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

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

DEFENDANTS' JOINT REPLY MEMORANDUM IN SUPPORT
OF THEIR MOTION TO DISMISS UNDER F.R.CIV.P. 12(b)(6)

As defendants' opening brief showed, relator Linda Nicholson's suit under the False Claims Act (FCA) fails as a matter of law, because it depends on an unsettled and controversial legal theory -- that the federal Medicaid statute renders drugs prescribed for "off-label, non-compendium" uses *per se* ineligible for reimbursement. The only court decision that has considered this theory against a contrary interpretation of the statute found the issue unclear and declined to resolve the dispute. CMS, the federal Medicaid agency, has rejected relator's theory. So have most states, including Illinois, whose Medicaid regulations generally reimburse off-label, non-compendium uses if the physician deems them necessary for the patient.

Given this state of the law, defendants showed that Nicholson's FCA claim is hopeless. First, the fact that these uses were reimbursable under Illinois' Medicaid regulations negates as a matter of law the scienter required by the FCA. Second, the FCA case law overwhelmingly and unanimously holds that where a relator's theory of "falsity" depends on an unsettled legal theory, the relator as a matter of law cannot satisfy the *scienter* requirement -- and in the Seventh Circuit, she cannot even satisfy the "falsity" requirement. *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999).

As this reply will show, Nicholson all but ignores defendants' arguments. Instead, she advocates a startling new theory of FCA liability for "legal falsity" cases like this one. ("Legal falsity" cases do not allege that a claim is factually false, but rather that it is ineligible for payment because of "an extrinsic legal, regulatory or contractual reason." *U.S. ex rel. Sharp v. Eastern Oklahoma Orthopedic Center*, 2009 WL 499375, at *5 n. 7 (N.D.Okla. 2009) (citation omitted).) Nicholson's new theory asserts that it is irrelevant to defendants' *scienter* that Illinois regulations made these claims eligible, because defendants had a duty to read the federal statute and to conclude that Illinois had violated that statute by issuing the regulations and that CMS had violated it by approving Illinois' state Medicaid plan. Under her theory, it is also irrelevant to defendants' *scienter* that her interpretation of the statute is unsettled and challenged, because the statute's text is so clear that her interpretation will ultimately prevail in the courts. As defendants will show, this theory lacks even a shred of case support, and has nothing to be said in its favor.[1]

I. Nicholson does not seriously contest the controlling legal and regulatory framework.

A. The competing interpretations of the federal Medicaid statute, and the lack of an authoritative judicial resolution of the issue.

As defendants showed, there is a serious dispute over Nicholson's legal theory -- that 42 U.S.C. §1396r-8's definition of "covered outpatient drug" in that section acts as a *ceiling* on Medicaid reimbursement by forbidding states from reimbursing a drug that does not fit that definition. Under a competing interpretation, this definition acts as a *floor* on Medicaid reimbursement -- *i.e.*, it *requires* states to reimburse all drugs that are "covered outpatient drugs" while *allowing* states not to reimburse non-"covered outpatient drugs." Defendants' 12(b)(6) Memorandum ("Defs.' Mem."), at 4-5. As defendants further showed, there has been no

[1] Defendants' opening memorandum urged this Court to decide the present motion before taking up the separate Rule 9(b) motion. As defendants showed, the legal issues addressed by the present motion depend on the undisputed state of the law on the proper interpretation of the federal Medicaid statute and on the undisputed fact that Illinois Medicaid regulations allow reimbursement of off-label, non-compendium uses. Hence no amendment of the complaint to try to cure its Rule 9(b) deficiencies can moot the issues presented by this motion. Defs.' Mem. at 2. Nicholson does not dispute that it is appropriate to address the present motion first, and to consider the Rule 9(b) motion only if this Court denies the present motion.

authoritative judicial resolution of this question. No federal appeals court has examined it. In deciding motions in "off-label marketing" cases against drug manufacturers, several courts have assumed that the definition acts as a ban on reimbursement of non-"covered outpatient drugs," but on none of those motions was that interpretation disputed, or the competing "floor" interpretation argued. Only one published decision has compared the merits of these two interpretations. It found the "ceiling" interpretation problematic and declined to resolve the dispute. *U.S. ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255, at *2 (D.Mass. 2003) ("*Parke-Davis II*") (Saris, J.).

Nicholson does not question the accuracy or completeness of defendants' summary of the case law on this issue. Amazingly, she never mentions *Parke-Davis II*, or the other cases discussed by defendants.

Without disputing the unsettled status of this issue in the courts, Nicholson appears to argue that this status is irrelevant, because the text of the statute is incontestably clear. Relator's Memorandum ("Rel. Mem.") at 10-11. The implication of this argument is that Judge Saris erred in *Parke-Davis II* by concluding that the text was unclear and by declining to resolve the issue.

The argument has no merit. Judge Saris was right to find the meaning of this statute unclear. Nicholson offers nothing to dispel the difficulty in the "ceiling" interpretation that Judge Saris pointed out. To the contrary, Nicholson simply assumes the answer to the issue -- *i.e.*, she begs the question. The statute *defines* "covered outpatient drug," but has no separate provision prohibiting states from reimbursing a non-"covered outpatient drug." Thus, the question is whether the definition's use of the adjective "covered" *implies* that prohibition. Nicholson says it does. But it is equally if not more plausible that the word "covered" in the definition implies only that a state with a rebate agreement with a drug manufacturer *must* reimburse the manufacturer's drugs that fit that definition, and may elect not to reimburse drugs which do not. This "floor" interpretation fits §1396r-8's purpose, which is to require rebate agreements between drug manufacturers and to specify what manufacturers receive in return for signing those agreements. And as Judge Saris noted, the "floor" interpretation is supported by

§1396r-8(d)(1)(B)(1), whose language makes it *optional* for a state not to cover a drug which is *not* for a "medically accepted indication" and therefore which does not fit the definition of "covered outpatient drug." She pointed out, and Nicholson does not dispute, that if the "ceiling" interpretation were correct, then §1396r-8(d)(1)(B)(1) would serve no purpose and would be "superfluous," contrary to a basic rule of statutory interpretation. *Parke-Davis II*, 2003 WL 22048255, at *3.

In short, Nicholson is not credible in characterizing the "ceiling" interpretation as indisputably obvious from the text of this convoluted provision. Some day the federal courts -- perhaps the Supreme Court -- may decide which interpretation is right. Meanwhile, this is one of the countless debatable federal statutory issues unresolved by authoritative judicial interpretation.

B. The federal Medicaid drug reimbursement regulations.

As defendants showed, the federal Medicaid regulations governing prescription drugs do not forbid reimbursement for off-label, non-compendium uses. Defs.' Mem. at 6, *citing* 42 C.F.R. Part 447. Nicholson does not assert otherwise. She never mentions these regulations.

C. CMS's rejection of the "ceiling" interpretation.

As defendants showed, CMS, the federal agency charged with overseeing the Medicaid program and approving state Medicaid plans, rejected the ceiling interpretation in its 2007 and 2008 correspondence with Utah's Attorney General. Defs.' Mem. at 6-7. Nicholson does not question that these letters were exchanged between CMS and Utah, and that the two CMS letters purport to be authored by high-level CMS officials. The first was from the Director of CMS's Center for Medicaid and State Operations, which deals with Medicaid as opposed to Medicare. Defs.' Mem., Ex. D. The second was from the Director of the Disabled and Elderly Health Programs Group, which, as the letter states, is the entity within the Center for Medicaid and State Operations with responsibility for coverage of outpatient drugs. Defs.' Mem., Ex. F.

Nonetheless, Nicholson argues that it is "dubious" that these letters represent CMS's position, because on each letter an assistant indicated that he or she was signing for the letter's author. Nicholson implies that the assistants had no authority to sign and that the authors for whom they signed do not hold the views the letters describe. Rel. Mem. at 12-14.

This is a preposterous argument. First, there is no dispute that CMS is authorized by law to advise states on what federal law permits and does not permit them to do under the Medicaid program, since it is CMS that approves or disapproves state Medicaid plans. 42 C.F.R. §430.15. Second, Nicholson offers no case holding that a letter communicating an agency's position cannot be signed by an assistant on behalf of the letter's author. "One person may authorize another to sign a document on his behalf." *Patterson v. Leyden*, 947 F.Supp. 1211, 1215 (N.D.Ill. 1996). The only reasonable inference is that these signatures were authorized. The likelihood that they were not, and that the purported authors did not agree with the positions in this letter, is infinitesimal, and Nicholson offers no evidence that any such bizarre occurrence happened. Other evidence confirms that CMS holds the view on this issue that these letters express. As noted above, the federal Medicaid drug regulations, which were issued by CMS, do not forbid off-label, non-compendium uses. And CMS for years has approved the Medicaid plans of Illinois and other states whose regulations expressly provide for reimbursing such uses.

D. The Department of Justice's position.

Defendants showed that between 2003 and 2009, the Department of Justice hedged on whether it supported the "ceiling" interpretation of the Medicaid statute. In 2003, it declined Judge Saris's invitation in *Parke-Davis II* to take a stand on that issue and in 2008, it told Judge Saris that she need not decide it. Only within the last year has it appeared to advocate the "ceiling" interpretation, and only in the context of lawsuits against drug manufacturers who had illegally promoted "off-label" uses of their drugs. Defs.' Mem. at 7-8.

Nicholson does not dispute defendants' summary of the Department's behavior. But she implies that the Department's recent advocacy of the "ceiling" interpretation settles the issue of

what the statute means. *See* Rel. Mem. at 11-12, calling the Department's recent position "the government's official position." Any such implication is wrong. "[B]ecause it is not considered an administrative agency when it enforces statutes, the Department of Justice is not entitled to *Chevron* deference in interpreting statutes that it enforces." *U.S. v. Philip Morris USA, Inc.*, 310 F.Supp.2d 68, 72 n. 5 (D.D.C. 2004).

E. The Illinois Medicaid and DCFS regulations.

As defendants showed, Illinois Medicaid regulations disagree with Nicholson's "ceiling" interpretation of the federal Medicaid statute. *See* Defs.' Mem. at 8, *discussing* 89 Ill. Admin. Code 140.414(a), which allows reimbursement of "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." Nicholson does not dispute this fact.

Defendants also showed that (1) relator's daughter (like all minors at Hephzibah) was a ward of the State of Illinois Department of Children and Family Services (DCFS); (2) under DCFS regulations, such a minor can be treated with a psychotropic drug only after the physician provides justification for prescribing that drug to that minor and obtains DCFS's consent; (3) these regulations do not forbid consent to off-label, non-compendium uses; and (4) DCFS gives consent to such uses knowing Medicaid will pay for the drug. *See* Defs.' Mem. at 8-9, *discussing* 89 Ill. Admin. Code Part 325. Nicholson does not dispute these facts.

In short, Nicholson has no serious response to defendants' showing that the legal theory on which she bases her FCA claims -- the supposed *per se* ineligibility of off-label, non-compendium uses under the Medicaid statute -- is seriously disputed, unresolved by any authoritative judicial interpretation, and rejected by key participants in the Medicaid scheme, including CMS, Illinois, and most other states.

II. Nicholson has no adequate response to defendants' legal arguments.

A. Nicholson does not dispute the legal standard of *scienter*.

Defendants showed, and Nicholson does not dispute, that the only FCA section she alleges defendants to have violated is 31 U.S.C. §3729(a)(1)A), which makes a person liable who "knowingly presents, or causes to be presented [to the United States], a false or fraudulent claim for payment or approval." Defs.' Mem. at 9. Defendants further showed, and Nicholson does not dispute, that to allege that defendants acted "knowingly" under this section, she must validly allege that they either knew that claims for off-label, non-compendium uses were legally ineligible for reimbursement under the Medicaid statute, that they deliberately kept themselves in ignorance of this supposed ineligibility, or that they acted in "reckless disregard" of this supposed legal ineligibility. *Id.* at 10, *discussing* 31 U.S.C. §3729(b)(1).

Defendants further showed, and Nicholson's response confirms, that she is relying on the "reckless disregard" prong, and that to show "reckless disregard" she must plead, at the least, "aggravated gross negligence." *See* Rel. Mem. at 5, where she argues that defendants' purported failure to understand the "real" meaning of the federal Medicaid law "went far beyond simple negligence to aggravated gross negligence."[2]

B. Nicholson ignores the argument that the unsettled status of her legal theory rules out her claim as a matter of law.

Defendants discussed an avalanche of federal cases holding that where a relator's theory of the "falsity" of a claim depends on a legal theory of eligibility, and that theory is subject to a serious dispute that has not been authoritatively resolved by the courts, then as a matter of law the scienter requirement cannot be met -- and, in the Seventh Circuit, the claim cannot even be regarded as false. Defs.' Mem. at 12-15.

[2] Nicholson makes a perfunctory nod to the "deliberate ignorance" prong. Rel. Mem. at 5 ("[a]s a violation of defendants' contractual duty and condition of their Medicaid participation to know the requirements of the law, it was reckless disregard or deliberate ignorance"). It does not matter whether she really intends to invoke "deliberate ignorance." Since as a matter of law she cannot meet the "reckless disregard" standard, neither can she meet the more demanding "deliberate ignorance" standard.

Remarkably, Nicholson ignores this discussion. She never mentions this line of authority. She cites no case that sustained the validity of a relator's *scienter* allegations where the relator's theory of falsity depended on a disputed and unsettled legal theory. She does not dispute that in *Lamers*, the Seventh Circuit held that the falsity and *scienter* requirements are inextricable and that "differences in interpretation growing out of a disputed legal question are...not false under the FCA." *Lamers*, 168 F.3d at 1018.

Nicholson's failure to contest this monolithic body of law should end this Court's inquiry. Where, as here, a theory of "falsity" depends on a legitimately disputed legal theory, the relator loses, because she cannot allege the requisite *scienter*, or, in this Circuit, the requisite falsity.

C. Nicholson has no serious response to the argument that the Illinois regulations defeat *scienter* as a matter of law.

As defendants showed, and as Nicholson agrees, CMS has approved Illinois and other state Medicaid plans knowing that the plans allow reimbursement of off-label, non-compendium uses. As shown above, when the Utah Attorney General complained about CMS's stance on this issue, CMS politely sent him packing. The Illinois regulations are similarly clear on their face that they allow reimbursement of such uses if a physician deems them necessary for the patient.

As defendants showed, the fact that Illinois and other states allow reimbursement of off-label, non-compendium uses negates defendants' *scienter* as a matter of law. Providers submit claims to Illinois Medicaid, not to the federal government. They have a right to rely on Illinois regulations, particularly since those regulations are part of a state Medicaid plan that has been approved by CMS, the federal government's official Medicaid agency. Providers do not act with "aggravated gross negligence" by failing to conduct their own examination of the federal Medicaid statute to see whether Illinois is misinterpreting that statute, or whether CMS has misinterpreted that statute by approving Illinois' plan. Defs.' Mem. at 11-12.

Nicholson, however, appears to argue that the Illinois regulations, and CMS's approval of them, are irrelevant to the scienter issue. She argues as follows:

1. Each defendant is a Medicaid provider, required by the Illinois Department of Public Health's *Handbook for Providers of Medical Services* to agree to "comply with the requirements of applicable federal and state laws and not engage in practices prohibited by such laws." Rel. Mem. at 4-5. Each defendant "accepted and certified, under penalties of perjury, an individual duty to review, clarify as necessary, and comply with federal law." *Id.* at 5.

2. Because defendants so "accepted and certified," they had a duty to "look beyond the Illinois regulations" to see if they were contrary to federal law. *Id.* Defendants acted *per se* with "aggravated gross negligence" by not doing so. *Id.*

3. Defendants' failure to "look beyond" the Illinois regulations was particularly blameworthy because they chose to conduct themselves according to regulations "which they had reason to believe would most benefit their own remuneration, or to clarify and understand stricter terms to which their attention was specifically directed in writing." *Id.*

4. Illinois violated the federal statute by promulgating the regulations, and CMS did likewise in approving Illinois' plan. Federal case law rules out reliance on the acts of government agents contrary to law. Hence the Illinois regulations' allowance of the claims in question does not negate defendants' *scienter*. *Id.* at 6.

5. Moreover, *U.S. ex rel. Hagood v. Sonoma Cty. Water Agency*, 929 F.2d 1416 (9th Cir. 1991) (hereafter "*Hagood I*") holds that "government officials' approval of a contract based on an erroneous interpretation of law" does not defeat a FCA claim. *Id.* at 7.

6. At a minimum, the purported fact that the federal statute forbids reimbursement of off-label, non-compendium uses creates a "presumption" that defendants knew their claims were false, and they should be required to "come forward with evidence that they relied on a specific good-faith interpretation *before* submitting the false claims." *Id.* at 8 (emphasis in original).

This argument is nonsense from start to finish.

1. Nicholson's complaint never alleges that *any* defendant was a Medicaid provider or signed any agreement. Had Nicholson made a reasonable pre-lawsuit investigation, she would

have learned that only Sears Pharmacy was a Medicaid provider on these claims, and that Dr. Spigelman was not a Medicaid provider, period.

But even ignoring this failure, Nicholson's complaint does not allege that any defendant accepted and certified, under penalties of perjury, a duty to "review" or "clarify" federal law. And she cites no regulation or agreement imposing this purported sworn-certification requirement, or a requirement that providers "review" or "clarify as necessary" federal law.

2. Even for Medicaid providers, Nicholson's theory -- that providers have a duty to "look beyond the Illinois regulations" to see whether those regulations are contrary to federal law -- is unsustainable. An agreement to "comply with the requirements of applicable federal...law" imposes no legal duty to go to unreasonable lengths to ascertain what those federal requirements are. In passing state Medicaid regulations, "[t]he presumption is that the state has acted within its authority and consistent with applicable federal law." *Carbon Hill Health Care, Inc. v. Beasley*, 528 F.Supp. 421, 423 (D.Ala. 1981). Moreover, where, as in the present case, "the federal agency charged with administering the Social Security Act approves the state plan it expresses its view that the plan is in compliance with applicable statutes and regulations. The interpretation of such an agency is entitled to substantial deference." *Park Nursing Center, Inc. v. Michigan Dep't of Social Services*, 28 B.R. 793, 803 (E.D.Mich. 1983). Hence providers who submit Medicaid claims eligible under Illinois regulations may reasonably presume them eligible under the federal statute. It would flout that presumption to impose a duty on providers to conduct legal investigations of whether state Medicaid eligibility rules are consistent with the text of the federal Medicaid statute. And as a practical matter, the idea of requiring pharmacies, doctors, and charitable organizations to pore over the mammoth and all-but-unreadable federal Medicaid statute for this purpose is laughable.

Moreover, even if defendants had "looked beyond" the Illinois regulations by reviewing the relevant statutes, regulations, and court cases, they would not have concluded that off-label, non-compendium uses were barred by the federal statute. At most, they would have concluded (as Judge Saris concluded in *Parke-Davis II*) that the statute was unclear, and that CMS, the

official federal Medicaid agency, saw nothing unlawful about submitting such claims. Under these circumstances, defendants could have submitted the claim without fear of FCA liability. As *Hagood*, on which Nicholson relies, put it: "To take advantage of a disputed legal question, as may have happened here, is to be neither deliberately ignorant nor recklessly disregardful." 929 F.2d at 1421. Many other cases hold the same, as discussed below.

3. Nicholson's accusation that defendants failed "to look beyond that one particular set of regulations [the Illinois Medicaid regulations] which they had reason to believe would most benefit their own remuneration, or to clarify and understand stricter terms to which their attention was specifically directed in writing" (Rel. Mem. at 5) can only be called wild. First, the complaint does not allege that defendants Hephzibah or Dr. Spigelman "sought and received public funds" (Rel. Mem. at 3). Hephzibah and Dr. Spigelman had no monetary interest in whether Medicaid reimbursed these prescriptions. Only defendant Sears Pharmacy sought and obtained Medicaid reimbursement for them. Second, the complaint does not allege that defendants knew of any requirement governing off-label drug reimbursement other than the Illinois rules. Nothing in the complaint alleges that any defendant's "attention was specifically directed in writing" to any "stricter terms" of reimbursement of these prescriptions (see Rel. Mem. at 5) than those contained in the Illinois Medicaid regulations and the *Handbook*.[3]

4. In the "estoppel against the government" cases, federal officials gave advice that conflicted with settled federal law, and courts held that such advice could not estop the government from enforcing the law. *See Heckler v. Community Health Services*, 467 U.S. 51, 59-62 (1984); *Federal Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 383-84 (1947); *Kennedy v. U.S.*, 965 F.2d 413, 420 (7th Cir. 1992). Nicholson argues that (a) in promulgating the regulations, Illinois violated the federal Medicaid statute; (b) in approving Illinois' Medicaid plan, CMS

[3] Nicholson cites only from the *Handbook*'s preliminary chapter, Chapter 100 (Rel. Mem., Ex. 2). But the *Handbook* also offers detailed guidance on eligibility of various services. Unlike the federal Medicaid statute (which most providers could not even *find* without a lawyer), reasonable providers do and should read and rely on the *Handbook* in deciding what claims the law allows them to submit. Chapter P-200, whose current version is attached as Exhibit A to this reply memorandum (and is available online at http://www.hfs.illinois.gov/handbooks), deals with drugs. Part P-204 lists "Covered Services and Coverage Limitations," and Part P-206 lists "Non-Covered Services." Neither section excludes off-label, non-compendium uses.

"acquiesce[d]" with that violation (Rel. Mem. at 7); and (c) if defendants' *scienter* were negated by the eligibility of these claims under the Illinois regulations, that would overrule the "estoppel against the government" cases. Rel. Mem. at 6-8.

This argument has no merit, because the issue on this motion has nothing to do with estoppel. Estoppel is an affirmative defense. F.R.Civ.P. 8(c)(1); *Central Arizona Water Conservation Dist. v. U.S.*, 32 F.Supp.2d 1117, 1138 (D.Ariz. 1998). The issue on this motion is not whether defendants can defend against this FCA claim by estopping the United States from enforcing the federal Medicaid statute. It is whether Nicholson, in the name of the United States, can allege the necessary *scienter* element of a FCA claim. As discussed above, where the alleged falsity of the claim depends on a disputed legal theory, she cannot do so.

Moreover, the conduct of the government agents in Nicholson's estoppel cases cannot be analogized to the conduct of Illinois and CMS here. In those cases, the conduct on which the defendants relied for their estoppel arguments was the giving of *advice*. In *Heckler*, that advice was an oral opinion by a Medicare third-party administrator that certain costs need not be deducted from the amount the provider claimed. 467 U.S. at 66. In *Merrill*, the advice was a statement from a committee that the defendant's wheat crop was insurable. 332 U.S. at 382. In *Kennedy*, the advice was an IRS agent's opinion as to how much tax the defendant owed. 965 F.2d at 414. All three decisions held that to establish the "reliance" element of estoppel, defendant could not reasonably rely on mistaken advice that was contrary to statute.

The present case has nothing to do with such "mistaken advice" situations. The Illinois Medicaid regulations are not "advice." They are regulations prescribed after following the notice-and-comment procedures of the Illinois Administrative Procedure Act, 5 ILCS 100/1-1 *et seq.* As such, they have the "force of law." *Stull v. Dep't of Children & Family Services*, 239 Ill.App.3d 325, 332, 606 N.E.2d 786, 791 (5th Dist. 1992). Likewise, CMS's approval of Illinois' state Medicaid plan was not "advice" or "opinion." It was the official act of the United States, conducted pursuant to the authority granted by statute and regulation.

5. Nicholson's *Hagood* argument is irresponsible. She cites and mentions only the first of the two *Hagood* decisions. Taken together, they shred her theory of FCA liability.

Hagood was not a "legal falsity" case, in which the falsity of the claim depended exclusively on the interpretation of a statute or regulation. Rather, the relator alleged that the California Water Agency had obtained the Army Corps of Engineers' approval for a contract by submitting cost allocations that were not "'true and correct, and current and accurate,'" as well as making "various other misstatements and material omissions relating to the contract." 929 F.2d at 1418. He alleged he had informed his superiors in the Corps of these misrepresentations but they had approved the contract anyway. The issue in *Hagood I* was whether these federal officials' knowledge of the alleged fraud barred a claim against the California agency under the FCA. The Ninth Circuit decided that it did not, because the complaint alleged that the California Water Agency had "played an active part in having presented for signature a contract that the Water Agency knew was based on false information." *Id.* at 1421. If the Water Agency caused the "knowing presentation of what is known to be false," the fact that federal officials "kn[e]w of the falsity is not in itself a defense." *Id.* Nothing in *Hagood I* implies that where the alleged falsity of a submitted claim depends on a disputed legal interpretation of a statute, a defendant can "knowingly" cause the submission of a false claim.

When *Hagood* came before the Ninth Circuit again, it affirmed summary judgment against relator. *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478-79 (9th Cir.), *cert. denied*, 519 U.S. 865 (1996) ("*Hagood II*"). The Ninth Circuit found that "[a]t most, Hagood has shown that the Water Agency took advantage of a disputed legal issue. This, as we have previously held [in *Hagood I*], is not enough." *Id.* Numerous decisions (collected in the footnote below) cite *Hagood II* to reject FCA claims whose alleged falsity depends on disputed legal interpretations, even if the defendant is deliberately taking advantage of legal uncertainty.[4] Some

[4] *U.S. ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 957-58 (10th Cir. 2008); *U.S. v. Southland Management Corp.*, 326 F.3d 669, 682 (5th Cir. 2003) (en banc); *Crane Helicopter Ser., Inc. v. U.S.*, 45 Fed.Cl. 410, 434 (1999); *U.S., ex rel. Ramadoss v. Caremark Inc.*, 586 F.Supp.2d 668, 686 (W.D.Tex. 2008); *U.S. ex rel. Longhi v. Lithium Power Technologies*, 513 F.Supp.2d 866, 876 (S.D.Tex. 2007); *Fru-Con Const. Corp. v. Sacramento Mun. Utility*, 2007 WL 1791699, at *18 (E.D.Cal. 2007); *U.S. ex*

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of these decisions hold that disputed legal questions rule out *scienter*; others follow the Seventh Circuit's approach in *Lamers* and hold that such disputes rule out falsity.

6. Nicholson's fallback "presumption" theory asserts that (a) defendants are presumed to know the law; (b) federal law *per se* forbids reimbursement of off-label, non-compendium uses; (c) hence a "presumption" arises that defendants knew these claims were ineligible; and (d) hence defendants must "come forward with evidence that they relied on a specific good-faith interpretation *before* submitting the false claims." Rel.Mem. at 8 (emphasis in original). Nicholson cites *U.S. v. Mackby*, 261 F.3d 821 (9th Cir. 2001), *cert. denied*, 541 U.S. 936 (2004), in which the owner of a physical therapy clinic was held liable under the FCA for circumventing Medicare payment ceilings by instructing his staff to provide, on claim forms, the identification number of a different physician than the actual provider of the service. The Ninth Circuit brushed off Mackby's argument that he was not familiar with Medicare requirements, holding that as the manager director of the clinic who was responsible its day-to-day operations, he had a duty to be familiar with the legal requirements necessary to obtain Medicare reimbursement for physical therapy services. *Id.* at 828.

Nicholson's "presumption" argument has no merit. First, the maxim that everyone is "presumed to know the law" assumes the law is clear. (In *Mackby,* for example, the law indisputably required claimants to supply the identification number of the real service provider.) No case presumes anyone to know the law when that law is disputed. If Judge Saris found it unclear whether the "ceiling" or "floor" interpretation of the Medicaid statute was the correct one, these lay defendants cannot be "presumed" to find the matter clear.

Second, no one is "presumed" to know that a duly-passed state regulation conflicts with federal law. To the contrary, as discussed above at p. 10, Medicaid providers may presume that the state enacted its Medicaid regulations "within its authority and consistent with applicable federal law." *Carbon Hill Health Care, supra*, 528 F.Supp. at 423.

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rel. Gudur v. Deloitte Consulting LLP, 512 F.Supp.2d 920, 932 (S.D.Tex. 2007); *U.S. ex rel. Englund v. Los Angeles County*, 2006 WL 3097941, at *7 (E.D.Cal. 2006); *U.S. v. Prabhu*, 442 F.Supp.2d 1008, 1026 (D.Nev. 2006).

To sum up: that Illinois Medicaid regulations allow reimbursement of off-label, non-compendium uses thought necessary by the prescribing physician defeats Nicholson's claim that defendants acted in "reckless disregard" of the supposed ineligibility of such uses under the federal Medicaid statute.

CONCLUSION

Defendants respectfully request that the Court dismiss the complaint with prejudice pursuant to Rule 12(b)(6).

Respectfully submitted,

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