

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,)	
)	No. 10 C 3361
v.)	
)	The Honorable Gary Feinerman
LILIAN SPIGELMAN M.D., HEPHZIBAH)	
CHILDREN'S ASSOCIATION, and)	Magistrate Judge Sidney I. Schenkier
SEARS PHARMACY,)	
)	
Defendants.)	

DEFENDANTS' JOINT RESPONSE TO RELATORS'
"MOTION FOR LEAVE TO FILE A HIGHLY RELEVANT
U.S. GOVERNMENT STATEMENT AND REPORT"

Each successive motion relator Linda Nicholson has brought to cite additional materials only serves to emphasize why her suit should be dismissed.

1. Her latest filing asks the Court to consider a report of the Office of Inspector General of the Department of Human Services entitled "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents." In its report, the OIG asserts that "Medicare requires that drugs be used for medically accepted indications supported by one or more of three compendia to be eligible for reimbursement." Report at p. i. One of the OIG's four recommendations is that "CMS explore alternative methods beyond survey and certification processes to promote compliance with established Federal standards regarding unnecessary drug use in nursing homes." *Id.*, at ii. Nicholson cites this provision to argue that her interpretation of the federal *Medicaid* statute is correct and that False Claims Act suits like hers are an appropriate "alternative method" to promote compliance with unnecessary drug prescriptions. Motion at 2.

2. Defendants have no objection to the Court considering this report, but it provides no support for Nicholson's position. To the contrary, it further undermines that position.

3. First, the report deals with Medicare, not Medicaid. The present suit deals with Medicaid, and the issue on defendants' Rule 12(b)(6) motion has to do with the controversy over the proper interpretation of the Medicaid statute, not the Medicare statute.

4. Second, even if the discussion in the report about Medicare were transferable to Medicaid, CMS's response to the report confirms one of the basic points on which defendants' Rule 12(b)(6) motion depends. CMS's response to the above-quoted recommendation was:

CMS concurs with this recommendation, but do [*sic*] not believe the examples provided in the report are practicable (excluding provider education). The report recommendations suggest CMS adopt (1) provider education and incentive programs, (2) *strategies to prevent Medicare payments*, and (3) requirements for nursing homes to reimburse for claims not meeting CMS standards. Although CMS can identify opportunities to improve provider education in this area, the remaining recommendations (incentive programs, *prevention of payment*, and nursing home reimbursement) *are beyond our statutory authority*. CMS is, however, continuing to explore alternative strategies within our statutory authority that more directly address the financial incentives in contractual arrangements among pharmaceutical manufacturers, LTC pharmacies, facilities and consultant pharmacies that are responsible for the increased and unnecessary use of atypical antipsychotics by patients in nursing homes.

Report at 56 (emphasis added). This carefully worded response suggests that CMS disagrees with the view of OIG that "Medicare requires that drugs be used for medically accepted indications supported by one or more of three compendia to be eligible for reimbursement." There is no other apparent explanation for CMS's statement that prevention of payment under Medicare for the kinds of claims the report deals with is "beyond our statutory authority." As discussed in defendants' Rule 12(b)(6) motion to dismiss, this is how CMS reads the Medicaid statute as well on the issue of reimbursement of off-label, non-compendium uses.

5. In short, this report, to the extent it applies at all to Medicaid, supports defendants' point: that the federal government, to put it bluntly, does not have its act together on whether the Medicaid statute, as Nicholson claims, makes off-label, non-compendium uses *per se* unreimbursable. Because this issue of statutory interpretation remains unresolved and controversial within the federal government itself, the claims at issue in this case as a matter of law could not be not "knowingly false" within the meaning of the FCA.

6. The same conclusion argues for granting the Government's motion to dismiss without reaching the merits, for reasons which defendants discussed in replying two weeks ago to relators' previous motion to cite additional materials. It is highly rational that the Government prefers that issues raised by the Medicaid statute be addressed not in the present frivolous lawsuit, but rather in the large-scale lawsuits the Government is pursuing against what it considers the appropriate targets in cases raising off-label use issues: drug manufacturers.

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 17th day of May, 2011.

/s/ Lisa Mecca Davis
Lisa Mecca Davis