UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

IN RE CARDIAC DEVICES QUI TAM LITIGATION,	:	Case No. 3:03MD1505(GLG) **ALL CASES**

Pending before the Court are three motions to dismiss filed on behalf of the forty hospital-defendants[1] in this Multidistrict Litigation, addressed to the following issues: (a) failure to comply with the pleading requirements of Rule 9(b), Fed. R. Civ. P. **[Doc. # 38]**; (b) failure to state a cause of action pursuant to Rule 12(b)(6), Fed. R. Civ. P. **[Doc. # 40]**; and (c) whether the actions are barred by the relevant statutes of limitations **[Doc. # 42]**. Additionally, individual defendants have filed supplemental motions to dismiss and/or briefs addressed to issues or facts unique to that particular defendant.[2] For the reasons discussed below, defendants' motion to

[1] Cedars-Sinai Medical Center, Hospital of the Good Samaritan, Loma Linda University Medical Center, Stanford University, Yale-New Haven Hospital, Washington Hospital Center, Florida Hospital Medical Center, Crawford Long Hospital of Emory University, St. Joseph's Hospital of Atlanta, Northwestern Memorial Hospital, Foster G. McGaw Hospital, Methodist Hospital of Indiana, St. Vincent Hospital and Health Care Center, Johns Hopkins Hospital, Massachusetts General Hospital, Lahey Clinic Hospital, William Beaumont Hospital, St. Joseph Mercy Hospital, Harper-Hutzel Hospital, St. Louis University, Jewish Hospital of St. Louis, St. Francis Hospital of Roslyn, New York, Montefiore Medical Center, Duke University Medical Center, Cleveland Clinic, University Hospitals of Cleveland, St. Vincent Hospital and Medical Center, Hospital of the University of Pennsylvania, St. Thomas Hospital, Methodist Hospitals of Memphis, Baylor University Medical Center, Methodist Hospital of Lubbock, Texas, Sentara Norfolk General Hospital, Sacred Heart Medical Center, Providence Medical Center, St. Luke's Medical Center, Inc., Sinai Samaritan Medical Center, Presbyterian University of Pennsylvania Medical Center of Philadelphia, Emory University Hospital, and Brigham & Women's Hospital.

[2] Supplemental briefs and/or motions have been filed by the following hospitals: (1) Motions to Dismiss for Failure to Plead Fraud With Particularity: Yale-New Haven Hospital, St. Joseph Mercy Hospital, St. Thomas Hospital and St. Vincent Hospital and Health Care Center,

dismiss for failure to plead fraud with particularity will be denied; their motion to dismiss for failure to state a claim upon which relief may be granted will be denied; and their motion to dismiss on statute of limitations grounds will be granted in part and denied in part.

Before delving into the substantive merits of these motions, a review of the procedural background of this litigation is warranted.

I. Procedural Background

On March 31, 1994, Relator Kevin Cosens (hereinafter "Cosens" or "Relator"), a private citizen who served as a sales representative and clinical support person for cardiovascular device manufacturers, filed under seal a qui tam action under the False Claims Act ("FCA"), 31 U.S.C. § 3729 et seq., in the United States District Court for the Western District of Washington against 132 clinical trial hospitals from thirty states as well as thirty "John Doe" defendants. United States ex rel. Cosens v. University of Alabama, et al., Case No. C94-474D (W.D. Wash.). Cosens alleged that these hospitals had defrauded Medicare and other federal health care programs by submitting claims and receiving payments for hospital services provided to patients who elected to participate in clinical trials involving nearly sixty different investigational cardiac devices that had not been approved for marketing by the Food and Drug Administration ("FDA").[3]

Brigham & Women's Hospital, Johns Hopkins Hospital, St. Francis Hospital of Roslyn, New York, St. Louis University, Harper-Hutzel Hospital, and Northwestern Memorial Hospital; (2) Motions to Dismiss for Failure to State a Cause of Action: Johns Hopkins Hospital, St. Francis Hospital of Roslyn, New York, St. Louis University, St. Joseph Mercy Hospital, and Harper-Hutzel Hospital; (3) Motion to Dismiss Based on Statute of Limitations: Good Samaritan Hospital, Providence Medical Center, St. Louis University, St. Francis Hospital of Roslyn, New York, St. Joseph Mercy Hospital, and Harper-Hutzel Hospital.

[3] As discussed in more detail infra, the FDA is charged with the responsibility for ensuring that medical devices are safe and effective before they can be marketed. Under the Medical Devices Amendments Act of 1976, 21 U.S.C. §§ 360(k), 360c, 360e, 360j, before a

Reimbursement for these services involving these non-FDA-approved devices, he alleged, was in direct contravention of a 1986 Medicare Manual provision (the "Manual provision")[4] stating that payment would not be made for such procedures or services since they were not considered "reasonable and necessary" under 42 U.S.C. § 1395y(a)(1).[5] See Medicare Hospital Manual §

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medical device may be commercially distributed or marketed, notification must be given to the FDA so that the device can be classified according to the degree of regulatory control necessary to insure its safety and effectiveness. See 21 U.S.C. §§ 360(k), 360c(a)(1), (b)(1). Devices are divided into three classes. All of the cardiac devices at issue in these cases are Class III devices, those for which there is insufficient information to determine that the regulatory controls available to the FDA will provide a reasonable assurance of the device's safety and effectiveness. See 21 U.S.C. §§ 360c(a)(1)(C), 360e. Class III devices require "premarket approval" from the FDA before they may be commercially distributed. In 1980, the Secretary promulgated new regulations that provided an exemption to the premarket approval requirement for certain Class III investigational devices used in clinical trials. Under this investigational device exemption ("IDE"), a Class III device may be lawfully shipped for the purpose of conducting investigations of that device. See 21 C.F.R. § 812.1(a); 21 U.S.C. § 360j(g). These devices must be labeled as such, and a consent form must be obtained from all patients participating in clinical trials involving IDE devices. See 21 C.F.R. Pt. 812.

All of the devices in this case were cardiac devices that had received an IDE from the FDA for purposes of clinical trials, and thus had not received final approval for marketing from the FDA.

[4] Between July 1986 and November 1995, § 260.1 of the Hospital Manual provided:

> Medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary for the diagnosis and treatment of illness or injury, or to improve the functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures or services performed using devices which have not been approved for marketing by the FDA.

The Intermediary Manual § 3151.1 and the Medicare Carriers Manual § 2303.1 contained identical provisions.

[5] Section 1395y, entitled "Exclusions from coverage and medicare as secondary payer," provides:

(a) Items or services specifically excluded.

260.1(B) (eff. July 15, 1986); Medicare Carriers Manual § 2303.1; Intermediary Manual § 3151.1.

As required by the FCA, Cosens' qui tam action was filed under seal, 31 U.S.C. § 3730(b)(2), and was served on the United States Government so that it could investigate the allegations of the complaint and make a determination whether to intervene.[6] See 31 U.S.C. § 3730(b). In June 1994, the complaint was forwarded to the Office of the Inspector General ("OIG") of the Department of Health and Human Services ("HHS"), which then issued subpoenas to all of the named hospitals in "connection with an investigation concerning the possible submission of false or improper claims to and their payment by the Medicare and Medicaid programs under Titles XVIII and XIX of the Social Security Act, respectively," requesting documents concerning procedures performed from April 5, 1984 through March 31, 1994,

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> Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services –
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> > (1)(A) which, except for items and services described in a succeeding paragraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, . . .

[6] The FCA permits private citizens, called "relators," to initiate lawsuits alleging that the United States has been defrauded in connection with federal procurement activities and/or federal programs. See 31 U.S.C. § 3730(b)(1). Under the FCA, a relator files an action ex parte and under seal, and the lawsuit remains sealed and unknown to the named defendants for an initial period of sixty days. 31 U.S.C. § 3730(b)(2). During the sixty-day period, the United States is to commence and, if possible, complete an investigation of the allegations in order to make a decision whether to intervene and assume prosecution of the action or, alternatively, whether to decline to intervene and allow the relator to proceed with prosecution of the matter. 31 U.S.C. § 3730(c)(3). The United States may move the court for extensions of time for good cause shown. 31 U.S.C. § 3730(b)(3). During these extensions, the complaint continues to remain under seal. Id.

involving devices that were not approved for marketing by the FDA. (Gov't Ex. 1 to 9(b) Mot.)[7] For each procedure, the hospital was requested to identify the patient's name, date of birth, Social Security number, date of service, the experimental device involved, the responsible physician and/or clinical investigator, the insurer billed for the procedure, the amount billed, and the amount paid. In July 1994, HHS issued an amended subpoena limiting the devices to a defined list of experimental cardiac devices and limiting the patients to Medicare and Medicaid beneficiaries.[8] By late August 1994, the hospitals began producing documents in response to the subpoenas. In March 1995, the Government represented to the court that the hospitals were "all substantially in compliance with the subpoena." (DOJ Mem. dtd. 3/3/95 in Support of Ex Parte App. for Ext. of Time at 3.)

On December 28, 1995, Cosens filed his first amended complaint, which added two hospitals as defendants. (First Am. Compl. dtd. 12/28/95.)

On May 1, 1995, twenty-five of the hospitals, including thirteen of the current defendants,[9] filed suit in the Central District of California, seeking to have the Manual provision declared invalid because it was a substantive rule promulgated in violation of the notice-and-

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[7] The three motions will be referred to as the "9(b) Mot.", "12(b)(6) Mot.", and "S/L Mot."

[8] In 1997, some of the hospitals received similar subpoenas from the Department of Defense regarding CHAMPUS patients.

[9] The thirteen defendants in the instant case, which were also plaintiffs in the Cedars-Sinai ligation, are Cedars-Sinai Medical Center, Johns Hopkins Hospital, Loma Linda University Medical Center, Northwestern Memorial Hospital, St. Francis Hospital, St. Joseph's Hospital of Atlanta, St. Luke's Medical Center, Sinai Samaritan Medical Center, Montefiore Medical Center, St. Thomas Hospital, Yale-New Haven Hospital, Florida Hospital Medical Center, and Washington Hospital Center.

comment rule-making provisions of the Administrative Procedures Act, 5 U.S.C. § 553 ("the APA"). Cedars-Sinai Med. Ctr. v. Shalala, 939 F. Supp. 1457, 1462 (C.D. Cal. 1996), aff'd in part and remanded in part, 125 F.3d 765 (9th Cir. 1997), appeal after remand, 177 F.3d 1126 (9th Cir. 1999) ("the Cedars-Sinai litigation"). In the complaint, the hospitals stated that the action was being filed as a direct defense to the allegations in the qui tam action. The complaint also sought to enjoin the Secretary of HHS from enforcing the 1986 Manual provision and sought an order compelling the Secretary to comply with the Medicare Act and the APA in promulgating new regulations. Id.

On August 4, 1995, Cosens moved to partially lift the seal in the qui tam action so that he could provide a redacted copy of the complaint to the court and the plaintiff-hospitals in the Cedars-Sinai litigation. (Pl.'s Ex Parte Appl. dtd. 8/4/95 to Partially Unseal Compl.) That motion was granted and the qui tam complaint was unsealed except for the names of the Relator and the hospitals in the qui tam action that were not plaintiffs in the Cedars-Sinai litigation.[10] (Ex Parte Order dtd. 8/11/95 Partially Unsealing Compl.)

On September 19, 1995, after completing a formal notice-and-comment rule-making process regarding coverage for investigational devices under the statutory "reasonable and necessary" standard, the Secretary of HHS published final regulations addressing the coverage of medical devices categorized by the FDA as "investigational." The new regulations provided Medicare coverage for those "non-experimental/investigational" devices as to which the initial

[10] In ruling on a motion to dismiss and to preclude Government intervention in the qui tam action, the Honorable Robert S. Lasnik of the Western District of Washington, found that the hospitals in the Cedars-Sinai litigation were aware of the qui tam action, despite the fact that they had not been served with the qui tam complaint. (Order dtd. 3/6/02 on Mot. to Dismiss and to Preclude Gov't Intervention at 2.)

questions about the devices' safety and effectiveness had been resolved. See 42 C.F.R. §§ 405.201(b), 405.203, 405.211(b). In contrast to the total exclusion from coverage of such devices under the Manual provision, the new regulations classified such devices as either experimental/investigational ("Category A") for which there continued to be no coverage, or non-experimental/investigational ("Category B") which were eligible for Medicare coverage. See 42 C.F.R. §§ 405.201, 405.203(a), 405.205, 405.209, 405.211.

In February 1996, the United States Senate Permanent Subcommittee on Investigations held hearings on the alleged Medicare fraud involving hospitals' billing for non-FDA-approved medical devices. Relator Cosens, cloaked in a black hood, testified anonymously at this hearing, as well as John E. Hartwig, Deputy Inspector General for Investigations, Office of the Inspector General of HHS; Thomas Ault, Director of Policy Development for the Health Care Financing Administration; and several witnesses for the hospitals. See Improper Billing by Hospitals, 2/14/96 Cong. Testimony, available at 1996 WL 7135556-7135563.

On April 8, 1996, the California district court in Cedars-Sinai ruled that the 1986 Manual provision was a substantive rule subject to the notice-and-comment rule-making provisions of the APA, with which the Secretary had not complied. Accordingly, the court declared the provision void ab initio. Cedars-Sinai, 939 F. Supp. at 1462. On appeal, the Ninth Circuit remanded the case to the district court for the limited purpose of determining whether the hospitals' claims filed in 1995, challenging a 1986 policy, were barred by the six-year statute of limitations applicable to actions for judicial review of agency regulations under the APA, 28 U.S.C. § 2401(a). Cedars-Sinai, 125 F.3d at 767, 771. On remand, the district court held that the statute of limitations defense had not been waived by the Secretary and that the hospitals' claims were time-barred.

See Cedars-Sinai, 177 F.3d at 1128. That decision was ultimately affirmed by the Ninth Circuit, which held that the hospitals' cause of action challenging procedural irregularities in the promulgation of the Manual provision accrued at the time the Manual provision was issued, not when the hospitals' claims were denied and, therefore, was time-barred. Id. at 1129. The Court of Appeals also rejected the hospitals' argument that the Government should be equitably estopped from raising a limitations defense because of its delayed enforcement efforts. Id. at 1130. Accordingly, the judgment of the district court dismissing the complaint as time-barred was affirmed.

In the meantime, while the Cedars-Sinai litigation was pending, the Government requested and was granted numerous extensions of time by the district court in Washington to pursue its investigation of the Cosens' qui tam matter, to evaluate the evidence, and to determine whether to intervene. See 31 U.S.C. § 3730(b)(3).[11] Each of the requested extensions of time was consented to by the Relator. The qui tam complaint remained under seal, except to the extent that the Government was given permission to disclose the amended complaint to any named defendant as long as the identity of the Relator was kept confidential and that any disclosure was subject to a confidentiality order. (Order dtd. 4/4/96.) Other extensions of time were requested by the Government while HHS re-evaluated its policy of non-coverage embodied

[11] The longest extension was for three years, during which the parties waited for the Ninth Circuit's decision in the Cedars-Sinai litigation. The Government represented to the district court in Washington that the decision in Cedars-Sinai, although not binding on the Washington litigation, was "likely to directly and significantly impact the Medicare claims in the Relator's lawsuit." (Gov't Mem. dtd. 7/22/96 in Support of Mot. for Ext. of Time at 4-5.) Thus, to avoid the unnecessary expenditure of considerable human and financial resources by all parties, and given the uncertainty as to the validity of the Manual provision, the Government urged the Washington court to grant an extension of time until the Ninth Circuit had an opportunity to resolve this pivotal issue. Id. at 5.

in the Manual provision and while HHS promulgated new regulations allowing coverage and reimbursement for some, but not all, of the non-FDA-approved devices. Following the decision of the Ninth Circuit in Cedars-Sinai, the Government requested additional extensions of time to complete its evaluation of those defendant-hospitals against which it intended to intervene and to pursue settlement discussions with other defendants, including a "global" settlement with approximately forty hospitals. (U.S. Ex Parte Applications for Enlargement of Time dtd. 10/15/99 and 2/15/00.) These requests were granted by the district court. Altogether, sixteen enlargements of time were granted by the Washington district court.

Beginning in June of 1999, the Government filed motions for transfer of venue as to particular defendants. In each instance, the Government sought transfer to the judicial district where the hospital was located and where the action originally could have been brought. The Government argued that it was the real party in interest and, as such, its choice of forum should be given substantial weight. (E.g., United States' Ex Parte Application for Partial Transfer of Venue dtd. 8/17/99.) The Government represented that counsel for the Relator had been apprised of the application and fully concurred. (Id.) Each application for transfer of venue was granted by the court.

Additionally, as the Government successfully negotiated settlements with various defendants, it sought partial intervention and then sought dismissal of the qui tam proceedings as to those defendants. (E.g., United States' Notice of Election to Intervene dtd. 9/15/99; United States' Notice of Partial Intervention dtd. 5/25/01.) Ultimately, the Government entered into settlement agreements with all of the hospital-defendants except the forty hospitals that are now defendants in this MDL litigation and those hospitals that were voluntarily dismissed from the

Washington litigation.[12]

In late 2001, nine of the hospital-defendants that had not yet been served with the qui tam complaint filed with the district court in Washington a motion to dismiss for failure to prosecute with due diligence and to preclude Government intervention; a motion to dismiss for misjoinder, improper venue, and lack of personal jurisdiction in the Western District of Washington; and a motion to dismiss for lack of subject matter jurisdiction. The latter two motions were stricken as premature, and Judge Lasnik denied the motion to dismiss for failure to prosecute with due diligence and to preclude government intervention.[13]

Finally, in 2002, the Government and Relator moved to sever the action against each hospital and to transfer each individual case to the federal district where the hospital was located. These motions were granted and the thirty-five cases were transferred to twenty-seven federal districts throughout the United States. Ultimately, between August and December 2002, the Government filed complaints in intervention in each of the cases, challenging a total of 9,848

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[12] On April 3, 2002, the Government and Relator filed a notice of their intent to voluntarily dismiss thirty-nine defendants and of the Government's intent not to intervene against these defendants. (Notice dtd. 4/3/02.)

[13] Judge Lasnik stated that the movant hospitals could file a motion to dismiss once they were served with the complaint, showing the extent to which their ability to defend was actually frustrated due to the time lag between filing and service. (Order dtd. 3/6/02 re. Mot. to Dismiss and to Preclude Gov't Intervention at 3 n.1.) He reiterated that extensions of time had been granted based upon a finding of good cause, as contemplated by the FCA. He noted that, according to the Government, the hospitals that had filed the Cedars-Sinai lawsuit were largely responsible for the delay, since this litigation created uncertainty as to the validity of the Medicare provision that was at the heart of the qui tam action. Id. at 4. Thus, he declined to order dismissal under Rule 4(m), Fed. R. Civ. P. He further declined to dismiss the case under Rule 41(b), Fed. R. Civ. P., based on the strong public interest in disposing of a case such as this on the merits and the availability of less drastic sanctions, particularly where there had been no showing of misconduct. (Id. at 4-5.)

Medicare, Medicaid, and CHAMPUS claims submitted by the forty hospitals between 1986 and 1995.[14]

Each of the complaints asserts six counts against the defendant-hospitals, including three counts under the FCA and three common-law counts: (1) violation of the FCA, 31 U.S.C. § 3729(a)(1), submission of false claims (Count I); (2) violation of the FCA, 31 U.S.C. § 3729(a)(2), making or using a false record or statement to get a claim paid (Count II); (3) violation of the FCA, 31 U.S.C. § 3729(a)(7), making a false record or statement to conceal an obligation to pay a debt owed to the United States (Count III); (4) payment by mistake of fact (Count IV); (5) unjust enrichment (Count V); and (6) recoupment (Count VI). Additionally, complaints against five of the defendants contain a seventh count alleging common-law fraud.[15]

On September 30, 2002, the United States and Relator Cosens filed with the United States Judicial Panel on Multidistrict Litigation a joint motion to transfer the thirty-five cases to the Western District of Washington for coordinated or consolidated pretrial proceedings, pursuant to 28 U.S.C. § 1407. The motion to transfer was granted and, with the consent of this Court, the cases were assigned to the District of Connecticut. Following an initial pretrial conference, this Court then entered a Case Management Order, which addressed the filing of motions to dismiss and stayed all discovery until resolution of the motions to dismiss.[16]

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[14] For ease of reference, throughout this opinion, these will be referred to simply as "claims" or "Medicare claims."

[15] The defendants against which fraud claims have been asserted are Loyola University of Chicago, Northwestern Memorial Hospital, St. Joseph's Hospital of Atlanta, Yale-New Haven Hospital, and the Cleveland Clinic.

[16] All motions to dismiss pending in the transferor districts on March 5, 2003, were denied as moot without prejudice to refiling in this district.

Thereafter, the motions to dismiss were fully briefed and oral argument was heard by the Court.

II. Motion to Dismiss Standard

The function of a motion to dismiss for failure to state a claim upon which relief may be granted, Rule 12(b)(6), Fed. R. Civ. P., "is merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." Ryder Energy Distrib. Corp. v. Merrill Lynch Commodities Inc., 748 F.2d 774, 779 (2d Cir. 1984) (internal citations and quotation marks omitted). Thus, "[t]he issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." Scheuer v. Rhodes, 416 U.S. 232, 236 (1974), overruled on other grounds by Harlow v. Fitzgerald, 457 U.S. 800 (1982).

A motion to dismiss should not be granted for failure to state a claim unless the movant proves beyond doubt that the plaintiff can prove no set of facts that would entitle him to relief. Conley v. Gibson, 355 U.S. 41, 45-46 (1957); Jaghory v. New York State Dep't of Educ., 131 F.3d 326, 329 (2d Cir. 1997); Ryder Energy Distrib., 748 F.2d at 779. In ruling on a motion to dismiss, the Court is limited to the facts set forth on the face of the complaint, any documents attached thereto as exhibits or incorporated by reference, and matters of which the Court may take judicial notice. Kramer v. Time Warner Inc., 937 F.2d 767, 773 (2d Cir. 1991).

For purposes of ruling on a Rule 12(b)(6) motion, the Court must accept all factual allegations of the complaint as true and draw all reasonable inferences in favor of the plaintiff. Scheuer, 416 U.S. at 236; Bernheim v. Litt, 79 F.3d 318, 321 (2d Cir. 1996). However, conclusions of law or unwarranted deductions of fact are not admitted. First Nationwide Bank v. Gelt Funding Corp., 27 F.3d 763, 771 (2d Cir. 1994), cert. denied, 513 U.S. 1079 (1995).

Because the Federal Rules of Civil Procedure require only "notice" pleading, the Court will construe a plaintiff's allegations liberally. See Rule 8(a), Fed. R. Civ. P.; Swierkiewicz v. Sorema N.A., 534 U.S. 506, 514 (2002). However, when fraud is asserted, the complaint must meet the more stringent pleading requirements of Rule 9(b), Fed. R. Civ. P., which provides that "the circumstances constituting fraud or mistake shall be stated with particularity." See First Nationwide Bank, 27 F.3d at 771; Shields v. Citytrust Bancorp, Inc., 25 F.3d 1124, 1129 (2d Cir. 1994); Shemtob v. Shearson, Hammill & Co., 448 F.2d 442, 445 (2d Cir. 1971).

III. Allegations of the Complaints[17]

At all times relevant to the complaints, each hospital was a participating provider in the Medicare program. (Harper-Hutzel Compl. ¶ 7.) Part A of the Medicare Program, set forth in Title XVIII of the Social Security Act, authorizes payment for institutional care, including inpatient hospital care and related services. See 42 U.S.C. §§ 1395c-1395i-5. (Harper-Hutzel Compl. ¶ 9.) HHS is generally responsible for the administration and supervision of the Medicare Program. The Centers for Medicare and Medicaid Services ("CMS"), formerly known as the Health Care Financing Administration ("HCFA"), a component of HHS, is directly responsible for administration of the Medicare Program. To assist in the administration of Medicare Part A, CMS contracts with "fiscal intermediaries," typically insurance companies, who are responsible for processing and paying claims and auditing cost reports. See 42 U.S.C. § 1395h. (Harper-Hutzel Compl. ¶ 10.)

Under the Social Security Act, 42 U.S.C. § 1395y(a)(1), the Medicare Program is

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[17] The following allegations are taken from a typical complaint, United States v. Harper-Hutzel Hospital, Case No. 3:03CV689(GLG)(D. Conn). To the extent that material differences exist in complaints against specific hospitals, those differences are discussed infra.

authorized to pay only for items and services that are medically "reasonable and necessary." The Secretary of HHS is authorized to define what services meet that criteria. 42 U.S.C. § 1395ff(a). (Harper-Hutzel Compl. ¶ 11.) HHS issues a Hospital Manual, which is distributed to all Medicare providers, to inform them of its reimbursement policies and procedures. Similar manuals are provided to the fiscal intermediaries (the "Intermediary Manual"). These manuals are an essential source of information to Medicare providers and intermediaries regarding Medicare coverage policies. (Harper-Hutzel Compl. ¶ 12.) The Medicare providers have a legal duty to familiarize themselves with Medicare's reimbursement rules, including those stated in the Manuals. (Harper-Hutzel Compl. ¶ 13.) The Medicare regulations require the providers to furnish to the fiscal intermediaries sufficient information to determine if payment was due and the amount of payment see 42 C.F.R. § 424.5(a)(6).[18] (Harper-Hutzel Compl. ¶ 14.)

Under the Medicare Program, CMS enters into provider agreements with the hospitals in order to establish their eligibility to participate in the Medicare Program. Upon discharge of a Medicare beneficiary from the hospital, the hospital submits an interim reimbursement claim for items and services provided to that patient. These claims are submitted on a standard form, Form HCFA-1450 (UB-82). (After 1994, a modified version called a Form HCFA-1450 (UB-92) was used.) (Harper-Hutzel Compl. ¶ 15.) In addition to claims for inpatient services, Medicare providers are required to submit annually a Hospital Cost Report, Form HCFA-2552, which summarizes the amount of interim payments received and the amount to which they claim

[18] This regulation went into effect on March 2, 1988. Prior to that time, the regulation required the provider to furnish such information to the intermediary as may be necessary to assure proper payment by the program. See 42 C.F.R. § 405.406(d).

entitlement from Medicare.[19] (Harper-Hutzel Compl. ¶ 16.) The Hospital Cost Report contains a certification that must be signed by the hospital administrator, certifying that the report is a true, correct, and complete statement prepared from the books and records in accordance with applicable instructions.[20] (Harper-Hutzel Compl. ¶ 17.) The applicable instructions referenced in the certification included the provisions in the Hospital Manual, including the provisions in Sections 260.1[21] and 210.12.[22] (Harper-Hutzel Compl. ¶ 19.) The Hospital Cost Report Form (HCFA-2552-81) also stated that "intentional misrepresentations or falsifications of any information contained in this cost report may be punishable by fine and/or imprisonment under federal law." (Harper-Hutzel Compl. ¶ 20.) By statute, Medicare providers are required to disclose all known errors and omissions in their claims for Medicare reimbursement to their fiscal intermediaries. See 42 U.S.C. § 1320a-7b(a). (Harper-Hutzel Compl. ¶ 21.)

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[19] The hospitals disagree with the Government's characterization of the payments received for patient billings as "interim" payments. They state that under the prospective payment system that went into effect in 1983, see Note 36, infra, the payments received for individual patients, following the submission of the Form HFCA-1450, were final payments, 48 Fed. Reg. 39752, 39779 (Sept. 1, 1983), and that the annual cost reports merely accounted for payments received during the year.

[20] The certification provides in relevant part:

> [T]o the best of my knowledge and belief, it [the Hospital Cost Report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted.

(Harper-Hutzel Compl. ¶ 17.)

[21] See Note 4, supra.

[22] Between July 1986 and November 1994, § 210.12 of the Hospital Manual stated in part that "[s]ervices related to non-covered services during the hospital stay" were not covered under Medicare. The Intermediary Manual § 3101.14 and the Carriers Manual § 2300.1 contained identical provisions. (Harper-Hutzel Compl. ¶ 23.)

Between July 1986 and November 1995, payment by Medicare for any medical procedure in which a medical device was used was expressly conditioned upon the FDA's approval of the medical device for marketing, which signifies that the FDA had determined that the device was safe and effective for general medical use and could be commercially distributed. (Harper-Hutzel Compl. ¶¶ 24, 25.) All of the devices discussed in the complaints were cardiac devices that had not been approved for marketing by the FDA. Rather they were provided by the manufacturers to the defendant-hospitals pursuant to an "Investigational Device Exemption," which restricted their use to carefully monitored clinical trials, the purpose of which was to gather evidence of the safety and effectiveness of the devices. (Harper-Hutzel Compl. ¶ 25.) Prior to 1986, in order for a provider to bill Medicare for procedures involving investigational devices, it had to provide the fiscal intermediary with "authoritative evidence" of the safety and effectiveness of the devices at issue when it submitted its claims. (Harper-Hutzel Compl. ¶ 26.)

Provider hospitals participating in the Medicaid program are required to file annual cost reports with the state agencies administering that particular state's Medicaid program and are required to submit claims forms identical to those used in the Medicare program. (Harper-Hutzel Compl. ¶ 28.) These forms contained the following certification:

> This is to certify that the foregoing information is true, accurate and complete.
>
> I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.

(Harper-Hutzel Compl. ¶ 28.) When a provider submits a Medicaid cost report that contains the same false or incorrect information contained in the provider's Medicare cost report, false statements and false claims have been made for reimbursement from Medicaid. (Harper-Hutzel

Compl. ¶ 29.)

The Government alleges that between 1986 and 1995, defendants billed Medicare and Medicaid for numerous procedures involving cardiac devices that had not been approved for marketing by the FDA, and for services related to those procedures. (Harper-Hutzel Compl. ¶ 30.) Defendants received millions of dollars in Medicare and Medicaid reimbursements for these procedures and services. (Harper-Hutzel Compl. ¶ 31.) In each complaint, the Government then provides the total number of procedures that it has identified for which that defendant-hospital received improper reimbursement and states that "[i]n order to protect patient confidentiality, the Government will provide [or is providing] the defendant with a list of those procedures under separate cover." (Harper-Hutzel Compl. ¶ 32.) The complaint then breaks down the number of procedures performed involving each particular cardiac device. For example, the complaint against Harper-Hutzel states that it charged Medicare and/or Medicaid for at least thirty-seven procedures involving prosthetic heart valves manufactured by St. Jude that had not received marketing approval from the FDA. These procedures are then identified on the patient list provided to the defendant.[23] (Harper-Hutzel Compl. ¶ 34.) Similar allegations are

[23] When the Government served its complaints on the hospitals, it provided them with a chart, which in the case of Sentara Hospital was an abbreviated version of the spreadsheet that Sentara had provided to the Government. (See Gov't Ex. 5 to 9(b) Mot.) The spreadsheet included the patient's name, account number and medical records number, the admission and discharge dates, and information on the device that was used. This information was reportedly taken from information provided by Sentara Hospital to the Government a spreadsheet (see Gov't Ex. 4 to 9(b) Mot.), which included, inter alia, the account number, patient name, medical records number [these three items have been redacted from the Court's copy for reasons of patient privacy], the admission and discharge dates, the total charges and whether the device was the primary procedure, the total reimbursement the hospital received, the MCR/MCD reimbursement [the amount the hospital received from the Government], the device name, manufacturer and model number, a column entitled "Approved" that indicated whether the FDA had approved this device at the time of the procedure, and a column entitled "Financial Class"

set forth involving other cardiac devices. (Harper-Hutzel Compl. ¶¶ 35-43.)

The Government alleges that defendants had access to current copies of the Hospital Manual at all times relevant to the complaint and, thus, were on notice of the fact that Medicare considered medical procedures involving cardiac devices that had not been approved for marketing by the FDA, and any services related to such procedures, to be non-covered and non-reimbursable. (Harper-Hutzel Compl. ¶ 44.) If the defendant-hospitals did not regularly review the Hospital Manual to keep informed of the Medicare policies, then they acted with reckless disregard. Any express or implied representations that they made that they were complying with Medicare rules or instructions were knowingly false within the meaning of the FCA, 31 U.S.C. § 3729. Alternatively, if they did review the Hospital Manual properly, then they had actual knowledge of the provisions at issue. (Harper-Hutzel Compl. ¶ 45.) Similar allegations are set forth with respect to defendants' alleged violations of Medicaid policies. (Harper-Hutzel Compl. ¶ 46.)

The complaint further alleges that the defendant-hospitals did not inform their fiscal intermediaries that the claims identified were for procedures involving investigational cardiac devices. Instead, they filled out the claims forms as if the services being billed were covered by Medicare. Prior to April, 1994, when the defendants submitted their claims using HCFA Form UB-82, which had a box for "remarks," they did not explain on the form that the patient had received an investigational cardiac device. After April, 1994, when they submitted their claims using HCFA Form UB-92, which had a column to indicate that the services were "non-covered charges," they listed their charges in the column for "covered charges," rather than in the column

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that identified each patient as a Medicare or Medicaid patient.

for "non-covered charges." The complaint alleges that defendants did not submit any supplemental documents with their claim forms explaining that the procedures involved investigational cardiac devices. (Harper-Hutzel Compl. ¶ 47.) By failing to disclose to the fiscal intermediaries that their initial claims for payment were for non-covered services, defendants violated the False Claims Act. (Harper-Hutzel Compl. ¶ 48.)

"Upon information and belief," between 1987 and 1995, defendants regularly submitted Hospital Cost Reports to Medicare that were false and/or fraudulent because they (a) failed to disclose that defendants had received reimbursement for non-covered services, and (b) falsely certified that they had been prepared in accordance with applicable instructions. (Harper-Hutzel Compl. ¶ 50.) By submitting these false Hospital Cost Reports, defendants also evaded their legal obligations to reimburse Medicare and violated the False Claims Act. (Harper-Hutzel Compl. ¶ 51.)

The Government then asserts as a First Cause of Action, a violation of the FCA, 31 U.S.C. § 3729(a)(1), "Presentation of False Claims," which alleges that defendants "knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States." (Harper-Hutzel Compl. ¶ 53.) For a Second Cause of Action, the Government alleges a violation of the FCA, 31 U.S.C. § 3729(a)(2), "Making or Using False Record or Statement to Cause False Claim to be Presented," and alleges that defendants "knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the United States." (Harper-Hutzel Compl. ¶ 56.) The Third Cause of Action alleges a violation of § 3729(a)(7) of the FCA, "Making or Using False Record or Statement to Avoid an Obligation to Refund," which claims that defendants "knowingly made,

used or caused to be made or used false records or false statements to conceal, avoid or decrease an obligation to pay or transmit money or property to the United States." (Harper-Hutzel Compl. ¶ 59.) The Fourth Cause of Action is for payment by mistake of fact in which the Government states that it acted in reasonable reliance on the truthfulness of the claims and defendants' certifications in paying defendants sums of money to which they were not entitled, and, therefore, defendants are liable to account and pay for such amounts to the United States. (Harper-Hutzel Compl. ¶ 62.) For a Fifth Cause of Action, the complaint asserts a claim for unjust enrichment, seeking to recover monies to which defendants were not entitled and by which they have been unjustly enriched. (Harper-Hutzel Compl. ¶ 66.) Lastly, for a Sixth Cause of Action, the Government seeks recoupment of monies unlawfully paid by the United States to defendants contrary to statute or regulation. (Harper-Hutzel Compl. ¶ 68.)

Additionally, in the complaints against five defendants,[24] for a Seventh Cause of Action, the Government has alleged common-law fraud, based on specific evidence cited therein that hospital officials had knowledge that the devices at issue were not properly reimbursable by Medicare.[25]

IV. Discussion

A. Motion to Dismiss for Failure to Plead Fraud with Particularity, Rule 9(b), Fed. R. Civ. P.

1. The Parties' Contentions

[24] See Note 15, supra.

[25] These complaints are discussed in greater detail at 40-43, infra. See, Loyola Compl. ¶¶ 46(A)-(E); St. Joseph's Atl. Compl. ¶ 63; Northwestern Compl. ¶¶ 30, 32, 35, 37, 39; Yale-New Haven Compl. ¶ 40; Cleveland Clinic Compl. ¶ 48.

Invoking the pleading requirements of Rule 9(b), the hospital-defendants[26] have moved this Court to dismiss all counts of the Government's complaint except Count VI, which asserts a cause of action for recoupment. Defendants raise three primary arguments in support of their motion to dismiss for failure to plead fraud with particularity:

> (1) The complaints merely allege a "per se" fraud theory, equating fraud with an alleged violation of the Medicare Hospital Manual and do not allege particular fraudulent misconduct.
>
> (2) The complaints do not identify specific claims submitted to the Government and do not allege the "who, what, when, where, and why" of the defendants' allegedly fraudulent misconduct.
>
> (3) The complaints do not allege facts giving rise to a strong inference of fraudulent intent.

(Defs.' 9(b) Mem. at 2.)

The Government responds that its complaints provide sufficient detail about the claims at issue to meet the pleading requirements of Rule 9(b). Rule 9(b), it asserts, is intended to insure that defendants receive enough information about a plaintiff's claims to be able to prepare a defense and to guard against baseless accusations of fraud. See Reingold v. Deloitte Haskins & Sells, 599 F. Supp. 1241, 1266 (S.D.N.Y. 1984) (Gov't's Opp'n to 9(b) Mot. at 1.) Because virtually all of the 9,848 claims identified in the Government's complaints[27] and most of the

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[26] All forty hospitals have joined in this motion.

[27] As defendants correctly argue, despite the fact that these cases have been consolidated for certain purposes under the multidistrict litigation rules, each of the complaints stands alone. Each alleges a different number of procedures involving different investigational cardiac devices.

information on the patient lists provided to the defendants came directly from the defendants' responses to government subpoenas, the Government contends that defendants have had knowledge of these specific claims for years and billed the Government for each of the procedures at issue. (Id. at 2.) Thus, the Government asserts that there is no merit to defendants' claim that they lack sufficient information to prepare a defense.

As to defendants' argument that the complaints fail to provide evidence of "fraudulent intent," the Government responds that the FCA expressly states that no proof of a specific intent to defraud is required to prove an FCA violation. Proof of reckless disregard or deliberate indifference will suffice. Further, under Rule 9(b), "intent, knowledge, and other condition of mind" may be averred generally. In any event, the Government asserts that its complaints do in fact plead fraud with the requisite particularity. (Id.)

2. Principles Governing The Pleading Requirements of Rule 9(b)

Rule 9(b), Fed. R. Civ. P., requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." "Malice, intent, knowledge, and other condition of mind of a person may be averred generally." (Id.) It is well-settled, and the Government concedes, that Rule 9(b), Fed. R. Civ. P., applies to FCA claims.[28] Gold v. Morrison-Knudsen Co., 68 F.3d 1475, 1476-77 (2d Cir. 1995)(citing cases), cert. denied, 517 U.S. 1213 (1996); see also United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360

The Wisconsin complaint, for example, covers over 1,100 procedures; the Massachusetts complaint against Massachusetts General and Brigham & Women's Hospital covers over 700 procedures; the Ohio complaint against Cleveland Clinic and University Hospitals of Cleveland involves nearly 500 procedures.

[28] At oral argument, both sides agreed that the law of the Second Circuit applied to this case. (Hr'g Tr. at 70.)

F.3d 220, 227 (1st Cir. 2004); United States ex rel. Bledsoe v. Community Health Sys., Inc., 342 F.3d 634, 641 (6th Cir. 2003); United States ex rel. Costner v. United States, 317 F.3d 883, 888 (8th Cir.), cert. denied, — U.S. —, 124 S. Ct. 225 (2003); United States ex rel. Totten v. Bombardier Corp., 286 F.3d 542, 551 (D.C. Cir. 2002); Bly-Magee v. California, 236 F.3d 1014, 1018 (9th Cir. 2001); United States ex rel. Russell v. Epic Healthcare Mgmt. Group, 193 F.3d 304, 308 (5th Cir. 1999); Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 783-84 (4th Cir. 1999). Likewise, Rule 9(b) has been held to apply to common-law claims where the counts are premised on allegations of fraudulent conduct. See Daly v. Castro Llanes, 30 F. Supp. 2d 407, 414 (S.D.N.Y. 1998); Ramapo Land Co. v. Consolidated Rail Corp., 918 F. Supp. 123, 128 (S.D.N.Y. 1996); Krieger v. Gast, No. 4:99-CV-86, 2000 WL 288442, at **6-7 (W.D. Mich. Jan. 21, 2000); Securities Investor Protection Corp. v. Stratton Oakmont, Inc., 234 B.R. 293, 311 (Bankr. S.D.N.Y. 1999).

The Second Circuit has held that in order to satisfy the requirements of Rule 9(b), a plaintiff's complaint must (1) specify the statements that the plaintiff contends were fraudulent; (2) identify the speaker; (3) state where and when the statements were made; and (4) explain why the statements were fraudulent. Shields v. Citytrust Bancorp, Inc., 25 F.3d at 1127-28; see also Rombach v. Chang, 355 F.3d 164, 170 (2d Cir. 2004). The purpose of the specificity requirement is to ensure that the complaint provides a defendant with fair notice of a plaintiff's claim and with adequate information to frame a response. Rombach, 355 F.3d at 171; United States ex rel. Capella v. Norden Sys., Inc., No. 3:94-CV-2063, 2000 WL 1336487, at *5 (D. Conn. Aug. 24, 2000). Additionally, this heightened pleading requirement is designed to protect defendants from meritless claims of fraud, to discourage "strike suits," and to prevent the filing

of suits simply to uncover relevant information during the discovery process. Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir. 1996).

Frequently, however, in cases involving complex or extensive schemes of fraud, the courts have relaxed the pleading requirements of Rule 9(b). See United States ex rel. Hill v. Morehouse Med. Assocs., 82 Fed. Appx. 213, — F.3d —, 2003 WL 22019936, n. 6 (11th Cir. Aug. 15, 2003) (unpublished table decision), reh'g and reh'g en banc denied, 87 Fed. Appx. — F.3d —, 2003 WL 22670918 (11th Cir. Oct. 31, 2003)(unpublished decision); In re Pharmaceutical Industry Average Wholesale Price Litigation, 307 F. Supp. 2d 196, 208 (D. Mass. 2004); United States ex rel. Harris v. Bernad, 275 F. Supp. 2d 1, 8 (D.D.C. 2003); United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc., 238 F. Supp. 2d 258, 269 (D.D.C. 2002). As the court held in United States ex rel. Johnson v. Shell Oil Co., 183 F.R.D. 204, 206-07 (E.D. Tex. 1998),

> It is only common sense that the sufficiency of pleadings under Rule 9(b) may depend "upon the nature of the case, the complexity or simplicity of the transaction or occurrence, the relationship of the parties and the determination of how much circumstantial detail is necessary to give notice to the adverse party and enable him to prepare a responsive pleading." Payne v. United States, 247 F.2d 481, 486 (8th Cir. 1957), [cert. denied, 355 U.S. 923 (1958)]. Similarly, it has been widely held that where the fraud allegedly was complex and occurred over a period of time, the requirements of Rule 9(b) are less stringently applied. Anthony Distributors, Inc. v. Miller Brewing Co., 904 F. Supp. 1363, 1366 (M.D. Fla. 1995); Fujisawa Pharmaceutical Co., Ltd. v. Kapoor, 814 F. Supp. 720, 726 (N.D. Ill. 1993); In re Sunrise Litig., 793 F. Supp. 1306, 1312 (E.D. Pa. 1992); P & P Mktg., Inc. v. Ditton, 746 F. Supp. 1354, 1362-63 (N.D. Ill. 1990); In re Olympia Brewing Co. Sec. Litig., 674 F. Supp. 597, 620 (N.D. Ill. 1987); Hirt v. UM Leasing Corp., 614 F. Supp. 1066, 1072 (D. Neb. 1985) (quoting 2A J. Moore's Federal Practice 9.093 at 9-28 (1979)); In re Catanella and E.F. Hutton Co. Sec. Litig., 583 F. Supp. 1388, 1397 (E.D. Pa. 1984). To approach the issue otherwise would allow the more sophisticated to escape liability under a False Claims case due to the complexity of their scheme and their deviousness in escaping detection.

In other instances, where the alleged fraudulent scheme involved numerous transactions that occurred over a long period of time, courts have found it impractical to require the plaintiff to plead the specifics with respect to each and every instance of fraudulent conduct. See United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 47 (D. Mass. 2001); Corley v. Rosewood Care Ctr., Inc., 142 F.3d 1041, 1050 (7th Cir. 1998); United States ex rel. Johnson v. Shell Oil Co., 183 F.R.D. at 206-07 (collecting cases).

For example, in In re Pharmaceutical Industry, an MDL case, the plaintiffs alleged that forty-two pharmaceutical companies had fraudulently overstated the published wholesale prices of many of their prescription drugs, resulting in inflated payments by consumers, Medicare beneficiaries, insurers, and other end-payors. The complaint identified 321 specific prescription drugs. The defendants challenged the sufficiency of the complaint under Rule 9(b) on numerous bases, including its failure to identify the who, when, where, and specifics of the alleged fraud. The court, quoting United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d at 46, held that "[w]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible. Courts facing similar claims under the False Claims Act have not placed the bar so high as to require pleading with total insight." In re Pharmaceutical Industry, 307 F. Supp. 2d at 208 (internal quotation marks omitted).

Likewise, in United States ex rel. Harris, the court held that a complaint, alleging that defendants violated the FCA by "upcoding"[29] their claims submitted to Medicare over a six-year period, met the pleading requirements of Rule 9(b) even though the complaint alleged only a

[29] The plaintiff alleged that the defendants had submitted claims with reimbursement codes representing a higher level of care than was actually provided.

span of time, it provided only a sampling from patient files exemplifying the alleged scheme, and it used a statistical sample to determine damages. 275 F. Supp. 2d at 8.

In United States ex rel. Pogue, another FCA case, the plaintiff alleged that the defendant had violated the anti-kickback laws in numerous hospitals around the United States over a twelve-year period. 238 F. Supp. 2d at 267. The court denied the defendant's motion to dismiss, holding that Rule 9(b) does not require a detailed description of each and every false claim when the alleged fraud took place over many years, particularly given the complexity of the scheme involved. Id. at 268.

Furthermore, courts have held that Rule 9(b)'s heightened pleading standard may be applied less stringently when the specific factual information is peculiarly within the defendant's knowledge or control. See United States ex rel. Hill, 2003 WL 22019936, at *3; Epic Healthcare Mgmt. Group, 193 F.3d at 308. A court should also hesitate to dismiss a complaint under Rule 9(b) if the defendant has been made aware of the particular circumstances for which it will have to prepare a defense at trial and that the plaintiff has substantial prediscovery evidence of those facts. Harrison v. Westinghouse Savannah River Co., 176 F.3d at 784.

Thus, the courts have tempered the heightened pleading requirements of Rule 9(b) when the underlying purposes of Rule 9(b) have been met or when pleading each instance of the allegedly fraudulent conduct would be impractical.

We now turn to defendants' specific arguments in support of their motion to dismiss.

3. Whether the Complaints Allege Merely a "Per Se" Fraud Theory

Citing Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001), United States ex rel. Clausen v. Laboratory Corporation of America, Inc., 290 F.3d 1301 (11th Cir. 2002), cert. denied, 537 U.S.

1105 (2003), and United States v. Southland Management Corp., 326 F.3d 669 (5th Cir. 2003), defendants initially assert that the complaints fail to meet the pleading requirements of Rule 9(b) because they merely allege a "per se" fraud theory, equating fraud with an alleged violation of a provision in a 1000-page manual, and do not allege any particular fraudulent conduct. We disagree and find that each of these cases is distinguishable on its facts from the instant cases.

Mikes involved a qui tam plaintiff's challenge to Medicare claims submitted for medical services that were not performed in accordance with the relevant standard of medical care. The plaintiff, a pulmonologist, brought suit under the FCA against her former employer, a partnership of physicians, alleging that they had submitted fraudulent Medicare claims for spirometry procedures that were performed by medical assistants who were not properly trained, and who had used a spirometer that had not been properly calibrated. The Second Circuit held that defendants' claims for reimbursement from the Government were not legally false simply because the particular services furnished failed to comply with the mandates of a statute, regulation or contractual term that was only tangential to the service for which reimbursement is sought. Mikes, 274 F.3d at 697. "[M]edical necessity for a procedure and its quality are distinct considerations." Id. at 699.

In United States ex rel. Clausen, the relator generally alleged that the defendant laboratory had violated the FCA over a ten-year period by knowingly submitting false claims for unauthorized, unnecessary or excessive medical tests and for over-charging for other tests, but he failed to identify any specific claims submitted by the defendant to the Government. The Eleventh Circuit noted that the FCA does not "create liability merely for a health care provider's disregard of Government regulations or improper internal policies unless, as a result of such acts,

the provider knowingly asks the Government to pay amounts it does not owe." 290 F.3d at 1311 (emphasis added). The Court held that "[w]ithout the presentment of such a claim, while the practices of an entity that provides services to the Government may be unwise or improper, there is simply no actionable damage to the public fisc as required under the False Claims Act." Id. (emphasis in original). "The submission of a claim . . . is the sine qua non of a False Claims Act violation." Id. Thus, the Court held that the relator's failure to allege with any specificity if, or when, any improper claims were actually submitted to the Government was fatal to his complaints. Id. at 1312.

Likewise, in Southland Management, the Fifth Circuit held that "[t]here is no liability under [the FCA] for a false statement unless it is used to get a false claim paid." Southland Management, 326 F.3d at 675. Applying that standard, the court found that the defendants' submission of claims for housing assistance payments during a two-year period when their housing units were not sanitary or safe did not constitute the submission of a false claim because under the regulations the owners were entitled to continue to receive payments until certain conditions occurred. Thus, their submissions of these claims did not constitute the submission of a false claim. Id. at 676.

As this Court held in United States ex rel. Capella, "a violation of a statute or regulation does not, by itself, trigger FCA liability because it is the false certification of compliance which creates liability when certification is a prerequisite to obtaining a government benefit." 2000 WL 1336487, at *8 (internal citations and quotation marks omitted). "A false certification of compliance with a statute or regulation cannot serve as the basis for a qui tam action under the FCA unless payment is conditioned on that certification." Id. (citing United States ex rel

Siewick v. Jamieson Science & Eng'g, Inc., 214 F.3d 1372, 1375 (D.C. Cir. 2000)); see also United States ex rel Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1998) (holding that false certifications with compliance with Medicare statutes were actionable under the FCA).

In the instant case, the Government has challenged defendant-hospitals' billing Medicare for procedures using non-FDA-approved devices, which it contends were not "reasonable and necessary" based on the Manual provision, which stated that "[m]edical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not considered reasonable and necessary." The Government does not challenge the manner in which the devices were used, whether the procedures were performed in accordance with applicable medical standards, or whether the persons performing the procedures were properly trained, as did the plaintiff in Mikes. Nor, does the Government contend that the procedures were not performed in a safe manner or under proper conditions, which would be somewhat analogous to the claims in Southland Management. Nor, is this a case in which the Government has failed to identify specific claims,[30] as was the case in Clausen. As the Second Circuit discussed in Mikes, because the Medicare statute expressly provides that "no payment may be made under the Medicare statute for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury," 42 U.S.C. § 1395y(a)(1)(A), a provider's submission of a claim form for payment implicitly certifies compliance with this provision. Mikes, 274 F.3d at 701. The requirement that a service be reasonable and necessary generally pertains to the selection of the particular procedure and not to the manner of its

[30] See Discussion at 31-34, infra.

performance. Id. In the instant case, it is defendants' submission of claims relating to the use of a particular device, not to the manner in which the services were performed, which the Government has challenged.

Thus, contrary to defendants' assertion, the Government's complaints assert more than a mere regulatory violation. They assert that defendants filed claims for services that were not reasonable and necessary. This is not a case where the allegedly false claims are premised solely on a regulatory violation that was not a condition to payment. The Government is challenging the claims because they allegedly violated the underlying condition to payment, that the services must have been reasonable and necessary. Thus, defendants' motion to dismiss the complaints on the ground that they allege no more than a regulatory violation is denied.

4. Whether the Complaints Adequately Identify a False Claim or Adequately Allege the "Who, What, Where, When and How" of the Fraud

Citing Acito v. IMCERA Group, Inc., 47 F.3d 47 (2d Cir. 1995), defendants next assert that the complaints fail to meet the pleading requirements of Rule 9(b) because they fail to adequately plead the "who, what, where, when, and how" of the alleged fraud, as required by Second Circuit caselaw.

As defendants argue, the sine qua non of FCA liability is the presentation of a claim that is false. United States ex rel. Clausen, 290 F.3d at 1311. As the Eleventh Circuit held, "Rule 9(b)'s directive that 'the circumstances constituting fraud or mistake shall be stated with particularity' does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted

to the Government. . . . [I]f Rule 9(b) is to be adhered to, some indicia of reliability must be given in the complaint to support the allegation of an actual false claim for payment being made to the Government." Id. (emphasis in original).

Unlike the complaint in Clausen which "failed to provide any . . . information linking the testing schemes to the submission of any actual claims," 290 F.3d at 1313, the Government in the instant case has described in detail the alleged violations of the FCA and has provided categorical information in the complaints about the actual claims that were submitted to the Government, listing the number of false claims involving a particular device. Additionally, "[i]n order to protect patient confidentiality," rather than identify each patient and medical procedure in the complaint, the Government provided the defendants with a list of those procedures under separate cover, and so states in the complaints. (Harper-Hutzel Compl. ¶¶ 32, 34-43.) The complaints further allege that during specific years, defendants submitted annual cost reports that were false or fraudulent because they failed to disclose that defendants had received reimbursement for non-covered services and/or falsely certified that they had been prepared in accordance with applicable instructions. (Harper-Hutzel Compl. ¶ 50.)

The patient lists that accompanied the complaints and were served on each defendant were prepared by the Government from information supplied by the defendants, providing information on the specific patients and procedures. The spreadsheets varied, but generally listed the patient, some identifying number regarding the patient's account or medical record, the make and model of the medical device, and the date of service or the admission and discharge dates for

the hospital stay.[31] Some of the spreadsheets included the specific amount of the Medicare or Medicaid reimbursement for the specific procedure. (E.g., Gov't's Ex. 5 to 9(b) Mot..) Given concerns over patient confidentiality, the Government was justified in presenting this information in this format. In United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d at 47-48, the court held that, where the complaint referenced disclosures made to the defendants, it was appropriate to look to disclosures made to the defendants to determine whether the plaintiff had supplied enough information to the defendants to allow the action to go forward. See also United States ex rel. Kneepkins v. Gambro Healthcare, Inc., 115 F. Supp. 2d 35, 44 & n.5 (D. Mass. 2000) (holding that the Government's providing defendant with a computerized list of every claim alleged to involve unnecessary testing would satisfy Rule 9(b) to the extent that it provided the necessary details of the time, place, and content of each allegedly false claim).

In this case, when the complaints are read in conjunction with the patient lists provided to the hospitals, the Court finds that the complaints sufficiently identified the submission of specific false claims. This is not a situation where only a general scheme of fraud was alleged that might have resulted in the submission of false claims. Here, the fraudulent scheme was the submission of the claims themselves. This stands in sharp contrast to the complaints in Clausen, which "[a]t most, . . . raise[d] questions about [the defendant's] internal testing policies. But nowhere in the blur of facts and documents assembled by Clausen regarding six alleged testing schemes can one find any allegation, stated with particularity, of a false claim actually being submitted to the

[31] According to defendants St. Thomas Hospital and St. Vincent Hospital and Health Care Center, the lists they received from the Government indicated "device not specified." (Consol. Supp. Mem. in Support of 9(b) Mot. at 2-3.) They state that a cursory review of the list indicates that many of the patients did not even receive a cardiac device. These specific lists, however, have not been produced for the Court.

Government." 290 F.3d at 1312. Given the large number of procedures involved (9,848 total), it would have been unwieldy and have served no useful purpose for each of the claims to have been discussed individually in the complaints. The alleged fraudulent activity with respect to each claim was the same. To detail each procedure, involving each investigational cardiac device, for hundreds or thousands of patients would have unreasonably increased the length of the complaints filed.

Additionally, we find that the complaints satisfy the "who, what, where, when, and why" requirements of Second Circuit case law. The "who" in the complaints is the hospitals. Given the specificity of the remaining information that is provided in the complaints and patient lists, it was not necessary for the Government to identify by name the individuals filling out each claim form.[32] The "what" is the submission of claims for procedures involving the specific investigational cardiac devices identified in the complaints for the patients identified in the lists and spreadsheet submitted to the defendants, as well as the annual cost reports for the years at issue. The "where" is the place the claims and reports were filed, either with the fiscal intermediaries, the state Medicaid office or elsewhere, facts that should be within the knowledge of the hospitals. The "when" of the false claim is sufficiently identified or ascertainable based

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[32] To the extent that the defendant-hospitals contend that the specific individuals who actually filled out the forms should have been named, several courts have upheld complaints filed under the FCA where they did not identify specific individuals by name. See, e.g., United States ex rel. Johnson v. Shell Oil, 183 F.R.D. at 207-08; United States ex rel. Pogue, 977 F. Supp. at 1333.

Additionally, the Court notes that the defendants in the Cleveland-Clinic case moved to strike from the Government's complaint the names of physicians who were personally informed that the Government might not pay for some of the procedures at issue because they were experimental. The defendants argued that the names of the physicians were immaterial. The Court granted the motion to strike. These defendants, in particular, should not now be heard to complain that the complaints against them fail to identify individuals by name.

upon the dates of the patients' hospitalizations or the year of the annual cost report was filed.[33] The "how" of the alleged fraud is detailed in the portion of the complaints describing defendants' alleged wrongdoing, in which claims and cost reports were submitted and certified regarding procedures involving these investigational devices. See generally United States ex rel. Capella, 2000 WL 1336487, at **6-11; United States ex rel. Harris v. Bernad, 275 F. Supp. 2d at 8; United States ex rel. McCauley v. Best Care Home Health, Inc., No. 98-1261, 2003 WL 21955039, at *4 (D. Minn. Aug. 14, 2003); United States ex rel. Johnson v. Shell Oil, 183 F.R.D. at 207.

Defendants cite a number of cases in which the courts have held that the complaints were too vague to satisfy Rule 9(b). However, each case must be considered on its own facts to determine whether the facts, as alleged, satisfy the underlying purposes of Rule 9(b). Rule 9(b) does not impose a "one size fits all" list of facts that must be included in every FCA complaint. Oftentimes, when a complaint was dismissed, it failed to provide factual support for a key element of the asserted cause of action. For example, in United States ex rel. Thompson, the Fifth Circuit held that the plaintiff had failed to provide any factual basis in his complaint to support his belief that the defendants had submitted claims for medically unnecessary services other than referring to statistical studies, which did not necessarily implicate the defendants. Those allegations, the court held, amounted "to nothing more than speculation, and thus fail to satisfy Rule 9(b)." 125 F.3d at 903.

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[33] Each complaint identifies by year which cost reports the Government contends were false. See, e.g., Harper-Hutzel Compl. ¶ 49 (1987 to 1995); Yale-New Haven Compl. ¶ 43 (1986 to 1995); Cleveland Clinic Compl. ¶ 51 (Cleveland Clinic: 1990 to 1995), ¶ 60 (University Hospital 1990-1994).

Here, the defendants have been provided with fair notice of the substance of the claims against them. The complaints, read in conjunction with the patient lists provided to the hospitals, contain sufficient detail to accomplish the basic purposes of Rule 9(b). To require the Government to provide the specifics relating to each of the 9,848 claims in the complaints against these forty hospitals would be cumbersome, unwieldy, and would accomplish no purpose. As the court noted in United States ex rel. Johnson v. Shell Oil, 183 F.R.D. at 207, "[s]uch a requirement would cause the complaint to be in the hundred of pages, if not hundreds of pounds." Further, in light of privacy concerns, a significant portion of each complaint would have to have been redacted. Accordingly, we find that the complaints adequately plead the "who, what, where, when, and how" of the alleged fraud, and we deny the motion to dismiss on that basis.

5. Whether the Complaints Allege Facts Giving Rise to a Strong Inference of Fraudulent Intent

Lastly, defendants ask this Court to dismiss the complaints under Rule 9(b) because the complaints do not allege facts giving rise to a strong inference of fraudulent intent. Defendants, citing Acito and Shields, argue that the complaints must either allege motive and opportunity to commit fraud or facts constituting strong circumstantial evidence of conscious misbehavior or recklessness. More specifically, they argue that motive entails a "concrete benefit" that could be realized by the false statements.[34] See Chill v. General Electric Co., 101 F.3d 263, 268 (2d Cir. 1996). In this case, because Medicare pays the hospitals a single flat payment for inpatient services provided to a given patient based upon that patient's diagnosis-related group ("DRG"),

[34] The defendants' reliance on cases alleging securities fraud is misguided. Those cases are governed by 15 U.S.C. § 78u-4(b)(2), which explicitly requires that such complaints "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind."

see 42 U.S.C. § 1395ww, they assert that there could have been no motivation to use one device instead of another because it would have had no effect on the hospital's reimbursement.[35]

The Government, relying on Gold v. Morrison-Knudsen Co., 68 F.3d at 1477, responds that the FCA has a liberal scienter requirement. "No proof of specific intent to defraud is required" to state a claim under the FCA. 31 U.S.C. § 3927(b). Additionally, under Rule 9(b), "[m]alice, intent, knowledge, and other condition of mind of a person may be averred generally." Rule 9(b), Fed. R. Civ. P. Thus, in Gold, a case brought under the FCA, the court did not require the plaintiff to particularize the defendants' specific intent to defraud. 68 F.3d at 1477. The Government further argues that, even if a heightened pleading requirement is applied to its allegations of scienter, it has alleged evidence of actual knowledge in over one-half of the complaints and evidence of reckless disregard in the rest.

In reply, defendants stress the fact the Government has made the "stunning admission that thirty-five of the forty Complaints in this case do not allege fraud." (Defs.' 9(b) Reply Mem. at 1)(emphasis in original). Since the FCA is a fraud statute, they argue that the complaints should be dismissed for this reason alone.

Although the courts have applied the heightened pleading requirements of Rule 9(b) to FCA cases, those pleading requirements do not change the substantive burden of proof in an FCA case. A plaintiff is not required to plead fraud in a False Claims action, rather, only that the

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[35] As explained by the Court in Huntington Hospital v. Thompson, 319 F.3d 74, 76 (2d Cir. 2003), the prospective payment system was enacted by Congress in 1983. It established a number of DRGs, which describe particular classes of patients and treatments, and the amount Medicare will pay for inpatient hospital services associated with each. DRG cost schedules are generated from national and regional average costs for treatment of particular illnesses. See 42 U.S.C. § 1395ww(d)(2)(D). It is not based on the actual cost to any hospital of treating particular DRG-classified illnesses.

conduct by the defendants was done knowingly. "Liability under the Civil False Claims Act is statutory--that is liability arises from performance of one of the acts set forth in 31 U.S.C. § 3729(a). This statutory liability underscores that the False Claims Act ("F.C.A.") is not a fraud statute; instead it is a false claim/false statement statute in which common law principles do not necessarily apply." United States ex rel. Johnson v. Shell Oil, 183 F.R.D. at 208 (quoting John T. Boese, Civil False Claims And Qui Tam Actions, 2-5 (1998 Supp.)).

The FCA establishes liability, inter alia, for anyone who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1), or "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government," 31 U.S.C. § 3729(a)(2), or "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7) (emphasis added). The FCA defines "knowing" and "knowingly" as having actual knowledge of the information, or acting in either deliberate ignorance of or in reckless disregard of the information's truth or falsity. 31 U.S.C. § 3729(b). As the Government argues, the Act expressly provides that "no proof of specific intent to defraud is required." Id. (emphasis added). Additionally, Rule 9(b) allows conditions of the mind, in this case, to "knowingly" file a false claim, to be pled generally. Fraudulent intent needs neither to be pled nor proven in order for a plaintiff to state a claim under the FCA.

The Second Circuit has adopted the Ninth Circuit's standard that the "requisite intent is the knowing presentation of what is known to be false" as opposed to negligence or innocent

mistake. Mikes, 274 F.3d at 703 (citing Hagood v. Sonoma County Water Agency, 81 F.3d 1465, 1478 (9th Cir. 1996), cert. denied, 519 U.S. 865 (1996)). Indeed, Congress specifically amended the FCA to include this definition of scienter, to make "firm . . . its intention that the act not punish honest mistakes or incorrect claims submitted through mere negligence." United States ex rel. Hochman v. Nackman, 145 F.3d 1069, 1073 (9th Cir. 1998) (quoting S. Rep. No. 99-345, at 7 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5272). "Known to be false" does not mean scientifically untrue, but "a lie." United States ex rel. Anderson v. Northern Telecom, Inc., 52 F.3d 810, 815-16 (9th Cir. 1995), cert. denied, 516 U.S. 1043 (1996) (internal citations and quotation marks omitted). Nevertheless, the courts have recognized that "'[p]rotection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law.'" United States v. Mackby, 261 F.3d 821, 828 (9th Cir. 2001) (quoting Heckler v. Cmty. Health Servs. of Crawford County, Inc., 467 U.S. 51, 63 (1984)). "Participants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment." Mackby, 261 F.3d at 828 (citing Heckler, 467 U.S. at 64). Thus, where the defendant failed to inform himself of those requirements, the Ninth Circuit held in Mackby that he 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.

In the three counts under the FCA, the Government has pled that the defendants "knowingly" presented or caused to presented false or fraudulent claims for payment or approval to the United States (Count I), 31 U.S.C. § 3729(a)(1); "knowingly" made, used or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the United States (Count II), 31 U.S.C. § 3729(a)(2); and "knowingly" made, used, or caused to

be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States (Count III), 31 U.S.C. § 3729(a)(7). In the preceding paragraphs, which are incorporated by reference, the Government has set forth the statutory and regulatory requirements for the hospitals to receive Medicare reimbursements, including their regulatory duty to provide the fiscal intermediaries with sufficient information for them to be able to make an informed payment decision. (Harper-Hutzel Compl. ¶ 14, citing 42 C.F.R. § 424.5(a)(6).) The complaints further set forth the Hospital Manual provision expressly prohibiting payment for the procedures involving non-FDA approved medical devices. The complaints state that between 1986 and 1995, the defendant-hospitals billed Medicare for a specific number of procedures involving non-FDA-approved cardiac devices. The complaints allege that a copy of the Hospital Manual was provided to each of the defendant-hospitals, each of which had a legal duty to familiarize itself with its provisions. The complaints aver that the hospitals were on notice that Medicare considered procedures involving non-FDA-approved cardiac devices to be non-covered. They further assert that if the hospitals did not actively and regularly review the Hospital Manual, then they acted with reckless disregard of their compliance with Medicare rules and instructions, and any express or implied representations that they were complying with such rules and regulations were "knowingly" false within the meaning of 31 U.S.C. § 3729 of the FCA. (Harper-Hutzel Compl. ¶ 45.) Alternatively, if the hospitals did review the Hospital Manual properly, then they had actual knowledge of the provisions at issue. (Id.)

We find that the Government has met its burden of pleading scienter under the FCA. Whether the facts will bare out these claims or whether the facts will show only an innocent

mistake or mere negligence on the part of the defendant-hospitals are issues that cannot be resolved on a motion to dismiss. At this juncture, we are required to accept as true all factual allegations of the complaint and draw all reasonable inferences in favor of the plaintiff. Scheuer, 416 U.S. at 236. Rule 9(b) allows the plaintiff to aver generally intent, knowledge, and other conditions of mind. See Goldman v. Belden, 754 F.2d 1059, 1070 (2d Cir. 1985). Accordingly, we decline to dismiss the three FCA counts under Rule 9(b) for failure to allege facts giving rise to a strong inference of fraudulent intent.[36]

As to Counts Four and Five, alleging payment by mistake and unjust enrichment, fraudulent intent is not an element of either of these claims.[37]

As to the Government's seventh count for fraud, which is contained in five of the complaints, these complaints have alleged additional facts regarding knowledge on the part of

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[36] That is not to say that none of the complaints contain allegations from which conscious misbehavior or recklessness could be inferred. For example, the Johns Hopkins complaint quotes a number of internal memoranda that express concern about whether the procedures at issue were reimbursable and a 1991 letter from the Chairman of the Joint Committee on Clinical Investigations to the Director of Interventional Cardiology questioning "[w]hat patient in their right mind would risk the financial responsibilities involved in using an unproven experimental device for the treatment of coronary disease, when there is a proven device which would be covered by their health/care system?" (Johns-Hopkins Compl. ¶ 44.) Six other complaints quote patient consent forms that warned patients that the procedures might not be covered by Medicare because of their experimental nature. (E.g., Methodist Hosp. of Indiana Compl. ¶ 41.) Four other complaints contain evidence that the hospitals had knowledge that Medicare and others did not cover the procedures at issue. (E.g., Mass. Gen. Hosp. Compl. ¶ 53, quoting a 1994 memo from the General Counsel to hospital physicians reminding them that "Medicare and Medicaid do not pay for services . . . using devices which have not received premarket approval from the FDA;" Montefiore Med. Ctr. Compl. ¶¶ 36-36, stating that the hospital submitted a claim for an investigational device even after receiving a bulletin from its fiscal intermediary warning against the practice.)

[37] As discussed supra, the defendants have not addressed their 9(b) motion to Count VI, which is a common-law claim for recoupment.

certain individuals within the hospitals that Medicare did not provide coverage for these procedures and yet the hospitals continued to bill for these procedures. A plaintiff can establish a strong inference of fraudulent intent in two ways: "either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." Shields, 25 F.3d at 1128. Here, the Government has alleged facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.

The complaint against Loyola quotes a December 1988 memo from the Chairman of Loyola's Institutional Review Board to one of the hospital's physicians warning that patients in one of the clinical trials should be advised that they might be financially responsible for the procedures. "Since this device is an investigational device, third party carriers such as Medicare may not reimburse for this implantation." (Loyola Compl. ¶ 46(A).) The physician dismissed the warning as "a somewhat ridiculous issue since Medicare never asks what type or brand of pacemaker is implanted." (Loyola Compl. ¶ 46(B).) According to the complaint, the hospital charged Medicare for these procedures anyway. The complaint also quotes a 1993 memo from one of the manufacturers instructing the hospital to warn patients participating in the trial of one of their devices that "[i]nsurance companies or government health care programs may limit their obligation to pay for investigational or experimental treatment and its consequences." (Loyola Compl. ¶ 46(E).)

The complaint against St. Joseph's Hospital of Atlanta quotes a 1990 memo from the hospital's Director for Patient Financial Services to the Assistant Vice President for Surgical Services, relating that HHS's position had been reiterated to him, just as they had heard it before:

"If the product is not FDA and Medicare approved, it is not covered by the Medicare program." The memo stated that all vendors were aware of this and were prepared to inform the hospital of a product's covered or non-covered status. He states that it is their responsibility not to bill Medicare for non-covered charges, which can be submitted on the UB-82 form in the "non-covered area." (St. Joseph's Compl. ¶ 63.)

The complaint against Northwestern Memorial Hospital quotes a July 1988 internal memo projecting revenues for one of the clinical trials at issue based on the assumption that the procedures were not reimbursable and stating that "it would be unlikely that insurance carriers or Medicare will pay for an investigational procedure." (Northwestern Compl. ¶ 30.) It also cites a 1989 memo involving another investigational procedure and noting that it may not be reimbursed. Nevertheless, the Government alleges that Northwestern billed Medicare for at least fifty-two procedures involving this particular device. (Northwestern Compl. ¶ 29.)[38]

The complaint against Yale-New Haven Hospital states that the hospital continued billing Medicare for investigational devices even after receiving a subpoena about the practice in 1994. (Yale-New Haven Compl. ¶ 40.)

The original complaint against the Cleveland Clinic states that it was reminded by one of the manufacturers in April 1992 that insurance companies and Government health care programs often limited coverage of investigational or experimental treatments. Moreover, it was

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[38] Defendant Northwestern has filed a Supplemental Memorandum disputing the inferences that the Government has drawn from these memos. It states that it never billed Medicare for any procedures involving the particular device referenced in the first memo. This matter is not properly before the Court in deciding a motion to dismiss. As to the second memo, Northwestern states that the quoted portion is taken out of context and that the document had no relevance to the Spectranetics laser trials. Again, this is an evidentiary matter not properly before the Court at this time. (Supp. Mem. in Support of 9(b) Mot.)

specifically directed by that manufacturer to warn patients in its clinical trials of Wiktor stents that the patients would be financially responsible for the costs of the procedures at issue. (Cleveland Clinic Compl. ¶ 48.)

These additional allegations of actual knowledge on the part of these hospitals provide sufficient evidence of conscious misbehavior from which a reasonable trier of fact could draw an inference of fraudulent intent with respect to the submission of claims after the dates on which the hospitals acquired such knowledge.

Accordingly, the Court denies defendants' Rule 9(b) motion to dismiss the complaints for failure to plead fraud with particularity.

B. Motion to Dismiss for Failure to State a Claim Upon Which Relief May Be Granted, Rule 12(b)(6), Fed. R. Civ. P.

1. The Parties' Contentions

The hospital-defendants'[39] second motion seeks to have the Court dismiss the complaints in their entirety pursuant to Rule 12(b)(6), Fed. R. Civ. P., for failure to state a claim upon which relief may be granted. Defendants maintain that the FCA counts should be dismissed because the Government has failed to allege a false or fraudulent claim by the hospitals.[40] First, citing Mikes,

[39] Again, all forty defendant-hospitals join in this motion.

[40] Count I, which is brought under § 3729(a)(1) of the FCA, applies to false "claims." Count II, brought under § 3729(a)(2) of the FCA, applies to an "affirmative or express false record or statement to get the false or fraudulent claim paid or approved." Shaw v. AAA Engineering & Drafting, Inc., 213 F.3d 519, 531-32 (10th Cir. 2000). Likewise, an affirmative or express false record or statement is a mandatory element of a cause of action under the "reverse false claims" provision in § 3729(a)(7), on which Count III is based. United States ex rel. Lamers v. Green Bay, 998 F. Supp. 971,. 996-97 (E. D. Wis. 1998), aff'd, 168 F.3d 1013 (7th Cir. 1999). Defendants argue that even if Count I survives on an "implied false certification" theory, this theory is inapplicable to the "false record or statement" element of Counts II and III, which should be dismissed on that ground alone.

274 F.3d at 697, defendants argue that their claims were not false or fraudulent. The Second Circuit has recognized three theories under which a claim may be false or fraudulent: it may be factually false, legally false under an "express false certification" theory, or legally false under an "implied certification" theory. Defendants maintain that their claims were neither factually nor legally false. Nothing on the forms required the hospitals to disclose that the devices were investigational nor did anything in the instructions direct the hospitals as to how these disclosures should be made.[41] Thus, they contend their alleged non-disclosures could not possibly constitute false or fraudulent claims. Without a false claim, defendants argue, there can be no liability under the FCA. The Cost Reports were simply compilations of payments actually received.

Second, defendants argue that the FCA counts rely on a Manual provision that was (1) either an invalid legislative rule adopted in violation of the notice-and-comment requirements of the APA or a non-binding interpretive rule; (2) arbitrary and capricious and therefore invalid; and (3) ambiguous on its face and the subject of a disputed legal question. Because the Manual provision was invalid, it cannot form the basis of a claim under the FCA. Defendants assert that the common-law claims also fail because they rely on the same Manual provision and because the hospitals have a statutory right to administrative adjudication of overpayments by HHS. See

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[41] At oral argument, defendants argued that the forms that were allegedly fraudulently submitted do not have a space that inquires as to whether the device was approved by the FDA for marketing. They conceded that if the forms had asked this question and they had knowingly and incorrectly answered "no," the Government would have a claim against them under the FCA. But, this is not what the forms required and this is not what is alleged.

Defendants attempted to introduce a 1994 memorandum from the Director of the Bureau of Policy Development of HCFA, reportedly acknowledging that the then-current forms did not require the information necessary to identify whether a medical device was investigational. This Court ruled that the memorandum would not be considered in ruling on a motion to dismiss. (Hr'g Tr. 108, 131, 151.)

42 U.S.C. §§ 1395ff(a), (b), 1395pp(d); 42 C.F.R. §§ 405.701 et seq. (setting forth the administrative appeals process); United States ex rel. Rahman v. Oncology Assocs., P.C., 198 F.3d 502, 514 (4th Cir. 1999). Likewise, the Government's equitable claims should be dismissed because it has an adequate remedy at law under the Medicare statute, which provides the Government with full and adequate remedies to recover any funds to which the hospitals were not entitled.

The Government responds that to adopt the defendants' position would be to allow Medicare providers to bill Medicare for millions of dollars for services that are not covered under Medicare rules, without revealing that the services are not covered, and without challenging or seeking clarification of the coverage rule. Then, if the provider is caught, it can escape liability by arguing that the rule was never valid in the first place. (Gov't 12(b)(6) Mem. at 1.) Instead, when a recipient of federal funds submits claims to Medicare that disguise non-covered services as covered services, it has violated the FCA. (Id.) In fact, the Government contends, these are classic false claims -- a provider's concealing a material fact in order to receive a payment that is not due.

The Government relies on both express and implied certification theories in arguing that the defendants' claims were legally false. The hospitals made false certifications on each of their annual Cost Reports that the reports were true, correct, and accurate and prepared in accordance with applicable instructions, which included the Manual provision, when in fact the provisions of the Manual had not been followed. The hospitals also implicitly certified that the services billed for were "reasonable and necessary," when in fact they were not, according to the Manual provision that was binding on the hospitals.

The Government, citing the Supreme Court's decision in Shalala v. Guernsey Memorial Hospital, 514 U.S. 87, 97-100 (1995), argues that the Manual provision is the "prototypical" interpretive rule, which was not required to be issued with notice and comment. See also St. Mary's Hospital v. Blue Cross & Blue Shield Ass'n, 788 F.2d 888, 890 (2d Cir. 1986) (holding a Medicare manual provision to be interpretive). Medicare manual provisions are the official explanation of the Medicare statute and regulations by the Secretary, which the intermediaries are required to follow in making payment decisions and of which the hospitals were required to inform themselves in submitting claims. Furthermore, the Government argues that the language of the Manual provision was clear and unambiguous. To the extent that it changed the prior rule, the agency's interpretation is entitled to substantial deference. White v. Shalala, 7 F.3d 296, 300 (2d Cir. 1993). Lastly, even in the Manual provision is found to be invalid, defendants were not at liberty to violate it. In United States v. Weiss, 914 F.2d 1514, 1522 (2d Cir. 1990), cert. denied, 501 U.S. 1250 (1991), the Second Circuit, quoting Dennis v. United States, 384 U.S. 855, 866 (1966), held that "'[w]hen one undertakes to cheat the Government or to mislead its officers . . . by false statements, he has no standing to assert that the operations of the Government in which the effort to cheat or mislead is made are without constitutional sanction." Likewise, the Court reasoned, it is no defense to a charge of filing false statements that the government document that prescribed the details of filing had not been approved by the appropriate Government official, as required by statute. Id.

2. Whether the Complaints Have Alleged a False or Fraudulent Claim

In Mikes, the Second Circuit held that to impose liability under the FCA, the Government must show that defendants (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. 274 F.3d at 695.

a. What Constitutes a Claim Under the FCA?

With respect to the first element, the Second Circuit held that the FCA "expansively defines the term 'claim' to cover 'any request or demand, whether under a contract or otherwise, for money or property . . . if the United States Government provides any portion of the money or property which is requested or demanded.'" Id. (quoting 31 U.S.C. § 3729(c)). In the instant case, defendants' submission of Form HCFA-1450 (UB-82 and UB-92) clearly constituted the submission of a "claim" to the United States government. See Id. (holding that each submission of a reimbursement claim for spirometry tests on Form HCFA-1500 met the first two elements). These were the hospitals' requests for payments for the services provided to the Medicare beneficiary.

Additionally, based on the allegations of the complaints, we find that the submission of the annual Cost Report forms with their accompanying certifications that the reports were true, correct, and complete and prepared in accordance with applicable instructions, constituted the submission of a claim. See Gublo v. Novacare, Inc., 62 F. Supp. 2d 347, 355 (D. Mass. 1999) (holding relator stated an FCA claim where defendants submitted annual cost reports that included a certification of compliance); United States ex rel. Thompson, 125 F.3d at 902 (holding that cost reports were claims).

Defendants argue that under the prospective payment system, the Cost Reports merely accounted for DRG payments actually received, although they did reconcile interim payments for other items or services that were paid on a reasonable cost basis, as opposed to being paid on a

prospective payment system, none of which is in question here.[42] (Defs.' 12(b)(6) Mem. at 12.) They state that the Cost Reports were not the proper place to modify prospective DRG payments for individual claims, which were to be adjusted during the ninety-day period following submission of the initial bill, and thus they cannot be considered claims for payment. Id. The Government responds that even under the prospective payment system, a year-end retrospective adjustment would be made if a particular payment was found to have been improper or inaccurate. See Defs.' Ex. 11 to 12(b)(6) Mot., PRM § 2405.1(A). Additionally, if the fiscal intermediary determined that the provider had submitted claims for services that were not medically necessary or were non-covered services, those overpayments could be recouped as part of the cost report settlement process. See Gov't's Ex. 9 to 12(b)(6) Mem, PRM §§ 2409.2 & 2409.3(B)(2).

Although the Cost Reports were not requests for payment with respect to the specific

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[42] Under the Medicare program, a provider files annual cost reports setting forth information and calculations identifying the Medicare costs that the hospital claims should be reimbursed by Medicare for that year. In addition to reporting the DRG payments received for services provided to Medicare beneficiaries, the cost reports allocate portions of overhead costs, such as employee salaries and benefits, supplies, and utilities to each of the reimbursable costs as administrative and general costs. Medicare factors these costs into the PPS/DRG reimbursement and administers the reimbursement throughout the fiscal year in periodic interim payments. Other costs which secure real property or other capital assets, such as depreciation, interest on certain long-term debt, and lease expenses, are capital-related costs. The providers file the cost reports with the fiscal intermediaries, who distribute Medicare funds based upon the claims included in their cost reports. The fiscal intermediaries are responsible for reviewing the cost reports and processing payment of claims. After an audit process, the fiscal intermediary's cost report review culminates in a notice of program review or final settlement. Both the fiscal intermediary and the provider have a three-year period in which to reopen a cost report in order to make changes. In the event of a claims dispute between the fiscal intermediary and the provider, the provider can either appeal an audit adjustment, or claim the disputed cost. If the provider claims the disputed cost, it must disclose this in the cost report itself on the protest line or the settlement page or in the transmittal letter that accompanies the filed cost report. United States v. Whiteside, 285 F.3d 1345, 1346-47 (11th Cir. 2002).

services provided to the Medicare beneficiaries, those charges were included in the Cost Reports and were subject to the certification that they were true and correct. Given the Second Circuit's expansive interpretation of the term "claim," we find that the annual Cost Reports constituted "claims" within the meaning of the FCA.

b. Has The Government Sufficiently Alleged That The Claims Were False or Fraudulent?

Regarding the third element of an FCA cause of action, the FCA does not define "false or fraudulent." Mikes, however, instructs that these terms must be considered in the context of the statute and that a claim cannot be determined to be false or fraudulent unless the Government would not have paid the claim if the actual facts had been known. 274 F.3d at 696. Here, the Government states that it would not have paid the claims if defendants had disclosed the fact that the cardiac devices were investigational devices, not approved for marketing by the FDA.[43]

The Second Circuit in Mikes held that a claim may satisfy the falsity element of the FCA in one of three ways. It may be factually false if it "incorrectly describes the goods or services provided or a request for goods or services never provided," id. at 697, or it may be legally false because of an express false certification or an implied false certification. Id. at 697-98. In Mikes, the Second Circuit held an "expressly false claim is . . . a claim that falsely certifies compliance with a particular statute, regulation or contractual terms, where compliance is a prerequisite to payment." Id. at 698 (emphasis added). Under an implied false certification theory, the act of

[43] Defendants contend otherwise and point to the fact that the intermediaries had been paying for procedures involving these devices for years and that HHS did not enforce the Manual provision until 1994. That may well be true, but that is not what is alleged in the complaints. Our decision today is on a motion to dismiss, which is limited to the facts alleged, which the Court must assume to be true for purposes of this ruling.

submitting a claim for reimbursement itself implies compliance with the governing federal rules that are a precondition to payment. Id. at 699 (emphasis added).[44] The Court emphasized that "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid." Id. at 700 (emphasis in original). "Liability under the [FCA] may properly be found therefore when a defendant submits a claim for reimbursement while knowing - as that term is defined by the Act, see 31 U.S.C. § 3729(b) – that payment expressly is precluded because of some noncompliance by the defendant."[45] Id. Here, the Government has alleged that defendants' claims were false or fraudulent under all three theories identified by the Second Circuit.

i. Were The Claims Factually False?

The Government asserts that the claims were factually false because they failed to identify the services provided as non-covered because they involved an investigational device. The regulations, 42 C.F.R. § 424.5(a)(6), required the hospitals to furnish the intermediaries with sufficient information to determine whether payment was due and the amount of payment. Additionally, the hospitals had an obligation to submit their claims on forms approved by

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[44] Other courts have embraced an implied false certification theory as well. See United States ex rel. Augustine v. Century Health Servs., Inc., 289 F.3d 409, 414 (6th Cir. 2002); Shaw v. AAA Eng'g & Drafting, Inc., 213 F.3d 519, 531 (10th Cir. 2000); Ab-Tech Constr., Inc. v. United States, 31 Fed. Cl. 429, 433-34 (Fed. Cl. 1994), aff'd, 57 F.3d 687, 700 (Fed. Cir. 1995).

[45] For example, in Ab-Tech Construction, 31 Fed. Cl. at 431-32, a construction company had submitted payment vouchers to the SBA. There were no express misrepresentations on the face of the payment vouchers. However, the SBA later discovered that Ab-Tech was ineligible to participate in the program. It filed suit under the FCA to recover the payments that Ab-Tech had received. The court held that the payment vouchers contained an implied certification by Ab-Tech of its continued adherence to the requirements for participation in the program. Its failure to comply with these implied certifications rendered its claims for payment false. Id.

Medicare and in accordance with Medicare instructions. 42 C.F.R. § 424.32. The UB-82 claim forms, used until 1994, contained a "Remarks" box on the form where the hospitals were instructed to enter any remarks not shown elsewhere on the bill but which were necessary for proper payment. See Gov't Ex. 2 to 12(b)(6) Mem. at 119.27E (Item 94). There was also a blank column that could have been used for non-covered charges. See Gov't Ex. 2 to 12(b)(6) Mem. at 119.21A (Items 54, 55, and 56). On the UB-92 forms, in use after April 1994, in addition to the box for "Remarks," there was a column bearing the heading "Non-Covered Charges" in which the hospitals should have listed charges that were not covered.[46] Likewise, the Cost Report instructions required providers to identify any non-covered items as "protested items." The Hospital Manual contained instructions on how to complete theses forms. The Government asserts that "defendants failed to notify Medicare in any other way that the claims they were submitting were for non-covered investigational devices." (Gov't 12(b)(6) Mem. at 7.) Thus, it describes these as "garden variety 'factually false'" claims. (Id.)

The Court is not convinced that defendants' failure to interpret the instructions on the UB-82 form as requiring the disclosure of non-covered items in the "Remarks" section or in the blank column on that form renders the claim factually false. A stronger argument can be made that defendants' failure to disclose this information on the UB-92 form, which contained a column for "non-covered" charges, was factually false.

Both sides rely on the case of United States ex rel. Berge v. Board of Trustees of University of Alabama, 104 F.3d 1453 (4th Cir.), cert. denied, 522 U.S. 916 (1997), in which the

[46] The Hospital Manual dated September 1994 contained detailed instructions for completion of this form and provided "[t]he total non-covered charges pertaining to the related revenue code in FL 42 are entered here." (Gov't Ex. 4to 12(b)(6) Mem. at 4-552.5.)

Fourth Circuit reversed a jury's finding of liability under the FCA where the plaintiff-relator complained, inter alia, that the University had omitted her name from grant progress reports submitted to the Government. The Court stated, "There can only be liability under the False Claims Act where the defendant has an obligation to disclose omitted information." 104 F.3d at 1461. Defendants cite this case for the proposition that, because they were not expressly directed to disclose that the devices at issue were investigational, they had no obligation to disclose this information and, therefore, cannot be liable under the FCA for failing to do so. The Government, on the other hand, cites this case for the proposition that, because these were non-covered items, defendants had an obligation to disclose this information somewhere or somehow and that their failure to do so rendered the claims factually false.

To adopt defendants' position would allow providers to ignore the Manuals in their entirety, which is an untenable result. At the same time, we have difficulty with the Government's position that the forms were factually false because this information was not set forth in the "Remarks" box or in an unlabelled column. We need not reach the issue of whether the claim forms themselves were factually false, however, because we find that they were legally false under the implied certification theory discussed in Mikes.

ii. Were The Claims Legally False?

As Second Circuit held, because the Medicare Act, 42 U.S.C. § 1395y(a)(1)(A), contains an express condition of payment – "no payment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury," it "explicitly links each Medicare payment to the requirement that the particular item or service be 'reasonable and necessary.'" Mikes, 274 F.3d at

700 (emphasis in original). Citing Heckler v. Ringer, 466 U.S. at 605, the Second Circuit observed "[t]he Supreme Court has noted that this section precludes the government from reimbursing a Medicare provider who fails to comply." Id. Thus, the Court concluded "[s]ince § 1395y(a)(1)(A) expressly prohibits payment if a provider fails to comply with its terms, defendants' submission of the claim forms implicitly certifies compliance with its provision." Id. at 701 (emphasis in original).

Based on the holdings in Mikes and Heckler, we find that in submitting the claims forms, defendants implicitly certified compliance with the Medicare Act § 1395y(a)(1)(A), that they were only seeking payment for services that were reasonable and necessary. To the extent that the forms included requests for payment for services that were not reasonable and necessary, the claims were legally false under an implied certification theory.

On the annual Cost Reports, defendants expressly certified that they were "true, correct, and complete" and "prepared . . . in accordance with applicable instructions, except as noted."[47] To the extent that defendants included in their Cost Reports payments for non-covered items, this would render their certifications false. Thus, as pled, these claims would be legally false under an express certification theory. To hold otherwise would give defendants free reign to submit claims for any and all types of non-covered services.

The Medicare regulations imposed on defendants the obligation to provide the intermediaries with all information necessary to determine whether payment was due. Critical to this determination would be information concerning whether services were provided for a non-

[47] The Government does not rely on an express certification theory in connection with defendants' submission of the UB-82 and UB-92 claim forms.

covered item. As the Eleventh Circuit stated in United States v. Calhoon, 97 F.3d 518, 529 (11th Cir. 1996), cert. denied, 522 U.S. 806 (1997),

> While it is true that a provider may submit claims for costs it knows to be presumptively nonreimbursable, it must do so openly and honestly, describing them accurately while challenging the presumption and seeking reimbursement. Nothing less is required if the Medicare reimbursement system is not to be turned into a cat and mouse game in which clever providers could, with impunity, practice fraud on the government.

Thus, in submitting their claims, defendants were obligated to seek payment only for those services that were covered. To the extent that they sought payment for services that were not covered, the claims were legally false. The Government has alleged in its complaints that defendants knowingly submitted claims for payment of non-covered services provided in connection with investigational devices that were not reasonable and necessary. These FCA causes of action, as pled, set forth sufficient facts to satisfy the third element, that the claims were false or fraudulent.

Regarding the fourth element of a cause of action under the FCA, as discussed above, the Government has pled that the defendants "knowingly" presented false claims; "knowingly" made or used false records to cause false claims to be paid; and "knowingly" made or used false records to avoid the obligation to refund money to the United States, as that term is defined by the FCA. As discussed above, whether the Government will ultimately be able to prove that these claims were submitted "knowingly" is an issue for another day. It is not one that can be resolved on a motion to dismiss.

Finally, the fifth element of a cause of action under the FCA, that the claims sought payment from the federal treasury, is not disputed.

Therefore, we find that the Government has adequately alleged that defendants submitted false or fraudulent claims for purposes of stating a claim under the FCA.

3. The Validity of the Manual Provision

The second ground urged by defendants in support of their Rule 12(b)(6) motion is the invalidity of the Manual provision. They assert that "the Government relies exclusively upon the Manual Provision to support its allegations that inpatient hospital services involving the use of an IDE device were per se non-covered, and that submitting claims to Medicare for such services automatically violated the FCA. . . . The Government's reliance is misplaced." (Defs.' 12(b)(6) Mem. at 16.) Defendants contend that, if they were bound by the Manual provision, then it must be considered a legislative rule subject to the notice-and-comment rule-making requirements of the APA, with which the Government unquestionably did not comply. If it is considered merely interpretive, then it was not binding and cannot form the basis of the Government's FCA claims or the common-law claims, which rely exclusively on the Manual provision. Additionally, they argue that it is arbitrary, capricious, and ambiguous.

The Government maintains that the Manual provision is the "quintessential" interpretive rule and, thus, is not subject to the rule-making requirements of the APA. More importantly, however, it argues, that even if it were invalid, defendants were not at liberty to simply ignore it by submitting claims for non-covered services in violation of its provisions.

As discussed above, all of the cardiac devices at issue were IDE devices being used in clinical trials at the various hospitals. The complaints allege that none of the devices had been approved for marketing by the FDA. (Harper-Hutzel Compl. ¶ 31.) The approval of medical devices for marketing is governed by the Medical Devices Amendments to the Federal Food,

Drug, and Cosmetic Act, enacted in 1976. As discussed in Note 3, supra, all of the devices in these cases were classified by the FDA as "Class III" devices as to which insufficient information existed to "provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(C)(i). Because of the lack of information about the safety and effectiveness of a Class III device, before it can be marketed, it must have "premarket approval" from the FDA.[48] 21 U.S.C. §§ 360c(a)(1)(C) & 360e(a). In 1980, the Secretary promulgated regulations providing a narrow exception to the premarket approval requirement for investigational devices used in clinical trials. This "investigational device exemption" or "IDE" permitted each of the devices in the instant cases to be shipped lawfully by the manufacturers to the hospitals for the purpose of conducting investigations of that device. See 21 U.S.C. § 360j(g); 21 C.F.R. Pt. 812; see generally, Cedars-Sinai, 939 F. Supp. at 1459-60. This exemption, however, says nothing about whether Medicare will provide coverage for services involving that device.

That issue is governed by the Medicare Act, which, as discussed above, provides that "no payment may be made . . . for items or services . . . which . . . are not reasonable and necessary for the diagnosis and treatment of illness or injury. . . .." 42 U.S.C. § 1395y(a)(1)(A). The Act does not define what services are "reasonable and necessary." Rather, pursuant to 42 U.S.C. § 1395ff(a), the Secretary is authorized to define what services meet that criteria. See also Heckler,

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[48] Class I devices are those for which "general controls" are sufficient to provide a reasonable assurance of safety and effectiveness. See 21 U.S.C. § 360c(a)(1)(A). Class II devices are those devices for which general controls in and of themselves are insufficient to provide a reasonable assurance of safety and effectiveness but such assurances can be provided with special controls, such as through performance standards, patient registries, post-market surveillance, or the development of guidelines by the Secretary. See 21 U.S.C. § 360c(a)(1)(B). Class I and Class II devices can be commercially distributed after notification to the FDA without pre-market approval. See 21 U.S.C. § 360c(a)(1)(C).

466 U.S. at 617. This the Secretary has done through regulations and rules published in manuals provided to carriers, intermediaries, and providers, including hospitals. A regulation governing the coverage for IDE devices was not promulgated until 1995. Prior thereto, there was the 1986 Manual provision, and prior to that, only general guidelines set forth in letters to fiscal intermediaries.

In a 1977 letter to fiscal intermediaries regarding coverage of investigational medical devices, HCFA stated:

> Denial of payment for a medical item or service because it is considered experimental or investigational is required by the law excluding unreasonable or unnecessary services from payment (section 1862(a)(1)). Such decisions are based on qualified professional medical community; they are not judgments that a physician's choice is inappropriate or that a patient does not need treatment.

(Defs.' Ex. 3 to 12(b)(6) Mot., Part A Intermediary Letters Nos. 77-4, retrieved from CCH 1976 MED-GUIDE-TB ¶ 28152). Then in a sample letter provided to intermediaries, which was suggested for use in responding to inquiries concerning the coverage of experimental or investigational items and services, "where the inquirer expresses the belief that Medicare dictates what treatment the physician should use," the Guide explains that in making the decision whether a service can be covered under a general provision of the Medicare law, "a basic consideration is whether the service has come to be generally accepted by the professional and medical community as an effective and proven treatment for the condition for which it is being used." Id. at 3. A service would not be covered if it were "rarely used, novel, or relatively unknown" absent "authoritative evidence" of its safety and effectiveness. Id.

As defendants point out, CMS (formerly HCFA) contracts with private fiscal intermediaries, generally insurance companies, to process and pay claims and audit cost reports.

This includes, among other things, making Medicare Part A "reasonable and necessary" coverage determinations as to whether the claims submitted are for covered services and the appropriate amount of reimbursement to the provider. 42 U.S.C. § 1395h(a); 42 C.F.R. § 421.100(a). In making these determinations, the fiscal intermediaries are bound to follow the instructions promulgated by the Secretary. 42 C.F.R. § 405.806. Generally these determinations are made on a case-by-case basis.

The hospitals interpret the 1977 intermediary letters as stating that coverage decisions involving investigational medical devices would likewise be made on a case-by-case basis, and depended on whether the particular service was generally accepted by the professional medical community as an effective and proven treatment.[49] The Government states in its complaints that the 1986 Manual provision represented a change from the prior practice but contends that, even under the previous rule, defendants had an obligation to identify the investigational nature of the devices such that the intermediary would have an opportunity to determine whether there was "authoritative evidence" of the safety and effectiveness of the device. (E.g., Harper-Hutzel Compl. ¶ 26.) Thus, even prior to the 1986 Manual provision, the Government claims that the defendants' submissions would have false because they did not indicate that the devices were classified by the FDA as investigational.

However, as of 1986, when HCFA inserted the provision at issue into the Hospital Manual, Carriers' Manual, and Intermediaries' Manual, a per se rule was established that no

[49] The hospitals point to the fact that the fiscal intermediaries regularly reimbursed hospitals for services involving investigational devices. This is not properly before the Court on this motion to dismiss. Additionally, it is not clear whether, in so doing, the fiscal intermediaries were aware of the fact that investigational devices were involved.

coverage would be provided for medical procedures or services performed using "medical devices which have not been approved for marketing by the FDA," because they were considered not reasonable and necessary for the treatment and diagnosis of illness or injury. (E.g., Hospital Manual § 260.1B.) This was identified as a "new policy," with a prospective effective date of July 15, 1986. It is undisputed that this provision was added to the Manuals without notice-or-comment.

As discussed above, on September 19, 1995, HHS for the first time published regulations concerning the coverage for IDE devices. In contrast to the total exclusion from coverage of such devices under the Manual provision, the new regulations classified such devices as either experimental/investigational ("Category A") for which there continued to be no coverage, or non-experimental/investigational ("Category B") which were eligible for Medicare coverage. See 42 U.S.C. §§ 405.201, 405.203(a), 405.205, 405.209, 405.211. Over 90% of the medical devices sold for use in FDA-approved clinical trials are Category B devices and are eligible for Medicare coverage. 61 Fed. Reg. 15491, 15501-04 (Apr. 8, 1996).

a. Was The Manual Provision A Legislative Rule?

Section 553 of the APA requires that when an agency engages in rule-making, it must provide notice of the proposed agency rules, followed by a period for public consideration and comment. 5 U.S.C. § 553(b), (c); see Sweet v. Sheahan, 235 F.3d 80, 90 (2d Cir. 2000). The statute, however, provides an exception for "interpretative rules, general statement of policy, or rules of agency organization, procedure or practice." 5 U.S.C. § 553(b)(3)(A). While the APA does not define "interpretative rules," (often referred to as "interpretive rules"), the Second Circuit has developed several general formulations to distinguish interpretive rules from those

that are substantive or legislative. Sweet, 235 F.3d at 90.

In White v. Shalala, 7 F.3d at 303, the Second Circuit, following the lead of the Seventh Circuit in Metropolitan School District v. Davila, 969 F.2d 485, 488 (7th Cir. 1992), cert denied, 507 U.S. 949 (1993), held that the "better approach"[50] to deciding whether a rule was subject to the notice-and-comment requirements of the APA was to determine whether the rule was interpretive or "legislative." "The central question is essentially whether an agency is exercising its rule-making power to clarify an existing statute or regulation, or to create new law, rights, or duties in what amounts to be a legislative act." Id. ; see also Sweet, 235 F.3d at 91 (holding that "legislative rules are those that create new law, rights, or duties, in what amounts to a legislative act") (internal citations and quotation marks omitted). Applying this standard in White, the Second Circuit held that the Social Security rule at issue was interpretive rather than legislative, because it determined only how a portion of the veteran's benefits would be treated "under an existing statutory provision, rather than creating an extra-statutory requirement, and thus is a paradigmatic example of an interpretive rule." Id. at 304. "Because the rule clarifies an ambiguous term, it fits within the definition of an interpretive rather than a legislative rule." Id. The Court specifically addressed and rejected the position that the rule was legislative because it was a change from the Secretary's prior interpretation. "[A]n interpretive rule changing an

[50] The Second Circuit had previously held that the proper approach was to focus on whether the rule is interpretive or substantive. A substantive rule "'grants rights, imposes obligations, or produces other significant effects on private interests,' while an interpretive rule is an agency's 'intended course of action, its tentative view of the meaning of a particular statutory term, or internal house-keeping measures organizing agency activities." White v. Shalala, 7 F.3d at 303 (quoting Perales v. Sullivan, 948 F.2d 1348, 1354 (2d Cir. 1991)). Noting that at least one circuit had criticized the interpretive/substantive approach on the ground that an interpretive rule could have substantive effects, the Court held that the better course was to follow the interpretive/legislative approach. Id.

agency's interpretation of a statute is not magically transformed into a legislative rule." Id. "If the rule is an interpretation of a statute rather than an extra-statutory imposition of rights, duties or obligations, it remains interpretive even if the rule embodies the Secretary's changed interpretation of the statute." Id.

We agree with the Government that, in the instant cases, the Manual provision was an interpretation of the statutory phrase "reasonable and necessary" rather than an "extra-statutory imposition of rights, duties or obligations."[51] Numerous other courts have found Medicare manual provisions to be interpretive, rather than legislative. In Shalala v. Guernsey Memorial Hospital, the Supreme Court characterized a provision in the Medicare Provider Reimbursement Manual as the "prototypical example of an interpretive rule." 514 U.S. at 99. The manual provision required the provider hospital to amortize an accounting loss realized from the refinancing of its bonded debt over a number of years, rather than claiming the entire loss in one year. Id. at 90-91. The Court found that the manual provision was "the means to ensure that capital-related costs allowable under the regulations are reimbursed in a manner consistent with the statute's mandate that the program bear neither more nor less than its fair share of costs. 42

[51] Our holding is contrary to that of the Central District of California, which on summary judgment, held that the Manual provisions were substantive rules, subject to the notice-and-comment rule-making provisions of the APA. Cedars-Sinai, 939 F. Supp. at 1464-65. In that case, the court found that the Manual provision was "substantive," applying the test of whether it effected a change in existing law or policy, or removed previously existing rights. Id. at 1464 (citing Linoz v. Heckler, 800 F.2d 871, 877 (9th Cir. 1986)). The court considered the evidence of record (which is not before this Court), that demonstrated that prior to the 1986 Manual provision, fiscal intermediaries determined on a case-by-case basis whether an investigational device was reasonable and necessary. Because the Manual provision categorically excluded from coverage all investigational devices if they were not approved for marketing by the FDA, the court held that "instead of simply clarifying 'necessary and reasonable,' the Manual provision carved out a per se exception." Id. at 1465. Thus, the court found it to be a substantive rule, subject to the notice-and-comment requirements of the APA. Id.

U.S.C. § 1395x(v)(1)(A)(i)." Id. at 97. Likewise, in St. Mary's Hospital, 788 F.2d at 891, the Second Circuit held that "Manual rules have consistently been held to be 'interpretive rules," and thus exempt from the notice and comment requirements."[52] And, in St. Francis Health Care Center v. Shalala, 205 F.3d 937, 946-47 (6th Cir. 2000), the Sixth Circuit held that a provision in the provider reimbursement manual, which established a new method for calculating upward adjustments to statutory reimbursement cost limits for skilled nursing facilities, was an interpretive rule. The court held that the rule reasonably interpreted a statute and regulation that placed the determination of the "reasonableness" of costs and the "typicality" of services in the hands of the Secretary. Id.; see also Mt. Sinai Medical Center v. Shalala, 196 F.3d 703, 711 (7th Cir. 1999)(holding that a provision in a provider reimbursement manual was interpretive).

In the instant case, the fact that the Manual provision may have been a departure from the prior position of the Secretary is not determinative. See White, 7 F.3d at 303. Moreover, the fact that a regulation was subsequently adopted does not transform this interpretive rule into a legislative rule.[53] Accordingly, because we find that it was interpretive as opposed to legislative,

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[52] The Court further noted that the Manual provisions at issue were adopted in 1968 and Medicare regulations became subject to the APA only in 1971, and, thus, the APA does not apply to actions taken by the agency pursuant to those regulations before that time. St. Mary's Hospital, 788 F.2d at 891.

[53] In 1987, as part of the Omnibus Budget Reconciliation Act, Pub. L. 100-203 § 4035, 101 Stat. 1330-78 (1987), the Medicare Act was amended to add a rule-making requirement, which provides:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals [or others] to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

it was not subject to the notice-and-comment requirements of the APA and cannot be held invalid based on the Secretary's failure to comply with these provisions. See White, 7 F.3d at 304.

b. Were The Hospitals Bound By This Interpretive Rule?

Defendants argue in the alternative that if the Court finds that the Manual provision was an interpretive rule, then the provision must be treated as non-binding. If the Manual provision is non-binding, then the hospitals argue that they cannot be liable for falsely claiming payment for services that would not have been covered based on the Manual provision.

The Government responds that it has never been the law that defendants were at liberty to violate an interpretive Manual provision. Indeed, there have been numerous cases imposing FCA liability, and even criminal false claims liability, based on violations of Medicare manual provisions. See, e.g., United States v. Weiss, 914 F.2d 1514 (2d Cir. 1990); United States v. Mackby, 261 F.3d 821 (9th Cir. 2001);[54] United States v. Larm, 824 F.2d 780 (9th Cir. 1987),

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42 U.S.C. § 1395hh(a)(2). In Cedars-Sinai, 939 F. Supp. at 1463, the court held that this section could not be applied retroactively to the Manual provision.

[54] In United States v. Mackby, the Ninth Circuit affirmed the judgment against the owner of a physical therapy clinic for violating the FCA when he submitted Medicare claims using the personal identification number ["PIN"] for his father, who was a physician, thus giving the impression that the physical therapy services had been performed by a physician. Under Part B of Medicare, physical therapy services are covered only when rendered by a physician or a qualified employee of a physician or physician-directed clinic or by a physical therapist in an independent practice. 261 F.3d at 824 (citing Medicare Bulletin, Mar. 1993, at 22). The court relied on the Medicare fiscal intermediaries bulletin in finding that box 24k on the HCFA-1500 form was to be filled in with the assigned PIN for the performing physician or supplier. The court noted that while the purpose of box 24k is not specified on the form itself, Medicare bulletins sent to the defendant's clinic stated that this box was to be used for the PIN of the performing physician. Placing his father's PIN in this box indicated that his father was the performing physician and therefore constituted a false statement. Id. at 261. The court rejected the defendant's argument that the claims were not false because the services were actually

cert. denied, 484 U.S. 1078 (1988);[55] United States v. Calhoon, 97 F.3d 518 (11th Cir. 1996).[56] The Government asserts that defendants could have challenged this provision through the administrative process, but they could not secretly bill for non-covered items, where there was no way of telling that the devices were investigational, and then claim that this is not a false claim. See United States v. Knox, 396 U.S. 77, 79 (1969) (upholding a criminal conviction of defendant despite his constitutional challenge to the statute he violated).

None of the cases cited by defendants stands for the proposition that the hospitals were at liberty to ignore the Manual provision simply because it was an interpretive rule, as opposed to a

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performed. "[T]he fact that physical therapy services were actually rendered does not negate [defendant's] false representation that Dr. Mackby performed the services described on the claim forms . . . It is the representation of Dr. Mackby's involvement that is 'false,' and that falsity is sufficient to satisfy the first element of an FCA claim [a false or fraudulent claim]." Id. at 827.

[55] In United States v. Larm, a doctor and his wife were convicted of Medicaid fraud. They were accused of using the wrong billing codes for medical services that were performed. They challenged their conviction in part based on the fact that the code book was never adopted as a rule in conformance with the state's APA. The Ninth Circuit held that their argument was "without merit. The Larms were prosecuted under 42 U.S.C. § 1396h(a)(1), not the billing codes." 824 F.2d at 784. "Any attack on the billing codes which formed the factual backdrop that made the statements false is ultimately an attack on the sufficiency of the evidence. . . If the Larms had proved that they did not know of the codes, or had proved that the codes were too vague to be understood, then there could be no knowingly false statement. But the jury found that they understood the significance of the billing codes that they used, and the record supports this finding." Id.

[56] In United States v. Calhoon, the defendant was convicted of submitting Medicare cost reports to fiscal intermediaries, claiming amounts that he knew not to be reimbursable. The defendant challenged his conviction on the ground that the administrative guidelines in the Provider Reimbursement Manual gave only presumptive guidance, that the intermediaries' decisions were only presumptive, and that the denial of reimbursement could be challenged. 97 F.3d at 529. The Eleventh Circuit disagreed and held that "[w]hile a provider may submit claims for costs that it knows to be presumptively nonreimbursable, it must do so openly and honestly, describing them accurately while challenging the presumption and seeking reimbursement." Id. In that case, defendant Calhoon could have filed the cost report under protest, in accordance with the instructions in the Provider Reimbursement Manual.

legislative rule promulgated after notice and comment. Indeed, in United States v. Yuzary, 55 F.3d 47 (2d Cir. 1995), cited by defendants, the Second Circuit upheld a criminal defendant's conviction based upon his violating an interpretive rule. There, the defendant challenged his conviction for willfully failing to file an accurate report as to the amount of currency he was transporting out of the United States and for making false statements to the U.S. Customs Inspector on a Customs form. The defendant claimed that the Customs form was a legislative rule that had not been promulgated in accordance with the notice-and-comment requirements of the APA. The Second Circuit held that it was an interpretive rule, not subject to the notice and comment requirements of the APA, yet binding on the defendant and, therefore, the Court upheld his conviction.[57]

Drake v. Honeywell, Inc., 797 F.2d 603 (8th Cir. 1986), also cited by defendants, is distinguishable. In that case, the Eighth Circuit held that the defendant's failure to comply with product hazard reporting rules, which were interpretive rules issued by the Consumer Products Safety Commission, did not give rise to a private cause of action. In this case, neither a private party nor the Government is attempting to assert a cause of action for defendants' violation of the Manual provision. Rather, the Government is claiming a violation of the FCA, based upon defendants' filing of allegedly false claims.

Likewise, the case of United States ex rel. Swafford v. Borgess Medical Center, 98 F. Supp. 2d 822, 828 (W.D. Mich. 2000), aff'd, 24 Fed. Appx. 491, 2001 WL 1609913 (6th Cir. Dec. 12, 2001), cert. denied, 535 U.S. 1096 (2002), is distinguishable on its facts. In Swafford,

[57] The Second Circuit also rejected as "frivolous" the defendant's claim that the form was ambiguous because, while requiring him to disclose the "amount" of transported currency, it did not specify that the total or exact amount had to be disclosed. Yuzary, 55 F.3d at 53.

the relator brought an action under the FCA against a group of doctors, claiming that they had improperly billed Medicare for venous ultrasound studies. Since there were no specific billing regulations governing venous ultrasounds, the relator relied on HCFA's Carriers Manual regulations on radiology as governing venous ultrasounds. The court "decline[d] to judge the truth or falsity of defendants' representations" based upon the Carriers Manual, which did not even "purport to address the physician's decision to submit a claim for reimbursement, and most importantly, [did] not dictate" the services required of the physician in order to use a particular billing code. 98 F. Supp. 2d at 828. Here, however, the Government's FCA claims are based on a provision in the Hospital Manual, which was intended for use by the Hospitals and which addressed the very subject on which they were submitting claims.

In United States v. Weiss, the defendants were convicted of making false statements on Medicare claims in violation of the instructions in the Medicare Carriers Manual. The Second Circuit held that even if the provision was invalid under the Paperwork Reduction Act, that would not be a defense to defendants' conviction for knowingly providing false information to Medicare.[58] 914 F.2d at 1521-23.

Defendants seek to distinguish Weiss on the ground that it involved a defendant's

[58] The Court in Weiss cited the Supreme Court's decision in Dennis v. United States, 384 U.S. 855, 867 (1966), which held that defendants, who had been convicted of conspiring to defraud the United States by filing non-Communist affidavits with the National Labor Relations Board, could not challenge their convictions on the ground that the statute requiring the filing of the affidavits was unconstitutional. "This is a prosecution directed at petitioners' fraud. It is not an action to enforce the statute claimed to be unconstitutional." Id. Applying this holding, the Second Circuit in Weiss held, "[if], as those cases held, it is no defense to a charge of filing false statements that the statute requiring the filing is unconstitutional, a fortiori, it is no defense to a charge of filing false statements that the government document that prescribed the details of filing had not been approved by the Director of the Office of Management and Budget, as the Paperwork Reduction Act allegedly required." 914 F.2d at 1522-23.

intentional misstatement on a Medicare claim form. "In contrast to Weiss and like cases, there are no allegations here that the hospitals mischaracterized the services provided or likewise lied on the claims." (Defs.' 12(b)(6) Reply Br. at 2.) "The Government has alleged no such false statements here, nor could it. Instead, the Government argues that the Defendants' claims were false because the Defendants should have somehow alerted HHS that they were for hospital care involving the use of an 'investigational device' or that such care was automatically 'non-covered' solely by virtue of the Manual Provision." (Defs.' 12(b)(6) Reply Br. at 4) (footnotes omitted, emphasis in original).

We fail to appreciate the difference between the instant case, where defendants are accused of putting non-covered services on Medicare claims forms without disclosing that the services were not covered, and the defendant's failure in Calhoon to properly identify advertising costs in accordance with the Providers' Reimbursement Manual, or the defendant's putting the wrong address on a Medicare form in Weiss in violation of a Medicare manual provision, or the defendant's putting the wrong provider number on a Medicare form in Mackby, also in violation of a Medicare manual provision, or the defendant's using the wrong billing code in Larm in violation of a state Medicaid code book. Here, the Government is seeking to hold defendants liable for violations of the FCA based upon defendants' submitting claims for non-covered services based on a Hospital Manual provision applicable to the hospitals.

To adopt defendants' position that interpretive rules are not binding would effectively nullify the Medicare manuals in their entirety and would allow defendants to submit claims for any and all types of non-covered services that clearly were not reasonable or necessary. As the Court held in Mikes, 274 F.3d at 701, in light of the express statutory prohibition on payment for

services that are not reasonable and necessary, 42 U.S.C. § 1395y(a)(1)(A), the defendants' submission of the claim forms implicitly certified compliance with this provision – that the services for which they were seeking payment were reasonable and necessary or otherwise covered by Medicare.

The Second Circuit's decision in Weiss was cited by the Ninth Circuit in Cedars-Sinai, 125 F.3d at 769, in response to an argument by the Relator that the hospitals were merely forum-shopping in an effort to invalidate the Manual provision, which they would then use as a defense in the qui tam action. In rejecting this argument, the Court noted "[e]ven if the Hospitals succeed in having the rule declared invalid, . . . that will be no defense to the Relator's claims under the False Claims Act. . . . If the Hospitals did indeed knowingly submit false claims in order to receive payment for devices not covered under the 1986 rule, the invalidity of the rule will be no defense." Id. To paraphrase the Supreme Court's decision in Dennis v. United States, 384 U.S. at 867, "One who elects [to file false claims] as a means of self-help may not escape the consequences by urging that his conduct be excused because the [Manual provision] which he sought to evade is [invalid]."

Thus, we disagree with defendants' position that an interpretive rule cannot form the basis of a claim under the FCA. However, that is not to say that a violation of a Manual provision is per se a violation of the FCA. As discussed above, the FCA requires the submission of a false claim to have been done "knowingly," as that term is defined by the Act. Although this has been alleged by the Government, it has not been proven and is a matter that cannot be resolved on a motion to dismiss.

c. Whether The Manual Provision Was Invalid Because It

Was Arbitrary And Capricious Or Ambiguous?

Defendants next claim that the Manual provision was "arbitrary and capricious" because it arbitrarily reversed its prior position, without explanation, and took the implausible position that no IDE device, including refinements in technology already approved for general commercial marketing, could ever be reasonable and necessary. Additionally, defendants argue that the provision was "ambiguous" since it is not clear whether or not IDE devices were considered devices that were approved for marketing or devices that were "reasonable and necessary," particularly in light of the 1995 regulations.

The difficulty we have with defendants' argument is two-fold. First, courts are required to give substantial deference to an agency's interpretation of its own regulations. Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994). An agency's interpretation must be given "controlling weight unless it is plainly erroneous or inconsistent with the regulation." Id. (internal citations and quotation marks omitted). A court must defer to the Secretary's interpretation unless an "alternative reading is compelled by the regulation's plain language or by other indications of the Secretary's intent at the time of the regulation's promulgation." Gardebring v. Jenkins, 485 U.S. 415, 430 (1988). This deference is particularly warranted when the regulatory program is highly technical and complex. Thomas Jefferson University, 512 U.S. at 512. Clearly, the Medicare reimbursement regulations would qualify as highly technical and complex.

Second, based on the information before the Court on this motion to dismiss, including the 1977 Intermediary Letters, we cannot say that the Manual provision was arbitrary and capricious. The fact that the devices at issue were investigational and were provided to

defendants pursuant to an IDE is not disputed. The 1977 Intermediary Letter, provided to the Court by defendants, states that "[d]enial of payment for a medical item or service because it is considered experimental or investigational is required by the law excluding unreasonable or unnecessary services from payment (section 1862(a)(1))." While the decision as to whether a device was investigational may have been left to the intermediaries to be made on a case-by-case basis, it cannot be said that there was no precedent for the exclusion of coverage for investigational devices.

Additionally, this issue comes before the Court on a motion to dismiss where we are limited to considering the complaint and matters of which the Court can take judicial notice. We have little information (other than general statements by defendants' counsel) as to the treatment of investigational devices prior to the 1986 Manual provision. We cannot state at this juncture, based on the limited information before us, that the Manual provision was a total departure from the Secretary's previous treatment of IDE devices.

We likewise reject defendants' argument that the provision was ambiguous. There is nothing in the statute or regulations governing IDE devices, discussed above, that would indicate that they were approved for marketing.

Therefore, for the reasons stated above, we deny defendants' motion to dismiss for failure to state a claim upon which relief may be granted.

C. Motion to Dismiss on Statute of Limitations Grounds

1. The Parties' Contentions

The third motion to dismiss filed by the defendants collectively[59] is a motion to dismiss

[59] Again, this motion is joined in by all forty defendants.

the Government's complaint as barred by the statute of limitations. Defendants argue that the Government did not file its complaints until 2002 at the earliest,[60] yet its claims concern Medicare billings from 1986 through 1995. The FCA claims, defendants contend, are barred by the six-year statute of limitations applicable to claims under the FCA, 31 U.S.C. § 3731(b)(2). The common-law claims are barred by the six-year statute of limitations set forth in 28 U.S.C. § 2415(a). Additionally, the fraud claims asserted against five of the hospitals are barred by the three-year statute of limitations applicable to fraud claims. Finally, the government's complaints should be dismissed pursuant to Rule 41(b), Fed. R. Civ. P., for failure to prosecute. The Government, by litigating this matter ex parte, was able to extend the sixty-day period of the FCA to over eight years, without any adversary party's having the opportunity to challenge the numerous requests for extension of time. Additionally, no party was able to challenge the Government's request that the individual actions be severed and transferred. Defendants contend that there were fatal flaws in the Relator's original complaint, most notably that venue was improper with respect to all defendants except two and that there was a misjoinder of the 132 defendants in a single action, in contravention of Rule 20(a), Fed. R. Civ. P. Therefore, citing Spar, Inc. v. Information Resources, Inc., 956 F.2d 392 (2d Cir. 1992), and Nassau County Association of Insurance Agents, Inc. v. Aetna Life & Casualty Co., 497 F.2d 1151 (2d Cir. 1974), they assert that the qui tam action should have been dismissed rather than transferred. They argue that further prosecution of this action would violate their fundamental right to due process since they cannot adequately defend themselves against the charges raised against them.

Both the Government and Relator Cosens have filed memoranda in opposition to this

[60] The Government's complaints were filed between August 15, 2002, and May 29, 2003.

motion.

The Government responds that under the FCA, the critical date for purposes of the statute of limitations is when the Relator filed his complaint, 1994, not the date on which the Government filed its complaints-in-intervention. The Government asserts that under Rule 15(c)(2), Fed. R. Civ. P., its complaints relate back to the filing of the original qui tam complaint for statute of limitations purposes, since they are based on the same transactions and occurrences as the original complaint. Additionally, defendants have overlooked the second part of the statute of limitations for FCA claims, 31 U.S.C. § 3731(b)(2), which provides that an action must be brought within three years of when the Government learns of its right of action, but in no event not more than ten years after the date on which the violation is committed. Defendants do not contend that the Government was aware of the Relator's claims more than three years before the qui tam complaint was filed. Therefore, the Government maintains that it can recover for any claims that arose within ten years of the date the Relator filed his complaint on March 31, 1994. Since all of the Medicare claims were filed within ten years of the date the Relator filed his complaint, none of the claims is time-barred. To the extent that the hospitals argue they have been denied procedural due process, they were on notice of these claims for years, dating back to 1994 when subpoenas were issued to each of the hospitals. They were involved in lobbying efforts to change the Medicare policy, a number of the defendants were involved in the Cedars-Sinai litigation and received redacted copies of the complaint, and some of the defendants filed motions in the qui tam action even though they had not been served with the complaint. Also, before the Government decided to intervene in these cases, virtually every defendant had an opportunity to enter into settlement negotiations.

The Relator responds to defendants' argument that his complaint, as originally filed, should have been dismissed for improper venue. He states that in filing a single action in the Western District of Washington against 132 hospitals, he relied in good faith on the 1986 amendments to the FCA, 31 U.S.C. § 3732(a),[61] which added a special venue provision and relaxed the joinder rules, thus allowing him to bring one action in one district against all defendants that had engaged in a common scheme of fraud. Additionally, to the extent the hospitals claim that they had not been on notice of the suit, Relator Cosens states that, since 1994, there has been national newspaper coverage and trade publication articles about the subpoenas, the allegations, the Government's investigation, the defendants' attempt to change the regulations retroactively. He also notes that all of the defendants received subpoenas from the Government, and prior to the filing of his suit, his counsel met with counsel for over 100 of the hospitals in an effort to settle this litigation. Therefore, he argues, there is no merit to their claim that they did not have notice.

2. The FCA Statute of Limitations

The FCA provides that "[a] civil action under section 3730 may not be brought–

> (1) more than 6 years after the date on which the violation of section 3729 is committed, or
>
> (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the

[61] Section 3732(a), "Actions under section 3730," added by Pub. L. 99-562, § 6(a), Oct. 27, 1986, 100 Stat. 3158, provides in relevant part:

> Any action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred.

official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,

whichever occurs last.

31 U.S.C. § 3731(b)(2) (emphasis added). Thus, section 3731(b) establishes two alternative limitations periods for FCA actions. Whichever occurs last is the period that will govern.

a. Does the Government's Complaint Relate Back to the Relator's Complaint?

The initial issue that must be addressed is whether the controlling date for statute of limitations purposes is when the Government filed its complaints-in-intervention or when the Relator filed his original qui tam complaint. The Government contends that a plain reading of section 3731(b) compels a finding that the date the Relator filed his complaint controls and that Government's complaints relate back to the filing of the Relator's complaint under Rule 15(c)(2), Fed. R. Civ. P.[62] Defendants argue that Rule 15(c)(2) applies only to "amended" complaints, and the Government has not filed an "amended" complaint. Moreover, they argue that there can be no relation back because they were not given notice of the original qui tam complaint.[63]

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[62] Rule 15(c), Fed. R. Civ. P., provides in relevant part:

(c) Relation Back of Amendments. An amendment of a pleading relates back to the date of the original pleading when

. . .

(2) the claim or defense asserted in the amended pleading arose out of the conduct, transaction, or occurrence set forth or attempted to be set forth in the original pleading. . . .

[63] Defendants have provided the Court with a chart showing the dates on which the forty defendants in this MDL case received copies of the qui tam complaint from the Government. The Government disagrees with the information provided. According to defendants, ten defendants, which were also involved in the Cedars-Sinai litigation received the complaint in August of 1995; another hospital in the Cedars-Sinai litigation received it in 1996; two

One of the difficulties we encounter in ruling on this motion to dismiss is attempting to reconcile traditional procedural rules with the unique nature of qui tam proceedings. At the outset, we hold that the title given the Government's complaint is not determinative of the relation back issue. See United States ex rel. Purcell v. MWI Corp., 254 F. Supp. 2d 69, 75 (D.D.C. 2003) (rejecting this argument). This argument by defendants elevates form over function. Additionally, the Relator brought his initial complaint on behalf of the United States. Thus, although the Relator and the United States are one and the same, there is an identity of interest between the original plaintiff and the United States. We hold that Rule 15(c)(2) may apply to a complaint-in-intervention filed by the United States in a qui tam proceeding, even though it is not technically an amended complaint by the original party.

Rather, the critical issue, as set forth in Rule 15(c)(2) is whether "the claim or defense asserted in [the Government's pleading] arose out of the conduct, transaction, or occurrence set forth or attempted to be set forth in the original pleading." In this case, the Government's complaints clearly arose out of the same conduct as the Relator's complaint, and the substance of the Government's complaints and the Relator's complaint is the same – that the defendants improperly billed Medicare for procedures involving investigational cardiac devices in violation of the FCA. Although the Government's complaints break down the FCA allegations into three counts and include common-law counts that were not set forth in the qui tam complaint, nevertheless, as defendants have frequently pointed out, all of the counts are premised on the

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defendants received it in the fall of 1999, two in 2000, five in 2001, eight in 2002, and ten claim to have never received a copy from the Government. (Defs.' Ex. 45 to Reply to S/L Mot.) In particular, Good Samaritan Hospital argues in a separately filed memorandum that, although it received a government subpoena in 1994, it never heard from the Government or Relator again until 2002.

same factual allegations as the Relator's original complaint. "The Second Circuit has repeatedly made clear that where a revised pleading contains alternative theories based on the same core facts as presented in a prior pleading, the alternative pleadings relate back to the original. Provided the amended pleading is based on the same series of transactions and occurrences alleged in the original pleading, the revised pleading will relate back to the original pleading, even where the revised pleading contains legal theories not included in the original. " Wells v. Harris, 185 F.R.D. 128, 131 (D. Conn. 1999) (citing White v. White Rose Food, 128 F.3d 110, 116 (2d Cir.1997); Travelers Ins. Co. v. 633 Third Assocs., 14 F.3d 114, 125 (2d Cir. 1994)) (footnotes omitted).

In United States ex rel. Downy v. Corning, Inc., 118 F. Supp. 2d 1160, 1170 (D.N.M. 2000), the defendants argued that the critical date for statute of limitation purposes is when the relator's complaint was unsealed, as opposed to when it was filed. The court noted that section 3731(b) refers to a "civil action under 3730," which concerns actions by private persons, as well as by the Attorney General. The court held that the limitations provisions of section 3731 refer to the relator's initial act of filing the civil action, not to the date when the complaint is unsealed. Id. To hold otherwise, the court reasoned, would pressure the Government to decide immediately whether to intervene in a relator's lawsuit, rather than requesting extensions of the sixty-day period for good cause, as permitted by § 3730(b)(2) and (3). "[N]othing in the statute or in the legislative history indicates Congress intended such a result." Id. "[U]nder Defendants' argument, each time an extension is granted to the government more potential false-claim recoveries recede behind the barrier of the continuously-moving limitations period." Id.; see also United States ex rel. Costa v. Baker & Taylor, Inc., No. C-95-1825-VRW, 1998 WL 230979, at

*3 (N.D. Cal. Mar. 20, 1998) (holding that the critical date for FCA claims is when the relator filed his complaint).

Thus, we hold that Rule 15(c)(2) applies to allow the Government's FCA claims asserted in its complaints-in-intervention to relate back to the filing of the Relator's original complaint.[64] See United States ex rel. Purcell, 254 F. Supp. 2d at 76. Our holding in this regard is in keeping with the purposes underlying the FCA and the statutory framework for the filing of qui tam actions.

b. What Is The Applicable Limitations Period?

The next issue is which limitations period to apply. Defendants, citing United States ex rel. Thistlethwaite v. Dowty Woodville Polymer, Ltd., 6 F. Supp. 2d 263, 265 (S.D.N.Y. 1998), and United States ex rel. Drake v. Norden Systems, Inc., No. 3:94cv963, 2000 WL 1336497 (D. Conn. Aug. 24, 2000), argue that subsection (2) of § 3731(b) does not apply to actions brought by a relator. Thistlethwaite, however, supports the Government's position that a ten-year limitations period should apply, running from the date the Relator filed his complaint, so long as the Government did not know of the Relator's claims more than three years prior to the filing of the qui tam action. In Thistlethwaite, the relator had filed his qui tam action on May 12, 1994 and the Government intervened in 1995, seeking damages for all claims dating back to May 12, 1984. The court held that all government claims arising on or after May 12, 1984, ten years prior to the date the relator filed his action were timely so long as the Government had not learned of the claims more than three years prior to when the action was filed. 6 F. Supp. 2d at 265. This

[64] Having found that the Government's complaints relate back to the Relator's original filing, we need not address the tolling arguments raised by defendants.

is the position urged by the Government in the instant case. As defendants point out, the Thistlethwaite court did hold that the relator's time for filing his complaint was not extended to three years after the United States learned of the violation and applied the six-year limitations period of § 3731(b)(1). Id. But, that is not the issue before this Court.

In United States ex rel. Drake, also relied upon by defendants, the United States had declined to intervene and the relator's case was unsealed and served on the defendants. The Court held that subsection (b)(2) applied only to qui tam actions in which the Government intervened and, thus, the Court considered only the six-year statute of limitations of subsection (b)(1) with respect to the relator's action. 2000 WL 1336497, at *13; but see, United States ex rel. Downy, 118 F. Supp. 2d at 1168-70 (holding that § 3731(b)(2) did apply to a relator's action where the Government declined to intervene and noting the split among the courts on this issue). Here, however, the Government has intervened and, thus, the limitations period of subsection (b)(2) applies.

Under this section, so long as the Government was not aware of the Relator's claims more than three years prior to when he filed the original qui tam action (and there is nothing in the complaint that would indicate that the Government knew of these claims prior to March 31, 1991), the Government's action reaches all Medicare claims filed by defendants ten years prior thereto, that is, all claims filed on or after March 31, 1984. Based on the allegations of the complaints, which challenge claims between 1986 and 1995, the Government's complaint-in-intervention was timely filed as to all of the challenged claims.

3. Statute of Limitations Applicable to Common-Law Claims for Unjust Enrichment, Restitution, and Payment by Mistake

Defendants also argue that the Government's common-law claims for unjust enrichment, restitution, and payment by mistake are barred by the six-year statute of limitations set forth in 28 U.S.C. § 2415(a), which provides that "every action for money damages brought by the United States . . . which is founded upon any contract express or implied in law or fact, shall be barred unless the complaint is filed within six years of when the cause of action accrues." The Government has not addressed this issue in its opposition papers. We agree with defendants that this statute of limitations governs the Government's common-law claims for restitution, unjust enrichment, and payment by mistake. See United States v. Intrados/International Management Group, 265 F. Supp. 2d 1, 13-14 (D.D.C. 2002). The more difficult issues are whether the Government's common-law claims relate back to the Relator's filing of his qui tam complaint and when the causes of action accrue.

We have already held that the Government's claims under the FCA relate back to the filing of the Relator's original qui tam complaint on March 31, 1994. Defendants urge us not to apply this relation back doctrine to the common-law claims based on the holdings from several other district courts. As they note, the Second Circuit has not addressed this issue and there is sparse authority from other courts. Indeed, what authority there is has reached conflicting results.

In United States ex rel. Wilkins v. North American Construction Corp., No. Civ. A. H-95-5614, 2001 WL 34109383, *13 (S.D. Tex. Sept. 26, 2001), the court held the Government's common-law fraud claims set forth in its complaint-in-intervention did not relate back to the filing of the relator's original complaint where the defendants had no prior notice of the claims. In United States v. Reagan, No. CIV 97-169-TUC-WDB, 1999 U.S. Dist. LEXIS 22287, at **14-15 (D. Ariz. 19, 1999), although the court allowed the Government's FCA claim to relate back, it

held that the Government's common-law claim for unjust enrichment did not relate back to the filing of the relator's complaint because this was a claim that could not have been asserted by the relator. There was no identity of interest because only the United States could prosecute and seek relief on that claim.

On the other hand, in United States ex rel. Purcell, the court applied the relation back doctrine to the entire complaint brought by the Government. The Government's common-law claims arose out of the same nucleus of operative facts set forth in the relator's complaint and the relator's complaint provided the defendants with adequate notice of the Government's claims. 254 F. Supp. 2d at 76. And, in United States ex rel. Campbell v. Lockheed Martin Corp., 282 F. Supp. 2d 1324 (M.D. Fla. 2003), the court held that under Rule 15(c)(2), the Government's common-law claims related back to the date the relator filed his complaint.

The Second Circuit has held repeatedly that an amended pleading, which is based on the same series of transactions and occurrences alleged in the original pleading, will relate back to the original pleading, even where the revised pleading contains legal theories not included in the original. See, e.g., White v. White Rose Food, 128 F.3d at 116; Travelers Ins. Co. v. 633 Third Assocs., 14 F.3d at 125; Villante v. Department of Corrections of City of New York, 786 F.2d 516, 520 (2d Cir. 1986). Although we have not found a Second Circuit decision addressing this issue in the context of common-law claims first asserted by the Government in a qui tam action, we discern no reason why that the same analysis would not apply. If anything, the reasons for allowing the Government's complaint to relate back are more compelling in the context of a qui tam action, where the very statute under which the action is brought contemplates that, if the Government intervenes, an amended complaint or complaint-in-intervention will be filed.

Moreover, to allow the FCA causes of action to relate back but not the common-law claims would deprive the Government of its ability to plead alternative theories of liability arising out of the same conduct, transaction, or occurrence that underlies the FCA causes of action. See, e.g., United States v. McLeod, 721 F.2d 282 (9th Cir. 1983) (finding that defendant's conduct constituted both a violation of the FCA and common-law conversion).

Therefore, based on what we believe to be the better-reasoned line of authority and in keeping with overall principles governing the relation back of pleadings in the Second Circuit, we hold that the Government's common-law claims in this case relate back to the filing of the Relator's complaint on March 31, 1994, and, thus, any claims accruing prior to March 31, 1988, are barred by the six-year statute of limitations unless tolled.

Generally, causes of action for unjust enrichment, recoupment, and payment by mistake accrue upon the occurrence of the wrongful act giving rise to the duty of restitution. See Golden Pacific Bancorp v. F.D.I.C., 273 F.3d 509, 519 (2d Cir. 2001) (applying New York law); United States v. Erie County Medical Center, No. 02-CV-0305E, 2002 WL 31655004 (W.D.N.Y. Oct. 30, 2002) (holding that Government's contract and unjust enrichment claims accrued as of date of submission of claims) ; but see In re. Chicago, Milwaukee, St. Paul & Pacific R.R. Co., No. 77B8999, 1991 WL 66187, at *4 (N.D. Ill. Apr. 24, 1991) (holding that under Illinois law, a cause of action for unjust enrichment accrues when the injured party knew or should have known of the injury). Using the dates on which defendants submitted their claims for payment as the accrual dates, all common-law causes of action based upon claims filed by defendants prior to March 31, 1988, would be barred by the six-year statute of limitations, unless tolled.

Section § 2416(c), Title 28, provides that the statute of limitations for government

common-law claims are tolled during any period in which "facts material to the right of action are not known and reasonably could not be known by an official of the United States charged with the responsibility to act in the circumstances." The Government does not address the tolling of these claims. There is no question that the Government knew of the material facts no later than April 1994, when it received a copy of the Relator's complaint and supporting materials, but whether it knew or reasonably should have known of these claims at an earlier date is a matter that cannot be determined on a motion to dismiss.[65]

Accordingly, all common-law causes of action for restitution, unjust enrichment, and payment by mistake, arising out of claims filed prior to March 31, 1988, are dismissed without prejudice to the Government's establishing that a different accrual date should be applied in a specific case or that the limitations period should be tolled under 28 U.S.C. § 2416(c).

4. Statute of Limitations Applicable to Common-Law Fraud Claims

Defendants likewise argue that the Government's common-law fraud claims asserted against five defendants are barred by a three-year statute of limitation. Section 2415(b), Title 28, provides that "[s] ubject to the provisions of section 2416 of this title, and except as otherwise provided by Congress, every action for money damages brought by the United States or an officer or agency thereof which is founded upon a tort shall be barred unless the complaint is filed within three years after the right of action first accrues. . . ." The Government's fraud claims are actions for money damages founded upon a tort and, thus, governed by this three-year limitations

[65] Defendants suggest that the Government "undoubtedly 'knew' of its cause of action much earlier than April 1994, however, for purpose of this motion to dismiss, defendants will measure the government's knowledge from the time of the relator's filing." (Defs.' S/L Mem. at 23 n.27.)

period. The courts have generally held that a cause of action for fraud accrues when the claim could have been sued upon. See Erie County Medical Ctr., 2002 WL 31655004, at *6. The Government's fraud claims accrued when it suffered a loss, that is, when it paid the claim, rather than when the fraud was allegedly committed. Id. Accordingly, the Government's common-law fraud claims against five of the defendants are time-barred to the extent that they involve claims paid more than three years before the date the Relator filed his original qui tam complaint. These claims are dismissed without prejudice to the Government's establishing that the limitations period should be tolled under 28 U.S.C. § 2416(c).

5. Whether The Government's Claims Should Be Dismissed Based on the Government's Failure to Prosecute

Although we reach this question last, this is the issue which defendants argued most vehemently to the Court at oral argument. Defendants charge that the Government litigated this case under seal and ex parte for eight years so that no court, until now, has been in a position to determine in an adversary proceeding whether the Government's numerous requests for extensions of time were warranted, or whether prior to intervention the Government had standing to seek a severance and transfer of the individual actions, or whether the proper remedy for misjoinder[66] and improper venue of the original qui tam complaint was dismissal, as opposed to

[66] Defendants argue that joinder of 132 defendants in one action, where no claims of conspiracy were pled, was improper under Rule 20, Fed. R. Civ. P. The Relator contends that at the time his qui tam action was filed, joinder of all defendants in one action filed in one district where one of the defendants was located was proper in light of the 1986 amendments to the FCA, which added 31 U.S.C. § 3732(a), providing that "[a]ny action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred." Based on the "legal landscape" in 1994, he avers that his filing was made in good faith and contrasts this case to the situation in Biby v. Kansas City Life Insurance Co., 629 F.2d 1289 (8th Cir. 1980), and United States v. St. Joseph's Regional Health Center, 240 F.

transfer. (Defs.' S/L Mem. at 2.) They contend that the Government misused the statutory seal process[67] far beyond anything authorized by the FCA and, "like any other litigant," it must live with the consequences of its litigation decisions, which should be a dismissal of this action with prejudice. (Id.) Citing Shannon v. General Electric Company, 186 F.3d 186, 193 (2d Cir. 1999),[68] they ask this Court to dismiss the Government's complaint for failure to prosecute with due diligence pursuant to Rule 41(b), Fed. R. Civ. P.[69] Defendants claim that they were prejudiced by the extensions granted to the Government, since they were not in a position to engage in discovery and many of the government agencies have destroyed relevant documents.[70]

Supp. 2d 882 (W.D. Ark. 2002), cited by defendants, where there was bad faith in the plaintiffs' original choice of forum.

[67] In particular, defendants point to the inconsistent representations made by the Government to the court in Seattle regarding the progress of its investigation.

[68] In Shannon v. General Electric Company, 186 F.3d at 193-94, the Second Circuit listed five principal factors that it would consider in determining whether the district court abused its discretion in dismissing a case for failure to prosecute: (1) the duration of plaintiff's failures; (2) whether plaintiff had received notice that further delays would result in dismissal; (3) whether defendant is likely to be prejudiced by further delay; (4) whether the district judge has taken care to strike the balance between alleviating court calendar congestion and protecting a party's right to due process and a fair chance to be heard; and (5) whether the judge had adequately assessed the efficacy of lesser sanctions. See also Nita v. Connecticut Dep't of Environmental Protection, 16 F.3d 482, 485 (2d Cir. 1994). No one factor is dispositive. Id. at 194.

[69] Rule 41(b), Fed. R. Civ. P., provides in relevant part:

> (b) Involuntary Dismissal: Effect Thereof. For failure of the plaintiff to prosecute or to comply with these rules or any order of court, a defendant may move for dismissal of an action or of any claim against the defendant. . . .

[70] As defendants recognize, this is not something that the Court can properly consider in ruling on a motion to dismiss. Thus, they request that, if the Court does not presume prejudice to the defendants in this case, we make no findings on the issue of prejudice at this time and defendants reserve their right to renew this part of their motion following discovery. (Defs.' S/L Mem. at 22.)

They suggest that given the extraordinary length of the delay, this Court should presume that they were prejudiced in their ability to prepare a defense and, thus, will be denied procedural due process if these cases are not dismissed.[71]

The Government responds that the extension requests were explicitly authorized by statute, 31 U.S.C. § 3730(b)(3), and were sanctioned by ten district judges,[72] who found "good cause" to grant the requested extensions. These decisions, it argues, are law of the case. Additionally, the longest delay was occasioned by defendants' filing the Cedars-Sinai litigation. Judge Lasnik was well aware of defendants' position that the case should be dismissed for misjoinder and improper venue when he severed and transferred the individual cases. Several defendants had moved the court to dismiss the qui tam action on these very grounds. Although Judge Lasnik struck defendants' motion[73] as premature, see Note 13, supra, this issue was fully briefed and orally argued prior to his decision to transfer the actions. Moreover, even assuming

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[71] For example, defendant St. Joseph Mercy Hospital states in its Supplemental Memorandum that, after it completed the production of documents in 1994, it heard nothing further from the Government until 2002. In the intervening eight years, it underwent a substantial change in organizational structure and no one was assigned continuing responsibility for the investigation. It does not believe that any claims forms were even submitted to the Government. Thus, it argues that it has no access to witnesses and documentary evidence. Again, this is not properly before the Court in ruling on a motion to dismiss.

[72] In addition to Judges Dimmick and Lasnik in Seattle, who presided over the original qui tam action, eight other judges ruled on requests for extension of time after some of the cases were transferred in 1999, including Chief Judge Magnusen and Judge Rosenbaum in Minnesota, Judge King in the Southern District of Florida, Judge Jenkins in the Northern District of California, Judge Gonzalez in the Southern District of California, Judge Oliver in the Northern District of Ohio, and Judge Eliason and Judge Osteen in the Middle District of North Carolina.

[73] Nine defendants filed a motion to dismiss for misjoinder and improper venue. At that time, the Government had not intervened, the complaint had not been unsealed, and these defendants had not been served with the complaint.

that venue of the non-Seattle defendants was not proper in the Western District of Washington, dismissal would have been inappropriate since 28 U.S.C. § 1406(a)[74] gives the court broad discretion to transfer the case "in the interest of justice."

As the Government notes, during oral argument on a motion to dismiss in the case of Cosens ex rel. United States v. Yale New Haven Hospital, 3:02CV688(GLG), and Yale New Haven Hospital v. Shalala, 3:99CV2546(GLG), this Court previously expressed its opinion that the prior decisions of Judge Lasnik and Judge Dimmick, granting the Government's requested extensions, are law of the case, and denied Yale-New Haven Hospital's motion to dismiss for failure to prosecute based upon these prior decisions. (9/5/02 Hr'g Tr. at 102-110, 119.)

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[74] Defendants note that Judge Lasnik did not indicate the basis for his transfer decision. They argue that the Government did not seek a transfer under § 1406(a), which they assert can be granted only if venue was improper in the original district, which the Government has been unwilling to concede. In Goldlawr, Inc. v. Heiman, 369 U.S. 463, 466 (1962), the Supreme Court held that a district court lacking both personal jurisdiction and proper venue can transfer a case to a district where personal jurisdiction and venue are proper. The Second Circuit in Corke v. Sameiet M.S. Song of Norway, 572 F.2d 77 (2d Cir. 1978), extended the holding of Goldlawr to cases where jurisdiction was lacking but venue was proper. The Court did so by reading § 1404(a) together with § 1406(a). Since Corke, the majority of courts in the Second Circuit have held that, whether or not venue was proper in the original court, lack of personal jurisdiction could be cured by transferring the case to a district in which personal jurisdiction could be exercised, with the transfer authority derived from either § 1404(a) or § 1406(a). See Posven, C.A. v. Liberty Mutual Ins. Co., 303 F. Supp. 2d 391, 400 n.3 (S.D.N.Y. 2004)(discussing cases); see also SongByrd, Inc. v. Estate of Grossman, 206 F.3d 172, 179 n.9 (2d Cir.), cert. denied, 531 U.S. 824 (2000); Spar, Inc., 956 F.2d at 394 (holding that a transfer under § 1406(a) could be permitted in the interests of justice, notwithstanding that venue was proper in the transferor court); Fresca v. Arnold, 595 F. Supp. 1104, 1105 (E.D.N.Y. 1984)(holding that plaintiff's reliance on § 1406(a), as opposed to the general transfer statute, § 1404(a), was irrelevant, since a district court does not need to elect between the two statutes); see also Porter v. Groat, 840 F.2d 255, 257-58 (4th Cir. 1988); Taylor v. Love, 415 F.2d 1118, 1120 (6th Cir. 1969), cert. denied, 397 U.S. 1023 (1970); Mayo Clinic v. Kaiser, 383 F.2d 653, 654-55 (8th Cir. 1967); Dubin v. United States, 380 F.2d 813, 815-16 (5th Cir. 1967) . In Posven, the court held that the key inquiry under both § 1404(a) and § 1406(a) is whether the transfer is in the interests of justice. 303 F. Supp. at 401, n.3.

"The law of the case doctrine 'posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.'" DiLaura v. Power Authority of State of New York, 982 F.2d 73, 76 (2d Cir. 1992) (quoting Liona Corp. v. PCH Assocs., 949 F.2d 585, 592 (2d Cir. 1991)). "This 'doctrine is admittedly discretionary and does not limit a court's power to reconsider its own decisions prior to final judgment.'" Id. (quoting Virgin Atlantic Airways, Ltd. v. National Mediation Bd., 956 F.2d 1245, 1255 (2d Cir.), cert. denied, 506 U.S. 820 (1992)). The major grounds justifying reconsideration are an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice. Id. Although this Court has the discretion to revisit prior decisions in this case, see Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 817 (1988), we choose not to do so. There has been no intervening change in the law. Although defendants argue that new evidence is available now that the record has been unsealed, that evidence was before Judge Lasnik. And, the Court is not convinced that revisiting these rulings is warranted to prevent manifest injustice or to correct clear error. Having declined to revisit Judge Lasnik's rulings, we need not address defendants' argument that these cases should have been dismissed rather than being severed and transferred.

Defendants emphasize that these rulings were made ex parte, but that is the nature of a qui tam proceeding until such time as the complaint is unsealed and the defendants are served. Furthermore, this is not a case in which defendants were kept in the dark about the qui tam proceedings, as is often the case. As discussed above, in 1994 defendants received subpoenas requesting relevant records, they initiated litigation involving the Manual provision, they were involved in Congressional hearings, many received a copy of the actual qui tam complaint, and a

number of defendants filed motions in the qui tam litigation.

The extensions of time received by the Government were requested pursuant to statute, 31 U.S.C. § 3730(b)(3), and were granted by the court based upon a finding of good cause. We decline to nullify these orders retroactively. To the extent that defendants claim that they were prejudiced by these extensions, we decline to presume prejudice. Whether defendants were actually prejudiced by the delay is not a matter that can be resolved on a motion to dismiss based on the papers now before the Court. We therefore deny defendants' motion to dismiss for failure to prosecute with due diligence.

V. Conclusion

For the reasons discussed above, Defendants' Motion to Dismiss for Failure to Plead Fraud with Particularity is DENIED; Defendants' Motion to Dismiss for Failure to State a Claim Upon Which Relief May be Granted is DENIED; Defendants' Motion to Dismiss on Statute of Limitations Grounds is GRANTED without prejudice as to all common-law causes of action for unjust enrichment, restitution, and payment by mistake relating to Medicare claims and Cost Reports filed prior to March 31, 1988, and as to all common-law causes of action for fraud relating to Medicare claims paid by the Government prior to March 31, 1991; in all other respects, the Motion to Dismiss on Statute of Limitations Grounds is DENIED.

SO ORDERED.

Date: May 12, 2004.
Waterbury, Connecticut.

_____/s/_____
GERARD L. GOETTEL,
United States District Judge