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

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

RESPONSE BY *RELATOR* NICHOLSON TO UNITED STATES MOTION TO DISMISS

Qui tam Relator Nicholson opposes The United States' Motion to Dismiss, Dkt. No. 47.

I. THE UNITED STATES MUST SHOW REASONABLE CAUSE, A LEGITIMATE GOVERNMENT PURPOSE, A RATIONAL RELATION BETWEEN DISMISSAL AND A LEGITIMATE GOVERNMENT PURPOSE, AND MAY NOT HAVE THE CASE DISMISSED FOR ARBITRARY AND IMPROPER PURPOSES.

The Senate Report to the False Claims Amendments Act of 1986, states with regard to 31 U.S.C. § 3730(c)(2)(A):

> Subsection (c)(1) [now (c)(2)(a)] provides qui tam plaintiffs with a more direct role not only in keeping abreast of the Government's efforts and protecting his financial stake, but also in acting as a check that the Government does not neglect evidence, cause unduly delay, or drop the false claims case without legitimate reason. Specifically, paragraph (1) provides that when the Government takes over a privately initiated action, the individual who brought the suit will be served, upon request, with

> copies of all pleadings filed as well as deposition transcripts. Additionally, the person who brought the action may formally object to any motions to dismiss or proposed settlements between the Government and the defendant.
>
> Any objections filed by the qui tam plaintiff may be accompanied by a petition for an evidentiary hearing on those objections. The Committee does not intend, however, that evidentiary hearings be granted as a matter of right. We recognize that an automatic right could provoke unnecessary litigation delays. Rather, evidentiary hearings should be granted when the qui tam relator shows a 'substantial and particularized need' for a hearing. Such a showing could be made if the relator presents a colorable claim that the settlement or dismissal is unreasonable in light of existing evidence, that the Government has not fully investigated the allegations, or that the Government's decision was based on arbitrary and improper considerations.[1]

The language of the statute and the legislative history mean the standard for granting dismissal over the *relator's* objection requires the government to show it has fully investigated the allegations and that dismissal is reasonable in light of existing evidence. Considering § 3730(c)(2)(a) in light of this legislative history, the Ninth Circuit in *United States ex rel Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998), held:

> A two step analysis applies here to test the justification for dismissal: (1) identification of a valid government purpose; and (2) a rational relation between dismissal and accomplishment of the purpose. If the government satisfies the two-step test, the burden switches to the relator "to demonstrate that dismissal is fraudulent, arbitrary and capricious, or illegal.

(Citations omitted.) The Ninth Circuit held this was the minimum required to comport with the requirements of Due Process. *Id.*, 151 F.3d at 1146.

It is true that the D.C. Circuit in *Swift v. United States*, 318 F. 3d 250 (D.C. Cir. 2003), held the government has almost untrammeled, unreviewable discretion to dismiss without any judicial review at all. The *Swift* court thus decided that the only

[1] Reprinted in 1986 U.S.C.C.A.N. 5266, 5290-5291, emphasis added.

purpose of the statutory hearing right is "to give the relator a formal opportunity to convince the government not to end the case." *Id.*, 318 F.3d at 253. It is respectfully suggested that *Swift* cannot possibly be what Congress intended in the statutory language mandating that the *relator* be notified and has a right to a hearing. Such result renders the right to a hearing meaningless. As far as *relator* has determined, there is no other circuit that has adopted *Swift*. The Tenth Circuit adopted *Sequoia* in *Ridenour v. Kaiser-Hill Co., LLC*, 397 F.3d 925, 936 (10th Cir. 2005), and the Second Circuit all but adopted *Sequoia* in *U.S. ex rel. Stevens v. State of Vt. Agency of Natural Resources*,162 F.3d 195, 201 (2nd Cir. 1998), rev'd on other grounds, 529, U.S. 765 (2000).

The rights to notice and a hearing are Due Process terms, which denote the right to a judicial determination of the merits, not just the opportunity to try to persuade the opposing party to change its mind. In *Hamdi v. Rumsfeld*, 542 US 507, 533, 124 S.Ct. 2633, 2648-2649 (2004), the United States Supreme Court reiterated that Due Process requires consideration by a neutral decision maker and:

> 'Parties whose rights are to be affected are entitled to be heard; and in order that they may enjoy that right they must first be notified.' It is equally fundamental that the right to notice and an opportunity to be heard 'must be granted at a meaningful time and in a meaningful manner.' "

The procedure suggested by the Government does not comport with these Due Process standards.

For the reasons that follow, the government's motion to dismiss should be denied.

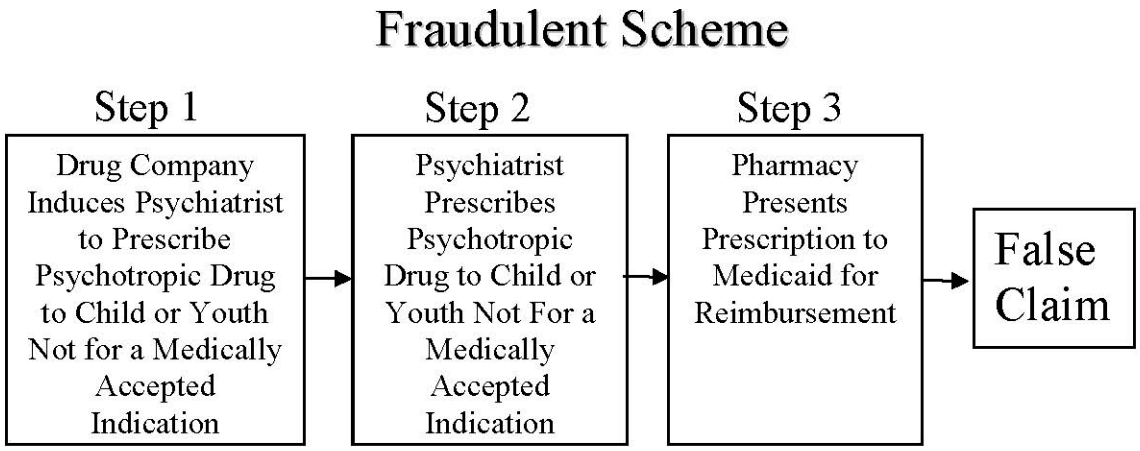
II. FAR MORE IS AT STAKE THAN REPRESENTED BY THE GOVERNMENT.

The government's representation that it has lost only $320 seems disingenuous. 31 U.S.C. § 3729(a) provides that each false claim carries a minimum penalty of $5,500,[2] plus treble damages. Thus, the five identified false claims result in a minimum penalty of $28,460. This is admittedly small, but it is only the tip of the iceberg because these are just five prescriptions out of thousands of false claims caused or presented by the defendants. The government implicitly recognizes this when it complains that it will to be subjected to discovery requests to fill out the full scope of the false claims. The statement that only $320 in damages has been suffered thus seems disingenuous.

The government acknowledges that the prescriptions at issue here represent false claims when it states it has already settled with Forest Laboratories for causing false claims, by inducing doctors to prescribe Celexa to Medicaid recipients under the age of 18.[3] It is inescapable that if Forest caused false claims by inducing doctors to prescribe Celexa to Medicaid recipients under the age of 18, then the doctors are also causing false claims, and the pharmacies are presenting false claims when they seek reimbursement for those same prescriptions.

The situation can be depicted graphically as follows:

[2] As adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990.
[3] The claims are false because they are not for "medically accepted indications."



The Government has pursued the drug companies at Step 1, but is not pursuing the other participants in the fraudulent scheme at Steps 2 & 3. The problem with this is, the drug companies' dirty work is still done, and the doctors are still causing false claims by continuing to prescribe Celexa and other psychiatric drugs to Medicaid recipients under the age of 18 that are not for medically accepted indications. This represents a huge amount of money in false claims in general, and a considerable amount of false claims caused or presented by the defendants here.

Again, the government's assertion that there is not enough at stake to worry about seems disingenuous. What is going on here? The government hints at it, when it states at page 2:

> It is clear from the briefs filed by both the defendants and the relator that government payment decisions, by both the Centers for Medicare and Medicaid Services ("CMS") and Illinois Medicaid program, are central determinations for this litigation.

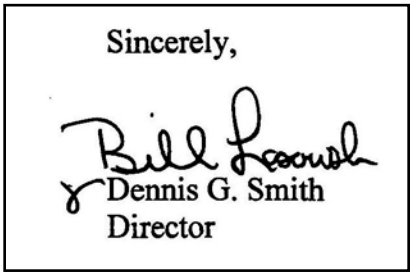
What apparently underlies this (unless CMS is now acting differently than was stated in the two 2007 letters to the Utah Attorney General's Office), is that the government has decided to allow massive Medicaid fraud to continue. Thus the motion to dismiss is unreasonable and made for an arbitrary and improper purpose. Moreover, that the

Government would say only $320 is at stake demonstrates it has not fully investigated the claim.

III. THE GOVERNMENT'S DECISION SEEMS FURTHER BASED ON ARBITRARY AND IMPROPER CONSIDERATIONS.

In addition to the foregoing, as set forth in *relator's* opposition to the defendants' Rule 12(b)(6) motion, Dkt No. 41, pp. 12-14, there are two very suspicious letters on CMS letterhead, essentially allowing doctors to continue to cause and pharmacies to continue to present false claims for psychotropic drugs used on Medicaid recipients under the age of 18 that are not for medically accepted indications.

This correspondence was initiated in October, 2007, by the Utah Attorney General's Office asking whether CMS interpreted the Medicaid statute as prohibiting Medicaid coverage of outpatient drugs that are not for a "medically accepted indication." Dkt. No. 39-3. A letter responding to this question in December, 2007, states, "(the Act) does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter, nor have we addressed this issue in implementing Federal regulations." Dkt. No. 39-4. The letter is signed *for* the Director of the Center for Medicaid and State Operations by someone else:


Sincerely,

Dennis G. Smith
Director

Incredulous at the response, the Utah Attorney General's Office promptly wrote back:

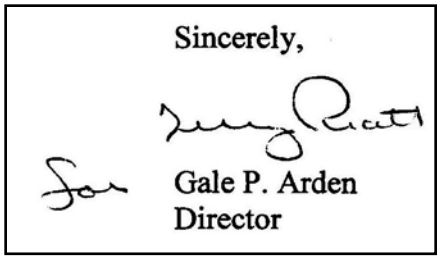
> *With all due respect, I beg to differ and direct your attention to Section 1927(k)(3) regarding a specific exception to the definition of "covered outpatient drug." In pertinent part it states that the term "covered outpatient drug" (which would otherwise be eligible for Medicaid Federal Financial Participation) does not include "a drug or biological used for a medical indication which is not a medically accepted indication."*

(Dkt. No. 39-5) After addressing why the permissive language in 42 USC §1396r-8(d)(1)(B)(i) allowing states to restrict coverage to those that are for a medically accepted indication cannot override the specific prohibition contained in 42 U.S.C. § 1396r8(k)(3) and (k)(6), the Utah Attorney General's Office wrote:

> *I strongly encourage you to run this issue by your legal counsel and am confident that they will conclude that the clear, unambiguous definition of "covered outpatient drug" means that States are eligible for Federal Financial Participation with respect to drugs that are reimbursed only for "medically accepted indications," i.e., only for uses either approved by the FDA or "supported" in the specified compendia.*

Id.

In response, without addressing the legal issues involved and without any indication CMS was following the interpretation of its legal counsel, a letter was sent back after another six-week delay, re-affirming the previous letter. This letter is signed *for* the Director of the Center for Medicaid and State Operations, Disabled and Elderly Health Program Group (apparently a subordinate of the Director of the Center for Medicaid and State Operations over whose name the previous letter was issued):



All four persons whose names appear on these two letters from CMS can thus claim they did not write the letter over their name.

So, we have a situation where the United States Department of Justice interprets the Medicaid statute in the same way as *relator* to prosecute drug companies for causing false claims substantially identical to those of which *relator* complains. Yet it now moves to dismiss *relator's* action, in an apparent effort to allow doctors and pharmacies to continue to perpetrate the same massive fraud, i.e., claims for prescriptions of psychotropic drugs to Medicaid recipients under the age of 18 that are not for medically accepted indications.

This is arbitrary and improper, and the government's motion should be denied. If there is any question that this is what is going on, the *relator* should be allowed limited discovery to establish these facts, particularly depositions of the four persons associated with the two letters to the Utah Attorney General's Office.

IV. THE GOVERNMENT'S ASSUMPTION THAT IT WILL BE SUBJECTED TO BURDENSOME DISCOVERY REQUESTS IS INVALID.

Otherwise, the government is simply incorrect when it assumes it is going to be subjected to burdensome discovery requests.[4] *Relator* intends to flesh out the full extent of the false claims presented by these defendants through discovery on the defendants and, perhaps, the Illinois Medicaid office, but not the United States Government. *Relator* is certainly willing to stipulate that beyond the specific discovery requested below, she will not seek discovery against the United States Government

[4] But for the extant U.S. Government's motion to dismiss, *relator* did not intend to depose the four people associated with the two letters to the Utah Attorney General's Office, because it is clear that Congress did not allow coverage of outpatient drugs unless they are for a medically accepted indication.

without leave of this Court. She frankly doesn't anticipate any such discovery. Thus, there is no rational relation between dismissal and the Government's stated purpose.

V. REQUEST FOR LIMITED DISCOVERY & EVIDENTIARY HEARING.

In the event this Court does not deny the government's motion on this showing, *relator* requests that she be allowed to take the depositions of the four persons associated with the two letters by CMS to the Utah Attorney General's Office, and that an evidentiary hearing be scheduled following the completion of that discovery.

VI. 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,

/s/ S. Randolph Kretchmar_____
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ARDC Reg. # 6275303

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