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 RESPONSE TO RELATOR NICHOLSON'S "MOTION FOR LEAVE TO FILE A HIGHLY RELEVANT RECENT RESEARCH STUDY"

The defendants have no objection to relator Nicholson's motion to file the recent study entitled "Strategies and Practices in Off-Label Marketing of Pharmaceuticals: A Retrospective Analysis of Whistleblower Complaints," published by an on-line research journal called "PLoS Medicine." However, this study provides no support for Nicholson's arguments in opposition to the Government's motion to dismiss or the defendants' Rule 12(b)(6) motion to dismiss.

1. The only subject of this study is illegal marketing by pharmaceutical manufacturers of their drugs for off-label uses. The study does not question the *prescription* of drugs for off-label uses, a practice that the study's opening paragraph acknowledges as lawful. Study at 2.

2. In particular, the study never mentions Medicaid eligibility rules, much less the disputed and unsettled legal issue of whether the federal Medicaid statute acts as a "ceiling," forbidding reimbursement for so-called "off-label, non-compendium" uses, or whether it acts as a "floor," requiring that uses that are approved by the FDA or supported by one or more of the three compendia be reimbursed, and giving states discretion as to whether to reimburse other off-label uses. (That this issue remains both disputed and unsettled is one of the two bases of defendants' Rule 12(b)(6) motion to dismiss. The other is that Illinois Medicaid rules approved

by the federal Center for Medicare and Medicaid Services (CMS) allow, as Nicholson concedes, reimbursement of off-label, non-compendium uses.)

3. Nicholson misinterprets the study's conclusion, which reads:

> Off-label marketing has been ubiquitous in the health care system and features some behaviors and strategies that may be resistant to external regulatory approaches. Our findings suggest that no regulatory strategy will be complete and effective without physicians themselves serving as a bulwark against off-label promotion. Aside from sales representatives and other company insiders, who play important roles as whistleblowers, physicians are alone in having a full view of many of the most insidious forms of illegal marketing outlined in the complaints we reviewed. As physicians' understanding of these practices and the consequences of inappropriate off-label promotion for public health evolves, so may their enthusiasm for shutting them down.

Study at 7. According to Nicholson, this conclusion supports her lawsuit, because:

> Relator's entire case is uniquely intended to discourage physicians from prescribing psychotropic medicines to children for not medically accepted indications. In other words, this litigation will tend to effect a precise strategy, which a multi-disciplinary, academic study now suggests will be vital to for the future of our health care system.

Motion at 2. This interpretation is unwarranted. Nothing in the conclusion, or the study in general, advocates litigation against physicians or other providers, much less says that such litigation should be part of any "strategy" in dealing with illegal marketing by drug manufacturers of off-label uses.

4. Accordingly, nothing in the study supports Nicholson's arguments against defendants' Rule 12(b)(6) motion to dismiss. If the United States deems it desirable to discourage providers from prescribing off-label non-compendium uses, the way to achieve such an objective is not to pursue ruinous FCA liability against providers and charities like defendants, but to change present law to specify that such prescriptions cannot be reimbursed by Medicaid -- through Congress amending the present statute, or through CMS disapproving state Medicaid plans (such as Illinois' plan) which permit such reimbursement. Unless and until Congress or CMS chooses so to act, however, the case law under the FCA, as well as common sense and justice, preclude the imposition on providers and charities like defendants of treble damages and penalties under the False Claims Act. Nothing in the study suggests any argument against such reasoning.

5. Nor does the study provide an argument against the Government's pending motion to dismiss. It is plain that the Government, which filed its motion after the defendants' Rule 12(b)(6) motion was fully briefed, believes the interest of the United States is better served by leaving the issues raised by that motion for determination elsewhere, especially given its pending lawsuits against drug manufacturers, where millions or even billions of dollars are potentially at stake. Hence there is nothing "arbitrary and capricious" about the Government's request to dismiss the present lawsuit's implausible claims without reaching the merits of defendants' Rule 12(b)(6) motion. Nothing in the study cited by Nicholson argues against this request.

Respectfully submitted,

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CERTIFICATE OF SERVICE

Lisa Mecca Davis certifies that she caused a copy of the foregoing Response to be served upon all counsel of record, by this Court's electronic-filing system, this 26th day of April, 2011.

/s/ Lisa Mecca Davis
Lisa Mecca Davis