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 corp.,	)	No. 10-35887
Relator-Appellants,	)	
OSAMU H. MATSUTANI, MD., et al.,	)	U.S. District Court for Alaska Nos. 3:09-cv-0080-TMB, 3:09-cv-00246-TMB
Defendants-Appellees.	)	

DEFENDANTS/APPELLEES' RESPONSE TO RELATORS' SECOND MOTION FOR JUDICIAL NOTICE [DKT. 37]

Relators once again request judicial notice of an irrelevant pleading from an unrelated case. This time, Relators submit the DOJ's statement of interest ("SOI") from a district court case, *United States ex rel. Polansky v. Pfizer, Inc.*, No. 04 CV 0704 (ERK) (SMG) (E.D.N.Y.), which alleges that a pharmaceutical manufacturer was illegally marketing its cholesterol drug Lipitor off-label (*i.e.*, beyond the particular uses approved by the Food and Drug Administration ("FDA")). Specifically, Relators proffer four sentences from the SOI (App. Dkt. 37-1 at 3) purportedly to address Defendants' alternative argument that, according to the Alaska Medicaid program, the Federal Centers for Medicare and Medicaid Services ("CMS") and sound statutory interpretation, the Social Security Act does not, as Relators allege, exclude Medicaid coverage of drugs prescribed for uses

that are not specifically FDA approved or listed in certain drug compendia ("off-label, non-compendium") because the "medically accepted indications" to which Relators' refer is a floor, not a ceiling, for coverage.[1] Relators' request for judicial notice fails for procedural and substantive reasons.

First, while there is no basis to take judicial notice of the SOI (as explained in the next two points), the Court should know up front that Relators mischaracterize the statements in the SOI. Those statements in fact support Defendants' – not Relators' – position on Medicaid coverage. Relators assert that the DOJ filed the SOI in the *Polansky* case "because it does not want the Eastern District of New York to conclude [that] Congress did not limit Medicaid coverage of outpatient drugs to 'medically accepted indications.'" (App. Dkt. 37-1 at 3.) The SOI, however, states: "Medicaid is *free to deny* payment for resulting claims for such an off-label [non-compendium] use." (App. Dkt. 37-2 at 4 (emphasis added); *see also id.* at 3 n.2 ("A State *may* [not must] restrict from coverage or exclude altogether certain drugs or classes of drugs or certain medical uses where

[1] The primary issue on appeal is whether the district court properly dismissed the two consolidated cases for lack of jurisdiction under the False Claims Act's Public Disclosure Bar. Relators claim that the SOI is relevant to Defendants' Rule 12(b)(6) motion to dismiss, which raised the proper interpretation of Medicaid coverage. The district court denied that motion as moot after finding that it lacked jurisdiction under the Public Disclosure Bar. If the Court affirms the dismissal based on the Public Disclosure Bar, it need not address the alternative argument or the present motion.

'the prescribed use is not for a medically accepted indication.' 42 U.S.C. § 1396r-8(d)(1)(B)(i).").) In other words, as Defendants contend and CMS has confirmed (*see* App. Dkt. 35 at 12-16.), the "medically accepted indication"/off-label, non-compendium standard sets a floor, not a ceiling, for Medicaid coverage. Although a state *may* choose not to cover off-label, non-compendium uses, Alaska did not. In fact, as Relators' acknowledge, the Alaska Medicaid program purposefully has covered off-label, non-compendium uses.[2]

Second, Relators fail to explain on what basis this Court should take judicial notice of the SOI.[3] Indeed, none exists: the SOI presents neither a legislative[4] nor

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[2] *See* 7 AAC 145.005 (covering off-label, non-compendium uses as permitted under 7 AAC 105.110(7)(D)).

[3] This omission violates Fed. R. App. P. 27(a)(2)(A), which requires that a moving party "state with particularity the grounds for the motion, the relief sought, and the legal argument necessary to support it." *See also* Fed. R. Evid. 201(d) (requiring a court to take judicial notice upon the request of a party only if "supplied with the necessary information").

Relators failed even to clear the first procedural hurdle for filing this motion – compliance with 9th Circuit Advisory Committee Note to Rule 27-1 ¶ (5), which states: "Unless precluded by extreme time urgency, counsel are to make every attempt to contact opposing counsel before filing any motion and to either inform the court of the position of opposing counsel or provide an explanation regarding the efforts made to obtain that position." (*See* Mot. [Dkt. 37] at 1 n.1 (incorrectly citing to ¶ (7) of Adv. Comm. Note).) Relators' counsel sent an email message to over thirty defense counsel at approximately 5:42 p.m. AKST on Friday, March 4, 2011. The message stated: "Please let me know your position on such a motion, ie., whether you will oppose it or not." Relators then filed the motion at 2:09 p.m. PST the very next day, which was Saturday. In other words, Relators gave the defense counsel not even one second of business hours to respond. Relators were not

an adjudicative fact[5] subject to judicial notice. It is an interested party's legal argument.

Relators cite the standard that a court "may take notice of proceedings of other courts . . . if those proceedings have a direct relation to matters at issue." (App. Dkt. 37-1 at 2, *quoting In re Heritage Bond Litig.*, 546 F.3d 667, 670 (9th Cir. 2008).) As the case law demonstrates, however, Relators misconstrue that standard. In *Heritage Bond*, the court took judicial notice of filings in another case to determine whether the previous order barred the plaintiff's claims. Similarly, the district court in the present cases properly took judicial notice of PsychRights's

(continued…)

"precluded by extreme time urgency," and providing defense counsel only Friday night and Saturday morning to respond to the inquiry cannot possibly be considered within the rule's spirit. For this reason alone, the Court may deny the motion.

[4] *See Korematsu v. United States*, 584 F. Supp. 1406, 1414 (D.C. Cal. 1984) (legislative facts are "established truths, facts or pronouncements that do not change from case to case but [are applied] universally") (quoting *United States v. Gould*, 536 F.2d 216, 220 (8th Cir. 1976)).

[5] *See* Fed. R. Evid. 201(b) (Courts may only take judicial notice of facts that are "generally known" or "are not subject to reasonable dispute."); Fed. R. Evid. 201, Adv. Comm. Notes ("[T]he adjudicative facts are those to which the law is applied in the process of adjudication. They are the facts that normally go to the jury. They relate to the parties, their activities, their properties, their businesses."); *Henderson v. State of Oregon*, 203 F. App'x 45, 52-53 (9th Cir. 2006) (declining to take judicial notice of an affidavit from another proceeding, noting that "adjudicative facts appropriate for judicial notice are typically different from facts found in affidavits supporting litigation positions, which often present facts subject to dispute.").

state court complaint in order to find that PsychRights had made public disclosures of its allegations in that earlier case. The SOI has no similar "direct relation" to this appeal, and is not subject to judicial notice.[6]

Third, Relators then argue that "it seems" that the DOJ's legal argument in an unrelated case "would be of interest to this Court." (App. Dkt. 37-1 at 3-4.) That explanation provides no basis for judicial notice. The DOJ's litigation position is due no deference by this Court and, as an unsupported legal argument that is only tangentially related to the motion to dismiss in the *Polansky* case, lacks any of the indicia of reliability required for judicial notice.

The DOJ's SOI is not entitled to *Chevron* deference here because CMS, not the DOJ, is the agency charged with administering the Medicaid statutes.[7] The SOI gives no indication that the DOJ consulted CMS or any legal or factual source.

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[6] *See Cuellar v. Joyce*, 596 F.3d 505, 512 (9th Cir. 2010) (declining to take judicial notice of materials that were not relevant to the disposition of the appeal); *Santa Monica Food Not Bombs v. City of Santa Monica*, 450 F.3d 1022, 1025 n.2 (9th Cir. 2006) (same).

[7] *See Alaska D.H.H.S. v. C.M.S.*, 424 F.3d 931, 939-40 (9th Cir. 2005). As noted earlier, CMS has already clarified that the "medically accepted indications" standard sets a floor, not a ceiling, for Medicaid coverage so that states may cover off-label, non-compendium uses, as Alaska chose to do. (See App. Dkt. 35 at 12-16.)

Furthermore, when the DOJ is just a party or real party in interest to litigation, its interpretation of a statute at issue is given no deference.[8]

Finally, the DOJ's statement about coverage for "medically accepted indications" – particularly how Relators interpret it – is superfluous to the issue raised in the motion to dismiss in the *Polansky* case, and should therefore be given even less credence. The *Polansky* case involves one pharmaceutical manufacturer, Pfizer, charged with widely marketing off-label uses for its cholesterol drug Lipitor. (*Polansky* Fifth Am. Complaint, *Polansky* Dkt. 77, ¶¶ 3-5.) A manufacturer may not market a drug's off-label uses regardless of whether those uses are supported by the drug compendia. (*Id.* ¶¶ 19, 23, 26.)[9] The *Polansky* case and the motion to dismiss center on whether Pfizer was marketing uses that were in fact off-label,

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[8] *See Citizens for Responsibility and Ethics in Washington v. U.S. Dep't of Justice*, 658 F. Supp. 2d 217 (D.D.C. 2009) (rejecting the DOJ's interpretation of the FOIA exemptions); *American Civil Liberties Union of N. Cal. v. Dep't of Justice*, No. C 04-4447 PJH, 2005 WL 588354, at *8 (N.D. Cal. March 11, 2005) (rejecting the DOJ's interpretation of the proper standard of review for FOIA request denials).

[9] Even the *Polansky* complaint acknowledges that physicians may legally prescribe FDA approved drugs for off-label uses, even those not listed in the compendia: "the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different than those approved by the FDA." (*Polansky*, Fifth Am. Complaint, *Polansky* Dkt. 77, ¶ 28; *see also id.* ¶ 28 ("Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved….").)

and particularly the proper interpretation of the National Institutes of Health guidelines to which the FDA's Lipitor label referred. (*See, e.g.*, Plaintiff's Resp. to Mot. To Dismiss 4th Am. Compl., *Polansky* Dkt. 49, at 16 ("Lipitor's FDA-approved label explicitly incorporates the Guidelines' drug therapy cutpoints such that promotion of the drug outside those cutpoints constitutes unlawful, off-label promotion.").) The plaintiff claims that Pfizer was marketing off-label, and Pfizer argues that it promoted only uses consistent with the guidelines incorporated into the FDA label. The quoted portion of the SOI is therefore a superfluous legal position, lacking the indicia of reliability needed for judicial notice.[10]

For the foregoing reasons, defendants respectfully request that the Court deny Relators' motion for the Court to take judicial notice of the statement of interest from the *Polansky* case.

[10] The DOJ may have wanted simply to correct the plaintiff's overly restrictive interpretation of Medicaid coverage – *e.g.*, "As detailed in the Complaint, neither Medicare, nor Medicaid, nor other federal healthcare programs will pay for off-label uses of drugs, including Lipitor. ¶¶ 35-63." (*Polansky* Memo, *Polansky* Dkt. 99, at 31.)

Dated: March 18, 2011

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CERTIFICATE OF SERVICE

I hereby certify that, on March 18, 2011, I filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit electronically through the appellate CM/ECF system, and also served co-defense counsel and Plaintiffs' counsel, James B. Gottstein, by email.

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