**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**

**Case No. 13-Civ-22782-COOKE/TORRES**

VITREO RETINAL CONSULTANTS
OF THE PALM BEACHES, P.A., a
Florida Corporation,

Plaintiff,

vs.

KATHLEEN SEBELIUS[1], in her official
Capacity as Secretary of the U.S. Dept. of
Health and Human Services,

Defendant.
_____/

**ORDER DENYING PLAINTIFF'S MOTION FOR RECONSIDERATION**

Plaintiff Vitreo Retinal Consultants of the Palm Beaches, P.A., a single–physician ophthalmology practice that serves Medicare beneficiaries in West Palm Beach, Florida, appealed the Secretary of Health and Human Services' determination that it improperly billed Medicare for its treatment of multiple patients using a single vial of Lucentis – a drug that treats neovascular age-related macular degeneration. (*See* ECF No. 1.) In its Motion for Summary Judgment, Plaintiff argued that the Secretary's decision was arbitrary and capricious, and not based on substantial evidence, because she mischaracterized the record evidence in order to create a new legal standard that was inconsistent with the law, agency guidance, and agency practice. Pl.'s Mot. Summ. J. at 1. Defendant filed its own Motion for Summary Judgment (ECF No. 35) in response, arguing that the Secretary's decision must be upheld as it was based on substantial evidence.

On September 30, 2014, I entered an endorsed order denying Plaintiff's Motion for Summary Judgment (ECF No. 43) and a separate endorsed order granting Defendant's Motion for Summary Judgment (ECF No. 44). Plaintiff now files this Urgent Motion for Reconsideration of Summary Judgment and Renewed Request for Oral Argument (ECF

[1] On June 9, 2014, Sylvia Matthews Burwell replaced Kathleen Sebelius as Secretary of the U.S. Department of Health & Human Services.

No. 45) requesting that I reconsider my grant of summary judgment to the Defendant. Defendant filed its Opposition to Plaintiff's Motion to Reconsider on October 20, 2014 (ECF No. 46), to which Plaintiff filed its Reply to Secretary Burwell's Response to Motion for Reconsideration of Summary Judgment and Renewed Request for Oral Argument on October 28, 2014 (ECF No. 47). Therefore, Plaintiff's Motion for Reconsideration is ripe for adjudication.

After considering Plaintiff's Motion for Reconsideration, the Response and Reply thereto, relevant legal authorities, and the record, Plaintiff's Urgent Motion for Reconsideration of Summary Judgment and Renewed Request for Oral Argument (ECF No. 45) is denied.

## I. BACKGROUND

In 2008, the Zone Program Integrity Contractor for the state of Florida, SafeGuard Services LLC, audited Plaintiff Vitreo Retinal Consultants of the Palm Beaches, P.A.'s ("Vitreo") Medicare billing records to determine if Vitreo multi-dosed single use vials of the drug Lucentis. Vitreo's sole physician, Dr. Salomon Melgen, "billed significantly higher for [Lucentis] in comparison to his peer group," raising "suspic[ion] that each vial of the drug [was being] administered to more than one patient." An investigation, that included interviews of Dr. Melgen and his staff, revealed that each vial of Lucentis was, indeed, administered to up to three patients.

In June 2009, SafeGuard determined that Vitreo overbilled Medicare for Lucentis by nearly $9 million in 2007 and 2008. SafeGuard concluded that multi-dosing Lucentis, contrary to the FDA-approved package insert instructions and the governing coverage determination, overstated Plaintiff's actual costs of the drug. In August 2009, SafeGuard forwarded its findings to the Medicare Administrative Contractor, First Coast Service Options, Inc. ("FSCO")[2], which sought to recoup the overpayments from Vitreo because Vitreo was not "without fault" in billing for multi-dosed vials of Lucentis. On October 13, 2009, FSCO denied Vitreo's petition for a redetermination of the initial decision.

Thereafter, Vitreo exhausted all available administrative remedies. On June 13, 2011, an Administrative Law Judge ("ALJ") upheld FSCO's determination that Vitreo multi-

[2] First Coast Service Options, Inc. is the Center for Medicare and Medicaid Services contractor tasked with administering Medicare payment processing and auditing functions in the Vitreo's geographic region.

dosed, and overbilled for, Lucentis. Vitreo then appealed the ALJ's decision to the Medicare Appeals Council ("MAC") of the Health and Human Services Departmental Appeals Board. On June 28, 2013, the Medicare Appeals Council concluded that Lucentis injections are only "medically reasonable and necessary to the extent the drug [is] administrated consistent with its FDA-approved label," multi-dosing was "not appropriate because it departs from accepted standards of practice," and it affirmed "that [Vitreo] was overpaid for the injections at issue." Vitreo timely moved for review by this Court.

## II. LEGAL STANDARD

"A motion for reconsideration must demonstrate why the court should reconsider its prior decision and set forth facts or law of a strongly convincing nature to induce the court to reverse its prior decision." *Fla. Coll. of Osteopathic Med., Inc. v. Dean Witter Reynolds, Inc.*, 12 F.Supp.2d 1306, 1308 (M.D. Fla. 1998) (internal quotation and citation omitted)). Courts generally grant motions for reconsideration when there is "(1) an intervening change in controlling law, (2) the availability of new evidence, and (3) the need to correct clear error or manifest injustice." *Id.* A motion for reconsideration "should raise new issues, not merely readdress issues previously litigated." *Id.* "[R]econsideration of a previous order is an extraordinary remedy to be employed sparingly." *Bautista v. Cruise Ships Catering & Serv. Int'l, N.V.*, 350 F. Supp. 2d 987, 992 (S.D. Fla. 2004) (internal quotation and citation omitted).

## III. DISCUSSION

In its Motion to Reconsider, Plaintiff argues that my endorsed orders "evidence clear error" as I failed to "apply the correct legal standard and fail[ed] to address the constitutional and other fundamental deficiencies of the Secretary's underlying findings." Pl.'s Mot. Reconsider 1. Plaintiff then reargues issues already argued in its Motion for Summary Judgment. Ultimately, Plaintiff fails to meet its burden on a motion for reconsideration because the Secretary's decision was supported by substantial evidence and it did not violate Plaintiff's due process rights.

The Secretary of Health and Human Services' ("Secretary") findings "as to any fact, if supported by substantial evidence, shall be conclusive." 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A). Therefore, "judicial review of the Secretary's decision regarding a claim for Medicare benefits is limited to 'whether there is substantial evidence to support the findings of the…[Secretary], and whether the correct legal standards were applied." *Gulfcoast Med.*

*Supply v. Sec'y, Dep't Health & Human Services*, 468 F.3d 1347, 1350 n. 3 (11th Cir. 2006) (quoting *Wilson v. Barnhart*, 284 F.3d 1219, 1221 (11th Cir. 2002)). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion," even if the Court "would have reached a different result based upon the record." *Barnes v. Sullivan*, 932 F.2d 1356, 1358 (11th Cir. 1991). It is "more than a scintilla, but less than a preponderance." *Bloodsworth v. Heckler*, 703 F.2d 1233, 1239 (11th Cir. 1983).

The Administrative Procedure Act ("APA") requires that the Secretary's decision must be upheld unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). The Eleventh Circuit has explained that this standard of review is "exceedingly deferential." *Fund for Animals v. Rice*, 85 F.3d 535, 541 (11th Cir. 1996). Thus, the reviewing Court considers only whether it "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). "Along the standard of review continuum, the arbitrary and capricious standard gives an appellate court the *least* latitude in finding grounds for reversal." *Fund for Animals*, 85 F.3d at 541-42. An agency decision "should be set aside in this context . . . only for substantial procedural or substantive reasons as mandated by statute . . . not simply because the court is unhappy with the result reached." *Id.*

The Secretary's interpretation of what is "reasonable and necessary" under the Medicare statute is entitled to administrative deference. *Gulfcoast Med. Supply*, 468 F.3d at 1351; *see also Chevron USA, Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984) ("considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer."). The reviewing court must give "considerable weight" to the Secretary's interpretation of any ambiguous language so long as it is "based on a permissible construction of the statute" because the Secretary is charged with administering the Medicare statute. *Id.*; *see also Almy*, 679 F.3d at 302. The Secretary is entitled to "substantial deference" for her interpretation of the regulations that implement the Medicare Act's "reasonable and necessary" standard. *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). Thus, "the agency's interpretation must be given 'controlling weight unless it is plainly erroneous or inconsistent with the regulation.'" *Id.* (citation omitted). "The Supreme Court has emphasized the importance of careful adherence to this

standard in the Medicare context, which deals with 'a complex and highly technical regulatory program, in which the identification and classification of relevant criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" *Almy*, 679 F.3d at 302 (quoting *Thomas Jefferson Univ.*, 512 U.S. at 512). Finally, "[b]ecause the determination of what is 'reasonable and necessary' also requires a significant degree of medical judgment, [the Court] must be mindful that '[w]hen examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.'" *Id.* (quoting *Baltimore Gas & Elec. Co. v. Natural Res. Def. Council*, 462 U.S. 87, 103 (1983)).

Therefore, in order to prevail at the summary judgment stage, Defendant Kathleen Sebelius needed only to show that the Department of Health and Human Services' (the "Agency" or "Department") decision was based on substantial evidence. This highly deferential standard recognizes a district court's limited expertise in matters that fall within the Agency's purview, thus, precluding district courts from second-guessing Agency decisions.

**A. The Department of Health and Human Services' Overpayment Determination is Supported by Substantial Evidence.**

It is undisputed that the Department of Health and Human Services, through its various levels of review, relied principally on four pieces of evidence in reaching its overpayment determination: (1) the Food and Drug Administration approved package insert; (2) the Lucentis local coverage determination issued by First Coast Service Options ("FCSO") that reflects the majority view of local health care providers; (3) Genentech, Inc.'s, Lucentis' drug manufacturer, letter to FCSO explaining the proper dosing and administration of Lucentis; and (4) Centers for Disease Control and Prevention's 2007 injection safety guidelines. I shall address each in turn.

**1. The Food and Drug Administration Approved Packet Insert**

In 2006, the FDA approved Lucentis to treat neovascular age-related macular degeneration. Admin. R. at 258. Lucentis is packaged in single-use, single-dose vials that contain 2.0 mg of the drug. Admin. R. at 236. According to the "Dosage and Administration" section of the FDA-approved package insert, the entire contents of the vial (in other words, all 2.0 mg of the drug) should be drawn into the syringe, and then the

excess drug product should be expelled until the recommended dose of 0.5 mg is obtained. *Id.* at 233. The insert goes on to explain, "Each vial should only be used for the treatment of a single eye. If a contralateral eye requires treatment, a new vial should be used and the sterile field, syringe, gloves, drapes, eyelid speculum, filter, and injection needles should be changed before Lucentis is administered to the other eye." *Id.* at 236. Thus, when properly administered, each vial of Lucentis treats a single eye on a single patient.

Despite Plaintiff's protests to the contrary, the FDA-approved labeling should be considered evidence of accepted standards of medical practice. While the Eleventh Circuit has not squarely addressed the issue of whether FDA-approved labeling establishes the standard of care for the administration of a drug, it has noted that the Physician's Desk Reference, which contains FDA-approved labeling information for all FDA-approved drugs, is a "standard medical reference." *Newmann v. United States*, 938 F.2d 1258, 1260 (11th Cir. 1991). The Physician's Desk Reference is widely used throughout the medical community when prescribing various medications. Even the Fifth Circuit, just after its split, concluded, "the Physician's Desk Reference **adequately establishes** . . . the standard of care for the administration of [a drug]." *Haught v. Maceluch*, 681 F.2d 291, 303 n.12 (5th Cir. 1982) (emphasis added). Thus, it is quite natural that the Department of Health and Human Services would rely on, and refer to, the same FDA-approved labeling information contained within the Physician's Desk Reference when determining the acceptable standard of care for administration of Lucentis.

**2. The Lucentis Local Coverage Determination[3]**

In 2008, First Coast Service Options published the first Lucentis local coverage determination ("LCD") that "was developed in cooperation with advisory groups . . . includ[ing] representatives from the Connecticut Society of Eye Physicians and the Florida Society of Ophthalmology." Admin. R. at 124. It stated, "Each vial should only be used for treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used." *Id.* at 121. Thus, the LCD in effect during the relevant period explicitly limited coverage of "each vial" to the treatment of a "single eye." *Id.* Plaintiff's arguments

[3] Local coverage determinations reflect the majority view of local health providers and are published after a public comment, consultation with experts in the field, and an advisory meeting. *See* Medicare Program Integrity Manuel, Ch. 13.

otherwise are illogical. By not explicitly incorporating all of the FDA labeling requirements, the LCD cannot have intended for a single vial of Lucentis to be approved for use among multiple patients but prohibited for use on both eyes of the same patient. Such a result would be nonsensical.

In addition, that same LCD expressly noted that treatment must "be performed as indicated by current medical literature and/or standards of practice." *Id.* at 123. It stands to reason that current medical literature incorporates the FDA-approved packet insert. Any attempt by Plaintiff to raise arguments to the contrary is simply unfounded and unsupported by the record.

**3. Genentech, Inc.'s Explanation of Lucentis Dosing**

It is well settled that "a drug manufacturer is . . . presumed to possess an expert's knowledge of the . . . administration of pharmaceutical products." *Reyes v. Wyeth Labs*, 498 F.2d 1264 (5th Cir. 1974).[4] Not only does a drug require intensive research before it is brought to market, a drug manufacturer faces substantial liability for failure to warn of potential risks. So it is incumbent upon a pharmaceutical company to have a heightened knowledge of any product that it manufactures. As the old adage holds, "no one can know you better than you know yourself." There is no question Lucentis' manufacturer Genentech, Inc. is the most authoritative source of information on Lucentis.

Genentech, Inc. explained, "the FDA-approved prescribing information does not . . . support the practice of administering the contents of one vial of Lucentis to more than one eye or to more than one patient." Admin. R. at 238. As stated in the prescribing information, each vial of Lucentis should only be used for the treatment of a single eye. *Id.* In fact, physicians are instructed to discard the excess drug product so that only enough drug product for one dose remains in the vial. According to Genentech, Inc., "[each] vial contains overfill . . . to account for loss [drug] product when the dose is being prepared and administered appropriately and according to the FDA-approved labeling. The vial is designed to contain enough liquid so that a single 0.5 mg (0.05 mL) dose can be administered." *Id.* The Department rightfully gave considerable authoritative weight to Genentech, Inc.'s instruction regarding the administration of Lucentis.

[4] The Eleventh Circuit adopted all decisions of the former Fifth Circuit handed down prior to the close of business on September 30, 1981 as binding precedent. *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc).

**4. The Centers for Disease Control and Prevention's 2007 Injection Safety Guidelines.**

In 2007, the Centers for Disease Control and Prevention ("CDC") enunciated guidelines that cautioned against administering medications from single-dose vials to multiple patients. Centers for Disease Control and Prevention, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. It read, in relevant part, "Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use." *Id.* at 83. Plaintiff even relied on a CDC publication titled "Injection Safety FAQs for Providers" in its May 2011 supplemental memorandum to the Administrative Law Judge. That publication directly answered the question, "Is it acceptable to use single-use medication vials or pre-filled syringes for more than one patient?" The CDC answered, "NO. Medication vials that are labeled for single-use and pre-filled medication syringes ***should never be used*** for more than one patient." (emphasis added). So Plaintiff knew or should have known of the prevailing standard of care regarding the administration of single-use vial drugs, such as Lucentis.

Each piece of evidence mentioned above was relevant to the Agency's determination regarding the proper administration of Lucentis. And the totality of the evidence would persuade a reasonable mind to clearly see that it supports the Department's determination that the Plaintiff, contrary to prevailing standards of acceptable medical care, improperly administered multiple doses of Lucentis from a single-use vial. Thus, the Department's determination is well supported by substantial evidence in the record.

**B. The Department of Health and Human Services Did Not Exceed its Authority Under the Medicare Act.**

Plaintiff's argument that the MAC exceeded its authority under the Medicare Act by promulgating a new Medicare reimbursement policy for Lucentis and then retroactively applying said policy to Plaintiff is unpersuasive. *See* Pl.'s Mot. Summ. J. at 35. First, Plaintiff concedes that the MAC rendered its determination after an adjudicatory process, as opposed to a rulemaking process. *Id.* at 14-20. Second, a MAC decision "applies only to the specific claim being considered and does not have precedential effect." 42 C.F.R. § 405.1062. The MAC's decision is only binding on the parties to the instant action and not on future providers. Thus, it is not a new policy. Lastly, Plaintiff's argument against

retroactivity smacks in the face of well-settled administrative law. Adjudications are inherently retroactive because they deal with what the law was at the time the aggrieved conduct occurred, and they implicitly seek to correct past behavior. Adjudications merely apply existing policy to a particular set of circumstances. They do not make what was then perfectly legal conduct illegal by virtue of a change in policy. Plaintiff's mischaracterization of the Agency's adjudicatory process is unavailing.

## IV. CONCLUSION

The law is clear regarding the standard for granting a Motion for Reconsideration under Federal Rule of Civil Procedure 59(e). Plaintiff presents no intervening change in controlling law, no new evidence, and no clear error or manifest injustice that needs to be corrected. Plaintiff has failed to demonstrate that the Secretary's decision was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). It is not this Court's job to question the weight and credibility of the evidence so long as there are no clear errors of judgment. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). A thorough review of the Agency's decision demonstrates that it is supported by substantial evidence. As the Eleventh Circuit noted, substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion," even if the Court "would have reached a different result based upon the record." Clearly, that standard is met here, and the Agency's decision is deserving of deference.

Accordingly, it is **ORDERED and ADJUDGED** that Defendant's Urgent Motion for Reconsideration of Summary Judgment and Renewed Request for Oral Argument (ECF No. 45) is **DENIED**.

**DONE and ORDERED** in Chambers, in Miami, Florida, this 10th day of April 2015.

Marcia G. Cooke

MARCIA G. COOKE
United States District Judge

Copies furnished to:
*Edwin G. Torres, U.S. Magistrate Judge*
*Counsel of Record*