting a claim. Again, Defendant has presented no evidence that it can fail to comply with Medicare requirements based on a physician's opinion. The risk of confusion and undue prejudice is also clear – a jury may conclude that the physician's opinion controls regardless of Medicare requirements.

Despite Defendant's claim that Dr. Deer's testimony is necessary to rebut Dr. Baer's testimony on the physician standard of care, Plaintiffs sufficiently counter that it is not. Plaintiffs argue that Dr. Baer's report only references the physician standard of care in passing. Pl. MEE at 14; *see* Baer Report; Exhb. 42 at 15; D.E. 316-9.[9] Further, Plaintiffs assert that Dr.

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his conclusion on the cause of a respiratory problem on a "differential diagnosis drawn from his examination of [plaintiff] Heller, the results of a series of medical tests, review of Heller's personal and family medical history, and Heller's descriptions of her personal activities (smoking, etc.) and environmental conditions ("cats, dogs, the type of heating system, rugs, pillows, things of that sort")). *Id.* at 153-54. The *Heller* expert's choice to use a fairly in depth alternative methodology, rather than published studies, to form his opinions is not similar Dr. Deer's choice in forming his opinions.

[9] The reference in Dr. Baer's report that Plaintiffs refer to reads:

> Boston Scientific has argued that supplies are 'necessary' to allow an SCS System to function but only a physician or authorized healthcare provider can make that determination. If a patient desires a replacement supply for an SCS device. Her treating physician may want to see the patient to determine if continued use

Baer only discussed the physician standard of care in his deposition because Defense counsel asked him about Dr. Deer's opinions on the physician standard of care. Pl. MEE at 14.[10] Thus, while the Court would also take issue with Dr. Baer testifying as to the physician standard of care, he does not appear to be doing so, absent prompting from Defendant.

To reiterate, while Dr. Deer's testimony concerning the standard of care is tangentially related, Dr. Deer's testimony would risk confusing the trier of fact over what this lawsuit hinges on. Namely, whether BSNC violated Medicare rules and regulations through its billing practices for the Replacement Supplies. In other words, even if Dr. Deer professionally believes that by

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> of the device is in order, if there is a problem with the device, if the device is causing harm to the patient, or if another form of therapy is necessary.

[10] The following testimony from Dr. Baer's deposition is illustrative of Plaintiffs' argument:

> Q: Well, you're a doctor, what do you understand the standard of care to be?
> A: Well, the standard of care has to do with – well, it's a broad definition, that's why I was asking you in what way are you applying it here. I'm not sure I can give you a definition of standard of care.
> Q: You're not – you've never testified as an expert about the standard of care for any sort of medical treatment or medical condition?
> A: Well, I've testified as to medical necessity. It's not exactly the same thing. I don't think specifically that I have.
> . . .
> Q: Would you agree with me that Dr. Deer is more familiar than you with the standard of care for patients with chronic pain who would benefit from the implantation of a spinal cord stimulator?
> Mr. Connors: Object to form.
> A: The reason I have trouble with this, because I didn't agree with some of the things that Dr. Deer said about the standard of care in spinal cord stimulators. According to his experience, he's had a lot of experience with it, but I thought he said some things in his report that were unreasonable with regards to his standard of care.

Exhb. 4 (Deposition of Richard Baer 160:4-16; 160:25-161:13); D.E. 363-2.

implanting a SCS system he is, in effect, finding medical necessity for future Replacement Supplies, that is not the issue. The issue is what Medicare requires before Defendant can submit claims for the Replacement Supplies. The decision certainly counsels against such testimony. *Cf. El-Amin*, 533 F. Supp. 2d at 25. Thus, Dr. Deer's testimony as to the physician standard of care for patients with implanted SCS systems does not "fit" with this case and is inadmissible.[11]

Plaintiffs' Experts:

A. Richard Baer

Dr. Richard Baer ("Dr. Baer") is a former medical director for Medicare Administrative Contractors ("MACs")[12] with extensive experience on Medicare coverage determinations and Medicare compliance issues. Pl. Opp. at 3-4. Plaintiffs hired Dr. Baer to review BSNC documents and BSNC expert witness testimony to determine whether BSNC's billing practices with regards to SCS Replacement Supplies violated Medicare rules and regulations. *Id.* Dr. Baer's report and deposition testimony speak to multiple issues, but Defendant seeks to exclude only Dr. Baer's testimony regarding his identification of false claims and his conclusions as to those claims' materiality and falsity. Def. MEE at 6.[13]

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[11] Plaintiffs only seek exclusion of Dr. Deer's testimony as to the physician standard of care for patients with implanted SCS systems. Therefore, the Court's ruling of inadmissibility only extends equally as far.

[12] MACs are private health insurance carriers that contract with the Centers for Medicare and Medicaid Services ("CMS"). MACs act as the primary operational contact between the Medicare program and health care providers.

[13] Defendant's motion does not seek to exclude Dr. Baer's testimony on "(1) whether certain Medicare regulations and guidelines apply to the claims at issue; (2) the standard of care for patients who have been surgically implanted with a permanent SCS following a determination of medical necessity therefor; (3) the timing of the determination of medical necessity for a patient's subsequent orders of supplies needed for the safe and efficacious use of the stimulator; (4) the usual clinical course of these patients' pain and underlying medical conditions." Def. MEE. at 6. The Court notes that Plaintiffs would likely disagree with the characterization and

Defendant argues that this testimony is unreliable and improper. Defendant, first, claims that Dr. Baer's opinions regarding allegedly false claims is unreliable because of the underlying methodology used. Def. MEE. at 8. In particular, Defendant takes issue with Dr. Baer's claims audit process. *Id.* Summarily, Defendant claims that Plaintiffs' counsel, Susman Godfrey, had staff members review and analyze approximately one million pages of BSNC medical records into distinct patient files. Defendant believes that the review lacked proper oversight and was filled with errors. *Id.* at 9-10. Second, Defendant asserts that Dr. Baer opines on legal, rather than factual, principles to conclude that BSNC submitted false claims. *Id.* at 15.

Plaintiffs counter that Dr. Baer used sound methodology to create a reliable report. They assert that Dr. Baer had the Susman Godfrey staff assist in developing a factual record of BSNC customer records because, Plaintiffs contend, the records were produced in a scattershot manner. Pl. Opp. at 9. Further, Plaintiffs argue that Dr. Baer oversaw this process by providing detailed instructions to Plaintiffs' counsel on how the review was to be conducted. *Id.* If the staff members came across a claim that was "anything more than a pure factual and non-technical comparison of dates" then Dr. Baer personally reviewed the claim. *Id.* Plaintiffs add that Dr. Baer twice supplemented his expert report after BSNC critiqued his opinions. *Id.* at 10.[14] Finally, Plaintiffs dispute Defendant's claim that Dr. Baer opined on legal matters. They claim

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added details summarizing Dr. Baer's uncontested areas of testimony. However, Defendant's listing of uncontested areas of testimony is helpful for record clarity.

[14] In fact, after receiving BSNC's critique of his methodology "Dr. Baer reviewed every document in every customer files himself to ensure that his earlier analysis was not affected by any biases or mistakes by the paralegal who assisted him. Baer Decl., Exhibit C (Second Supp. Report) at 1. Dr. Baer's personal review proved Boston Scientific's criticism unfounded. Dr. Baer confirmed his bottom-line opinions regarding 6,047 of the 6,051 claims that were still at issue. For only 4 claims—less than a tenth of one percent—Dr. Baer updated his opinions, all in Boston Scientific's favor." Pl. Opp. at 12.

that Dr. Baer's testimony provides a trier of fact with insight into FCA compliance issues, rather than improper legal opinions on FCA materiality standards. *Id.* at 27-29.

First, as the Court previously noted with regards to the admissibility of Mr. Van Halem and Mr. Russo's testimony, to the extent that Dr. Baer's testimony offers legal opinions or conclusions, his testimony is inadmissible. *Berckeley Inv. Grp., Ltd.*, 455 F.3d at 217. However, Dr. Baer may testify to factual background matters that would assist the trier of fact. Second, while the Court can appreciate Defendant's critique of Dr. Baer's methodology, alleged flaws in that methodology should impact the weight, not admissibility, of Dr. Baer's report. *See NN&R, Inc. v. One Beacon Ins. Grp.*, 2006 WL 2845703, at *3 (D.N.J. Sept. 29, 2006) (finding that although the expert witness's "opinions may be assailable at trial on cross-examination because he failed to personally examine the insurance claim files or other key documents, it appears to the Court that the expert's opinion and methodology are sufficiently reliable and relevant to meet the requirements of Fed.R.Evid. 702"). Defendant has not pointed to any fatal procedure error in the collection of the underlying data. To the extent that Defendant believes that errors were made, it is certainly free to cross-examine Dr. Baer on this area.

Further, the cases Defendant cites to support finding Dr. Baer's report inadmissible, actually illustrate why the Court should admit the report and Defendant may, if it chooses, cross-examine Dr. Baer on his report. For example, *In re TMI Litig.*, the Third Circuit affirmed the exclusion an expert witness who relied on medical history summaries prepared by plaintiffs' counsel's staff. However, in that case the summaries were not based on medical or hospital records, were the product of the staff interviewing people with questions not formulated by the expert, and were the only information the expert relied upon to testify about the health histories at issue. 193 F.3d 613, 697–98 (3d Cir. 1999), *amended,* 199 F.3d 158 (3d Cir. 2000). Likewise,

in *Montgomery Cty. v. Microvote Corp.*, the Third Circuit excluded the deposition of an expert witness who relied on a document created by a third party when the expert admitted "he did not know what the document was, who created it, or how it was created." 320 F.3d 440, 448–49 (3d Cir. 2003). In comparison, Dr. Baer relied upon the actual records provided by Defendant. To the extent that Defendant contends that the information should have been organized differently, it can cross-examine Dr. Baer. Therefore, the Court disagrees with Defendant and finds that Dr. Baer's testimony is admissible except to the extent he is going to opine on the law.

B. *Meredith Rosenthal*

Dr. Meredith Rosenthal ("Dr. Rosenthal") is a Professor of Health Economics and Policy at the Harvard School of Public Health. Pl. Opp. at 31. Dr. Rosenthal would testify as to potential damages and penalties resulting from the claims that Dr. Baer opined were false. Def. MEE. at 18. Defendant seeks to exclude Dr. Rosenthal's testimony as unreliable because Dr. Rosenthal calculated damages based on the sum of claims that Dr. Baer found false. *Id.* Since Defendant argues Dr. Baer's claim analysis was unreliable, Defendant asserts that it follows that calculations as to damages on those claims are unreliable.

As stated above, Dr. Baer's testimony is reliable under FRE 702 and, therefore, admissible. Thus, the Court finds no basis for excluding Dr. Rosenthal's testimony. Issues with Dr. Baer's methodology that may impact the weight of Dr. Baer's evidence may also impact the weight of Dr. Rosenthal's evidence, but they do not make it inadmissible.

IV. CONLCUSION

For the reasons stated above, Plaintiffs' motion to exclude expert testimony (D.E. 297) is **GRANTED** in part and **DENIED** in part. Defendant's motion to exclude expert testimony (D.E. 300) is **DENIED**. An appropriate Order accompanies this Opinion.

Dated: December 15, 2017

John Michael Vazquez, U.S.D.J.