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

UNITED STATES OF AMERICA *Ex Rel.* Linda Nicholson Plaintiffs, vs. Lilian Spigelman M.D., Hephzibah Children's Association, and Sears Pharmacy, Defendants.	))))))))))))	Case No. 10 C 3361 The Honorable Gary Feinerman Magistrate Judge Sidney I. Schenkier

REPLY TO DEFENDANTS' RESPONSE TO RELATOR'S MOTION FOR LEAVE TO FILE A HIGHLY RELEVANT U.S. GOVERNMENT STATEMENT AND REPORT

A. The Inspector General's Report Supports Relator's Position That the Government Motion To Dismiss Should Be Denied on the Current Record

The Defendants' Response To Relator's Motion For Leave To File A Highly Relevant U.S. Government Statement And Report, Dkt. No. 62, exemplifies why the United States' Motion to Dismiss, Dkt. No. 46, should be denied.

Defendants assert

> 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.

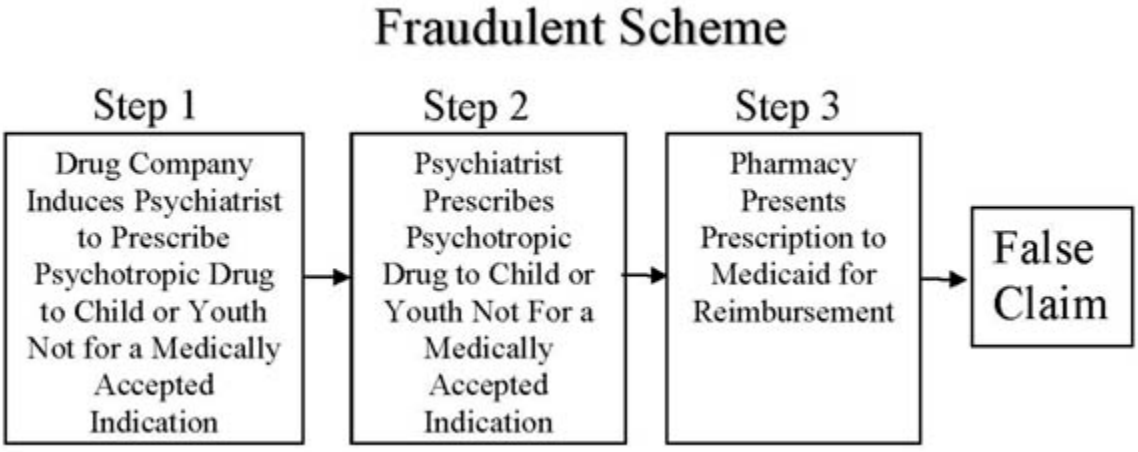
Dkt. No. 62, p.4.

However, the Statement of the Inspector General accompanying his report, directly belies any such targeting propriety. The Inspector General says:

> The drug companies have paid billions to resolve these civil and criminal liabilities under federal health and safety laws. But money can't make up for years of corporate campaigns that market drugs with questionable benefits and potentially deadly side effects for vulnerable, elderly patients.

Dkt. No. 61-2, p.3.

This statement directly supports Relator's position that prosecuting the drug companies at Step 1 of the following depiction of the Fraudulent Scheme does not achieve the goal of stopping the fraud:



This Court queried the Government about the issue when it asked during the April 19, 2011, oral argument:

> Are you saying that for purposes of Celexa, the Government's resources are better spent going after one entity at the top of the pyramid, as opposed to hundreds, if not thousands, of doctors and pharmacies and hospitals at the bottom of the pyramid?

And the Government replied:

> I can say that that is the sort of decision-making process that the Department of Justice goes through in allocating its prosecutorial resources. I don't think I'm authorized to make a representation as to what

> the DOJ's decision is specifically here, but that is the sort of analysis that one engages in.

In this case, however, as the Inspector General states, going after drug companies is not sufficient, because the fraud continues with doctors continuing to prescribe drugs that are not for medically accepted indications to Medicaid recipients. And while it might be "the sort of decision-making process that the Department of Justice goes through," the Government specifically disclaimed any assertion that it is the reason for the motion to dismiss here.

What the Government represented to this Court as its reason in its motion to dismiss was that because there were only five prescriptions involved, it was not worth the Government's time. This was reiterated at the April 19, 2011, oral argument, in which the Government said, "all we know is there are five claims alleged," to which this Court asked what investigation the Government had done to determine how many claims there might be. The Government's response to that question was, "We don't divulge our deliberative process in declining qui tams." Then, in response to this Court's question about whether it would make any difference if there were a thousand false claims involving Celexa, the Government said, "The answer is still no."

First, this demonstrates, as Relator suggested in its opposition to the Government's motion to dismiss, Dkt. No. 50, pp. 4 & 5, that the Government's stated reason for dismissal was disingenuous. Second, while the Government may not be required to divulge why it is declining to intervene, it has to have a proper reason for obtaining dismissal of a *qui tam* case which a relator elects to pursue independently.

Relator respectfully suggests, that where, as here, the Government's stated reason for seeking dismissal has proven false, its motion to dismiss must be denied. To

use the *Sequoia* formulation,[1] Relator has demonstrated the motion to dismiss is fraudulent, arbitrary and capricious. Also, as set forth above, the Government has demonstrated that it has not fully investigated the claims, and dismissal is unreasonable in light of existing evidence, which the Senate Report to the False Claims Amendments Act of 1986 states are additional grounds for denying dismissal.[2] After all, one purpose of the False Claims Act is to deputize the citizenry to pursue fraud in the face of Government inaction.

B. If The Court Does Not Find The Current Record Sufficient to Deny the Government's Motion to Dismiss Relator Should Be Allowed Limited Discovery

Should the Court find those indications in the current record that the Government's stated reason for moving to dismiss is untrue insufficient to deny the Government's motion to dismiss, the Defendants' comments in their Response about the Inspector General's Report additionally support a necessity of allowing Relator limited discovery into CMS's position on coverage of prescriptions not for medically accepted indications, including the two letters on CMS letterhead relied upon by defendants.

Defendants' assert that the only "apparent explanation for CMS's statement [in the Inspector General's Report] that prevention of payment under Medicare for the claims the report deals with is 'beyond [CMS's] statutory authority'" is that CMS disagrees with the Inspector General that Medicare coverage for drugs is limited to medically accepted indication. Dkt. No. 62, p.2. There are certainly other possible

[1] *United States ex rel Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998).
[2] Reprinted in 1986 U.S.C.C.A.N. 5266, 5290-5291.

interpretations of the "beyond our statutory authority" language by CMS. But even if the explanation is what Defendants see, it makes Relator's point.

As Relator has been showing, the Department of Justice's formal legal position in various cases is that Medicaid coverage of outpatient drugs is limited to prescriptions for medically accepted indications.[3] The just-released Inspector General's Report, Dkt. No. 61-1 (subject of the instant motion) agrees: *Because Medicare has incorporated the statutory language from the Medicaid statute relied on by Relator in this case, Medicare coverage is therefore restricted to those prescriptions which are for medically accepted indications.* Dkt. No. 61-1, p.12, fn 16.[4]

If, as Defendants assert, CMS disagrees with both the Department of Justice and the Inspector General, then (1) they should be open about it, rather than puting it in an inscrutable statement that "prevention of payment ... [is] beyond [CMS's] statutory authority," Dkt. No. 61-1, p. 27, and (2) the issue of whether Medicaid does or does not cover outpatient drugs that are not for any medically accepted indication should be decided.

The Defendants assert:

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[3] At 42 U.S.C. §1396r-8(a)(3)(A)(i) Congress provided an escape valve allowing Medicaid to pay for drugs that are not for medically accepted indications when it is essential to the health of beneficiaries of the state plan if:

> the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d) of this section.

[4] Defendants repeatedly assert the Inspector General's Report is irrelevant because it concerns Medicare, not Medicaid, in spite of this footnote 16 being highlighted in the Exhibit to the instant motion. Dkt. No. 61-1, p 12.

> [T]he 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.

Dkt. No. 62, 2.

As set forth in Part II.A., of the Opposition to Defendants' 12(b)(6) Motion, Dkt. No. 41, Relator believes *scienter* is established as a matter of law, but that is not the issue here. What is really the issue is defendants want this Court to not decide whether Medicaid coverage is restricted to those for a medically accepted indication *so that they can continue to claim ignorance*. At oral argument, Mr. Galland, on behalf of Defendant Hephzibah, made clear that this is exactly their strategy, when he said the issue of whether Congress limited coverage of outpatient drugs to medically accepted indications "shouldn't be decided. As long as it is unclear, we win." This Court should decide the issue so they (and others) can no longer “win” merely by ignorance.

As germane to the Government's motion to dismiss, if the current record demonstrating the stated reason for seeking dismissal to be untrue is not a sufficient reason to deny the motion, Relator should be allowed limited discovery to get to the bottom of this as it relates to the Government's motion to dismiss, including the two letters on CMS letterhead responding to the Utah Attorney General's Office queries. *See*, Dkt. No. 50, Section III.

C. CONCLUSION

Wherefore, *Relator* Nicholson respectfully requests that this Honorable Court

deny the United State's Motion to Dismiss, or in the alternative, allow limited discovery, and then a hearing regarding whether the Government's decision was based on arbitrary or improper considerations.

Respectfully submitted,

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