UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

FOR ONLINE PUBLICATION ONLY

UNITED STATES OF AMERICA,

Plaintiff,

ex rel. ELIZABETH RYAN,

Relator,

- versus -

GILBERT LEDERMAN and
GILBERT LEDERMAN, M.D., P.C.,

Defendants.

MEMORANDUM
AND ORDER

04-CV-2483

APPEARANCES:

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JOHN GLEESON, United States District Judge:

In this action, the United States claims that Gilbert Lederman, a doctor working at the Staten Island University Hospital ("SIUH"), improperly billed for medical procedures. It seeks damages under both the False Claims Act, 31 U.S.C. §§ 3729-3733, and common law. Both sides have moved for summary judgment. For the reasons given below, the government's motion is granted in part and denied in part, and Lederman's is denied.

BACKGROUND

A. *Factual Background*

Unless otherwise noted, the following facts are taken from the parties' Local Rule 56.1 statements and affidavits and are uncontroverted.

Lederman is a doctor who has performed various radiological procedures – usually for cancer treatment – since the 1980s. In 1987, he became Director of Radiation Oncology at Staten Island University Hospital, a position he held through the period relevant to this lawsuit (1996 through 2003). Lederman performed both conventional radiation treatment and stereotactic radiosurgery. The latter procedure, key to the dispute in this case, "is a form of radiation therapy that focuses high-power energy on a small area of the body." U.S. National Library of Medicine, "Stereotactic radiosurgery – Gamma Knife," *at* http://www.nlm.nih.gov/medlineplus/ency/article/007577.htm (last visited May 13, 2014); accord Stone Decl., ECF No. 166, Ex. 4 and 5.

This case centers on allegations that the federal government was improperly billed for health services under Medicare. As I previously described in deciding a motion of third-party defendants to dismiss in this case,

> The Medicare program was established by enactment of Title XVIII of the Social Security Act. Part B of the Medicare program provides federal funding for certain physician services provided to Medicare beneficiaries. Claims under Part B for Medicare payment for physician services are administered by private carriers ("Part B carriers"), which enter into contracts with the Secretary of Health and Human Services. Physicians bill their services to these carriers using standard 5-digit billing codes, which are based on codes designated by the American Medical Association . . . called "Physicians' Current Procedural Terminology" ("CPT") codes. Part B carriers determine the reimbursement amount of each claim based on the lesser of the actual charge and a standardized fee schedule for the appropriate CPT code.

U.S. ex rel. Ryan v. Staten Island Univ. Hosp., 04-CV-2483 JG CLP, 2011 WL 1841795, at *1 (E.D.N.Y. May 13, 2011) ("*Ryan I*").

By statute, "no payment may be made" under Medicare coverage for services that are not "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). Deciding what is "reasonable and necessary" is delegated in the first instance to the Secretary of Health and Human Services ("HHS"), and HHS may decide whether to exclude certain types of treatments by promulgating national coverage determinations ("NCDs"). 42 U.S.C. §§ 1395y, 1395ff; *see also State of N.Y. on Behalf of Bodnar v. Sec'y of Health & Human Servs.,* 903 F.2d 122, 124-25 (2d Cir. 1990). HHS contracts with Part B carriers to provide services, and carriers may create more refined guidelines. These are now called "local coverage determinations" ("LCDs"), but were previously known as "local medical review policies" ("LMRPs"). *See* 42 C.F.R. § 400.202. "LMRP's, which are now known as Local Coverage Determinations, set regional coverage determinations that govern in the absence of or as an adjunct to a national policy." *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1012 (D. Nev. 2006) (citing 68 Fed.Reg. 63,692, 63,693 (Nov. 7, 2003)). "Once an LMRP is adopted by the carrier, it acts as a filter, or screen, to ensure that only claims meeting the LMRP criteria for medical necessity are paid." *Arruejo v. Thompson*, CV-00-2402(JG)(SMG), 2001 WL 1563699, at *4 (E.D.N.Y. July 3, 2001), *adopted*, ECF No. 33 (Aug. 28, 2001).

The Part B carrier for the claims in this case, Empire Medical Services ("Empire"), issued two significant LMRPs related to stereotactic radiosurgery. First, on October 21, 1996, Empire issued an LMRP that, among other things, defines stereotactic radiosurgery as "high doses of ionizing radiation to a small intracranial target, usually 4 cm or less in diameter" delivered while the patient "wears a stereotactic frame affixed to the skull." Stone Decl., Ex. 4,

at 1. The LMRP also lists eight conditions for which stereotactic radiosurgery would be covered (along with corresponding ICD-9 codes[1]). *Id.* at 1-2. Second, on August 31, 2001, Empire issued an LMRP defining stereotactic radiosurgery as "a form of computer-assisted radiation therapy for intracranial and some extracranial lesions . . . ." Stone Decl., Ex. 5, at 1. Notably, the second LMRP states under "limitations" that "treatment of below the neck diseases such as lung carcinoma with stereotactic radiosurgery is considered investigational at this time." *Id.* at 2.

The government has not made entirely clear which claims for payment were allegedly improper, and the issue will be further developed at a trial on damages. For this motion, it is enough to note that, between 1996 and 2003, the government claims that Lederman performed and submitted unauthorized claims to Empire for at least 300 below-the-neck stereotactic radiosurgeries. *See* Govt.'s Corrected 56.1 Statement ¶ 33, ECF No. 172. Lederman does not dispute the 300 figure. *See* Lederman 56.1 Counterstatement ¶ 33.

B. *Procedural History*

In 2004, Elizabeth Ryan filed a False Claims Act complaint under seal in this Court; she brought claims against Lederman, his incorporated professional practice, and SIUH. *See* ECF No. 1. In 2008, the case was unsealed when the government filed a complaint in intervention as to some of the claims. *See* ECF Nos. 8, 9, 16. Shortly thereafter, the government settled all claims against SIUH for about $25 million. *See* ECF No. 30.

After substantial discovery, the parties filed cross motions for summary judgment in December of 2013. I heard argument on the motions on March 21, 2014.

[1] ICD-9-CM codes refer to "The International Classification of Diseases, Ninth Revision, Clinical Modification," which is "the official system of assigning codes to diagnoses and procedures associated with hospital utilization in the United States." Centers for Disease Control and Prevention, "International Classification of Diseases, Ninth Revision, Clinical Modification," at http://www.cdc.gov/nchs/icd/icd9cm.htm (last visited May 13, 2014).

DISCUSSION

A. *Summary Judgment Standard*

A court may grant summary judgment where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is "material" if its resolution "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute is "genuine" when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id*. In determining whether there are genuine disputes of material fact, the court must "resolve all ambiguities and draw all permissible factual inferences in favor of the party against whom summary judgment is sought." *Terry v. Ashcroft*, 336 F.3d 128, 137 (2d Cir. 2003).

The mere fact that I have been presented with cross motions for summary judgment does not require that I grant judgment to one side or the other; rather, I must evaluate each motion separately, each time resolving ambiguities in favor of the non-moving party. *See, e.g., Schwabenbauer v. Bd. of Ed. of City Sch. Dist. of City of Olean*, 667 F.2d 305, 313-14 (2d Cir. 1981).

B. *The False Claims Act*

As relevant here, the False Claims Act creates liability for "any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *id*. § 3729(a)(1)(B). The Second Circuit has interpreted the statute to require five elements: the plaintiff must show that a defendant "(1) made a claim, (2) to the United States government, (3) that is false or

fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury." *Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001).

Although both sides have moved for summary judgment, I will consider their motions together where possible. I address each of these five elements below.

1. *Undisputed Elements*

The parties do not dispute that Lederman made claims seeking payment from the federal government, satisfying elements 1, 2, and 5 of the *Mikes* framework. Essentially, any time a doctor bills a Part B provider for services under Medicare, these elements are satisfied, since the doctor causes to be submitted a claim for payment to the federal government seeking federal funds. *See, e.g., Mikes*, 274 F.3d at 695 (finding submission of Medicare reimbursement forms known as CMS/HCFA 1500 Forms, or their electronic equivalent, to satisfy these elements).

2. *Falsity*

The parties do disagree about whether any of Lederman's claims were false. The government advances two theories on which some of the claims for payment were false. First, the government argues that the claims were false because Lederman sought payment for treatments that were categorically not covered by Medicare. Second, the government argues that the claims were false because Lederman misrepresented the nature of the services for which he was billing. I find both theories meritorious. Because the determination of falsity depends only on disputed legal questions, including the interpretation of documents, it is appropriate to resolve them now, on summary judgment.

a. Procedures Not Covered

The government's first argument – that Lederman billed for procedures that were simply not covered by Medicare – centers on the two LMRPs discussed above. According to the government, both the October 1996 and the August 2001 LMRPs exclude from coverage stereotactic radiotherapy performed on parts of the body below the neck. A straightforward reading of the text of these LMRPs confirms the government's view. Rather than contest the government's reading, however, Lederman makes two arguments contesting the relevance of these LMRPs.

First, he argues that LMRPs are not controlling as a general matter. According to Lederman, LMRPs offer only "some guidance" as to whether a particular procedure will be covered. Lederman apparently relies on an HHS guidance document from 2000, which states:

> In order to provide some guidance to beneficiaries and health care providers and suppliers regarding which items and services will (or will not) be covered in a particular area in the absence of an NCD, our contractors may make an LCD. An LCD would provide guidance, in the absence of, or as an adjunct to, an NCD by describing the clinical circumstances and settings under which an item or service is available (or is not available) to a beneficiary under section 1862(a)(1)(A) of the Act. This notice seeks only to define the criteria for how we would make an NCD and our contractors would make an LCD.
>
> An LCD is not binding on a contractor in another area of the country or on an ALJ who decides cases at higher stages of the appeal process. Still, an LCD provides a service to the public by giving some advance notice about an item or service a contractor is likely to cover or not cover. If a local contractor makes an affirmative finding through a published LCD that an item or service is reasonable and necessary under the statute, beneficiaries and providers could reasonably expect that the service is available to the beneficiaries in that jurisdiction for the circumstances described in the LCD.

Medicare Program, Criteria for Making Coverage Decisions, 65 Fed. Reg. 31124, 31126 (2000).[2] Lederman emphasizes the phrase "some guidance," but in context, I do not believe that means that LCDs are advisory or not authoritative. Rather, the statement explains that LCDs are gap-fillers: where there is no national rule, a local contractor may make its own rules. Thus, LCDs as a whole provide additional rules, which together create more "guidance" than the NCDs do alone. (Put another way, "guidance" can be mandatory.)

My view is reinforced by statutory and administrative text. Federal law defines a local coverage determination as

> a determination by a fiscal intermediary or a carrier under part A of this subchapter or part B of this subchapter, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with [the determination of what is "reasonable and necessary" under] section 1395y(a)(1)(A) of this title.

42 U.S.C. § 1395ff(f)(2)(B). That is exactly the gap-filling role discussed above. The text gives no indication that particular LCDs are anything other than conclusive on matters they address.

The government also offers another set of HHS guidance (from before the name change from LMRP to LCD) that confirms this view:

> Medicare contractors review and adjudicate claims for services to assure that Medicare payments are made only for services that are covered under Medicare Part A or Part B. In the absence of a specific national coverage decision, coverage decisions are made at the discretion of the local contractors.
>
> Contractors may also publish local medical review policies (LMRPs) to provide guidance to the public and medical community within a specified geographic area. These LMRPs explain when an item or service will be considered "reasonable and necessary" and thus eligible for coverage under the Medicare statute. If a contractor develops an LMRP, its LMRP applies only

[2] This regulation refers to the appeal process by which individuals denied coverage may seek review of the denial in front of an administrative law judge (ALJ). While NCDs are binding on ALJs, LCDs are not. Neither party has argued that this difference is significant.

> within the area it serves. While another contractor may come to a similar decision, we do not require it to do so. An LMRP may not conflict with a national coverage decision once the national coverage decision is effective. If a national coverage decision conflicts with a previously made LMRP, the contractor must change its LMRP to conform it to the national coverage decision. A contractor may, however, make an LMRP that supplements a national coverage decision.

Medicare Program, Procedures for Making National Coverage Decisions, 64 FR 22619, 22621 (April 27, 1999). The passage makes clear that LCDs are mandatory for areas they cover. Thus, I reject Lederman's argument that the LCDs are merely advisory and therefore irrelevant to the question of whether his billings were false.

Lederman argues in the alternative that even if the October 1996 and August 2001 LMRPs cited above did not authorize the procedures he performed, a third LMRP bearing the subject "Radiation Oncology," effective May 30, 2000, did authorize them. The May 2000 LMRP is a sort of omnibus regulation encompassing many different techniques used in many different types of radiation therapy. *See* Tracy Decl., ECF No. 171, Ex. H. For example, the LMRP lists a number of CPT codes for services that "are bundled into the radiation treatment management codes" and should not be separately billed – such as codes for the use of IVs or catheterization, and codes for office visits. *Id*. at 11. Elsewhere, the LMRP gives general guidance about coding radiation therapy properly depending on the energy level administered to the patient and the frequency of the treatments. *Id*. at 7-8.

The government argues – and I agree – that the May 2000 LMRP gives only general guidance. Where (as here) more specific regulations exist, they control. That principle governs not only judges and lawyers, but anyone who must interpret complicated regulations. The October 1996 and August 2001 LMRPs discuss *only* stereotactic radiosurgery, not other, more general issues related to radiation therapy more broadly. The May 2000 LMRP discusses

issues that may arise in any of a number of different types of treatment (for example, whether catheterization may be separately billed) as well as issues that may arise in the delivery of traditional radiation therapy (for example, different codes scaled to different energy levels). But other than in an introductory paragraph that discusses the many types of radiation therapy, the May 2000 LRMP never mentions stereotactic radiosurgery. And it never specifically mentions the CPT codes at issue here: 61793, for stereotactic radiosurgery, and 77432, for radiation treatment of cerebral lesions (though this code falls within a range of covered codes).

To the extent that Lederman argues that procedures were covered because, according to Lederman, they were medically "reasonable and necessary," he is mistaken. It is up to HHS and its designees, such as Empire, to decide which types of treatment will be covered. As one court put it in denying a defendant's motion to dismiss a False Claims Act case, "[if] physician determinations" of reasonableness and necessity "controlled claim payment, there would be no need for a claim reimbursement process at all." *United States v. Vascular Solutions, Inc.*, Case No. 1:10-cv-00883-SS, ECF No. 44, at *7 (W.D. Tex. March 7, 2013).

In sum, then, I find that the government has proven as a matter of law that Lederman submitted claims that were false because they were not covered by his Medicare Part B carrier.

b. Misrepresentation of Claims

In addition, the government contends – and I agree – that Lederman's claims for payment were false because they embodied misrepresentations of the procedures Lederman performed.

A claim is straightforwardly false when it includes an "'incorrect description of goods or services provided or a request for reimbursement for goods or services never

provided.'" *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1266 (D.C. Cir. 2010) (quoting *Mikes*, 274 F.3d at 697 (2d Cir. 2001)). Here, according to the government, Lederman billed for services under certain CPTs when, in actuality, he was performing different services. Specifically, Lederman billed below-the-neck stereotactic radiosurgery under CPT codes 61793 and 77432. According to the American Medical Association, which promulgates CPT codes, code 61793, captioned "Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator), one or more sessions," falls under the subheading "Skull, Meninges, and Brain." *See* Stone Decl., Ex. 2, at 1, 3. Similarly, code 77432 is captioned "Stereotactic radiation treatment management of cerebral lesion(s) (complete course of treatment consisting of one session)." *See* Stone Decl., Ex. 3, at 2.

It is clear from these captions that neither code covers procedures performed below the neck, the procedures at issue here. Furthermore, Lederman does not dispute that some claims were miscoded: "Defendants concede that some of the coding for the treatments that are the subject of the complaint were incorrect, but do not agree that they were 'false' within the meaning of the False Claims Act . . . ." Def. Opp., ECF No. 5, at 2.

To be sure, the False Claims Act does not impose liability on doctors who accidentally or innocently miscode procedures and submit claims for payment to Medicare. But that is because of the FCA's mental state requirement, *not* because such claims are not "false." With falsity established, I turn to the final element of the False Claims Act case – knowledge.

3. *Knowledge*

A culpable mental state is the fourth *Mikes* element. Under both §§ 3729(a)(1) and (2), the defendant must act "knowingly." The statute then defines the term:

> (b) Knowing and knowingly defined**.** – For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information –
>
> (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) (1994).[3]

The statute thus makes clear that recklessness or deliberate indifference as to the truth or falsity of claims will suffice for liability, and no specific intent to defraud is necessary.

The determination of Lederman's mental state requires resolution of factual disputes, including credibility determinations, and the government therefore faces a difficult task at the summary judgment stage. While the question is close, I find that the government has not carried its burden of establishing as a matter of law Lederman's knowledge of the falsity of his claims.

The government emphasizes a few key documents. First, it cites a 1992 letter from an SIUH vice president to several recipients, including Lederman, noting that Lederman was improperly billing a neurosurgical code (apparently 61793, though it is not mentioned in the letter) as part of the radiosurgery process. Mantell Decl., ECF No. 167, Ex. 5. At that time, Lederman was not performing body radiosurgery, but was apparently only assisting in intracranial radiosurgery. Nonetheless, the government argues that this letter put Lederman on notice that code 61793 was not appropriate for non-neurosurgical procedures, including any procedure performed by Lederman, who is not (and never has been) a neurosurgeon.

[3] The most current version of the statute, which was amended in 2009, numbers these definitions as (b)(1), but otherwise (save for very minor changes) leaves the definitions intact.

Second, the government points to an October 5, 1998 letter to Lederman from Medaphis, the billing agent that Lederman had just terminated. *See* Mantell Decl., Ex. 6. The letter points out that 55% of Lederman's billings were for a single code, 61793, and that "many payers consider this procedure to be experimental, and refuse to reimburse your practice." While that sentence likely refers in part to private insurers, the government argues that Empire (Lederman's Medicare Part B carrier) also considered below-the-neck stereotactic radiosurgery to be experimental and therefore not reimbursable. At a minimum, the government argues, this letter contributed to Lederman's notice that his use of the procedure – and the code 61793 for it – was experimental.

Third, the government offers a letter from Empire itself to Advanced Health Management Services ("AHMS"). After terminating Medaphis, Lederman retained a new billing agent, Regency, which also served as the billing agent for SIUH itself. Regency hired AHMS to help resolve some of Lederman's billing questions, and in December of 1998, AHMS sent a letter to Empire with several questions about the use of code 77432. Empire wrote back on January 25, 1999, and explained that

> CPT procedure code 77432 is specifically for management of cerebral lesions. . . . It is specific to cerebral lesions and may not be used for stereotactic radiation treatment on parts of the body other than the brain. Currently Empire Medicare Services is covering stereotactic radiation treatment only on the brain. This type of treatment on any other part of the body is considered investigational.

Mantell Decl., Ex. 11.

Fourth, the government points to a conversation – initiated by Lederman – with a billing consultant, Rebecca Emerick, in August or September of 1999. *See* Mantell Decl., ¶ 48.

Lederman asked Emerick about the use of code 61793, and she told him that the code could only be used for intracranial treatment, and then only once, regardless of the number of sessions.

Fifth, the government offers a report written by Rebecca Emerick a year after her conversation with Lederman. SIUH independently retained Emerick to analyze billing and coding issues that arose from body stereotactic radiosurgery. Emerick prepared a report, dated August 18, 2000, which found

> significant evidence of erroneous billing with the radiosurgery CPT code of 61793 . . . I believe that there is the possibility that this code was intentionally billed when it was known that the service could not be appropriate to the billing. . . . There are ethical issues involved here.

Cover letter to Emerick Report, Mantell Decl., Ex. 15. The report also found significant problems with medical records indicating a lack of supervision of care by the radiation oncologist – that is, Lederman. *See id.* at 8-9.

The government's case is persuasive, but it is also largely circumstantial. Although the question is close, I cannot conclude as a matter of law on the current record that Lederman either knew or acted with reckless disregard of the fact that he was submitting false claims. In other words, a factfinder might reasonably conclude that Lederman neither personally knew (nor consciously avoided knowing[4]) that he was submitting false claims, and might also reasonably conclude that he did not act with reckless disregard for the truth or falsity of the claims he was submitting. I suspect that the issue of knowledge or recklessness might look different on a fuller record with the benefit of live testimony, but any doubts at this stage weigh heavily against a grant of summary judgment.

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[4] *See United States v. Nazon*, 940 F.2d 255, 259 (7th Cir. 1991) (approving use of conscious avoidance instruction in criminal false claims case).

To summarize, in order to prove a False Claims Act violation, the plaintiff must show that the defendant "(1) made a claim, (2) to the United States government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury." *Mikes*, 274 F.3d at 695. In this case, elements 1, 2, and 5 are undisputed. I grant summary judgment to the government on element 3. I reserve decision on element 4 for trial.

C. *Common Law Claims*

In addition to its causes of action under the False Claims Act, the government has also brought common law claims for payment based on a mistake of fact and unjust enrichment. As I previously explained,

> The elements of a claim for payment by mistake are that plaintiff made a payment under a mistaken apprehension of fact, that defendant derived a benefit as a result of this mistaken payment, and that equity demands restitution by defendant to plaintiff. A claim for unjust enrichment consists of three elements: that (1) defendant was enriched, (2) at plaintiff's expense, and (3) equity and good conscience militate against permitting defendant to retain what plaintiff is seeking to recover.

Ryan I, 2011 WL 1841795 at *5 (internal citation and quotation marks omitted).

The government argues that the miscoded claims were paid only based on a mistaken fact (*i.e.*, that the claims were for procedures performed above the neck, when they were actually for procedures below the neck). The government also argues that Lederman was unjustly enriched by the miscoded claims, for similar reasons.

In opposition, Lederman argues that these claims are barred by the statute of limitations, since they were first pleaded in the government's complaint in intervention in 2008. This argument ignores controlling law and is without merit. The FCA itself specifically provides that when the government files a complaint in intervention in a case that was earlier initiated only by a relator,

> For statute of limitations purposes, any such Government pleading shall relate back to the filing date of the complaint of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person.

31 U.S.C. § 3731(c). It is clear that these common law claims "arise[] out of the conduct, transactions, or occurrences set forth" in the relator's 2004 complaint that commenced this action. The common law claims relate to the same claims for payment.

Because these common law claims essentially duplicate the FCA claims, but do not require a mental element, I award summary judgment on these claims to the government.

CONCLUSION

For the reasons stated above, the government's motion for summary judgment is granted in part and denied in part, and defendant's summary judgment motion is denied. A bench trial will be held on Monday, September 8, 2014 at 9:30 a.m. to decide whether Lederman acted with a culpable mental state, subjecting him to liability on the government's False Claims Act claim, and to determine the amount of damages on the government's common law claims (and FCA claim if necessary). A status conference will be held on Wednesday, May 28, 2014 at 11:00 a.m. to discuss next steps in the case.

So ordered.

John Gleeson, U.S.D.J.

Dated: May 13, 2014
Brooklyn, New York