IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA *ex rel.* LINDA NICHOLSON,	)	
Plaintiff,	)	No. 10 C 3361
v.	)	The Honorable Gary Feinerman
LILIAN SPIGELMAN M.D., HEPHZIBAH CHILDREN'S ASSOCIATION, and SEARS PHARMACY,	)	Magistrate Judge Sidney I. Schenkier
Defendants.	)	

MEMORANDUM IN SUPPORT OF DEFENDANTS' JOINT MOTION TO DISMISS PURSUANT TO F.R.CIV.P. 12(B)(6)

In 2003, the daughter of relator Linda Nicholson was placed under the guardianship of the Illinois Department of Family Services (DCFS), which placed her temporarily to reside at Hephzibah Children's Association in Oak Park, Illinois. There Lilian Spigelman, M.D., prescribed the psychotropic drug Celexa for her. A local pharmacy, Sears Pharmacy (not to be confused with the retailer), filled several Celexa prescriptions and submitted claims to Illinois Medicaid to have them reimbursed.

Six years later, Dr. Spigelman, Sears, and Hephzibah have been sued for defrauding the United States. The suit is the brainchild of lawyers opposed to psychiatry and psychotropic drugs. *See* the blog of Nicholson's counsel, http://refusingpsychiatry.blogspot.com. Nicholson has used a "model complaint" prepared by PsychRights, an organization that says it is waging a "strategic legal campaign against forced psychiatric drugging and electroshock in the United States akin to what Thurgood Marshall and the NAACP mounted in the 40's and 50's on behalf of African American civil rights." *See* http://psychrights.org/index.htm.

The suit attacks Medicaid reimbursement for psychotropic drugs prescribed "off label" -- *i.e.*, for indications other than those for which the FDA has approved the drugs. Nicholson asserts that the federal Medicaid statute forbids reimbursement for off-label prescriptions unless

they are prescribed for indications supported by one of three "compendia." On this theory, she alleges that defendants violated the False Claims Act ("FCA") by causing the United States to reimburse Illinois for part of the cost the Illinois Medicaid program incurred in reimbursing these prescriptions. She filed the complaint under seal, as the FCA requires. The government swiftly declined to intervene. Nicholson now pursues the case in the name of the United States.

The complaint fails to state a claim for violation of the FCA, cannot be made to state one, and should be dismissed with prejudice under Rule 12(b)(6). Although defendants have filed a separate motion to dismiss under F.R.Civ.P. 9(b) for failure to plead fraud with particularity, defendants respectfully request the Court to take up the present motion first, since the legal issues it presents are independent of the defects attacked in the Rule 9(b) motion. (Defendants have also moved under F.R.Civ.P. 12(b)(1) to dismiss on account of prior public disclosure of substantially the same allegations. The Court has stayed briefing on that motion while the Seventh Circuit considers a "public disclosure" case presenting similar issues.)

Section I of this brief, which gives the relevant regulatory and legal background, shows (1) that the prescriptions as alleged in the complaint were eligible for reimbursement under Illinois' Medicaid regulations; and (2) that Nicholson's FCA claim depends on an interpretation of the Medicaid statute which a federal court has questioned, the federal Medicaid agency has disagreed with, and most states have rejected. Consequently, as Section II shows, Nicholson does not and cannot allege the necessary *scienter* for a FCA violation by any defendant.

I. REGULATORY AND LEGAL BACKGROUND.

The legal issues presented by the present motion must be considered against the backdrop of court decisions, regulations, and statements of position by government agencies in public records of which this Court may take judicial notice on this motion to dismiss. *General Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1080-81 (7th Cir. 1997).

A. "Off-label" uses of prescription drugs.

"Off-label use" means prescribing a drug for a different indication than those for which the drug has been approved by the FDA. The FDA "prohibits drug companies from promoting

off-label uses for medications they manufacture or market." *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 939 fn. 3 (7th Cir. 2001). However, it is not unlawful for a physician to prescribe the drug for an off-label use. "The decision to prescribe such 'off-label usage,' as it is called, is regarded as a professional judgment for the healthcare provider to make." *Nightingale Home Healthcare, Inc. v. Anodyne Therapy, Inc.*, 589 F.3d 881, 884 (7th Cir. 2009).

B. Relevant federal Medicaid provisions.

Medicaid is a state-federal partnership. A state participating in Medicaid must submit a state Medicaid plan for approval by the Centers for Medicare and Medicaid Services (CMS), part of the Department of Health and Human Services. 42 U.S.C. §1396a; 42 C.F.R. §430.15. Under 42 U.S.C. §1396a(54), if a state's plan chooses to cover prescription drugs, it must comply with applicable requirements of 42 U.S.C. §1396r-8, entitled "payment for covered outpatient drugs."

Section 1396r-8 (reprinted in Ex. A to this brief) is forbiddingly complex, but its main thrust is a simple *quid pro quo*: if a manufacturer agrees to pay certain rebates to a state, the state's Medicaid program must cover the manufacturer's drugs. *In re Vioxx Prods. Liab. Litiga.*, 2010 WL 2649513 (E.D.La. 2010), at *10. The section gives such a state the option of not covering certain limited categories of those drugs. 42 U.S.C. §1396r-8(d). In particular, a state "may exclude or otherwise restrict coverage of a covered outpatient drug" if "the prescribed use is not for a medically accepted indication." 42 U.S.C. §1396r-8(d)(1)(B)(i).

Under 42 U.S.C. §1396r-8(k)(2), a "covered outpatient drug" is any drug which requires a prescription and has been approved by the FDA (plus several other limited categories of drug), unless the drug is excluded by §1396r-8(k)(3)). One category excluded by §1396r-8(k)(3) from "covered outpatient drugs" is "a drug or biological used for a medical indication which is not a medically accepted indication." 42 U.S.C. §1396r–8(k)(6) defines "medically accepted indication" as "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section." The compendia named in that subsection are American Hospital Formulary Service

Drug Information, United States Pharmacopeia-Drug Information (or successor publications), and the DRUGDEX Information System. This brief will refer to drugs prescribed for non-FDA-approved indications that are not supported by any of the three compendia as "off-label, non-compendium uses."

C. The disagreement over whether 42 U.S.C. §1396r-8 acts as a limit or a floor on state Medicaid reimbursement.

The "limit" interpretation. This interpretation -- on which the present complaint's FCA theory depends -- asserts that the definition of "covered outpatient drugs" in the Medicaid statute acts as a *limit* on Medicaid reimbursement. The first court decision to articulate the "limit" interpretation came in 2001 in a suit against a drug manufacturer accused of unlawfully marketing its drug Neurontin for "off label" uses. After reviewing the Medicaid statute's definition of "covered outpatient drugs," Judge Patty I. Saris wrote that "unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid." *U.S. ex rel. Franklin v. Parke-Davis*, 147 F.Supp.2d 39, 44-45 (D.Mass. 2001) (hereafter "*Parke-Davis I*") (footnote omitted). She noted that the defendant did not contest this interpretation. *Id.*, at 51.

The "floor" interpretation. The competing interpretation is that the definition of "covered outpatient drugs" acts as a *floor*, not a limit, on coverage. Under this interpretation, the purpose of §1396r-8 is to require that states who accept rebates from drug manufacturers *must* cover all drugs that fit the definition of "covered outpatient drugs." Oddly, the "floor" interpretation was also first advanced in the *Parke-Davis* lawsuit. Two years after *Parke-Davis I*, Parke-Davis moved for summary judgment. Judge Saris wrote:

> Parke-Davis contends that Relator cannot prove the *sine qua non* of a False Claims Act violation: the existence of a false claim. In the early phases of this litigation, "Defendant d[id] not dispute that an off-label prescription submitted for reimbursement by Medicaid is a false claim within the meaning of the FCA." *Parke-Davis*, 147 F.Supp.2d at 51 Now Parke-Davis argues that forty-two state Medicaid programs permit reimbursement for off-label, non-compendium drug prescriptions, and that therefore claims for Medicaid reimbursement for off-label Neurontin prescriptions in those states were not false claims. Parke-Davis contends that the Medicaid statute gives states the discretion to provide reimbursement for such prescriptions; in particular, Parke-Davis points to 42 U.S.C. §1396r-8(d)(1)(B): "A state may exclude or otherwise restrict coverage of

> a covered outpatient drug if -- (i) the prescribed use is not for a medically accepted indication...." Parke-Davis argues that the language "may exclude or otherwise restrict" indicates that states have the option not to exclude (*i.e.*, may provide) coverage for drugs for which the prescribed use is not for a medically accepted indication.

U.S. ex rel. Franklin v. Parke-Davis, 2003 WL 22048255 at *2 (D.Mass. 2003) ("*Parke-Davis II*"). Judge Saris then summarized the counter-argument for the "limit" interpretation:

> Relator emphasizes that the Medicaid statute allows states to "exclude or otherwise restrict coverage *of a covered outpatient drug*," 42 U.S.C. §1396r-8(d)(1)(B) (emphasis added), implying that states are given discretion only within the category of "covered outpatient drugs." The Medicaid statute defines this category to exclude drugs for which the prescribed use is not a medically accepted indication. *Parke-Davis*, 147 F.Supp.2d at 45 ("Covered outpatient drugs do not include drugs that are 'used for a medical indication which is not a medically accepted indication.'") (quoting 42 U.S.C. §1396r-8(k)(3)). Thus, in Relator's view, §1396r-8(d)(1)(B)(i) is simply superfluous, giving states the discretion to exclude drugs that are not covered by Medicaid to begin with.

Id., at *3. Judge Saris remarked that this "limit" interpretation was disfavored by the basic rule that courts should "attempt to give meaning to each word and phrase" of a statute. *Id.* She concluded that "[i]t is not clear which side gets the better of the statutory-tail-chases-cat debate." She asked the Department of Justice for an *amicus* brief on "the extent to which the Medicaid statute empowers states to provide coverage of off-label, non-compendium prescriptions." *Id.* (DOJ did not file the requested brief.) Judge Saris also wrote that if even if the "limit" theory was correct, and a state violated the Medicaid statute by reimbursing off-label, non-compendium uses, relator in that state would likely fail the FCA's *scienter* requirement. *Id.* Thus, regardless of which interpretation was correct, it would be important to determine which states allowed reimbursement of Neurontin. She declined to conduct, at that stage, a state-by-state analysis of that issue. Instead, she denied the motion for summary judgment since Parke-Davis had conceded that eight states did ban reimbursement for off-label, non-compendium uses. *Id.*

So far as defendants can discover, *Parke-Davis II* remains the only judicial discussion of the relative merits of the "limit" and "floor" interpretations. Four other district courts in "off-label marketing" cases against drug manufacturers have quoted or cited Judge Saris' *Parke-Davis I* discussion without further discussion. *U.S. ex rel. Hess v. Sanofi-Synthelabo, Inc.*, 2006 WL 1064127 (E.D.Mo. 2006), at *2; *U.S. ex rel. West v. Ortho-McNeil Pharmaceutical, Inc.*, 2007

WL 2091185 (N.D.Ill. 2007), at *2; *U.S. ex rel. Carpenter v. Abbott Labs.*, 2010 WL 2802686 (D.Mass. 2010), at *11; and *U.S. ex rel. Bennett v. Medtronic, Inc.*, 2010 WL 3909447 (S.D.Tex. 2010), at *5.[1] None of the motions decided by these decisions turned on whether the "limit" interpretation was right. In none of them did a defendant argue the "floor" interpretation. None of the decisions mentioned Judge Saris' reconsideration of the "limit" interpretation in *Parke-Davis II*.

In an Alaska version of the present lawsuit, the parties in that case recently argued the "limit" versus "floor" interpretations on a Rule 12(b)(6) motion. The briefs are posted at PsychRights' website, http://psychrights.org/index.htm. The court did not decide the issue, instead dismissing the case on "public disclosure" grounds. *U.S. ex rel. Law Project for Psych. Rights v. Matsutani et al.*, No. 3:09-CV-00080-TMB (D.Alaska Sept. 24, 2010) (Ex. B).

D. CMS's position on the "limit" versus "floor" dispute.

CMS, which administers Medicaid for the federal government and must approve state Medicaid plans, has issued regulations on Medicaid drug reimbursement. 42 C.F.R. Part 447. The regulations do not forbid states from reimbursing off-label, non-compendium uses. To the contrary, CMS has rejected the "limit" interpretation of the federal statute in correspondence with Utah. In 2007, a Utah official wrote CMS, noting that many state Medicaid programs were reimbursing and presumably receiving federal reimbursement for off-label, non-compendium uses. He asked whether CMS interpreted federal law to restrict federal payment to drug uses that are either FDA-approved or supported in the compendia. Ex. C, p. 1. CMS's Director of Medicaid and State Operations replied that while 42 U.S.C. §1396r-8d authorizes states to exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication, "it does not explicitly require them to do so. States are responsible for defining this coverage in their approved Medicaid State plan and implementing

[1] *In U.S. ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11 (D.Mass. 2008), Judge Saris reviewed the complaint's allegations setting forth the "limit" interpretation of the statute, but expressed no view on whether this was correct. 253 F.R.D. at 13-14.

policies." Ex. D. The Utah official replied, challenging CMS's opinion and arguing the "limit" interpretation. Ex. E. CMS responded that "our previous response to you is correct." Ex. F.

The court may take judicial notice of CMS's statement of position in this public record. *Truhlar v. John Grace Branch No. 825 of the Nat'l Ass'n of Letter Carriers*, 2007 WL 1030237, at *8 (N.D.Ill. 2007) (taking judicial notice of a letter from the NLRB). The court in *Matsutani* quoted from and relied on this correspondence. *Matsutani*, Ex. B, at pp. 4-5.

E. DOJ's position on the "limit" versus "floor" interpretations.

The Department of Justice has participated in several "off-label marketing" suits against drug manufacturers under the federal anti-kickback statute and the FCA, either as an intervenor or as a non-intervenor filing "statements of position." Until recently, DOJ hedged on the "limit" versus the "floor" interpretation. As noted above, in 2003 it declined in *Parke-Davis* to state its position on this issue. In 2008, DOJ told one court:

> Notably, this case does not present -- at least not at this time -- the question this Court left open [in *Parke-Davis II*] as to whether States have discretion to cover off-label uses that are not supported by a citation in the compendia. [Citation to *Parke-Davis II* omitted.] The *Parke-Davis* defendants argued that States are permitted to cover prescriptions for off-label uses even if those uses are not supported by a citation in the compendia. In this case, defendants contend that the off-label indication of "short stature" is supported by compendium citations.

Statement of Interest of the United States in *U. S. ex rel. Rost v. Pfizer, Inc.*, No. 103CV11084 (D.Mass.), reprinted at 2008 WL 3049068, fn. 3. DOJ also chose its words carefully in its complaint in intervention in 2009 in *U.S. ex rel. Gobble v. Forest Labs., Inc.*, No. 03-10395-NMG (D.Mass.). Ex. I.[2] In 2010, however, DOJ as a non-intervenor in another such lawsuit

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[2] That complaint says:

> The Medicaid Rebate Statute generally prohibits federal financial participation for a covered outpatient drug unless there is a rebate agreement in effect with the manufacturer for that drug. Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a state is generally required to cover that drug under the state plan unless "the prescribed use is not for a medically accepted indication." 42 U.S.C. §1396r-8(d)((1)(B)(i). The Medicaid Rebate Statute defines "medically accepted indication" as any FDA approved use or a use that is "supported by one or more citations included or approved for inclusion in any of the compendia" set forth in the statute. 42 U.S.C. §1396r-8(k)(6). A drug does not generally meet the definition of a "covered outpatient drug" if it is being prescribed for a use that is neither FDA-approved nor supported by a citation included or approved for inclusion in the compendia. 42 U.S.C. §§1396r-8(k)(2)(A), (k)(3). Thus, even if a drug is

(continued...)

seemed to endorse the "limit" interpretation. Statement of Interest in *U.S. ex rel. Polanski v. Pfizer, Inc.*, No. 04-cv-0704 (E.D.N.Y. Sept. 24, 2010), p. 8 (Ex. J).

F. Illinois' position on Medicaid reimbursement of off-label uses.

Illinois Medicaid regulations (89 Ill. Adm. Code Part 140) do not agree with the "limit" interpretation. They allow reimbursement for any drug, regardless of indication, so long as the physician deems the drug necessary for the indication and the drug is not one of ten excluded drugs. Section 140.414(a) provides, in relevant part:

> (1) A prescriber may prescribe *any pharmacy item, not otherwise excluded, that, in the prescriber's professional judgment, is essential for the diagnosis or accepted treatment of a recipient's present symptoms.* The Department may require prior approval of any drug except as outlined in Section 140.442(a)(9). [Emphasis added.]
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> * * *
>
> (4) Items that shall not be prescribed are listed in Section 140.441.

Off-label, non-compendium uses are not on §140.441's list of non-prescribable items.

As Judge Saris noted (and defendant conceded) in *Parke-Davis II*, some states' Medicaid programs exclude off-label, non-compendium drugs. But most states do not. For example, in *Matsutani*, which dealt with Alaska, plaintiff PsychRights (whose "model complaint" Nicholson in the present case copied) acknowledged that Alaska's regulations covered off-label non-compendium uses and that the United States had been reimbursing Alaska for payments for such uses. Ex. G, at 10-11.

G. The Illinois regulations on prescribing psychotropic drugs for minors who are wards of the State.

While residing at Hephzibah, Nicholson's daughter was under the guardianship of the Illinois Department of Children and Family Services. The guardianship order (Ex. H) is a public

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(...continued)

> FDA-approved for a certain indication, Medicaid *ordinarily* does not cover uses that do not qualify as medically accepted indications. Many state programs prohibit covering such uses. [Citations to five states' statutes omitted.]

Ex. I, ¶¶27-30 (emphasis added, paragraph numbers omitted).

document that may be considered by this Court on this Rule 12(b)(6) motion. *Pugh v. Tribune Co.*, 521 F.3d 686, 691 (7th Cir. 2008).

Under DCFS regulations, "psychotropic medication shall never be administered to children for whom [DCFS] is legally responsible without the prior approval of an authorized agent as set forth in this Part." 89 Ill. Adm. Code §325.30(b). If the child is in a residential facility, the facility must submit the child's name; the proposed medication, dosage, frequency, and duration (no longer than 180 days); the target symptoms and behavior; other medication the child is receiving; potential side effects; and the name of the prescribing physician. §325.50(a). If the drug is not listed in DCFS's Pharmacy and Therapeutic Manual, the DCFS agent must consult with a psychiatrist before approving or denying the medication. §325.40(a).

Nothing in these regulations bans approval for off-label, non-compendium uses. Under the Illinois Public Aid Code, children under DCFS guardianship placed in facilities such as Hephzibah are eligible for Medicaid. 305 ILCS 5/4-1.2(a)(2). Thus, when Illinois through DCFS approves an off-label, non-compendium use under DCFS's procedures, it does so knowing the drug will be submitted to Medicaid for reimbursement.

II. THE COMPLAINT DOES NOT AND CANNOT PLEAD THE *SCIENTER* AND FALSITY REQUIREMENTS OF A FCA CLAIM.

Nicholson alleges violation of 31 U.S.C. §3729(a)(1)(A), which makes any person liable to the United States who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."[3] To plead a valid claim under this section, Nicholson must allege (a) a false or fraudulent claim; (b) which was presented, or caused to be presented by the defendant to the United States for payment or approval; (c) with the knowledge that the claim was false. *U.S. ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 740-41 (7th Cir. 2007),

[3] Paragraph 19 of the complaint also mentions the FCA provision, now found at §3729(a)(1)(B), making liable one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." However, the complaint does not allege any defendant made or caused to be made or used any "false record or statement." The liability allegations of the complaint ignore this provision, and allege only that Dr. Spigelman "caused [false] claims...to be made to Medicaid" (¶25), that Hephzibah "caused the presentment to Medicaid of [false] claims" (¶27), and that Sears "presented [false] claims to Medicaid" (¶28). This brief will accordingly ignore 31 U.S.C. §3729(a)(1)(B). In any event, the *scienter* analysis would be no different under §3729(a)(1)(B) than under §3729(a)(1)(A).

overruled in part on other grounds, Glaser v. Wound Care Consultants, Inc., 570 F.3d 907, 920 (7th Cir. 2009).

As discussed above, Nicholson pleads that the claims in question were "false" because the Medicaid statute made them ineligible for reimbursement. To satisfy the *scienter* requirement, Nicholson must allege that defendants acted "knowingly" as to this purported ineligibility. Under the FCA, "the terms 'knowing' and 'knowingly' mean...that a person, with respect to information -- (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information, and require no proof of specific intent to defraud." 31 U.S.C. §3729(b)(1). To prove "reckless disregard" of the falsity of a claim, simple negligence is not sufficient. *Hindo v. U. of Health Services*, 65 F.3d 608, 613 (7th Cir. 1995), *cert. denied*, 516 U.S. 1114 (1996). Rather, "aggravated gross negligence" is required. *U.S. ex rel. Farmer v. City of Houston*, 523 F.3d 333, 338 (5th Cir. 2008); *U.S. v. Krizek*, 111 F.3d 934, 941-42 (D.C. Cir. 1997); *U.S. ex rel. Aakhus v. Dyncorp*, 136 F.3d 676, 682 (10th Cir. 1998); *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996), *cert. denied*, 519 U.S. 865 (1996); *UMC Elecs. Co. v. United States*, 43 Fed.Cl. 776, 792 fn. 15 (1999).

Nicholson does not allege that defendants had "actual knowledge" of the supposed legal ineligibility of off-label, non-compendium uses under the Medicaid statute. She does not allege anyone ever told defendants that such uses were ineligible, or that defendants believed they were ineligible. Nor does the complaint allege that defendants did anything to deliberately keep themselves in ignorance of such supposed ineligibility.

Nor can she validly plead that defendants acted recklessly -- *i.e.*, with "aggravated gross negligence" -- by not concluding that the claims were ineligible. First, Illinois Medicaid regulations *allow* reimbursement for such uses. That negates *scienter* on defendants' part as a matter of law, even if Nicholson's theory of the federal Medicaid statute is accepted. Second, there is a substantial and judicially unresolved dispute over whether Nicholson's interpretation of

the Medicaid statute is correct. That dispute independently negates *scienter* -- and indeed, in this Circuit, prevents Nicholson from validly pleading a "false claim" as well.

A. Because Illinois' Medicaid regulations allow reimbursement for off-label, non-compendium uses, Nicholson cannot allege the requisite *scienter*.

By law, providers submit Medicaid claims not to the federal government, but to the state Medicaid program, which decides whether they are eligible under the state's regulations. The United States then periodically pays states a percentage of the aggregate claims the states have paid providers. 42 U.S.C. §1396b. The complaint does not and cannot allege that the prescriptions in question were ineligible under Illinois' Medicaid regulations. As discussed above, those regulations, like those of most states, allow payment for off-label, non-compendium uses if the physician deems them necessary and they do not fall into a list of excluded drugs.

Nicholson's inability to allege that these prescriptions were ineligible for reimbursement under Illinois' Medicaid regulations defeats any claim that defendants acted with "reckless disregard" of the purported ineligibility of these prescriptions. Providers do not commit negligence, much less "aggravated gross negligence," when they submit claims that comply with Illinois' Medicaid regulations and do not verify that the regulations are consistent with the federal Medicaid statute. Even a provider who decided to inquire into this subject would find that the United States, through CMS, approved Illinois' eligibility rules. It would never occur to reasonable providers that a prescription reimbursable under Illinois regulations was contrary to the federal Medicaid statute. And if someone asserted such a thing to them, they would likely (and reasonably) conclude that any such conflict was Illinois' problem, not theirs. It is particularly preposterous to expect providers to look beyond the Illinois regulations in the present case, where DCFS regulations require advance state consent, after a detailed justification, for every prescription of every psychotropic drug to every ward of the state, and where Illinois gives such approval knowing that Medicaid will reimburse the drug.

As mentioned earlier, in *Parke-Davis II*, Judge Saris pointed out that even if the "limit" interpretation of the Medicaid statute was right, the claim would likely fail for lack of *scienter* as to any prescription written in a state that reimbursed off-label, non-compendium uses:

> If the Medicaid statute gives states the discretion to cover off-label, non-compendium prescriptions, and a state exercised its discretion to cover such prescriptions, then an off-label Neurontin prescription in that state would not be a false claim. On the other hand, if the Medicaid statute does *not* give states the discretion to cover off-label, non-compendium prescriptions, but a state misconstrued the statute and authorized coverage of such prescriptions, an FCA action against Parke-Davis in that state would likely fail, as it would be difficult to establish Parke-Davis's scienter.

2003 WL 22048255 at *3.

B. Because Nicholson depends on a disputed interpretation of the Medicaid statute, she cannot validly plead *scienter*, or even that the claim was "false."

Nicholson's FCA claim rests entirely on her interpretation of a complex federal Medicaid statute. There is disagreement about that interpretation's validity, and there has been no definitive judicial resolution of that disagreement. This fact prevents Nicholson from validly alleging *scienter* by any defendant, and (in this Circuit) even from alleging a "false claim."

First, as discussed in Section I, in the one reported decision (*Parke-Davis II*) discussing the proper interpretation of the statute where that interpretation was contested, Judge Saris found its interpretation unclear. Judge Saris may be the country's most experienced federal judge in Medicaid matters, since she presides over the Neurontin off-label litigation and the gigantic "average wholesale price" multi-district litigation. If an experienced federal judge found this issue unclear in the face of detailed legal briefing, it is absurd to assert that lay defendants acted with "aggravated gross negligence" by failing to conclude that the "limit" theory is the law. Second, there is disagreement on the proper interpretation within the federal government itself. CMS, the federal agency that administers Medicaid, is on record supporting the "floor" interpretation, while DOJ, after hedging for years, may now be embracing the "limit" interpretation. Lay defendants do not commit "aggravated gross negligence" by failing to form a different legal conclusion than the federal Medicaid agency has expressed. Third, the majority of states, including Illinois, disagree with the "limit" interpretation, since their Medicaid plans (which CMS approves) pay for off-label, non-compendium uses if a physician deems them necessary. Again, lay providers cannot commit "aggravated gross negligence" by failing to conclude that these states are mistaken.

The case law overwhelmingly and unanimously holds that a defendant does not act knowingly or recklessly under the FCA by failing to conclude that a legal theory disputed to this degree is truly the law. Indeed, in the Seventh Circuit and many others, a claim that depends on such a contested legal theory cannot be a "false claim." In *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013 (7th Cir. 1999), the Seventh Circuit wrote:

> It is impossible to meaningfully discuss falsity without implicating the knowledge requirement. For example, we have held that "[i]nnocent mistakes or negligence are not actionable.."..And *imprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA*.

Id., at 1018 (emphasis added), *quoting Hindo, supra*, 65 F.3d at 613 (citation omitted). Other circuits likewise reject FCA claims where the falsity of the claim depends on a disputed legal interpretation of a statute, regulation, or contractual provision. *See U.S. ex rel. K&R Ltd. P'ship*, 530 F.3d 980, 983 (D.C. Cir. 2008) (that the competing interpretations were both "plausible" defeated *scienter* as a matter of law; court declined to decide which side had the better argument); *U.S. ex rel. Siewick v. Jamieson Science and Engineering, Inc.*, 214 F.3d 1372, 1375 (D.C. Cir. 2000) (case turned on a legal issue that another Circuit had found uncertain, so Nicholson could not satisfy the "reckless disregard" standard); *U.S. ex rel. Hochman v. Nackman*, 145 F.3d 1069, 1073-74 (9th Cir. 1998) (where defendants reasonably believed that a doctor was entitled to specialty pay pursuant to the VHA Guidelines, there is no *scienter* "[r]egardless of whether [the doctor] was actually entitled to specialty pay"); *U.S. ex rel. Loughren v. Unum Group*, 613 F.3d 300, 313 (1st Cir. 2010); *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 377 (4th Cir. 2008) (quoting *Lamers*); *U.S. ex rel. Farmer v. City of Houston*, 523 F.3d 333, 340 fn. 12 (5th Cir. 2008); *U.S. ex rel. Hixon v. Health Mgmt. Systems, Inc.*, 613 F.3d 1186, 1190 (8th Cir. 2010).

Many district court decisions hold the same. *See Little v. NI Petroleum Co., Inc.*, 2009 WL 2424215 at *4 (W.D.Okla. 2009) (even if defendants' challenged deductions were not allowed under regulations, they were not false or fraudulent because "defendants' interpretation of the regulation and [government letter] was reasonable, as shown by [the government's] ultimate approval of the deductions"); *U.S. ex rel. Kersulis v. RehabCare Group, Inc.*, 2007 WL

294122 at *16 (E.D.Ark. 2007) (defendants' interpretation of the applicable regulations was reasonable, even if incorrect, thereby barring a finding that they knowingly submitted a false claim); *U.S. v. Prabhu*, 442 F.Supp.2d 1008, 1029 (D.Nev. 2006) ("a defendant does not 'knowingly' submit a 'false' claim when his conduct is consistent with a reasonable interpretation of ambiguous regulatory guidance"); *U.S. ex rel. Ramadoss v. Caremark Inc.*, 586 F.Supp.2d 668, 686 (W.D.Tex. 2008) ("[b]ecause there was (and still is) a good-faith disagreement over a complex area of law regarding whether a plan restriction could be applied [to deny a state Medicaid request for reimbursement], applying the existing restriction is not a false statement or record under the FCA"); *U.S. ex rel. Englund v. Los Angeles County*, 2006 WL 3097941 at *10-12 (E.D.Cal. 2006) (where existence of an FCA violation turned on "a legal question upon which reasonable minds could differ" about a state code provision, "no reasonable jury could conclude that [the defendant] had the requisite *scienter* to establish liability").[4]

Hixon is typical of these cases. The federal Medicaid statute requires that if third-party tortfeasors are legally responsible to patients for expenses of medical treatment, then providers, as assignees of the patients, must seek payment from those tortfeasors before seeking Medicaid reimbursement. The *Hixon* relator claimed that defendant providers failed to seek such payment from tortfeasors, and consequently submitted claims for Medicaid reimbursement that were too high, resulting in presentation to the United States of "false claims." 613 F.3d at 1189. In response, defendants argued that an Iowa statute had eliminated the collateral source rule in malpractice cases and thereby had eliminated the tortfeasor's liability to the patient for medical expenses if Medicaid had paid for those expenses. Hence, they argued, the providers did not violate the federal statute by not pursuing tortfeasors for medical expenses, because there was no

[4] As can be seen, some of these courts, like the Seventh Circuit in *Lamers,* treat the *scienter* issue as inextricable from the "false claim" issue. A few courts, notably the Ninth Circuit, have tried to separate these issues in "disputed legal interpretation" cases. The Ninth Circuit originally held that "evidence [that] shows only a disputed legal issue...is not enough to support a reasonable inference that the allocation was *false* within the meaning of the False Claims Act." *Hagood v. Sonoma County Water Agency, supra*, 81 F.3d at 1477. However, *U.S. ex rel. Oliver v. Parsons Co.*, 195 F.3d 457 (9th Cir. 1999), *cert. denied*, 530 U.S. 1228 (2000), distinguished *Hagood* and held that a claim can be "false" even if the defendant acted according to a reasonable interpretation of a regulation that a court subsequently determines to be erroneous. *Id.*, at 463. *Oliver* held that the disputed nature of the regulation went to *scienter*, not falsity. *Id.*

tortfeasor liability for these expenses. *Id.* An Iowa trial court had rejected defendants' interpretation of the Iowa statute, while an Iowa Supreme Court decision in a different context arguably supported it. *Id.*, at 1190. The Eighth Circuit concluded it need not decide whether the defendants' interpretation was right, since "a statement that a defendant makes based on a reasonable interpretation of a statute cannot support a claim under the FCA if there is no authoritative contrary interpretation of that statute. That is because the defendant in such a case could not have acted with the knowledge that the FCA requires before liability can attach." *Id.*

This avalanche of case authority as a matter of law defeats Nicholson's ability to allege defendants' *scienter* under the FCA. It also teaches that this Court need not resolve whether the "limit" or "floor" interpretation of the Medicaid statute is the correct one, since the fact that this issue remains disputed and unsettled is sufficient to negate defendants' *scienter. See, e.g., K&R Ltd. P'ship*, 530 F.3d at 983; *Hixon*, 613 F.3d at 1190.

Common sense confirms what the case law holds. The FCA is a formidable weapon, providing treble damages, civil penalties, and fees. Nicholson threatens a charity, a retired psychiatrist, and a family-owned pharmacy with annihilating liability on the theory that they were required to analyze a complex statute that even sophisticated lawyers might find opaque, and to reach a legal conclusion that a federal judge questioned and that CMS and Illinois' Medicaid program have rejected. Holding defendants liable in these circumstances would "transform every inaccurate claim into a false claim and consequently replace the Act's knowledge requirement with a strict liability standard." *Fowler*, 496 F.3d at 743.

CONCLUSION

The Court should dismiss the complaint with prejudice under F.R.Civ.P. 12(b)(6).

Respectfully submitted,

/s/ George F. Galland, Jr.
George F. Galland, Jr.
One of the Attorneys for Defendant
Hephzibah Children's Association

Miner, Barnhill & Galland, P.C.
14 W. Erie St.
Chicago, IL 60654
(312) 751-1170

/s/ Stephen C. Veltman
Stephen C. Veltman
One of the Attorneys for Defendant
Lilian Spigelman, M.D.

Pretzel & Stouffer
One S. Wacker Dr., Ste. 2500
Chicago, IL 60606
(312) 578-7528

/s/ Masaru K. Takiguchi
Masaru K. Takiguchi
One of the Attorneys for Defendant
Sears Pharmacy

Masaru K. Takiguchi
1415 W. 22nd St.
Tower Fl.
Oak Brook, IL 60523
(630) 645-3833