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

| UNITED STATES OF AMERICA <i>ex rel.</i> LINDA NICHOLSON, |) |
|--|--------------------------|
| Plaintiff, | |
| V. |) No. 10 C 33 |
| |) The Honora |
| LILIAN SPIGELMAN M.D., HEPHZIBAH CHILDREN'S ASSOCIATION, and SEARS PHARMACY, |)) Magistrate .) |
| Defendants. |) |

No. 10 C 3361 The Honorable Gary Feinerman Magistrate Judge Sidney I. Schenkier

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

Defendants Hephzibah Children's Association ("Hephzibah"), Lilian Spigelman, M.D. ("Dr. Spigelman"), and Sears Pharmacy ("Sears) respectfully move to dismiss the complaint with prejudice pursuant to F.R.Civ.P. 12(b)(6) for failure to state a claim on which relief can be granted. In support of this motion, defendants state:

 This is a suit under the False Claims Act, 31 U.S.C. §3729(a)(1) (A). The "relator," Linda Nicholson, originally filed this case under seal. The government declined to intervene. Relator now pursues the case in the name of the United States.

2. Hephzibah is a charity in Oak Park, Illinois that among other activities runs a home where children under the guardianship of the Illinois Department of Children and Family Services are placed temporarily to live. Dr. Spigelman is a retired psychiatrist who formerly consulted under contract with Hephzibah to provide psychiatric treatment for children at Hephzibah. Sears is a local Oak Park pharmacy. Relator Linda Nicholson is the mother of a child who in 2003 was placed under DCFS guardianship and was placed at Hephzibah, where Dr. Spigelman in 2004 prescribed the psychotropic drug Celexa for her in prescriptions that were filled by Sears.

Case: 1:10-cv-03361 Document #: 36 Filed: 11/30/10 Page 2 of 4 PageID #:82

3. 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. Relator asserts that a provision of the federal Medicaid statute, 42 U.S.C. §1396r-8, forbids Medicaid reimbursement for off-label prescriptions unless they are prescribed for indications supported by one of three specified medical "compendia." On this theory, relator alleges that defendants violated the False Claims Act ("FCA") by submitting claims for off-label, non-compendium drugs to Medicaid and thereby causing the United States to reimburse Illinois for part of the cost the Illinois Medicaid program incurred in reimbursing these prescriptions. Relator invokes 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."

4. Defendants have filed a separate motion to dismiss pursuant to F.R.Civ.P. 12(b)(6) for failure to state a claim on which relief can be granted. The present motion under Rule 9(b) is filed in the alternative to that motion.

5. 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. 1990). 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).

6. 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 that a claim was presented to the United States for payment or approval; that each defendant *presented or caused the claim* to be presented; that the claim was "false"; and that the defendant acted "knowingly."

7. The complaint is deficient under Rule 9(b) as to all these elements.

(a) The complaint fails to allege with particularity the claims that were "presented to the United States." It 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

2

Case: 1:10-cv-03361 Document #: 36 Filed: 11/30/10 Page 3 of 4 PageID #:83

allege who submitted such claims, when they were submitted, 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. Under FCA case law, this is inadequate. *U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1358-59 (11th Cir. 2006); *U.S. ex rel. Crews v. NCS Healthcare of Ill., Inc.*, 460 F.3d 853, 856 (7th Cir. 2006).

(b) The complaint fails to allege what Hephzibah did to present or cause a claim to be presented. It 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.

(c) Even accepting relator's legal theory that the federal Medicaid statute makes "offlabel, non-compendium" uses non-reimbursable, the complaint fails to plead facts showing with particularity that the claims were "false" under that theory, because it does not allege with particularity that the prescriptions in question were off-label or that they were unsupported by any of the three compendia.

(d) The complaint alleges no facts that would particularize relator's general theory of *scienter*, even taking that theory on relator's invalid terms. First, while she alleges that defendants had an obligation to know the "requirements" of "Medicaid," she alleges no facts to support this conclusion. 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.

8. This motion is supported by a memorandum of law.

Respectfully submitted,

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

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