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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

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

**REQUEST FOR JUDICIAL
NOTICE OF U.S. STATEMENT
OF INTEREST IN POLANSKY
BY LAW PROJECT FOR
PSYCHIATRIC RIGHTS
AND DANIEL GRIFFIN**

Plaintiffs-Appellants United States of America *ex rel* Law Project for
Psychiatric Rights (PsychRights®) and Daniel Griffin hereby request (move) this
Court take judicial notice of the attached 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).¹

¹ Pursuant to ¶(7) of Circuit Advisory Committee Note to Rule 27-1, on March 4,
2011, counsel for Defendants-Appellees were sent an e-mail asking for their
position on taking such judicial notice and advised this motion was expected to be

"This Court may take notice of proceedings of other courts, both within and without the federal judicial system, if those proceedings have a direct relation to matters at issue."²

In the Appellees' Answering Brief, apparently concerned this Court would not uphold the District Court's dismissal of this case on the grounds granted -- that public disclosure of industry wide fraud triggers what is known as the "Public Disclosure Bar"³ --they requested the District Court's decision be upheld on the alternative ground that Congress did not prohibit Medicaid reimbursement for prescriptions of outpatient drugs that are not for a "medically accepted indication."⁴ Whether Congress limited coverage of outpatient drugs to "medically accepted indications," is currently under consideration in the Eastern District of New York in the *Polansky* case and the United States has filed the Statement of Interest therein for which judicial notice is sought here.

In its Statement of Interest, pp 3-4, attached hereto, the United States Government describes Medicaid's limitation of coverage of outpatient drugs to "medically accepted indications," as follows:

filed in the next day or so. No response has been received as of the filing hereof, but it is expected this motion will be opposed.

² *In re Heritage Bond Litigation*, 546 F.3d 667, 670 (9th Cir. 2008), citing to *U.S. ex rel. Robinson Rancheria Citizens Council v. Borneo*, 971 F. 2d 244, 248 (9th Cir. 1992).

³ 31 U.S.C. 3730(e)(4)(A). The District Court's decision appears to be contrary to the controlling decision of this Court in *U.S. ex rel. Foundation Aiding The Elderly v. Horizon West*, 265 F.3d 1011, n5 (9th Cir. 2001).

⁴ App-Dkt. 35, at brief pages 26, 56-61. To obscure that they are making the argument Congress did not prohibit Medicaid coverage of outpatient drugs that are not for "medically accepted indications," they use the term, "off-label, non-compendium uses."

Under the statute, a "covered outpatient drug" includes a drug dispensed by prescription and approved as safe and effective under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 355 and 357, but does not include "a drug . . . used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2), (3). The statute defines "medically accepted indication" as a use that is FDA-approved or a use that is "supported by a citation" in certain statutorily-identified compendia. *Id.* at § 1396r-8(k)(6). Thus, under this statutory scheme, an off-label use that is not "supported by a citation" in the compendia falls outside the definition of a covered outpatient drug under Medicaid, and Medicaid is free to deny payment for resulting claims for such an off-label use.

Courts have held that when a drug is prescribed for a use that is not covered by federal programs, the resulting claim for reimbursement of that prescription is "false" under the FCA.

(emphasis added, footnote omitted).

Because Plaintiffs-Appellants are *qui tam relators*, this action is brought on behalf of the United States, which is the real party in interest.⁵ Even when, as here, the United States declines to intervene in False Claims Act cases and the case proceeds *qui tam*, the United States still has its interest in the outcome of such cases.⁶ Thus, in the *Polansky* case, the United States filed the Statement of Interest because it does not want the Eastern District of New York to conclude Congress did not limit Medicaid coverage of outpatient drugs to "medically accepted indications."

This is directly related to the matter put at issue here by the appellees in their Answering Brief and therefore a proper subject of judicial notice. It seems to Plaintiffs-Appellants that the views of the United States on this issue would be of

⁵ *Cedars-Sinai Medical Center v. Shalala*, 125 F.3d 765, 768 (9th Cir. 1997); *U.S. ex rel. Hyatt v. Northrop Corp.*, 91 F.3d 1211, n.8 (9th Cir. 1996); *U.S. ex rel. Killingsworth v. Northrop Corp.*, 25 F.3d 715, 720 (9th Cir. 1994).

⁶ The United States makes this precise point in its Statement of Interest at p. 1.

interest to this Court. The reasons why the Statement of Interest was not presented to the District Court is it was filed the same day as the District Court's decision dismissing this case and they were not aware of it until after this appeal was filed. For these reasons, Plaintiffs-Appellants PsychRights and Griffin request the Court take judicial notice of the United States' Statement of Interest in *United States of America ex rel Polansky v. Pfizer, Inc.*, EDNY Case 1:04-cv-0074-ERK-ALC, a copy of which is attached hereto.

RESPECTFULLY SUBMITTED this 5th day of March, 2011.

Law Project for Psychiatric Rights, an Alaskan
non-profit corporation and Daniel I. Griffin,
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By: /s/ James B. Gottstein

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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 5, 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:

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