

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA *ex rel.*
Law Project for Psychiatric Rights, an
Alaskan non-profit corporation, and Daniel I.
Griffin,

Plaintiffs-Appellants,

vs.

OSAMU H. MATSUTANI, MD, *et al.*,

Defendants-Appellees.

No. 10-35887

U.S. District Court for Alaska
Nos. 3:09-cv-00080-TMB,
3:09-cv-00246-TMB

**REPLY TO DEFENDANTS/APPELLEES'
RESPONSE TO REQUEST FOR JUDICIAL
NOTICE OF U.S. STATEMENT OF INTEREST IN
POLANSKY (Dkt Entry 37: 41)**

At Dkt. Entry 41, the Defendants/Appellees, Matsutani *et al.*(Matsutani *et al.*), opposed the request (motion) by Plaintiffs/Appellants, Law Project for Psychiatric Rights and Daniel Griffin (PsychRights/Griffin), at Dkt Entry 37, that this Court take judicial notice of the United States' Statement of interest in *United States of America ex rel Polansky v. Pfizer, Inc.*, EDNY, Case No. 1:04-cv-0074-ERK-ALC (Statement of Interest). The opposition is not well taken.

**I. THE UNITED STATES' STATEMENT OF INTEREST
IS A PROPER SUBJECT OF JUDICIAL NOTICE**

Matsutani *et al.* suggest the Statement of Interest is not an appropriate matter for judicial notice, but at the same time acknowledge that Fed R. Evid. 201(b)

allows courts to take judicial notice of facts that are not subject to reasonable dispute. Judicial notice of the Statement of Interest is sought solely for the purpose of bringing to this Court's attention the United States' position on the issue of whether Congress limited Medicaid coverage of outpatient drugs to those that are for a "medically accepted indication," as defined in the statute. That the Statement of Interest presents the United States' position on this issue is not subject to reasonable dispute.

II. THE UNITED STATES HAS FORMALLY ADOPTED PSYCHRIGHTS/GRIFFIN'S POSITION

Matsutani *et al.*, also assert the United States has not taken the position in the Statement of Interest that Congress restricted Medicaid reimbursement for outpatient drugs to those that are for a medically accepted indication. However, in its Statement of Interest, the United States Government walks through the statutory provisions that a "covered outpatient drug . . . does not include a drug . . . used for a medical indication which is not a medically accepted indication."¹

Under 42 USC 1396r-8(k)(6), the term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], or the use of which is supported by one or more citations included or approved for inclusion in any of

¹ App. Dkt. Entry 27-2, pp. 3-4.

three specified compendia. In other words, covered outpatient drug only includes an unapproved use if it is "supported" by one of the specified compendia.

Polansky involves the drug Lipitor and thus the United States said with respect to it:

Prescription claims for Lipitor would be "false" if they were prescribed for unapproved uses that were not supported by a citation in one of the statutorily-identified compendia.²

The United States then went on to explain why Congress prohibited coverage of drugs that were not for a medically accepted indication, i.e., uses approved by the FDA or supported by one of the compendia:

It also would undermine the gatekeeping role of the federal government in protecting public health as well as the public fisc in ensuring that, based on the information available at the time, only indications that have been FDA-approved or are sufficiently supported by scientific literature as safe and effective are reimbursed.³

**III. IT IS DUBIOUS CMS HAS TAKEN THE POSITION
CONGRESS DID NOT LIMIT COVERAGE OF OUPATIENT
DRUGS TO "MEDICALLY ACCEPTED INDICATIONS"**


Matsutani et al., assert at page 3 that the Centers for Medicare and Medicaid Services (CMS) has confirmed the medically accepted indication standard sets a floor, not a ceiling, for Medicaid coverage. However, it is quite dubious that CMS

² App. Dkt. 37-2, pp 7-8.

³ *Id.*, at p. 8. *Matsutani et al.*, point out at footnote 9, that doctors are free to prescribe drugs for any use, which is true, but it is also true that if they prescribe a drug to a Medicaid recipient that is not for a medically accepted indication, they are causing a false claim.

has taken the position that Congress did not limit coverage of outpatient drugs to uses that are for a "medically accepted indication."

The support proffered for this proposition are two letters on CMS letterhead in response to letters from the Utah Attorney General's Medicaid Fraud Control Unit.⁴ This correspondence was initiated 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."⁵ A letter responding to this question 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." The letter is signed for the Director of the Center for Medicaid and State Operations by someone else, as follows:⁶



Sincerely,
Bill Leavitt
Dennis G. Smith
Director

Incredulous with this response, the Utah Attorney General's Office wrote back:

⁴ Exc. 57 & 60. References to "Exc. ___" are to the Excerpts of Record filed herein.

⁵ Exc. 55-56.

⁶ Exc. 57.

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."**⁷

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. § 1396r-8 (k)(3), (6); 42 U.S.C. § 1396r-8 (g)(1)(B)(I), 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.⁸

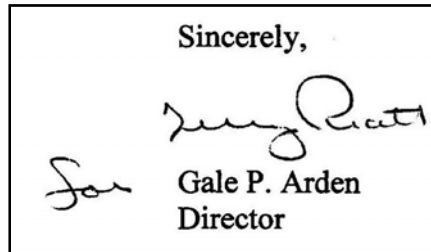
In response, without addressing the legal issues involved and without any indication CMS was following the interpretation of its legal counsel, a letter was sent back re-affirming the previous letter.⁹ This letter is signed for the Director of the Center for Medicaid and State Operations, Disabled and Elderly Health Program Group, who is apparently a subordinate of the Director of the Center for

⁷ Exc. 58.

⁸ Exc. 59.

⁹ Exc. 60.

Medicaid and State Operations over whose name the previous letter was issued, as follows:¹⁰



Sincerely,
Gale P. Arden
for Gale P. Arden
Director

All four persons whose name appears on these two letters from CMS can thus claim the letter over their name was not written by him or her. It is therefore questionable whether these letters even represent the true position of Smith and Arden, let alone the formal position of CMS. In other words, it is very dubious that these letters represent any sort of authorized interpretation of the statute by CMS.

Whether or not Smith & Arden take the position that Congress did not limit coverage of outpatient drugs to those used for a medically accepted indication, as asserted by Matsutani *et al.*, let alone whether CMS takes such a position, as set forth above, the formal representative of the United States Government, the United States Department of Justice, takes the position that Medicaid coverage is limited to medically accepted indications.

Matsutani *et al.*, interjected this issue into this appeal by requesting this Court affirm the dismissal on the alternative ground that Congress did not so limit

¹⁰ *Id.*

Medicaid coverage. It certainly seems to PsychRights/Griffin that should this Court entertain the notion that Congress did not limit coverage of outpatient drugs to medically accepted indications¹¹ as an alternative basis for affirming the dismissal of this action, that it might be interested in knowing the United States' position on the issue as stated in the *Polansky* Statement of Interest. There is certainly no reasonable dispute that the Statement of Interest sets forth the United States' formal legal position on the issue in *Polansky*. For that purpose alone judicial notice is sought.

RESPECTFULLY SUBMITTED this 25th day of March, 2011.

Law Project for Psychiatric Rights, an Alaskan
non-profit corporation and Daniel I. Griffin,
Plaintiffs-Appellants

By: /s/ James B. Gottstein

James B. Gottstein
Alaska Bar No. 7811100
406 G Street, Suite 206
Anchorage, Alaska 99501
Tel: (907 274-7686
Fax: (907 274-9493
E-mail: jim.gottstein@psychrights.org

¹¹ Because "covered outpatient drug" under 42 U.S.C. § 1396r-8(k)(2), (3), "does not include a drug . . . used for a medical indication which is not a medically accepted indication," Matsutani *et al.*, are asserting Congress did not limit Medicaid coverage of outpatient drugs to "covered outpatient drugs."

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on March 25, 2011. Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system. I further certify that some of the participants in the case are not registered CM/ECF users. I have mailed the foregoing document by First-Class Mail, postage prepaid to the following non-CM/ECF participants:

Carolyn Heyman-Layne
Sedor Wendlandt Evans & Filippi,
LLC
Suite 500
500 L Street
Anchorage, AK 99501

Thomas J. Cahill
SATTERLEE, STEPHENS, BURKE
& BURKE
Suite 1130
230 Park Avenue
New York, NY 10169-0079

John J. Tiemessen
Clapp, Peterson, Van Flein,
Tiemessen & Thorsness, LLC
411 Fourth Avenue
Suite 300
Fairbanks, AK 99701-4711

Vance A. Sanders
P.O. Box 240090
Douglas, AK 99824

Kay E. Maassen Gouwens
SONOSKY & CHAMBERS
Suite 700
900 W. 5th Avenue
Anchorage, AK 99501

/s/ James B. Gottstein
JAMES B. GOTTSTEIN