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' CONSOLIDATED MOTION TO DISMISS PURSUANT TO F.R.CIV.P. 9(B)

This lawsuit under the False Claims Act ("FCA") rests on the theory that the federal Medicaid statute, 42 U.S.C. §1396 *et seq.*, contains a *per se* prohibition on Medicaid reimbursement for drugs that are prescribed for "off-label, non-compendium" uses. An "off-label" use is a use for a different indication than the uses for which the Food and Drug Administration approved the drug in question. A "non-compendium use" is a use for an indication that is not supported by one of tree specified medical compendia: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications), and the DRUGDEX Information System. According to the present lawsuit, any person who causes a Medicaid reimbursement claim to be submitted for an off-label, non-compendium use violates 31 U.S.C. §3729(a)(1)(A), which makes any person liable to the United States who "knowingly...causes to be presented [to the United States], a false or fraudulent claim for payment or approval." 31 U.S.C. §3729(a)(1)(A).

This theory of *per se* ineligibility of off-label, non-compendium uses underlies this suit against three Chicago area defendants. During 2004, relator's daughter, then under the guardianship of the Illinois Department of Children and Family Services, was placed to live temporarily at defendant 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 ("Sears"), filled several Celexa prescriptions and submitted Medicaid claims to have them reimbursed. Relator now claims they violated the FCA by causing the United States to pick up part of the cost incurred by Illinois in reimbursing prescriptions that supposedly were ineligible for reimbursement under the federal Medicaid statute.

Defendants have filed a separate motion under F.R.Civ.P. 12(b)(6) to dismiss the case on the merits with prejudice.[1] That motion shows that (1) as a matter of law, relator's theory of FCA liability against all three defendants fails for lack of the requisite *scienter*, even if one accepts her interpretation of the federal Medicaid statute; (2) her claim against Dr. Spigelman fails as a matter of law, because a physician does not "cause" a Medicaid claim to be presented to the United States simply by writing a prescription for a drug, even if she knows that the pharmacy will likely submit a Medicaid claim to be reimbursed for it; and (3) her claim against defendant Sears fails as a matter of law because pharmacies are not told, and are not required to investigate, the diagnosis for which physicians write prescriptions.

The present memorandum in support of defendants' motion to dismiss under Rule 9(b) addresses defects in the complaint of a different sort. These are defects caused by relator's pervasive failure to plead her claim with anything remotely approaching the "particularity" Rule 9(b) requires. In theory, these are defects relator could try to cure by amendment. In contrast, on the issues addressed by the Rule 12(b)(6) motion, the complaint has clearly said everything that can be said. Defendants therefore respectfully request the Court to take up the Rule 12(b)(6) motion first, because even if the Rule 9(b) defects could be cured, the Court would still have to decide whether relator's basic legal theories of liability hold water. Defendants have written the present Rule 9(b) brief on the assumption that the Court will have first read their separate brief in support of that motion.

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[1] Defendants have also filed a Rule 12(b)(1) motion asserting that the complaint is barred under 31 U.S.C. §3730(e)(4)(A) by previous public disclosure of substantially the same allegations; briefing on this motion has been stayed since the Seventh Circuit currently has a case under consideration that may bear on this issue. That motion will become moot if this Court grants the Rule 12(b)(6) motion.

As noted in defendants' Rule 12(b)(6) brief, relator's complaint is nearly a *verbatim* copy of a "model complaint" posted on the website of PsychRights, a "public interest law firm" opposed to the use of psychiatric drugs in children. *See* http://psychrights.org/index.htm. The "model complaint" is attached as Exhibit A to this brief. It is designed to sue psychiatrists who prescribe psychotropic drugs to children and "providers" who submit or cause Medicaid claims for such drugs to be submitted. Relator's complaint (Ex. B) filled in the blanks of the "model complaint" and added a few details about the prescriptions to relator's daughter.

It would be surprising if an FCA complaint prepared by copying a generic "model complaint" satisfied the particularity requirement of F.R.Civ.P. 9(b). Relator's complaint assuredly does not. Section I will review what the complaint alleges and does not allege. Section II will show that the complaint falls pervasively short of what the rule requires.

I. WHAT THE COMPLAINT ALLEGES AND DOES NOT ALLEGE.

A. Allegations about defendants and what they did.

Dr. Spigelman. Paragraph 8 alleges that Dr. Spigelman prescribed and continues to prescribe psychiatric medications to relator's minor child and other minors. Paragraph 22 lists five specific Celexa prescriptions that Dr. Spigelman prescribed for relator's daughter, giving their dates, the dosage, an unexplained dollar figure for each prescription, and the fact that they were filled by Sears. The complaint does not allege that Dr. Spigelman presented these prescriptions for reimbursement.

Hephzibah. The complaint alleges no fact as to what Hephzibah is or its relation to relator's daughter. Paragraph 9 alleges that Hephzibah "presented or caused to be presented claims to Medicaid...." This paragraph does not allege that Hephzibah filed claims for reimbursement with any Medicaid agency; ¶23 backs off the "presented" claim, saying merely that Hephzibah "caused the presentment of Medicaid claims." Nothing in the complaint identifies any act through which Hephzibah "caused" such claims to be presented to "Medicaid."

Sears. Paragraph 10 alleges that Sears presented and continues to present claims to "Medicaid" for psychiatric medications prescribed and given to relator's child and other minors.

The complaint does not specify when or how Sears presented claims, to what agency it presented them, the amount of any claim, what the drug involved in the claim was, what information or statements Sears gave or made when presenting the claims, and whether each claim was allowed.

B. Allegations about the presentation of claims to the United States.

Paragraph 7 of the complaint says that prescriptions of psychiatric drugs for relator's minor daughter and others were presented for "Medicaid reimbursement," and ¶¶8, 9, 10, 23, and 24 allege that claims were presented to "Medicaid." The complaint offers no particularization of this assertion. It does not say what it means by "Medicaid." As mentioned above, the complaint does not say when the claims were presented, to what agency they were presented, what information was submitted with the claim, or when or in what amount (or even whether) the claims were allowed. It offers no particulars of how the United States ultimately paid money on account of these prescriptions, or how much it paid.

C. Allegations about the falsity of the claims.

Paragraphs 15, 16, and 17 set forth relator's legal theory that off-label, non-compendium uses of any drug are *per se* non-reimbursable under "Medicaid." These paragraphs support this conclusion solely by citing the federal Medicaid statute's definition of "covered outpatient drugs" and the exclusion of off-label, non-compendium uses from that definition. Relator's theory of *per se* ineligibility of off-label, non-compendium uses is discussed at length in defendants' separate Rule 12(b)(6) memorandum. As noted there, the complaint does not allege that off-label, non-compendium uses are non-reimbursable under *Illinois* Medicaid regulations or that the Illinois Medicaid regards them as non-reimbursable. As likewise discussed in that memorandum, such uses are reimbursable under the Illinois Medicaid regulations unless they fall into a list of ten excluded types of drug.

Paragraph 22 alleges that the Celexa for relator's daughter was "not for a medically accepted indication." By this, ¶22 means that the Celexa was not for a "medically accepted indication" as defined in the federal Medicaid statute -- *i.e.*, that it was not for a use approved by

the FDA or supported by one of the three compendia. The complaint alleges nothing about the prescriptions that would make them "not medically accepted" in any other sense.

Even as to the allegation that the prescriptions did not meet the statutory definition of "medically accepted indication," the complaint contains no particulars. It does not say for what diagnosis Dr. Spigelman wrote any prescription. It says nothing about what Celexa has and has not been approved for by the FDA. It says nothing about what any of the three compendia say or do not say about uses of Celexa.

D. Allegations about defendants' *scienter*.

Paragraphs 8 through 10 allege, without more, that each defendant "[knew] within the meaning of the [FCA]" that the claims to Medicaid for the prescriptions would be "false claims under the False Claims Act." Paragraph 20 quotes the FCA's *scienter* definition of 31 U.S.C. §3729(b), and ¶¶25 through 28 allege, without more, that each defendant satisfied the definition because she or it acted "(1) with actual knowledge; (2) in deliberate ignorance; or (3) in reckless disregard that such claims are false, and is therefore liable under the False Claims Act."

As discussed in defendants' Rule 12(b)(6) memorandum, the complaint pleads no facts to support "actual knowledge" or "deliberate ignorance." It does not allege that any governmental agency or anyone else ever told defendants that off-label, non-compendium uses were ineligible under the federal Medicaid statute. It does not allege that any defendant believed that any prescription was ineligible. It does not allege that any defendant failed to observe procedural safeguards in effect for prescribing psychotropics to minors, including the advance approval procedures required by DCFS regulations (discussed in defendants' Rule 12(b)(6) memorandum) for wards of the State of Illinois such as relator's daughter.

Rather, as discussed in the Rule 12(b)(6) memorandum, relator seems to assert that defendants acted in "reckless disregard" of the supposed *per se* ineligibility of off-label, non-compendium uses under the federal Medicaid statute. The "reckless disregard" theory is reflected in ¶¶5 and 18. Paragraph 5 alleges that "[u]nder Medicaid, (a) psychiatrists and other prescribers, (b) mental health agencies or providers, and (c) pharmacies, all have specific responsibilities to

prevent false claims from being presented," while ¶18 alleges: "Every Medicaid provider must agree to comply with all Medicaid requirements." The complaint does not specify what the "specific responsibilities" of providers are, or identify any legal provision or agreement imposing such "specific responsibilities." The complaint does not define what it means by "Medicaid provider" and it does not allege that any defendant is a "Medicaid provider." Nor does the complaint allege through what mechanism or document any defendant has "agree[d] to comply with all Medicaid requirements.

II. THE COMPLAINT SHOULD BE DISMISSED UNDER RULE 9(B).

F.R.Civ.P. 9(b) provides:

> In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.

Rule 9(b) requires pleading "the who, what, when, where, and how: the first paragraph of any newspaper story." *DiLeo v. Ernst & Young,* 901 F.2d 624, 627 (7th Cir.), *cert. denied*, 498 U.S. 941 (1990). It has three purposes: (a) protecting a defendant's reputation from harm; (b) minimizing "strike suits" and "fishing expeditions"; and (c) providing notice of the claim to the adverse party. *Vicom, Inc. v. Harbridge Merchant Servs., Inc.*, 20 F.3d 771, 777 (7th Cir. 1994).

Rule 9(b) applies to claims under the FCA. *U.S. ex rel. Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601, 604-06 (7th Cir. 2005); *U.S. ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 376 (7th Cir.), *cert. denied,* 540 U.S. 968 (2003); *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232-33 (1st Cir.), *cert. denied*, 543 U.S. 820 (2004). Numerous courts have invoked Rule 9(b) to dismiss FCA cases alleging that defendants, through marketing of "off-label" drugs or devices, violated 31 U.S.C. §3729(a)(1) by causing false claims to be presented to the United States. *See, e.g., U.S. ex rel. Hopper v. Solvay Pharm. Inc.*, 588 F.3d 1318, 1325 (11th Cir. 2009), *cert. denied*, 130 S.Ct. 3465 (2010); *U.S. v. Ortho-McNeil Pharm., Inc.*, 2007 WL 2091185 (N.D.Ill. 2007), at *3-*5; *U.S. ex rel. Bennett v. Medtronic, Inc.*, 2010 WL 3909447 (S.D.Tex. 2010) at *11 ff. (dismissing "off-label marketing" claim against medical equipment supplier for failure to meet Rule 9(b)); *U.S. ex rel. Stephens v. Tissue Science*

Labs., Inc., 664 F.Supp.2d 1310, 1319-20 (N.D.Ga. 2009); *U.S. ex rel. Polansky v. Pfizer, Inc.*, 2009 WL 1456582 (E.D.N.Y. 2009), at *5-*11; *U.S. ex rel. Poteet v. Lenke*, 604 F.Supp.2d 313, 323-25 (D.Mass. 2009); *U.S. ex rel. Hess v. Sanofi-Synthelabo, Inc.*, 2006 WL 1064127 (E.D.Mo. 2006), at *6-*11.

Relator's FCA complaint alleges violation of 31 U.S.C. §3729(a)(1)(A), which imposes liability on one who "knowingly presents, or causes to be presented, a false or fraudulent claim [to the United States] for payment or approval." This provision requires a relator to allege (a) that a claim was presented to the United States for payment or approval; (b) that each defendant *presented or caused the claim* to be presented; (c) that the claim was "false"; and (d) that the defendant acted "knowingly." *U.S. ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 740-41 (7th Cir. 2007), *overruled in part on another issue by Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009). As will now be shown, the complaint is deficient under Rule 9(b) as to all four prerequisites.

A. The complaint fails to allege with particularity the claims that were "presented to the United States."

The complaint offers no particularized fact about any claim being "presented to the United States." The complaint describes five Celexa prescriptions that Sears pharmacy filled, but does not state that those prescriptions were presented to "Medicaid" at all. Still less does the complaint allege who submitted such claims, when they were submitted, to what agency they were submitted, how much was claimed, and whether the claims were paid. And still less does the complaint allege how the United States ended up paying for these prescriptions.

In *U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350 (11th Cir. 2006), the Eleventh Circuit affirmed a Rule 9(b) dismissal of a FCA claim for failure to provide particulars in support of the conclusion that defendants submitted claims:

> [Relator] cites particular patients, dates and corresponding medical records for services that he contends were not eligible for government reimbursement. Just like the *Clausen* plaintiffs, though, Atkins fails to provide the next link in the FCA liability chain: showing that the defendants *actually submitted* reimbursement claims for the services he describes. Instead, he portrays the scheme and then summarily concludes that the defendants submitted false claims to the government for reimbursement.

Id., at 1358-59 (emphasis in original) (citing to *U.S. ex rel. Clausen v. Lab Corp. of Am.*, 290 F.3d 1301 (11th Cir. 2002). The Court said that "if Rule 9(b) is to be adhered to, some indicia of reliability must be given *in the complaint* to support the allegation of *an actual false* claim for payment being made to the Government." *Id.*, at 1357 (quoting *Clausen*, 290 F.3d at 1311).

The Seventh Circuit would clearly hold the same. In *U.S. ex rel. Crews v. NCS Healthcare of Ill., Inc.*, 460 F.3d 853 (7th Cir. 2006), the Seventh Circuit affirmed summary judgment against a relator who "did not provide a single false claim that was actually submitted." *Id.*, at 856. The court agreed that a FCA relator cannot merely "describe a private scheme in detail but then...allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." *Id., quoting Clausen*, 290 F.3d at 1131.

B. The complaint fails to allege what Hephzibah did to present or cause a claim to be presented.

Even if the complaint's failure to allege any particular claim being presented to the United States is overlooked, relator must also allege with particularity what each defendant *did* to present or cause a claim to be presented. Although this complaint has few virtues, it does at least reveal relator's *theory* of how Sears and Dr. Spigelman presented, or caused the presentation of, claims to the United States. Sears allegedly sent the claims to "Medicaid" for reimbursement. Compl., ¶24. And Dr. Spigelman allegedly "caused claims to be presented" simply by writing the prescriptions themselves. Compl., ¶25. (This latter theory is invalid as a matter of law, as shown in defendants' Rule 12(b)(6) motion.)

However, it is unfathomable from the complaint what *Hephzibah* is alleged to have done to cause a false claim to be presented. As discussed above, the complaint says nothing about what Hephzibah is or does. It does not allege that Hephzibah filed claims for reimbursement with any Medicaid agency or that it was involved in any way with the filing of such claims. As to Hephzibah, this complaint says nothing beyond the empty formula that Hephzibah "caused the presentment to Medicaid of claims for psychotropic drugs prescribed to Relator's minor child...." Compl., ¶23.

C. Even accepting relator's legal theory of falsity, the complaint fails to plead facts showing with particularity that the claims were "false" under that theory.

Relator's theory of falsity has two components: (1) her legal theory that the federal Medicaid statute *per se* makes off-label, non-compendium uses *per se* ineligible for reimbursement; and (2) the factual allegation that the prescriptions in question were off-label, non-compendium uses. The legal theory is clearly pled in the complaint (¶¶16-17, 25-27), and defendants' Rule 12(b)(6) motion shows why that theory is wrong. But even if that legal theory is accepted, the complaint does not allege the factual component of falsity -- that the prescriptions were for off-label, non-compendium uses -- with the particularity that Rule 9(b) requires.

To satisfy Rule 9(b) on this issue, it is not enough to allege the general statement that the indications for the prescriptions for relator's daughter did not satisfy the statutory definition of "medically accepted indications." If "particularity" means anything in this situation, it requires relator to allege what the child's diagnosis was and then allege facts about what the FDA label indications were and what indications are supported by the three compendia. The complaint alleges none of these facts, even though they were readily available to relator. As for the child's diagnosis, she has a statutory right (*see* 740 ILCS 110/4) to inspect Dr. Spigelman's and Hephzibah's records of their treatment of the child without filing a lawsuit -- a right she failed to take advantage of before suing.[2] The FDA labeling and the compendia are public documents as available to relator as to defendants.

[2] Relator filed a lawsuit accusing defendants of knowingly defrauding the United States without first seeking to review the records of treatment of her child. Had she inspected that file, she would have learned not only the specifics of the diagnosis of her daughter but would have seen the documentation that before each psychotropic prescription was written, consent was sought and obtained from a DCFS consulting psychiatrist, pursuant to the DCFS regulations, after full disclosure of the diagnosis, the requested drug, dosage and duration, the probable side effects, and other information. Defendants provided relator's counsel with this documentation in a letter requesting him to withdraw the lawsuit to avoid possible Rule 11 proceedings. Counsel declined.

D. The complaint alleges no facts that would particularize relator's general theory of scienter.

As discussed in defendants' Rule 12(b)(6) memorandum, relator's theory of defendants' *scienter* is essentially that (1) the federal Medicaid statute makes off-label, non-compendium uses *per se* ineligible; (2) defendants had an obligation to know that "fact"; and (3) by not complying with this obligation, defendants acted in reckless disregard of the ineligibility of these prescriptions. As mentioned above, defendants' Rule 12(b)(6) memorandum shows that this theory of *scienter* is invalid. But even on her own theory of *scienter*, relator runs afoul of Rule 9(b).

First, her attempt to plead that defendants had an obligation to know the "requirements" of Medicaid fails Rule 9(b). In support of this supposed obligation, she alleges in ¶5 that "[u]nder Medicaid, (a) psychiatrists and other prescribers, (b) mental health agencies or providers, and (c) pharmacies, all have specific responsibilities to prevent false claims from being presented," and in ¶18 that "[e]very Medicaid provider must agree to comply with all Medicaid requirements." Neither of these allegations comes close to satisfying Rule 9(b). They do not say what the "specific responsibilities" of providers are, much less identify any provision or agreement imposing such "specific responsibilities." Indeed, the complaint does not allege facts showing that any defendant is a "Medicaid provider." (This is no academic matter; during the period relator's daughter was at Hephzibah, it was *not* a Medicaid provider.) Nor does the complaint allege any mechanism or document in which any defendant has "agree[d] to comply with all Medicaid requirements."

Second, relator alleges nothing to the effect that any defendant was ever told anything by anyone that would have suggested that off-label, non-compendium uses were ineligible for reimbursement under Medicaid. In this respect, the complaint is no different than the complaint in *Fowler*. *Fowler* affirmed a dismissal of a FCA complaint because there was "no evidence in the proposed third amended complaint that Caremark had actual knowledge of this issue or otherwise ignored or disregarded this situation." 496 F.3d at 743.

Lacking these particulars, all this complaint says about *scienter* is that a charity, a psychiatrist, and a pharmacy should have figured out through their own devices that an obscure part of a complex Medicaid statute meant what relator thinks it means. That allegation would not satisfy Rule 9(b), even without regard to the deeper defects in relator's theory discussed in defendants' Rule 12(b)(6) memorandum.

CONCLUSION

In the event this Court denies defendants' motion to dismiss the complaint pursuant to Rule 12(b)(6), defendants respectfully request that it dismiss the complaint pursuant to Rule 9(b).

Respectfully submitted,

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