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.	)	

DEFENDANTS' REPLY MEMORANDUM IN SUPPORT
OF THEIR CONSOLIDATED MOTION TO DISMISS
PURSUANT TO F.R.CIV.P. RULE 9(b)

As defendants' opening memorandum showed, the "model complaint" that relator Linda Nicholson copied from the website of PsychRights fails the requirements of F.R.Civ.P. 9(b) as interpreted by cases under the False Claims Act (FCA).

Nicholson's five-page response is as inadequate as her response to defendants' Rule 12(b)(6) motion. Half of the Rule 9(b) response is devoted to an account of mistreatment of her daughter at various foster care facilities during the time that the Illinois Department of Children and Family Services (DCFS) was the child's guardian. These allegations do not appear in the complaint, and would be irrelevant if they did. This is not a suit by Nicholson's daughter for improper "drugging." It is a suit purportedly on behalf of the United States, alleging that defendants knowingly caused ineligible claims to be submitted to Medicaid on account of drugs prescribed for "off-label, non-compendium" uses.

It is tempting for defendants to reply to Nicholson's account by providing evidence of how Nicholson's daughter arrived at Hephzibah already placed on Celexa by previous treaters; how indications of serious emotional disturbance led Dr. Spigelman to continue the Celexa for a time, but then to taper and ultimately to discontinue it; how Dr. Spigelman and Hephzibah,

pursuant to DCFS's regulations, obtained the consent of a DCFS psychiatrist for each renewal of the Celexa prescription; how the child's condition improved during her stay at Hephzibah; and how Hephzibah and Dr. Spigelman tried to accommodate a mother whose parental rights had been affected by DCFS taking guardianship over her daughter. But such evidence would be as irrelevant on this motion as Nicholson's unsupported allegations are.

As for what defendants argued in their opening brief, Nicholson has no meaningful response.

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

As defendants showed, the complaint offers no particularized facts about causing any claim to be presented to the United States. It describes five Celexa prescriptions, but does not state they were submitted to "Medicaid" at all -- much less who submitted them, when they were submitted, how much was claimed, whether they were reimbursed, and whether the United States ended up paying for these prescriptions. This failure requires dismissal pursuant to *U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1358-59 (11th Cir. 2006), and *U.S. ex rel. Crews v. NCS Healthcare of Ill., Inc.*, 460 F.3d 853 (7th Cir. 2006). Defendants' Rule 9(b) Memorandum (hereafter "Defs.' Mem.") at 7.

Nicholson responds that her allegations "certainly show the nature of the charge in sufficient detail by identifying specific, individual prescriptions." Relator's Rule 9(b) Memorandum (henceforth "Rel. Mem.") at 4. Under *Atkins*, *Crews*, and many similar cases, it is not the prescriptions that she must describe with particularity, but the claims submitted on account of those prescriptions. Her complaint alleges nothing about those claims. It is not even true, as her memorandum asserts, that the complaint alleges that Sears was "the pharmacy which filled [the prescriptions] and submitted the claims to Medicaid." *Id.* The complaint does not say who submitted any claim, much less give details about that claim.

Nicholson offers no case law in support of her position on Rule 9(b). Of the seven cases she cites (Rel. Mem. at 3), six of them dismissed FCA claims under Rule 9(b), several for the

identical reason argued by defendants here. *See U.S. ex rel. Hopper v. Solvay Pharmaceuticals, Inc.*, 588 F.3d 1318, 1325-27 (11th Cir. 2009); *U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731-33 (1st Cir. 2007); *U.S. ex rel. Polansky v. Pfizer, Inc.*, 2009 WL 1456582 (E.D.N.Y. 2009), at *5-*8; *U.S. ex rel. Kennedy v. Aventis Pharmaceuticals, Inc.*, 2008 WL 5211021 (N.D.Ill. 2008), at *4; *U.S. ex rel. McDermott v. Genentech, Inc.*, 2006 WL 3741920 (D.Me. 2006), at *11 (dismissing complaint under Rule 9(b) for failure to plead at least some details of "the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices"); *U.S. ex rel. Walner v. NorthShore University Healthsystem, Inc.*, 660 F.Supp.2d 891, 898 (N.D.Ill. 2009).

Walner illustrates how the case law opposes Nicholson's position, particularly in this District. In dismissing the case under Rule 9(b), Judge Kendall cited the complaint's failure to state "who filed the allegedly false claim, the method by which it was filed, and how much the payment was for." 660 F.Supp.2d at 898. She cited Judge Andersen's decision in *U.S. ex rel. Grant v. Thorek Hosp.*, 2008 WL 1883454 (N.D.Ill. 2008), which dismissed an FCA complaint under Rule 9(b) for lack of details regarding: "the date on which any claim was submitted...the content of any claim; the identification number of any claim; who submitted any false claim to the government; [and] what amount of reimbursement improperly was claimed from the government" (*Grant*, at *3), and Judge Reinhard's decision in *Peterson v. Community General Hosp.*, 2003 WL 262515 (N.D.Ill. 2003), which dismissed a Medicare FCA case under Rule 9(b) for failure to particularize the submitted claims (*Peterson*, at *2-*3). *See Walner*, 660 F.Supp.2d at 898.

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

As defendants showed, the complaint says nothing about what Hephzibah is or does. It does not allege that Hephzibah filed claims with any Medicaid agency or that it was involved in

any way with the filing of such claims. All it offers is the conclusory and patently insufficient allegation that Hephzibah "caused the presentment to Medicaid of claims for psychotropic drugs prescribed to Relator's minor child." Compl. ¶23. Defs.' Mem. at 8.

Nicholson does not reply to this argument.

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

As defendants showed, relator's allegations of "false claims" depend on two components: (1) a legal theory that the federal Medicaid statute makes off-label, non-compendium uses *per se* ineligible for reimbursement; and (2) a factual allegation that the prescriptions in question were for off-label, non-compendium uses. While the complaint adequately informs defendants of Nicholson's legal theory, it fails to 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, Nicholson must 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 Nicholson. Defs.' Mem. at 9.

Again, Nicholson does not respond to this argument.

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

Defendants showed that even accepting Nicholson's invalid legal theory of *scienter* (the subject of defendants' Rule 12(b)(6) motion), she fails to satisfy Rule 9(b) in her factual *scienter* allegations. First, in trying to plead defendants' obligation to know the "requirements" of Medicaid, she 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," and that "[e]very Medicaid provider must agree to comply with all Medicaid requirements." These allegations do not satisfy 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." The complaint does not even allege facts showing that any defendant is a "Medicaid provider." Nor does the complaint allege any document in which any defendant has "agree[d] to comply with all Medicaid requirements." Defs.' Mem. at 10.

Second, defendants showed that Nicholson does not allege that anyone ever told any defendant anything that would have suggested that off-label, non-compendium uses were *per se* ineligible for reimbursement under Medicaid. *Id.* at 7, *citing 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). 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. Defs.' Mem. at 10-11.

Once again, Nicholson does not respond to either argument.

E. Nicholson's argument about how defendants can defend this case reflects a misunderstanding of Rule 9(b).

How thoroughly Nicholson misunderstands Rule 9(b) is apparent in her closing rhetoric:

> Perhaps defendants can make claims or defenses, as may be implied by their Rule 9(b) motion, e.g., that Spigelman had no idea her prescriptions would ever be presented to Medicaid for reimbursement; or that despite the fact of Relator's seven-year-old child being in the continuous custody and control of Hephzibah at the time, the foster care facility took no part at all in these five identified prescriptions being written and filled. Perhaps Sears will argue that it cannot know what Relator means in alleging that it presented claims for these five specifically identified prescriptions to "Medicaid," because there are so many different ways to present claims and so many different agencies called Medicaid; and perhaps Relator is wrong about there being *no* medically accepted indication *whatsoever*, for Celexa, for *a seven-year-old child*.

Rel. Mem. at 4-5 (emphasis in original).

Rule 9(b) does not work this way. Where it applies, as it indisputably does in this case, it forces plaintiffs to plead specific allegations in complaints, rather than forcing defendants to infer what those allegations might be and then be ready to defend at trial against them. To take each of the four statements in this paragraph:

(1) It is not Dr. Spigelman's burden to show that she "did not know her prescriptions would be presented to Medicaid." It is Nicholson's burden to plead that Dr. Spigelman did know that fact, which, as discussed above, Nicholson does not plead.

This is no mere formalism, because a serious legal issue of FCA liability would be raised if Nicholson had pled such an allegation. Pleading it would have raised the legal issue of whether a physician who believes her patient needs a drug that is legal to prescribe "causes the submission of a claim" to the United States simply by prescribing that drug with the knowledge that the pharmacy who fills it may request Medicaid reimbursement for it. Such a theory of FCA liability implies that physicians can prescribe drugs they deem necessary for indigent patients only at the risk of being sued under the FCA when a pharmacy later asks Medicaid to reimburse the prescription.

(2) It is not Hephzibah's burden to show that "despite the fact of Relator's seven-year-old child being in the continuous custody and control of Hephzibah at the time, [it] took no part at all in these five identified prescriptions being written and filled." It was Nicholson's burden to plead not only what Hephzibah's part was in the prescriptions being written and filled, but what part it played in causing these prescriptions to be submitted to Medicaid.

Again, this is no mere formalism. A serious legal issue would be raised if Nicholson pled such allegations: whether Hephzibah *caused* a claim to be submitted to the United States simply by cooperating with the transmission of Dr. Spigelman's prescription to a pharmacy. Residents of facilities like Hephzibah generally cannot take their own prescriptions to a pharmacy. Thus, Nicholson's theory of FCA liability would imply that where a consulting psychiatrist in good faith writes a prescription for an off-label, non-compendium use for a resident, the facility must chose between stymieing the physician's treatment plan by refusing to allow the prescription to be transmitted to a pharmacy, or helping get the prescription to the pharmacy and risking a suit under the FCA after the pharmacy asks for Medicaid reimbursement of the prescription.

(3) It is not Sears' burden to show that "it cannot know what Relator means in alleging that it presented claims for these five specifically identified prescriptions to 'Medicaid,' because

there are so many different ways to present claims and so many different agencies called Medicaid." As discussed above, it is Nicholson's burden to plead that Sears presented these claims to a specific Medicaid agency and what happened as a result of submitting them.

As with the other two defendants, requiring compliance with Rule 9(b) as to Sears is no mere formalism. For example, Nicholson does not allege in this complaint that Sears knew what her daughter's diagnosis was. (As Nicholson should know, pharmacies generally are *not* told the patient's diagnosis on prescriptions.) Forcing Nicholson to comply with Rule 9(b) would likely raise the legal issue of whether a pharmacy who fills a prescription without particular information about the patient and her diagnosis, and then later requests Medicaid reimbursement, can be said to have knowingly submitted a false claim under Nicholson's theory of falsity.

(4) It is not defendants' burden to show that "Relator is wrong about there being *no* medically accepted indication whatsoever, for Celexa, for a seven-year-old child." It is Nicholson's burden under Rule 9(b) to plead the facts that show that, for her daughter's particular problem, Celexa was both "off-label" and not supported by anything in any of the three "compendia" specified in 42 U.S.C. §1396r-8(k)(6). Yet again, this is no mere formalism. The three medical compendia are not simple checklists from which a computer can determine whether a prescription for a particular patient's problem was "supported by" a reference within one of the three compendia referred to in that definition. Rather, they are enormous collections of citations to the medical literature. It may be hard for Nicholson to comply with Rule 9(b) on this issue, but Rule 9(b) is intended to make plaintiffs work hard before they publicly accuse defendants of fraud.

CONCLUSION

As defendants stated in their opening brief, they hope this Court will end this case immediately by granting their motion to dismiss under Rule 12(b)(6). Nicholson's reply brief on the Rule 12(b)(6) motion does not dispute that the case presents two issues of law that would not go away even if Nicholson were able to cure the deficiencies pointed out in the present motion:

(1) whether she can allege the requisite *scienter* against defendants, given that Illinois' Medicaid regulations permitted these off-label, non-compendium claims; and (2) whether she can allege the requisite *scienter* and falsity, given the fact that her theory of *per se* ineligibility of off-label, non-compendium uses under the federal Medicaid statute is the subject of a substantial and unsettled legal controversy. Defs.' Mem. at 2.

Nonetheless, if the Court declines to reach the Rule 12(b)(6) motion, or denies it, defendants respectfully request the Court to dismiss the complaint for its multiple violations of Rule 9(b).

Respectfully submitted,

/s/ George F. Galland, Jr.
George F. Galland, Jr.
Attorney for Defendant Hephzibah Children's Association

George F. Galland, Jr.
Scott A. Entin
Miner, Barnhill & Galland, P.C.
14 W. Erie St.
Chicago, IL 60654
(312) 751-1170

/s/ Stephen C. Veltman
Stephen C. Veltman
Attorney for Defendant Lilian Spigelman, M.D.

Stephen C. Veltman
Scott L. Anderson
Pretzel & Stouffer, Chartered
One S. Wacker Dr., Ste. 2500
Chicago, IL 60606
(312) 578-7528

/s/ Masaru K. Takiguchi
Masaru K. Takiguchi
Attorney for Defendant Sears Pharmacy

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