No. 10-35887

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.,
Plaintiff-Appellants,

v.

OSAMU H. MATSUTANI, MD., et al.
Defendants-Appellees.

On Appeal From The U.S. District Court For Alaska
Nos. 3:09-cv-0080-TMB, 3:09-cv-00246-TMB

DEFENDANTS' JOINT ANSWERING BRIEF

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Attorney for Appellee Wal-Mart Stores, Inc.

See Signature Block for Additional Defendants' Counsel.

I. CORPORATE DISCLOSURE STATEMENT

Defendant-Appellee Wal-Mart Stores, Inc. is a publicly held corporation and has no corporate parent. No other publicly held corporation owns 10% or more of its stock.

Defendant-Appellee Safeway, Inc. is a publicly traded company, has no parent companies, and AXA Financial, Inc. owns 11.2% of its stock.

Defendant-Appellee Fred Meyer Stores, Inc. is a wholly owned subsidiary of The Kroger Co., a publicly traded corporation in the United States.

Defendant-Appellee Thomson Reuters (Healthcare) Inc. ("TR Healthcare") is a wholly owned subsidiary of the Thomson Reuters Corporation, a publicly traded corporation in the United States, the United Kingdom, and Canada.

Defendant-Appellee Alternatives Community Mental Health Center, Inc. is a privately held, nonprofit corporation doing business as Denali Family Services.

Defendant-Appellee Providence Health and Services is a nonprofit corporation and is not publicly held.

Defendant-Appellee Southcentral Foundation is an Alaska non-profit organization with no shareholders and no parent corporation.

Defendant-Appellee William Hogan is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee William Streur is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Tammy Sandoval is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Stephen McComb is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Osamu Matsutani, M.D. is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Sheila Clark, M.D. is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Lucy Curtiss, M.D. is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Heidi F. Lopez-Coonjohn, M.D. is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Rober D. Schults, M.D. is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Mark H. Stauffer, M.D. is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee City & Borough of Juneau, Alaska (Bartlett Regional Hospital) is not a publicly traded company, and has no parent corporation.

Defendant-Appellee Kerry Ozer, M.D. is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Claudia Phillips, M.D. is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Peninsula Community Health Services of Alaska is a privately held, nonprofit corporation.

Defendant-Appellee Elizabeth Baisi, M.D. is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee L. Judith Batista, M.D. is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Ruth Dukoff, M.D. is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Jan Kiele, M.D. is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Juneau Youth Services, Inc. is a privately held, nonprofit corporation.

Defendant-Appellee Ronald A. Martino, M.D. is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Irvin Rothrock, M.D. is not a subsidiary or affiliate of a publicly-owned corporation.

Defendant-Appellee Fairbanks Psychiatric and Neurological Clinic is a not a publicly held corporation and has no parent corporation.

Defendant-Appellee Anchorage Community Mental Health Services, Inc. is a privately held, nonprofit corporation.

Defendant-Appellee Family Centered Services of Alaska, Inc. is a privately held, nonprofit corporation.

Defendant-Appellee Frontline Hospital LLC d/b/a North Star Hospital is not a publicly held corporation and is a wholly owned subsidiary of Universal Health Services, Inc.

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IV. JURISDICTIONAL STATEMENT

A. District Court For District Of Alaska

As the district court properly found, the district court lacked subject matter jurisdiction pursuant to the False Claims Act's Public Disclosure Bar, 31 U.S.C. § 3730(e)(4)(A).

B. Court Of Appeals For The Ninth Circuit

Defendants agree with Relators' statement concerning this Court's appellate jurisdiction.

V. STATEMENT OF ISSUE PRESENTED FOR REVIEW

This appeal concerns whether the district court properly dismissed two consolidated *qui tam* False Claims Act cases under the Public Disclosure Bar where: (i) multiple public documents, of the type enumerated in Section 3730(e)(4)(A), disclosed the allegations upon which the relators based their complaints, including that physicians have been pervasively prescribing psychotropic drugs off-label to pediatric Medicaid patients and that Medicaid does not cover those claims; (ii) the relators concede that they are not an original source of their allegations and have no insider information about the defendants; and (iii) the relators added to the previously publicly disclosed allegations only information readily available to the government – claims information that they obtained from the Alaska Medicaid program through Freedom of Information Act requests and

the names of over twenty prominent Alaskan physicians and hospitals and the three largest chain pharmacies in Alaska.

Pertinent Statute

The version of the False Claims Act's Public Disclosure Bar relevant to this appeal, 31 U.S.C. § 3730(e)(4)(A), states:

> No court shall have jurisdiction over an action brought under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

VI. STATEMENT OF CASE

A. Nature Of Case And Preliminary Statement

The district court dismissed the two consolidated *qui tam* False Claims Act ("FCA") cases for lack of subject matter jurisdiction under the Act's Public Disclosure Bar, 31 U.S.C. § 3730(e)(4)(A). The two relators, the Law Project For Psychiatric Rights ("PsychRights") and Daniel Griffin ("Griffin") (together "Relators"), complain that, due to pharmaceutical manufacturers' ongoing marketing of psychotropic drugs for conditions or uses not approved by the Food and Drug Administration ("FDA"), health care providers have been pervasively prescribing, and pharmacies have been dispensing, psychotropic drugs to pediatric patients for conditions or uses neither approved by the FDA ("off-label") nor listed as supported in certain drug compendia ("off-label, non-compendium").

Relators concede that physicians may prescribe FDA-approved drugs for off-label uses,[1] that pharmacies generally may fill physicians' prescriptions, and

[1] Although pharmaceutical manufacturers may not market drugs for uses beyond those specifically approved by the FDA, physicians may lawfully prescribe FDA-approved drugs for off-label uses. Indeed, off-label prescribing is common and, for many conditions and populations including children, essential for effective medical care. *See* David C. Radley, et al., *Off-label prescribing among office-based physicians*, 166 ARCH. INTERN. MED 1021 (2006) (21% of drugs prescribed by office-based physicians are for off-label uses); Final Report on the Activities of the House Comm. on Government and Oversight, H.R. Rep. 104-874 (Section 2) (1997) at 114 (General Accounting Office estimating that approximately 80 percent of drugs prescribed for pediatric use are off-label). Off-

that the Alaska Medicaid program[2] purposefully covered off-label, non-compendium uses of the psychotropic drugs at issue. Relators nonetheless argue that by submitting or causing these claims to be submitted to Alaska Medicaid, the defendants *per se* caused "false" federal claims because, according to Relators, certain provisions in the Social Security Act preclude Medicaid coverage, and accordingly the United States from paying the federal share (Federal Financial Participation or "FFP"), for claims for off-label, non-compendium uses of drugs. Relators named thirty-two defendants – twenty-four prominent Alaskan pediatric psychiatric health care providers, the three largest chain retail pharmacies in

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label prescriptions are especially common in pediatrics in part because, as PsychRights notes (Exc. 99-100), obtaining FDA "on-label" approval requires clinical trials supporting the particular use, and pharmaceutical companies often decline or wait to conduct pediatric drug trials because they are expensive and pose unique challenges. *See Okla. Chapter of the Am. Acad. of Pediatrics (OKAAP) v. Fogarty*, 366 F. Supp. 2d 1050, 1093 (N.D. Okla. 2005) (noting that physicians often prescribe drugs "off-label" for children because many of these drugs have not been tested for safety and efficacy in children because of the high costs of testing); American Academy of Pediatrics Committee on Drugs, *Uses of Drugs Not Described in the Package Insert (Off-Label Uses)*, 110 PEDIATRICS No. 1 (July 2002), *available at* http://pediatrics.aapublications.org/cgi/content/full/110/1/181; reaffirmed October 2005, AAP Publications Reaffirmed, October 2005, Pediatrics 2006; 117; 577, *available at* http://www.pediatrics.org/cgi/content/full/117/2/577 (explaining that off-label use will remain a common practice in pediatrics).

[2] The United States and each state jointly fund the state's Medicaid program, while the state administers the program with the federal government's oversight. Relators also complain about claims to the Alaska Children's Health Insurance Program ("CHIP"). (Exc. 118-123.) For ease of reference and because Alaska's CHIP coverage is the same as the State's Medicaid coverage (Exc. 119), this brief will refer only to Medicaid.

Alaska, four state officials from the agency that administers the Alaska Medicaid program, and a publisher of pharmaceutical data.

This appeal primarily concerns whether the district court properly dismissed the cases for lack of subject matter jurisdiction under the Public Disclosure Bar because they were based on publicly disclosed information, of which Relators admit they were not an original source. This is not a typical *qui tam* whistleblower case. Relators and their counsel are not insiders in this industry and have no private information about Defendants. PsychRights is a political action group that opposes children's use of psychotropic medication, and Griffin is a patient recruited to be a plaintiff by PsychRights's counsel. (Exc. 93, 292.) Dissatisfied with the federal government's failure to sue parties other than the pharmaceutical manufacturers for off-label prescriptions and facing a motion to dismiss a state court case that PsychRights had filed to limit the State of Alaska's ability to pay for psychotropic drugs prescribed to children, Relators turned to the FCA's *qui tam* provision because, as it told the government in its relator's statement, "the False Claims Act might be an additional avenue to pursue to end the pervasive practice of prescribing harmful, ineffective, psychiatric drugs to children and youth." (Exc. 47; *see also* Exc. 89-91, 290-291; Opening Br. at 9.)

The district court found that Relators' complaints were based upon allegations that had been previously publicly disclosed in: news media reports

showing that physicians were commonly prescribing psychotropic medications to pediatric Medicaid patients for off-label, allegedly unsupported uses; FCA lawsuits against pharmaceutical manufacturers espousing Relators' theory of Medicaid coverage; a government investigation concluding that the Social Security Act does indeed permit Medicaid coverage of off-label, non-compendium uses; and PsychRights's state court case specifically alleging that Alaska Medicaid has been unlawfully covering claims for off-label, non-compendium uses of psychotropic drugs in children. The public record also shows that the Alaska Medicaid program intentionally covers these drugs pursuant to Alaska regulations.[3] Because the allegations had been publicly disclosed and Relators concede that they are not original sources of their allegations, the district court dismissed the cases for lack of subject matter jurisdiction. This Court should affirm.

B. Course Of Proceedings And Disposition Below

PsychRights filed its *qui tam* complaint on April 27, 2009. (Supp. Exc. 1-45.) The United States declined to intervene on December 31, 2009, and the complaint was unsealed on January 25, 2010. Defendants filed several motions to dismiss on April 5, 2010: (1) a motion for lack of subject matter jurisdiction under

[3] 7 AAC 105.110(7)(D) ("[I]f a drug has received final approval from the [FDA] for any indication, final approval is not required for the specific indication for which use is being proposed if . . . the prescription or order was issued by a licensed health care provider within the scope of the provider's license."); Exc. 197-277.

the FCA's Public Disclosure Bar (Dkt. 89); (2) a motion for failure to plead fraud with particularity under Rule 9(b) (Dkt. 83); (3) a motion for failure to state a claim because the Social Security Act and the Alaska Medicaid program permit the Medicaid claims about which Relators complain (Dkt. 92); and (4) a motion to dismiss the claims against the state officials because the FCA bars such claims (Dkt. 90). On May 6, 2010, PsychRights attempted to address the issues raised in the Rule 9(b) motion by filing an amended complaint. (Exc. 87-151.)

Griffin filed his complaint on December 14, 2009. (Exc. 290-299.) The United States declined to intervene on April 26, 2010, and the complaint was unsealed on May 17, 2010. (Exc. 336-338.) The case was consolidated with the PsychRights case on July 14, 2010. (Dkt. 140.) On July 27, 2010, Defendants filed motions to dismiss Griffin's complaint, similar to the motions filed in the PsychRights case: (1) a motion for lack of jurisdiction under the Public Disclosure Bar (Dkt. 141); (2) a Rule 12(b)(6) motion challenging the statutory interpretation upon which the Relators' cases are based (*id.*); and (3) a Rule 9(b) motion (*id.*).

On September 24, 2010, the district court granted both Public Disclosure Bar motions to dismiss and dismissed the cases with prejudice. (Exc. 4-28; *see also infra* part VII.B.2) The court denied the other motions to dismiss as moot. (*Id.*)

On September 30, 2010, the court issued a final judgment. (Exc. 3.) (For additional information about the dismissal order, see *infra* part VII.B.2.)[4]

VII. STATEMENT OF FACTS

A. The Public Disclosures

1. Starting in the 1990s, News Media Reported Pediatric Medicaid Beneficiaries' Off-Label Use of Psychotropics.

Starting in the 1990s, the news media frequently wrote about children, including Medicaid beneficiaries, receiving psychotropic medication that the FDA had approved only for adults or limited pediatric use and allegedly had insufficient support for children's use. A small sample of these articles follows.

- A report in 1999 addressed the increased use of psychotropic drugs by children:

> A decade after it vaulted into our consciousness, America's love affair with Prozac (and other new antidepressants) has worked its way down the age ladder. Last year, more than 2.5 million prescriptions for antidepressants were written for children and adolescents, according to IMS Health, a research firm that tracks prescription drug sales. That's a jump of nearly 60 percent since 1993 – despite the fact that most of these drugs have not been approved by the Food and Drug Administration for use with children . . . .

[4] The District Court later denied a motion for fees filed by certain Alaska-based defendants because the court found that Relators' arguments did not meet the "clearly frivolous" standard required for fee shifting under the FCA. (Dkt. 201 at 1.)

(Exc. 192.) The report specifically noted that, in 1996, investigators had found that pediatric Medicaid beneficiaries in Michigan were prescribed different psychotropic medications off-label. (*Id.*) The article continued:

> But drugs don't have to be approved for children to be used by them; any drug that has cleared the FDA for one group of patients can be prescribed to anyone for any reason at a doctor's discretion. This so-called "off-label" prescribing of antidepressants to children is based on research that is quite limited.

(Exc. 193.)

- In 2002, the *Chicago Sun-Times* reported that a study published in the Journal of the American Medical Association in 2000 found that children in Medicaid programs were taking psychotropic drugs such as Ritalin or Prozac for off-label uses. (Exc. 186-187; s*ee also* Exc. 188-190 (1999 *Business Week* article discussing use of Ritalin and Prozac to treat ADHD in young Medicaid patients).)

- Several articles from November 2004 described an investigation into pediatric Medicaid beneficiaries' off-label use of psychotropic drugs launched by the Texas Comptroller Carole Keeton Strayhorn, who was the head of a Medicaid fraud task force. (*See* Exc. 152, 154, 155-156, & 157-158.)

- In March of 2008, *The New York Post* wrote: "New York's Medicaid program paid nearly $90 million in 2006 for two dozen psychiatric drugs for kids . . . while most have not been tested adequately on kids or approved by the Food and Drug Administration for their use. Doctors may prescribe them to

children or teens 'off-label.'" (Exc. 161.) The article noted that "State Health Department officials told The Post they do not require a diagnosis when paying for the drugs." (*Id.*)

- That same month, the press again addressed pediatric Medicaid patients' use of psychotropic medications off-label: "One recent study found that psychotropic drug treatment was three or four times more common for youth in foster care than for other children receiving health care services through the Medicaid program. Additionally, children in foster care are often prescribed multiple psychotropic medications, and sometimes these drugs are used for off-label purposes . . . ." (Ex. 159-160.)

2. Around the Same Time, the U.S. Department of Justice and Private Relators Filed FCA Cases Against Manufacturers of Psychotropic Drugs, Alleging That Unlawful Marketing of Off-Label Uses Resulted in False Medicaid Claims.

Starting in the 1990s, the United States or relators for the United States filed several FCA cases against pharmaceutical manufacturers, alleging that the manufacturers engaged in illegal off-label marketing. While the cases focused on the manufacturers' marketing, the FCA "hook" was that the manufacturers' conduct led to submission of Medicaid claims for off-label, non-compendium drug prescriptions that, according to those complaints, were not covered by Medicaid and were therefore false under the FCA.

- In *United States ex rel. Franklin v. Parke-Davis*, No. 96-11651-PBS, 2003 U.S. Dist. LEXIS 15754 (D. Mass. Aug. 22, 2003), the relator alleged that his former employer promoted Neurontin (one of the drugs named in PsychRights's complaint) for off-label, non-compendium uses. The relator claimed that the off-label marketing violated the FCA because it resulted in claims to various Medicaid programs (including Alaska Medicaid) that were not reimbursable because they were not for "medically accepted indications" as defined by 42 U.S.C. § 1396r-8(k)(3).[5]

- In the widely-publicized MDL litigation *In re Zyprexa Products Liability Litigation*, Case No. 04-MD-01596 (JBW) (E.D.N.Y 2005), relators from a number of states (including Alaska) alleged that defendant Eli Lilly had defrauded Medicaid by illegally marketing its anti-psychotic drug Zyprexa (another drug named in PsychRights's Complaint) for off-label indications.[6]

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[5] The district court questioned the relator's interpretation of the statute, stating: "Thus, in Relator's view, § 1396r-8(d)(1)(B)(i) is simply superfluous, giving states the discretion to exclude drugs that are not covered by Medicaid to begin with. Basic rules of statutory construction, however, disfavor this interpretation." *Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at *8. *See also supra* part X.B.2.

[6] Relators' counsel here – James Gottstein – knew about the Zyprexa litigation. He subpoenaed documents from an expert in the case, purportedly for use in another case, but then leaked them to *The New York Times*. *Eli Lilly & Co. v. Gottstein*, 617 F.3d 186 (2d Cir. 2010).

- In *United States ex rel. West v. Ortho-McNeil Pharmaceuticals, Inc.*, No. 03-c-8239, 2007 WL 2091185 (N.D. Ill. July 20, 2007), a former employee of Ortho-McNeil alleged that defendants violated the FCA by marketing Levaquin and Ultram for off-label uses. The action alleged that the claims were false because Medicaid only reimburses for "covered outpatient drugs" that are prescribed for "medically accepted indications."

- In *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11 (D. Mass. 2008), the relator – a physician in the pharmaceutical industry – alleged that the defendant Pfizer had engaged in a scheme to promote the use of the drug Genotropin for off-label indications, resulting in unlawful submission of those claims to Medicaid for reimbursement. Like the relator in *Parke-Davis* and *West* (and Relators here), the relator alleged that those claims were "false" because they were for a non-medically accepted indication as defined by 42 U.S.C. § 1396r-8(k)(3).

3. In 2007 and 2008, Utah Investigated and Corresponded with the Federal Government About Whether Medicaid Covers Claims for Off-Label, Non-Compendium Uses.

From October 2007 through January 2008, Utah's Attorney General's Office and the U.S. Department of Health and Human Services' Centers for Medicare and Medicaid Services ("CMS") investigated allegations that "many state Medicaid programs are liberally reimbursing – and presumably receiving Federal Financial

Participation ('FFP') – for outpatient drugs used for indications that are neither FDA-approved nor supported in the relevant compendia." (Exc. 55.) Utah explained that the issue had come to its attention while "working on state actions recently [filed] against various pharmaceutical manufacturers for off-label promotion causing the filing of false Medicaid claims." (*Id.*)

Citing the same sections of the Social Security Act upon which Relators rely, the Utah Assistant Attorney General posed the following two questions to CMS:

> ISSUE #1: Does CMS interpret federal law to restrict FFP (Federal Financial Participation) for state Medicaid programs to uses of otherwise "covered outpatient drugs" that are either FDA-approved or supported in the specified compendia?
>
> ISSUE #2: If the answer to question #1 is yes, has the federal government delegated to the states any authority to approve exceptions, i.e., to expand FFP-eligible Medicaid prescription drug coverage?

(*Id*.)

CMS responded that the provision of the Social Security Act cited by Utah (and Relators in the cases on appeal) "authorizes" but "does not explicitly require" "States to exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication (as defined in section 1927(k)(6) of the Act) . . . ." (Exc. 57.)[7]

[7] CMS's position is well supported for the reasons explained in part X.B.2, *infra*. In addition, CMS had made clear two years earlier that the "medically

The Utah Assistant Attorney General pressed his interpretation of Section 1927(k)(3) of the Social Security Act with CMS:

> 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 <u>not</u> include "a drug or biological used for a medical indication which is not a medically accepted indication."**
>
> This federal statute defining the term "covered outpatient drug" clearly delineates that Medicaid drugs are covered only so long as they are used for "medically accepted indications." Congress apparently intended that Medicaid not be so restrictive as to prohibit all off-label use, but that it not be so expansive as to cover experimental uses not yet medically accepted. The criterion Congress chose for permissible off-label use was that the particular use be "supported" in at least one of the specified compendia [(k)(6)].

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accepted indication" standard is a floor, not a ceiling, for Medicaid coverage (i.e., state Medicaid programs must cover off-label uses listed as supported in the compendia, but they may cover more, as Alaska chose to do). *See* Exc. 281 (CMS Medicaid Drug Rebate Release No. 141 (May 4, 2006): "Section 1927(k)(5) defines 'medically accepted indication' to mean any use for a covered outpatient drug which is approved by the Food and Drug Administration, or a use which is supported by one or more citations included or approved for inclusion in the compendia specified in subsection (g)(1)(B)(II) . . . . The statute *requires* coverage of off-label uses of FDA-approved drugs for indications that are supported (as opposed to listed) in the compendia specified in section 1927(g)(1)(B)(II). Prior approval policies may be put in place, but *prior authorization cannot be used to deny the off-label indications supported by citations included or approved for inclusion in the above-referenced compendia*.") (emphasis added).

(Exc. 58-59 (emphasis in original).) The letter even pointed to children's off-label use of Zyprexa, a drug named in PsychRights's complaint, and the impact on Medicaid:

> A "poster child" example . . . is the atypical antipsychotic drug Zyprexa manufactured by Eli Lilly. For about 10 years it has been at or near the highest dollar volume drug reimbursed by Medicaid nationwide. It is only approved for schizophrenia and bipolar disorder in adults, a very narrow segment of the population. It has been widely reported that approximately 50% of utilization is off-label, including for infants and toddlers. Based on recent lawsuit settlements totaling over a billion dollars and involving thousands of Zyprexa users, the drug causes substantial weight gain and diabetes in a significant percentage of cases. In other words, Medicaid is not only paying for a very expensive drug for uses that are not "medically accepted indications," but its reimbursement of this drug is resulting in many Medicaid recipients developing diabetes, a life-threatening condition with many adverse health complications for the individuals and a significant cost burden on taxpayers for treating these complications.

(Exc. 59.)

CMS again rejected the Utah Assistant Attorney General's position:

> I wish to confirm that our previous response to you is correct. As we noted in that response, the State may limit coverage for drugs to medically accepted indications. To verify what Utah has chosen to do for coverage of a particular drug, we again suggest you contact State personnel and review the State's approved State plan and policies on the specific coverage of drugs, including Zyprexa.

(Exc. 60.)

PsychRights's own website has published this series of letters. (Exc. 278-280.)

4. Later in 2008, PsychRights Filed a State Court Case Against the State of Alaska, Seeking To Prevent or Limit Children's Use of Psychotropic Drugs and Alleging That the State May Not Lawfully Use Medicaid To Pay for Off-Label, Non-Compendium Prescriptions.

PsychRights, an Alaskan public interest group run by Relators' counsel, has a stated mission "to mount a strategic litigation campaign in the United States against psychiatric drugging and electroshocking people against their will." (Exc. 93.) Pursuant to this mission, PsychRights seeks to stop physicians from prescribing psychotropic medications to pediatric patients, particularly Medicaid patients in foster care. (*See id.*) To accomplish that goal, PsychRights filed a case in September 2008 in Alaska state court against the State of Alaska, then-Governor Sarah Palin, the Alaska Department of Health and Social Services and several Alaska officials, seeking declaratory and injunctive relief to prevent the administration of psychotropic drugs to children in Alaska unless and until Alaska had taken certain steps. (Exc. 205-258.)

PsychRights amended its complaint on November 24, 2008, to echo the issue that CMS and Utah had debated several months earlier:

> 22. It is unlawful to for (sic) the State to use Medicaid to pay for outpatient drug prescriptions except for indications approved by the Food and Drug

> Administration (FDA) or included in the following compendia:
>
> (a) American Hospital Formulary Service Drug Information,
>
> (b) United States Pharmacopeia-Drug Information (or its successor publications), or
>
> (c) DRUGDEX Information System.

(Exc. 197.) PsychRights amended its state complaint again on April 3, 2009, just prior to commencing the present FCA case, to allege that Alaska Medicaid did, in fact, authorize the alleged illegal claims:

> 236. The State approves and applies for Medicaid reimbursements to pay for outpatient psychotropic drug prescriptions to Alaskan children and youth that:
>
> (a) are not medically necessary, or
>
> (b) for indications that are not approved by the Food and Drug Administration (FDA) or included in (I) the American Hospital Formulary Service Drug Information, (ii) the United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System, or
>
> (c) both.

(Exc. 203.) At that time, to emphasize the alleged conduct's ongoing nature, PsychRights amended the prayer for relief to enjoin the defendants from approving or applying for Medicaid payments for psychotropic medication prescribed to pediatric patients for off-label, non-compendium uses. (Exc. 258.)

The amended state court complaint also contains other allegations that were repeated in some fashion in the present case. Paragraphs 23-30 of the amended state complaint describe Alaska state legislature hearings from as early as 2004 concerning the use of allegedly unapproved psychotropic medications on children in state custody. (Exc. 212-216.) Additionally, in its amended state complaint, PsychRights admitted that most of the allegations relating to the allegedly improper use of psychotropic medications for children were taken from the "Critical Think Rx Curriculum," which was developed and published under a grant from the Attorneys General Consumer and Prescriber Grant Program, of which Alaska's Attorney General is a participant. (Exc. 218.)

The state court dismissed the state case for lack of standing. *Law Project for Psychiatric Rights v. State of Alaska, et al.*, No. 3AN-08-10115 (Alaska Sup. Ct. 3rd Judicial Dist., May 29, 2009). The Alaska Supreme Court affirmed. *Law Project for Psychiatric Rights v. State of Alaska, et al.*, 239 P.3d 1252 (Alaska 2010).

B. The Cases On Appeal

1. In 2009, the Relators Filed FCA Complaints Based on the Same Allegation That Medicaid Should Not Pay Claims for Psychotropic Drugs Prescribed for Off-Label Non-compendium Pediatric Uses.

While facing the motion to dismiss in state court, PsychRights filed the federal FCA complaint leading to this appeal, rehashing many of its allegations

from the state court complaint. (Supp. Exc. 1-45.) PsychRights asserted in its relator's statement to the government that "the False Claims Act might be an additional avenue to pursue to end the pervasive practice of prescribing harmful, ineffective, psychiatric drugs to children and youth." (Exc. 47.) The United States declined to intervene, and the complaint was unsealed on January 25, 2010. (Dkt. 14 & 16.) On December 14, 2009, PsychRights's attorney filed a complaint on Griffin's behalf, based on the "model *qui tam* complaint" posted on PsychRights's website. (Exc. 290-299.) The Griffin complaint was unsealed after the federal government chose not to intervene, and was consolidated with the PsychRights case on July 12, 2010. (Dkt. 140.)

Relators allege that all claims to the Alaska Medicaid program for medication for off-label, non-compendium uses or conditions are "*per se*" false under the FCA. (Exc. 48-49.) Relators do not dispute that physicians may prescribe FDA-approved drugs for off-label conditions, that a pharmacy may fill any prescription by a licensed physician, and that the Alaska Medicaid program knowingly and purposefully authorized the claims at issue in the case. Instead, relying on the Social Security Act's definitions of "covered outpatient drugs"[8] and

[8] 42 U.S.C. § 1396r-8(k)(2) ("Subject to the exceptions in paragraph (3), the term 'covered outpatient drug' means-- (A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title [for medical assistance program], a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and-- (i) which is approved for safety and

"medically accepted indication"[9] and on Utah's argument that CMS had rejected, Relators' interpretation of Medicaid coverage boils down to the following assertions:

> Federal reimbursement for prescription drugs under the Medicaid program is, as relevant, limited to "covered outpatient drugs," 42 U.S.C. §1396b(i)(10), 1396r-8(k)(2), (3). . . . State Medicaid programs are not allowed to authorize reimbursement for prescriptions that are not for an indication that is either approved by the FDA or supported by one or more of the Compendia.

(Exc. 293; *see also* Exc. 119.)

Alleging a "pervasive" (Exc. 91), "wide-ranging" (Exc. 6) "scheme" (Opening Br. at 9) and echoing allegations from the previous FCA cases, PsychRights points to the pharmaceutical manufacturers as the root of the alleged problems:

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effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355 or 357] or which is approved under section 505(j) of such Act [21 U.S.C. § 355(j)] . . . ."). Section 1396r-8(k)(3) states: "Such term [covered outpatient drug] also does not include . . . a drug or biological [product] used for a medical indication which is not a medically accepted indication." *Id.* § 1396r-8(k)(3).

[9] 42 U.S.C. § 1396r-8(k)(6) ("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 the compendia described in subsection (g)(1)(B)(i) of this section").

> *As a result of aggressive drug company promotion* of the prescription of psychotropic drugs to children and youth for conditions not approved by the federal Food and Drug Administration (FDA), known as "off-label" use, . . . psychiatrists and other prescribers *pervasively* prescribe psychotropic drugs knowing that false claims will be presented to Medicaid and CHIP within the meaning of the False Claims Act.

(Exc. 91 (emphasis added).) Relators did not, however, sue the manufacturers. Instead, Relators accuse physicians, hospitals, retail pharmacies, officials with Alaska Medicaid, and a publishing company of submitting or causing to be submitted "false or fraudulent" Medicaid claims for psychotropic medications that the state Medicaid program affirmatively covered. Relators did not determine whom to sue based on any direct and independent knowledge (and neither claims to be an original source of their allegations). Instead, PsychRights obtained Medicaid data through FOIA requests to the Alaska Medicaid program, and identified the most prominent physicians and hospitals and the three largest chain pharmacies in Alaska. (Exc. 48-53.)

PsychRights's Section 3730(b)(2) relator's statement, in which PsychRights was required to disclose to the United States "substantially all material evidence and information the person possesses,"[10] relied on public information including several of the public disclosures identified above. The statement acknowledges that PsychRights learned of its allegations while "working" on the state court case.

[10] 31 U.S.C. § 3730(b)(2).

(Exc. 47.) The statement even quotes from the state court complaint: "Through ¶ 22 of its September 29, 2008 Amended Complaint in *PsychRights v. Alaska*, and a contemporaneous e-mail, PsychRights specifically brought to these [state defendants'] attention that the state of Alaska was authorizing reimbursement for and causing false Medicaid claims to be made." (Exc. 52.) PsychRights mentioned the Utah-CMS letters in its motion to unseal the complaint. (Supp. Exc. 54; *see also* Dkt. 91 at 4 n.6; Exc. 24-25; Exc. 55-60.) In other words, PsychRights was not bringing new, non-public information to the government's attention; instead, PsychRights was complaining that the government had chosen not to pursue the already publicly-disclosed information. (Opening Br. at 9.)

2. The District Court Dismissed Relators' Complaints for Lack of Subject Matter Jurisdiction Under the Public Disclosure Bar.

The district court dismissed the consolidated cases, with prejudice, for lack of subject matter jurisdiction under the FCA's Public Disclosure Bar. (Exc. 4-28.) The court found that the allegations were based upon multiple public documents – the media reports, previous FCA cases, the Utah-CMS correspondence, and PsychRights's previously-filed state case – that disclosed the allegations later brought by Relators: "(a) that health care providers are prescribing psychotropic drugs to minors; (b) that some of these minors are covered by Medicaid; (c) that in many instances, these drugs are being prescribed for 'off-label' or potentially

unsupported uses; and (d) that these unsupported uses may not be reimbursable through Medicaid under the law." (Exc. 22-23 (footnotes omitted).)[11] The court also found that neither Relator was an original source of the allegations given that both had disclaimed original source status. (Exc. 28.) The court recognized that the case fell squarely into Congress's concern "to discourage 'parasitic' suits brought by individuals with no information of their own to contribute to the suit."[12] The court noted that "[a] relator who merely 'echoes' previously disclosed fraud is not assisting the Government in its effort to expose fraud, but is rather optimistically seeking to share in the Government's recovery of funds from the defrauding party at the government's expense."[13]

VIII. SUMMARY OF ARGUMENT

The allegations in these cases were publicly disclosed prior to Relators filing their complaints in 2009:

- For the ten preceding years, news media publicly disclosed that physicians were prescribing psychotropic medications to pediatric patients,

[11] Relying on *Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1400 n.1 (2010), the district court properly applied the pre-amended version of the Public Disclosure Bar (Exc. 14-16), a ruling that the Relators do not challenge on appeal.

[12] Exc. 11 (citing *United States ex rel. Zaretsky v. Johnson Controls, Inc.*, 457 F.3d 1009, 1017 (9th Cir. 2009)).

[13] *Id.* (citing *United States ex rel. Harshman v. Alcan Elec. & Eng'g., Inc.*, 197 F.3d 1014, 1018-19 (9th Cir. 1999)).

including Medicaid beneficiaries, for off-label, non-compendium uses. (Exc. 152-161, 186-196.)

- Previously filed FCA cases alleged that off-label marketing of psychotropic drugs were resulting in false Medicaid claims. (Exc. 31-45, 61-83.)

- Utah's investigation of these issues resulted in letters with CMS from 2007 and 2008 that discussed (and rejected) precisely Relators' interpretation of Medicaid coverage and theory of liability. (Exc. 55-60.)

- PsychRights's state court lawsuit against the State of Alaska publicly disclosed the claim that Alaska Medicaid was covering (allegedly illegally) off-label, non-compendium prescriptions for psychotropic medication to pediatric patients. (Exc. 197-277.)

Relators admit that they are not original sources of the allegations. (Exc. 28; Dkt. 111 at 19; Dkt. 151 at 14 n.20.) Indeed, they have no insider information. Relators' counsel sent FOIA requests to the Alaska Medicaid program and merely identified twenty-four high-profile pediatric psychiatric providers in Alaska and the three largest chain pharmacies in the State. (Exc. 49, 93-98, 290-299.) Griffin

simply took the model *qui tam* complaint from PsychRights's website and filled in some personal information.[14]

Relators do not dispute the district court's finding that the publicly disclosed information and allegations put the federal government on the trail of the alleged fraudulent scheme. Relators further admit that they brought their cases, not because the United States did not know of the alleged fraudulent scheme, but because the government had chosen to pursue litigation only against pharmaceutical manufacturers for off-label Medicaid claims. (Exc. 212-218.) Relators did not, as the Public Disclosure Bar requires, ferret out non-public information and blaze a trail for the government to follow. Instead, Relators followed the trail blazed by government agencies and others.

Relators argue that the Public Disclosure Bar does not apply because the public documents do not identify by name all of the defendants in the case. This argument has been rejected by this and other courts, and must fail here where: Relators claim that all providers who prescribed or dispensed drugs to Medicaid patients for off-label, non-compendium uses are *per* se liable under the FCA and that this conduct has been ongoing and pervasive; and have no private information about the defendants or the Medicaid claims at issue, and instead identified

[14] *Compare* Exc. 290-299 *with* "*Model Qui Tam Fraud Complaint,*" *available at* http://psychrights.org/education/ModelQuiTam/PsychRightsModelQuiTamComplaint.pdf.

Defendants through information readily available to the government. Relators also argue that the Public Disclosure Bar does not apply to claims that postdate a specific public disclosure of ongoing conduct. This theory has no legal support and would impermissibly result in an endless series of complaints over the same alleged ongoing activity. Finally, Relators set up a "straw man" argument that the district court's holding would "immunize all past, present, and future participants in" a publicly-known nationwide scheme, despite the ability of the Department of Justice, which is not subject to the Public Disclosure Bar, to address it. (App. Dkt. 26-1 at 25.) This argument betrays a fundamental misunderstanding of the FCA and Congress's intent to block parasitic whistleblower litigation like these cases.

Alternatively, the Court should affirm the dismissal because (a) Relators have failed to meet the Rule 9(b) pleading standard and (b) Relators' principal assertion that Medicaid does not cover off-label, non-compendium uses of FDA-approved drugs is incorrect.

IX. STANDARD OF APPELLATE REVIEW

While a district court's ultimate decision about subject matter jurisdiction under the Public Disclosure Bar is a mixed question of law and fact which is reviewed *de novo*,[15] "[t]he district court's findings of fact relevant to its

[15] *United States ex rel. Biddle v. Bd. of Trustees of Leland Stanford, Jr., Univ.*, 161 F.3d 533, 535 (9th Cir. 1998).

determination of subject matter jurisdiction are reviewed for clear error."[16] For example, courts review for clear error whether the relator's allegations are "based upon" public disclosures.[17]

X. ARGUMENT

A. The District Court Properly Ruled That It Had No Jurisdiction Under The Public Disclosure Bar.

1. The Public Disclosure Bar

The "threshold question in a False Claims Act case is whether the statute bars jurisdiction."[18] The plaintiff bears the burden of establishing subject matter jurisdiction.[19] A district court lacks subject matter jurisdiction over an FCA case in which the United States has not intervened if the relator's complaint is based upon (i.e., substantially similar to) allegations and transactions that were previously

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[16] *Id. See also United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195, 1198 (9th Cir. 2009).

[17] *See United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1190 (9th Cir. 2001) ("Given the prior factual determinations and conclusions, the district court did not clearly err in determining that Lujan's claim was 'based upon' the same material facts" as a previous lawsuit.); *United States ex rel. Aflatooni v. Kitsap Phys. Servs.*, 163 F.3d 516, 521-22 (9th Cir. 1999) (applying clearly erroneous standard to district court's finding whether the case was based upon public documents). *See also United States ex rel. Vuyyuru v. Jadhav*, 555 F.3d 337, 350 (4th Cir. 2009) (district court's factual finding that the allegations were based upon the public disclosure was not clearly erroneous), *cert. denied*, 130 S. Ct. 229 (2009).

[18] *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 20 (1st Cir. 2009), *cert. denied*, 130 S. Ct. 3454 (2010).

[19] *See Meyer*, 565 F.3d at 1199.

publicly disclosed and the relator is not an original source of the allegations.[20] Courts interpret the Public Disclosure Bar consistent with the *qui tam* provision's purpose to "encourage insiders to disclose fraud" (*see* Opening Br. at 16) while preventing parasitic actions based on information already available to the government. Because Relators have disclaimed original source status (Exc. 28; Dkt. 111 at 19; Dkt. 151 at 14 n.20), that element is not an issue in this appeal.

The Ninth Circuit employs a two-part test to determine whether a document is a public disclosure under the FCA. The Court first "must decide whether the public disclosure originated in one of the sources enumerated in the statute."[21] Those sources include:

- A criminal, civil, or administrative hearing, including prior civil complaints brought by the same relator;[22]
- A federal or state congressional, administrative or government report, hearing, audit, statement, or investigation;[23] and

[20] *See* 31 U.S.C. § 3730(e)(4)(A) ("No court shall have jurisdiction over an action under [the FCA] based upon the public disclosure of allegations or transactions . . ., unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.").

[21] *A-1 Ambulance Serv. v. Cal.*, 202 F.3d 1238, 1243 (9th Cir. 2000).

[22] *See Meyer*, 565 F.3d at 1198-99; *Bly-Magee v. Premo*, 470 F.3d 914, 917 (9th Cir. 2006).

- The "news media," which includes newspapers, magazines, and other publications that "disseminate information to the public in a periodic manner."[24]

If the first part of the test is met, the court then determines whether the complaint is "based upon" the public disclosures.[25] The publicly disclosed facts need be only "substantially similar," not identical, to the relator's allegations.[26] A document meets this requirement if it "contain[s] enough information to enable the government to pursue investigation" against potential wrongdoers.[27] Adopting the D.C. Circuit's *Springfield Terminal* test, the Ninth Circuit has used the following test to determine whether the publicly disclosed information is sufficient:

> [I]f X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to

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[23] *See Bly-Magee*, 470 F.3d at 917-18 (following the Eighth Circuit in holding that non-federal reports, audits, and investigations qualify as public disclosures); *Hays v. Hoffman*, 325 F.3d 982, 988 (8th Cir. 2003) (Medicaid audits prepared by a state agency qualify as public disclosures).

[24] *United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y. 2002), *aff'd*, 53 F. App'x 153 (2d Cir. 2002).

[25] 31 U.S.C. § 3730(e)(4)(A).

[26] *See Meyer*, 565 F.3d at 1199; *Lujan*, 243 F.3d at 1189

[27] *United States ex rel. Harshman v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1019 (9th Cir. 1999). *See also In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d 367, 383 n.10 (D. Mass. 2008) (a disclosure need only "'set the government squarely on the trail of fraud' such that it would not have been difficult for the government to identify [the defendant] as a potential wrongdoer"); *In re Nat. Gas Royalties Qui Tam Litig.*, 562 F.3d 1032, 1043 (10th Cir. 2009).

> disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed.[28]

The "elements of the fraud allegation need not be made public in a single document,"[29] but rather can come from multiple sources, which are "considered as a whole."[30] "Any action based *even partly* upon public disclosures will be jurisdictionally barred."[31] Furthermore, "[a]n allegation need not include an express reference to the FCA to constitute a public disclosure."[32]

2. The Public Disclosures in This Appeal Are from Sources Enumerated in the FCA and Raise Types of Allegations Substantially Similar to Those in Relators' Complaints.

With respect to the first part of the public disclosure test, Relators do not dispute that the articles, the other FCA cases, and PsychRights's state court

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[28] *United States ex rel. Found. Aiding the Elderly v. Horizon West*, 265 F.3d 1011, 1015 (9th Cir. 2001) (quoting *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 653 (D.C. Cir. 1994)).

[29] *United States v. Catholic Healthcare W.*, 445 F.3d 1147, 1151 n.1 (9th Cir. 2006).

[30] *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 174 n.8 (5th Cir. 2004); *see also Dingle v. Bioport Corp.*, 388 F.3d 209, 214 (6th Cir. 2004) ("The fact that the information comes from different disclosures is irrelevant."); *A-1 Ambulance Serv.*, 202 F.3d at 1244-45 (holding that, when taken together, the contents of multiple administrative proceedings were sufficient to constitute public disclosure).

[31] *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 514 (6th Cir. 2009).

[32] *Harshman*, 197 F.3d at 1019.

complaint are among the types of public sources listed in Section 3730(e)(4)(A). (Opening Br. at 25-29.) Relators take issue only with the letters between Utah and CMS. (*Id.*)

The letters between the Utah Attorney General's Office and CMS, however, document an "investigation" under the Section 3730(e)(4)(A). "[I]nvestigations . . . may be informal or casual inquiries," comparable to a "police officer, hearing a particular noise in a dark shop, investigat[ing] by gingerly shining a flashlight inside and asking, 'What's up?'"[33] In *Glaser v. Wound Care*, for example, the Seventh Circuit held that a CMS letter demanding a doctor's repayment for improper use of billing codes was an "investigation."[34]

The letters between Utah and CMS certainly meet this standard. Utah explained that Utah was investigating the issue because it arose in "state actions

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[33] *United States v. Bank of Farmington*, 166 F.3d 853, 862 (7th Cir. 1999), *overruled on other grounds by Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 915-16 (7th Cir. 2009); *see also id.* (an "investigation" occurs whenever "[a]n official of an administrative agency faced with an anomaly . . . in a matter within his purview [makes] an inquiry to an official of a regulated industry for which the agency was responsible").

[34] 570 F.3d at 913-14 (reasoning that the letter signified that "the appropriate entity responsible for investigating claims of Medicare abuse had knowledge of possible improprieties with Wound Care's billing practice and was actively investigating those allegations and recovering funds"). *See also Seal 1 v. Seal A*, 255 F.3d 1154, 1161 (9th Cir. 2001) (documents obtained from the United States Attorney's office counted as "investigations" because the term "investigation" in Section 3703(e)(4)(A) encompasses "any kind of government investigation – civil, criminal, administrative, on any kind").

recently against various pharmaceutical manufacturers for off-label promotion causing filing of false Medicaid claims." (Exc. 55.) Utah then formally posed the issue to the federal agency responsible for interpreting Medicaid coverage. The investigation was far more than the officer looking around the corner. Utah continued to pursue the issue with another exchange of detailed letters with CMS.[35] Therefore, all of the public documents in this appeal are from sources enumerated in the Section 3730(e)(4)(A).

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[35] Relators also question, in footnote 45, the "legitimacy" of CMS's letters. The Court should disregard the argument because Relators had not raised this point to respond to the motion to dismiss in the district court, and have therefore waived their right to do so on appeal. *See Rothman v. Hosp. Ser. of So. Cal.*, 510 F.2d 956, 960 (9th Cir. 1975). In addition, Relators' relegation of this argument to a footnote referencing an unrelated document from the district court docket violates Cir. R. 28-1(b), which prohibits parties from incorporating by reference briefs submitted to the district court, or referring the Court to district court briefs for arguments on the merits of the appeal. *See Noel v. Hall*, 568 F.3d 743, 745 n.1 (9th Cir. 2009); *see also United States v. Kimble*, 107 F.3d 712, 715 n.2 (9th Cir. 1997) (arguments not developed are deemed abandoned).

Relators' argument also fails because the CMS letters are not necessary for the dismissal based on the Public Disclosure Bar. The letters from the Utah Attorney General's office, the authenticity of which Relators have not challenged, publicly disclosed the investigation and Relator's allegations. Moreover, to the extent that Relator's argument concerns the letters' signature lines, the argument fails; the letters were signed by Theresa Pratt, Deputy of CMS Disabled and Elderly Health Programs Group, on behalf of Gale Arden, Director. Furthermore, PsychRights found the letters legitimate enough to bring to the district court's attention in the motion to unseal the complaint (Supp. Exc. 54-56) and to post on its website to aide others in drafting complaints for other jurisdictions. *See* PsychRights' Medicaid Fraud Initiative Against Psychiatric Drugging of Children & Youth Model Medicaid Fraud Complaint, *available at* http://psychrights.org/education/ModelQuiTam/ModelQuiTam.htm.

The second part of the test – whether the case is "based upon" publicly disclosed information – is met as well. Employing the *Springfield Terminal* (X + Y = Z) standard in these cases requires no algebra because all variables – X (the false facts), Y (the actual facts), and Z (the allegation of fraud) – were publicly disclosed. Together, these public documents disclosed precisely the allegation raised in the present cases. Moreover, the district court's factual findings that the cases were based upon the identified public documents are entitled to deference and should not be reversed unless this Court finds them clearly erroneous.[36]

- The cited articles disclosed Relators' allegations that pediatric Medicaid patients were widely receiving psychotropic drugs off-label. For example:
    - In the late 1990s and early 2000s, several articles reported widespread Medicaid claims for pediatric patients' off-label and often non-compendium uses of psychotropic drugs such as Ritalin or Prozac for off-label uses. (Exc. 186-193.)
    - In 2008, a New York paper revealed the costs to New York Medicaid of off-label, mostly non-compendium psychotropic medications to pediatric patients. (Exc. 161.)
    - In 2008, the media reported on federal hearings on pediatric Medicaid beneficiaries' use of psychotropic medication. One article

[36] *See Lujan*, 243 F.3d at 1190.

noted that these children are often prescribed multiple psychotropic medications, and sometimes these drugs are used for off-label purposes. (Exc. 159.) The hearing itself is another public disclosure. (*Id.*)

- The previously filed FCA cases against pharmaceutical manufacturers made allegations about Medicaid claims similar to those in the present case. Indeed, in its brief in opposition to the motion to dismiss, PsychRights recognized that the United States has pursued FCA cases against large pharmaceutical manufacturers "for causing the presentment of claims to Medicaid for prescriptions of psychotropic drugs that are not for medically accepted indications, including Geodon and Seroquel for use in children," and quotes from allegations from one of those cases the precise theory that it espouses: "Medicaid can only pay for drugs that are used for a 'medically accepted indication,' meaning one that is either approved by the FDA or 'supported by citations' in one of three drug compendia, including DRUGDEX." (Dkt. 111, at 15 (quoting *United States ex rel. Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D. Mass. 2008)).) PsychRights even admitted in its motion to unseal the complaint in the present case that "the false or fraudulent nature of claims for prescriptions that are not for a medically accepted indication [] had been brought to the Government's attention in October of 2007 [] and the Government declined to stop the fraud." (Supp. Exc. 54.)

- Utah's investigation with CMS disclosed, and rejected, precisely Relators' theory that Medicaid does not cover pharmacy claims for off-label, non-compendium uses. (*See supra* part VII.B.2.) The investigation publicly disclosed that "many state Medicaid programs are liberally reimbursing – and presumably receiving Federal Financial Participation ('FFP') – for outpatient drugs used for indications that are neither FDA-approved nor supported in the relevant compendia." (Exc. 55.) Utah's second letter even referred to pediatric Medicaid patients' use of psychotropic drugs: "It has been widely reported that approximately 50% of [Zyprexa Medicaid] utilization is off-label, including for infants and toddlers." (Exc. 59.)

- In its amended state complaint, filed on November 24, 2008, PsychRights made the same allegation that it is making in this case:

> 22.It is unlawful to for the (sic) State to use Medicaid to pay for outpatient drug prescriptions except for indications approved by the Food and Drug Administration (FDA) or included in the following compendia . . . .

(*Compare* Exc. 197 *with* Exc. 127 ¶ 185.) PsychRights further alleged in that case that Alaska Medicaid authorized and continues to authorize these alleged illegal claims. (Exc. 254-255.)

The district court properly found that the public documents were of the type enumerated in Section 3730(e)(4)(A) and that Relators' allegations were based

upon those public disclosures. Because Relators are not original sources of their allegations, the court properly dismissed the cases under the Public Disclosure Bar.[37] Relators are left to argue that the Public Disclosure Bar does not apply because the documents did not identify all defendants by name or somehow disclose specific future Medicaid claims. As the next section shows, neither argument has merit.

3. Relators' Arguments Have No Merit.

a. The public disclosures put the government on the trail of the alleged fraud, even though they did not name all of the defendants.

The Public Disclosure Bar does not require that public documents name all defendants[38] or describe specifically each allegedly false or fraudulent claim.[39] It

[37] In addition, the Griffin complaint, based on the PsychRights model *qui tam* complaint, is barred by the FCA's first to file doctrine.

[38] PsychRights acknowledges that its argument is inapplicable to (i) Alaska officials William Hogan, William Streur, Tammy Sandoval and Steve McComb because the PsychRights's state court litigation identified those Alaska State Medicaid defendants (Opening Br. at 20, 25-26) and (ii) TR Healthcare because a October 23, 2003 *Wall Street Journal* article (Exc. 285) "identif[ied]" TR Healthcare. (*See* Opening Br. at 20.) Indeed, with respect to TR Healthcare, PsychRights does not and cannot dispute that the sparse allegations in its pleadings against TR Healthcare derive from that *Wall Street Journal* article, and not from any information discovered by PsychRights. *Compare* Supp. Exc. 39, at ¶ 193 ("One of Thomson's scientific and health-care division's biggest operations is running continuing medical education seminars paid by pharmaceutical companies which promote off-label prescribing of such drug companies' drugs . . . .") *with* Exc. 287 ("One of the division's biggest operations is running "continuing medical education" seminars for the pharmaceutical industry . . . Off-label uses of drugs are a frequent topic at medical-education seminars."). *Compare also* Supp. Exc.

requires only that the publicly disclosed information put the government on the trail of the alleged fraud. Public disclosure of each defendant's name is particularly unnecessary here where: Relators claim that all physicians who prescribe, and pharmacies that dispense, psychotropic medications to pediatric Medicaid patients for off-label, non-compendium uses are *per se* liable under the FCA, regardless of those parties' actual knowledge or intent; they allege that this conduct is continuous and pervasive across the industry;[40] and the potential defendants are readily identifiable from documents available to the government.

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39 ¶ 192 ("In 2002, Thomson's scientific and health-care divisions, which includes DRUGDEX, accounted for $780 million of Thomson's $7.8 Billion in revenue.") *with* Exc. 287 ("Thomson's scientific and health-care divisions, which includes Drugdex, accounted for $780 million of the company's $7.8 billion in revenue last year."). Aside from the alleged facts taken from the *Wall Street Journal* article, the Complaint and Amended Complaint are essentially devoid of any alleged facts relating to TR Healthcare (Opening Br. at 11). While PsychRights attempts to argue that it can still pursue claims against the Alaska officials and TR Healthcare because, according to PsychRights, the Public Disclosure Bar does not apply to false claims presented after the public disclosure, that argument is entirely without merit here. *See infra* part X.A.3.b.

[39] The Bar does not require that a public disclosure present the level of particularity that, for example, Federal Rule of Civil Procedure 9(b) demands. *See In re Natural Gas Royalties Qui Tam Litig.*, 467 F. Supp. 2d 1117, 1135 (D. Wyo. 2006) (rejecting relator's assertion that a public disclosure must contain the specificity required by Rule 9(b) in order to trigger the public disclosure bar to the FCA), *aff'd in part*, 562 F.3d 1032 (10th Cir. 2009), *cert. denied*, 130 S. Ct. 301 (2009).

[40] Telling in this regard are Relators' allegations of the widespread nature of the contested practice: "Nine of ten children and youth seeing a child psychiatrist receive psychotropic medication[, and c]hildren and youth in child welfare settings are two and three times more likely to be medicated than children and youth in the general community." (Exc. 106-107 at ¶¶ 95, 100.)

The United States needed only to determine, as PsychRights did, which doctors may have prescribed the medicine and which pharmacies may have submitted the Medicaid claims. That information was readily available to the government from Alaska Medicaid claims data.[41] PsychRights even acknowledged this fact in its relator's statement to the government: "No significant investigation is needed. . . . [I]t should be easy for the Government to confirm the facts." (Exc. 54.)

How Relators named pharmacies as defendants illustrates that Relators relied exclusively on public information. Relators did not work at, or have any particular knowledge about, any pharmacy. Instead, Relators merely named the three retail pharmacies – Wal-Mart, Safeway, and Fred Meyer – that PsychRights "believed are the largest pharmacies in Alaska." (Exc. 49, 53.) Relators do not allege that only these pharmacies dispensed, and filed Medicaid claims for, psychotropic medications prescribed for pediatric patients' off-label, non-compendium conditions, as if Medicaid patients assiduously avoided other

[41] As of January 1, 1999, the Balanced Budget Act of 1997 has required that all states participate in the Medical Statistical Information System (MSIS). *See* MSIS Overview, *available at* https://www.cms.gov/pf/printpage.asp?ref=http://www.cms.gov/MSIS/01_Overview.asp. Through MSIS, states supply CMS with eligibility and payment information on a claim-by-claim basis. *Id.* The claim-by-claim data submitted through MSIS for each prescription includes, among other things, the identity of the prescribing physician and the amount paid for the drug. *See* Medicaid and CHIP Statistical Information System File Specifications and Data Dictionary, *available at* https://www.cms.gov/MSIS/Downloads/msisdd2010.pdf.

pharmacies.[42] Relators provided no insider information unknown to the government.

The case law supports the district court's dismissal under the Public Disclosure Bar. *United States ex rel. Harshman v. Alcan Elec.& Eng., Inc.*, for example, rejected an argument that documents that did not name the defendants could not constitute public disclosures. The relator, a union member, alleged that contractors violated the FCA by misrepresenting to the United States that they were paying prevailing wage rates to their employees. In fact, the union was deducting 2.5 percent from union members' gross wages, in the form of "job targeting" dues, and remitting the money back to contractors. This Court affirmed the dismissal, finding that the allegations had been sufficiently publicly disclosed in a proposed complaint that the relator had lodged with the union and the district court (though not under seal and attached to an application for leave to file suit). That proposed complaint raised allegations (but not an FCA claim) against union officials (but not the contractors) about deducting the dues.[43]

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[42] In fact, Relators acknowledge that other pharmacies are involved in the allegedly fraudulent scheme. (Opening Br. at 9 ("After doctors prescribe such drugs they are taken to *pharmacies, including the pharmacy* Defendants here, which then fill the prescriptions and present false claims to Medicaid for payment.") (emphasis added).) Relators also do not allege how pharmacies are supposed to know for what condition a physician prescribes a medication.

[43] 197 F.3d 1014, 1016 (9th Cir. 1999).

This Court's reliance on the D.C. Circuit's *Findley* opinion is significant and merits quoting in full:

> The District of Columbia Circuit also addressed this issue in *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675 (D.C. Cir. 1997), *cert. denied*, 522 U.S. 865, 118 S. Ct. 172, 139 L.Ed. 2d 114 (1997). Findley charged the defendant with retaining money earned in vending machines on federal property that was owed to the government. *See id.* at 678. The practice of government employees' clubs retaining this income had been disclosed in a Comptroller General Opinion, in the legislative history of a federal statute, and in a lawsuit litigated in the Federal Circuit. *See id.* at 679. What Findley added to these disclosures was the identity of one of these employees' clubs. *See id.* at 687. The court said, "[l]ittle similarity exists between combing through the myriad of transactions performed [for example] by the various defense contractors in search of fraud and finding easily identifiable federal employee organizations that provide vending services on federal property." *Id.* at 687. The court concluded that "because relator Findley's complaint merely echoes publicly disclosed, allegedly fraudulent transactions that already enable the government to adequately investigate the case and to make a decision whether to prosecute, the public disclosure bar applies." *Id.* at 688.[44]

Although the *Harshman* court observed that the proposed complaint referred to "a narrow class of suspected wrongdoers – local electrical contractors who worked on federally funded projects over a four-year period [and] were required by statute to file certified payrolls with the government on a weekly basis," the standard was

[44] *Id.* at 1019.

(and still is) *how readily the government could identify defendants based on the earlier allegations*, not specifically the number of suspects:

> In this regard, the instant case is similar to *Sandia*, in that the government, as regulator and owner, presumably would have ready access to documents identifying those contractors. This ready access makes it highly likely that the government could easily identify the contractors at issue. Thus, the district court did not err in concluding that the allegations in the [proposed] complaint were sufficient to constitute a public disclosure.[45]

In *In re Natural Gas Royalties Qui Tam Litigation*, the relator sued 220 defendants in the natural gas industry, alleging misconduct relating to the calculation of royalties owed to the government.[46] Previous Senate documents, however, described similar misconduct. Even though the Senate documents did not name all alleged bad actors, the Tenth Circuit found that the documents were sufficient to put the government on the trail of the alleged fraud and to allow the government to "target its investigation toward specific actors and a specific type of fraudulent activity."[47] The court accordingly held that the documents precluded subject matter jurisdiction over the relator's case.

In *United States ex rel. Gear v. Emergency Medical Associates of Illinois, Inc.*, the relator alleged that the defendants had improperly billed Medicare for the

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[45] *Id.*

[46] 562 F.3d at 1037-38.

[47] *Id.* at 1042.

cost of physicians providing services that were actually performed by residents.[48] Prior to the relator filing the complaint, however, the General Accounting Office had reported a settlement between the Department of Justice and the University of Pennsylvania on this issue and that similar problems may be more widespread.[49] There also were several news articles about this potential fraud.[50] The relator argued that these disclosures were not public disclosures because none identified the particular defendants.[51] The Seventh Circuit disagreed: "*We are unpersuaded by an argument that for there to be public disclosure, the specific defendants named in the lawsuit must have been identified in the public records*. The disclosures at issue here were of industry-wide abuses and investigations. Defendants were implicated."[52]

The cases on appeal are similar to *Harshman*, *Natural Gas* and *Gear* because they involve a narrow class of easily identified suspected wrongdoers (here, Alaska health professionals and facilities that treat pediatric Medicaid patients and the pharmacies in Alaska that submit Medicaid claims). The government could have identified these parties, with no insider information, just as

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[48] 436 F.3d 726, 727 (7th Cir. 2006).

[49] *Id.*

[50] *Id.*

[51] *Id.* at 729.

[52] *Id.* (emphasis added).

easily as Relators' counsel did. There is a limited number of hospitals and clinics in Alaska and fewer still that provide psychiatric care to minors. Likewise, there is a very limited number of psychiatrists in Alaska and even fewer who provide care to minors. The number of pharmacies filing Medicaid claims in Alaska is limited. This information is easily identified from the Medicaid claims data. Data maintained by the Medicaid agencies reveal, on a claim-by-claim basis, the pharmacy that submits the claim, the drug for which the claim is being made, the age of the Medicaid beneficiary, and the prescribing physician.[53] Therefore, the potential defendants in Alaska could be easily identified by the government, as they were by PsychRights.

Indeed, here, Relators did not identify Defendants based on inside knowledge of any wrongdoing, prescribing or claims submission (as demonstrated by PsychRights's relator statement's and the complaint's lack of specificity about each defendant's conduct). Instead, Relators just identified prominent members of the Alaskan pediatric psychiatric healthcare community, the three largest chain pharmacies in Alaska, well known state officials, and a national publishing company.

Relators' rely heavily on *Foundation Aiding the Elderly*, but that opinion does not support their argument. In that case, the relator alleged that medical

[53] *See supra* footnote 41 (explaining the procedure for submitting data to the Medical Statistical Information System).

facilities billed Medicare and Medicaid for procedures that the facilities had not in fact conducted – *i.e.*, the defendants were defrauding the government with a specific intent to do so. Relators cite footnote 5, which addresses (a) a newspaper report that one of the defendants "received a citation, and a fine, for a premature entry on a patient's chart" and (b) "general allegations of fraud that were directed at the nursing home industry in general."[54] Analyzing whether the article "would give the government sufficient information to initiate an investigation against this facility" for the fraud alleged in the relator's complaint, the court noted the difference between making a premature entry on a chart and billing for a procedure not performed.[55] The court also held that general allegations of fraud in the industry did not disclose that the specific defendants were engaging in the specific misconduct of billing for, but not performing, procedures.[56] The court concluded:

> Consequently, these unrelated allegations of fraud cannot trigger § 3730(e)(4)(A)'s jurisdictional bar. Although "fraud" may have been generally alleged against some of the current Appellees in certain contexts, none of the evidence in the record "fairly characterizes" the kind of fraud alleged by Appellants here. To put it somewhat differently, "it is [im]possible to say that the evidence and information in the possession of the United States at the time the False Claims Act suit was brought was

[54] *Found. Aiding the Elderly*, 265 F.3d at 1016 n.5.

[55] *Id.*

[56] *Id.*

> sufficient to enable it adequately to investigate the case and to make a decision whether to prosecute.[57]

The public disclosures in the cases on appeal are very different from those in *Foundation Aiding the Elderly*.[58] Whereas that case addressed whether unrelated and otherwise general allegations of industry fraud disclosed specific defendants' affirmative misconduct of billing for medical procedures not performed, Relators here argue that public disclosures of all aspects of the alleged industry-wide fraud do not bar jurisdiction, solely because the disclosures did not name all defendants. But Relators had no insider information to provide the government, and the government did not need any to investigate the publicly disclosed allegations. According to Relators, *all* physicians prescribing, or pharmacies dispensing, psychotropic medication to pediatric Medicaid patients for off-label, non-compendium uses have filed false claims, and the conduct has been pervasive. Relators merely obtained Medicaid data and named the most prominent doctors, hospitals, and pharmacies.

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[57] *Id.* at 1016 (quoting *United States ex rel. Joseph v. Cannon*, 642 F.2d 1373, 1377 (D.C. Cir. 1981)).

[58] *See United States ex rel. Swan v. Covenant Care, Inc.*, 279 F. Supp. 2d 1212, 1219 n.9 (E.D. Cal. 2002) (distinguishing *Found. Aiding the Elderly* on the basis that the previously disclosed fraud complaint in that case involved "only general allegations" of fraud, whereas the previously filed state court complaint in *Swan* contained "detailed allegations of fraud" that raised "an inference of Medicare fraud," and therefore was a public disclosure for the purposes of the FCA).

Relators also rely on *Aflatooni*, but that case is very different as well. There, the medical provider-defendants submitted or caused the submission of claims to Medicare for tests and services that were alleged to be unnecessary, not performed, or improperly billed – again, affirmative misconduct, not a disagreement about the statutory breadth of coverage. The complaint involved one set of defendants' specific actions that had not been publicly disclosed. This distinction, which Relators ignore, was later recognized by the Ninth Circuit:

> In *Aflatooni*, we were faced with a similar issue. Aflatooni brought a *qui tam* action raising two different sets of allegations. Before filing the action, Aflatooni disclosed some of his allegations against certain defendants ("NDI Defendants") to the news media, but he did not disclose any of the allegations against other defendants ("PAKC Defendants"). The issue for this Court was "whether the disclosure of the allegations against the NDI Defendants should trigger the public disclosure bar with respect to the PAKC Defendants." The PAKC Defendants argued that because Aflatooni alleged a large conspiracy in his complaint, the allegations he disclosed to the media rendered his claims publicly disclosed as to all of the defendants. We rejected this argument because the allegations against the two groups of defendants were distinct. Implicit in this analysis is the proposition that Aflatooni's disclosures could have constituted public disclosure with respect to all of the defendants despite the failure specifically to name the PAKC Defendants, if the disclosures had encompassed his allegations against them.[59]

[59] *Harshman*, 197 F.3d at 1018 (internal citations omitted).

Here, Relators have not provided any details of specific fraudulent conduct by individual defendants. For example, the complaints say nothing about the diagnoses that led to the prescriptions. Instead, Relators merely acknowledged the publicly disclosed industry-wide conduct and named Alaskan providers and pharmacies.

The *Baltazar* case, from which Relators ask this Court to take judicial notice of the DOJ's amicus brief,[60] involves a very different set of facts. The relator, a chiropractor, alleged, based on her personal observations, that her former employer had billed for services not rendered and had upcoded services that had been performed.[61] Dismissing the case, the district court identified public documents that discussed only general billing issues for a few of the 50,000 chiropractors in the United States including a 2005 report stating that 16% out of a sample of 400 chiropractors' claims were for services that had been miscoded. Reversing, the Seventh Circuit recently ruled that the relator's private, insider information was necessary for anyone to bring the FCA case. For example, the relator's personal observations were necessary to distinguish the defendants' fraudulent upcoding from mere negligence. The relator's information went beyond the publicly disclosed allegations because "a statement such as 'half of all chiropractors' claims

[60] *See* App. Dkt. 20-1, 20-2.

[61] *United States ex rel. Baltazar v. Warden*, No. 09-2167, --- F.3d ---, 2011 WL 559393, at *1 (7th Cir. Feb. 18, 2011).

are bogus'" is hardly the kind of disclosure of an industry-wide conduct that has been found sufficient.

The *Baltazar* court specifically distinguished *Gear* in which "the GAO had concluded that the practice it described was normal, if not universal among teaching hospitals [and] Gear was unable to describe any *other* facts underlying the suit, which therefore must have been 'based on' the published report."[62] The court continued: "Once the GAO concluded that teaching hospitals routinely disregarded the required distinction between work in the teaching program and work as an attending physician, the only extra fact required was that the defendant is a medical school or a teaching hospital. That's public knowledge. Gear's suit did not add one jot to the agency's fund of information; the panel rightly called it 'parasitic.'"[63]

Here, Relators' cases involve a *per se* theory of FCA liability, based on their interpretation of Medicaid coverage, which could have been asserted against any physician or pharmacy writing or filling prescriptions for pediatric Medicaid patients in Alaska. Because the Alaska Medicaid program covered these services, every person or entity that participated in prescribing or dispensing these drugs to pediatric Medicaid beneficiaries is a potential defendant under Relators' theory. Indeed, Relators have not identified any doctor or pharmacy that has refused to

[62] *Id.* at *3.

[63] *Id.* at *4.

prescribe or dispense medications to Medicaid patients under Relators' interpretation of the Social Security Act. The government could have pursued the claims brought by PsychRights based on the publicly disclosed information and information well within the government's own control. This certainly is not the scenario claimed in the *Baltazar amicus* brief – "where the government has no viable alternative means to obtain the information provided by relator." (App. Dkt. 20-2 at 11.)

b. The Public Disclosure Bar precludes jurisdiction over claims that postdate public disclosures of ongoing conduct.

Relators' argument that the Public Disclosure Bar "cannot be triggered with respect to false claims presented after the public disclosure" (Opening Br. at 3) is legally wrong and does not apply to this case, in which both the public disclosures and the complaints allege ongoing conduct, and almost all of the identified Medicaid claims predate the public disclosures.

First, Relators misconstrue *Bly-Magee* by asserting that post-disclosure allegations could not have been publicly disclosed. (Dkt. 111, at 17.) The Ninth Circuit in *Bly-Magee* found that the public disclosures referenced *specific* time periods and that the relator's allegations relating to *another* time period had not been previously disclosed.[64] The Court did not hold that public disclosures

[64] *Bly-Magee*, 470 F.3d at 916-20.

describing an ongoing scheme or conduct bar allegations of conduct postdating the public disclosures. Indeed, PsychRights's requests for injunctive relief in its state court case and against the state defendants in the present case demonstrate its belief that the off-label use of psychotropic drugs on children is ongoing and not limited to a particular time period.

Second, Relators' argument ignores that public disclosures need only "set the government squarely on the trail of fraud," not outline all aspects of the fraud with specificity. Accordingly, the Public Disclosure Bar makes no distinction between an ongoing fraudulent scheme and fraud that has run its course, as long as the disclosures sufficiently inform the government about the alleged fraud for the government to figure out whom to investigate.[65] Here, PsychRights alleged ongoing conduct, but failed to identify any specific Medicaid claim. PsychRights

[65] *See United States ex rel. Lujan v. Hughes Aircraft Co.*, 162 F.3d 1027, 1033 (9th Cir. 1998) (previous *qui tam* action alleging false claims submitted from 1982-1984 constituted a public disclosure of all of relator's substantially similar allegations, including those relating to false claims submitted from 1985-1989); *see also United States ex rel. Boothe v. Sun Healthcare Group, Inc.*, 496 F.3d 1169, 1174 (10th Cir. 2007) ("Not a single circuit has held that a complete identity of allegations, even as to time, place, and manner is required to implicate the public disclosure bar; rather, all have held, at a minimum, that dismissal is warranted where the plaintiff seeks to pursue a claim, the essence of which is 'derived from' a prior public disclosure."); *United States ex rel. Rosales v. San Francisco Hous. Auth.*, 173 F. Supp. 2d 987, 996-97 (N.D. Cal. 2001) (holding that false grant applications made in the years after the public disclosures were publicly disclosed because the relator's "allegations remain substantially the same as those previously disclosed" and allegations "cannot be reanimated simply by complaining that defendants performed the same fraudulent acts in succeeding years").

added to its complaint allegations of some prescription data only in response to Defendants' Rule 9(b) motion to dismiss. The United States could have identified the sixteen Medicaid claims, totaling $5,956.45, that post-date the public disclosures just as easily as did PsychRights, with no insider information. (*See supra* part X.A.3.a.) Furthermore, Relators' argument would lead to absurd results – relators would be able to continuously file serial complaints raising the newest claims at issue.[66]

c. The District Court's ruling does not immunize any defendant or potential FCA defendant.

Relators' argument that the district court's opinion somehow immunizes FCA defendants also fails. First, the ruling does not immunize any defendant or potential defendant because it protects no one from the United States suing. The Public Disclosure Bar denies jurisdiction only over actions brought by a relator

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[66] *See United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 115 (1st Cir. 2010):

> Although these details [about an additional product not mentioned in the public disclosure] undoubtedly add some color to the allegation, the allegation ultimately targets the same fraudulent scheme. That is enough to trigger the public disclosure bar. *See* [*United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 58 (1st Cir. 2009)]; *see also Dingle v. Bioport Corp.*, 388 F.3d 209, 215 (6th Cir. 2004) (noting that a contrary ruling "would allow potential *qui tam* plaintiff's [sic] to avoid the public disclosure bar by pleading their complaints with more and more detailed factual allegations already publicly disclosed").

without the government's intervention.[67] The Bar in no way "immunizes" any FCA defendant where the U.S. government initiates or intervenes in the case.

Second, the Public Disclosure Bar, and particularly the standard for determining whether an action is "based upon" public disclosures, already takes into account Relators' concern. This Court has noted that "the FCA has been shaped by Congress's '[s]eeking the golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own.'"[68] There can be no doubt that Relators here fall on the second side of that "golden mean." They brought to the government no information that was not publicly disclosed or readily available to the United States. Therefore, Relators' notion that the district court's proper application of the Public Disclosure Bar to this parasitic FCA lawsuit will "immunize" all past, present, and future wrongdoers from fraud is misplaced and meritless.

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[67] *See* 31 U.S.C. § 3730(e)(4)(A); *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 478 (2007) (Public Disclosure Bar does not bar jurisdiction if the government initiates or intervenes in the case), *reh'g denied*, 550 U.S. 954 (2007).

[68] *United States ex rel. Devlin v. State of Cal.*, 84 F.3d 358, 362 (9th Cir. 1996) (citing *Springfield Terminal Ry.*, 14 F.3d at 649).

B. Alternatively, The Court Should Affirm The Dismissal Based On One Of The Arguments Raised In The Motions That Were Mooted By The Dismissal For Lack Of Jurisdiction.

Although the district court denied Defendants' Rule 9(b) and Rule 12(b)(6) motions to dismiss as moot given the lack of jurisdiction, this Court may affirm the dismissal based on any argument made in those motions.[69]

1. Alternatively, the Court Should Affirm the Dismissal Because Relators' Complaints Lack Particularity Under Rule 9(b).

The Court may affirm the dismissal on the basis that the complaints failed to plead the circumstances of fraud with particularity under Rule 9(b). Relators have simply parroted public allegations and applied them without specificity against the most prominent providers in the Alaskan pediatric psychiatric community, national pharmacy chains and the publisher TR Healthcare.

Relators offer no specific allegations as to how any defendant engaged in unlawful claims submission activities. Even after PsychRights amended its complaint (following Defendants' filing a Rule 9(b) motion), it was still unable to plead any additional details of fraud for fifteen of the medical provider Defendants.[70]

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[69] *See Cook v. AVI Casino Enters., Inc.*, 548 F. 3d 718, 722 (9th Cir. 2008) (appellate court may affirm dismissal on any grounds raised below), *cert. denied*, 129 S. Ct. 2159 (2009).

[70] Anchorage Community Mental Health Services, Inc., Bartlett Regional Hospital, Juneau Youth Services, Providence Health & Services, Southcentral

For those defendants, Relators do not identify a single claim, action, or circumstance linking them to the submission of any allegedly false claims. For the other nine medical provider defendants, the Amended Complaint identifies certain claims information for a handful of Medicaid beneficiaries, but provides no allegation as to how these defendants "caused" the identified claims to be submitted. Relators also fail to provide any specific allegation of wrongdoing, inaccuracy, falsification or fraud relative to these claims. Merely listing a drug, a date of unknown reference, and a monetary amount of unknown reference for a given patient does not identify with particularity how the defendant "caused" the alleged fraud or even what the alleged fraud is. For example, no information is pled concerning the patient's diagnosis, the use for which the drug was prescribed, or facts suggesting that the specific defendant knew, or should have known, that the drug was not properly payable, particularly given Alaska Medicaid regulations permitting coverage.[71] Moreover, in addition to the absence of specifics "linking"

Foundation, Peninsula Community Health Services, and Drs. Curtiss, Dukoff, Kiele, Lopez-Coonjohn, Phillips, Rothrock, Schults, Starks, and Stauffer.

[71] To illustrate how the claims information falls short of Rule 9(b) requirements, consider the allegations against Defendants Dr. Osamu Matsutani and Denali Family Services ("Denali"). PsychRights attributes the same universe of claims as having been "caused" by both Denali and Dr. Matsutani—i.e., twenty-three Cymbalta and fifty-two Risperdal prescriptions for patient "MG" with "dates" between January and December 2007. (Exc. 137-139, at ¶ 202; Exc. 141-143, at ¶ 206.) Yet there is no allegation as to any relationship between these two Defendants that would explain how both could have caused the same claims to be submitted or that describes the conduct in a manner to either join or differentiate

particular Defendants to specific purported false claims,[72] for all Defendants there is an equally glaring absence of particularity as to any knowingly wrongful and/or deceitful conduct.[73]

In addition to the lack of Rule 9(b) specificity regarding actual false claims or the circumstances of their submission, the complaints also fail as there is no plausible theory of the underlying alleged fraud[74] because the Alaska Medicaid program as approved by CMS expressly covered the drugs in question irrespective

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these two Defendants. Thus, the failure to specify any fraud leaves the Defendants with the task of sorting out and defending implausible allegations without responding to any identified wrongdoing.

[72] Notably, in terms of linking the alleged conduct to false claims, Relators acknowledged that with respect to TR Healthcare, it is in a "different category" because there is an "additional link" involved. (Dkt. 110 at 10.) But Relators provide no factual support for their conclusory assertion that Thomson can be causally "linked" to the presentation of false prescriptions through (a) its alleged provision of continuing medical education ("CME") programs paid for by pharmaceutical companies promoting off-label drug prescription and/or (b) allegedly false statements in its DRUGDEX compendium. Relators' complaints do not even specify: (a) the specific drugs allegedly promoted at these unidentified CME programs, (b) the specific off-label use or uses allegedly promoted, (c) the content of the CME programs, (d) the drug companies that allegedly sponsored them, and (e) when specifically (or even generally) these CME programs occurred. Similarly, there is no identification in the complaints of any specific statements in DRUGDEX relating to any particular indications for any identified drugs that Relators contend are false.

[73] *See Wang v. FMC Corp.*, 975 F.2d 1412, 1420-21 (9th Cir. 1992) ("The [FCA] is concerned with ferreting out 'wrongdoing,' not scientific errors … What is false as a matter of science is not, by that very fact, wrong as a matter of morals. The Act would not put either Ptolemy or Copernicus on trial.").

[74] *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-57 (2007); *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950-51 (2009).

of whether they were prescribed on an off-label basis. Amending the allegations to add particulars of fraud would be futile, as no facts could be pled demonstrating how legal conduct, such as off-label prescribing, or the State Defendants paying for drugs that are reimbursable under the State's own regulations, constitutes fraud. Accordingly, failure to comply with Rule 9(b) provides an alternative basis to dismiss this case with prejudice.

2. Relators' Interpretation of the Social Security Act and Medicaid Coverage Is Incorrect.

Relators' statutory interpretation, on which their cases depend, is contradicted by the relevant Medicaid statute's purpose, the statutory provisions that Relators cite and other provisions in the law, all of which make clear that the definition of "medically accepted indication" sets a floor, not a ceiling, for Medicaid coverage of outpatient drugs.[75]

The Social Security Act was amended in 1990 to include the Medicaid drug rebate law to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." (Supp. Exc. 62-75.) To that end, the Social Security Act

[75] In addition, Relators' theory fails to account for (i) how physicians, hospitals, and pharmacies can be charged with filing false claims when the Medicaid claims at issue were submitted to the State of Alaska, for payment by the State of Alaska, pursuant to state laws that Relators concede authorize the claims to be presented to and paid by the State of Alaska, 7 AAC 145.005, or (ii) how pharmacies are supposed to know the condition for which each drug is prescribed.

prohibits Medicaid federal financial participation (or "FFP") for a "covered outpatient drug" unless the drug's manufacturer has entered into an agreement to rebate a percentage of the drug's purchase price back to the government (a "rebate agreement").[76] Once a drug manufacturer has entered into a rebate agreement for a drug, however, a *quid pro quo* applies: states that offer a prescription drug Medicaid benefit are generally *required* to cover that drug under their plans.[77]

Relators' theory ignores this historical context and improperly reads "prescribed drugs" and "covered outpatient drugs" to mean the same thing under the Social Security Act. In fact, federal Medicaid law allowed states to cover "prescribed drugs" long before the Social Security Act was amended to add the Medicaid drug rebate provisions that included the narrower term "covered outpatient drug."[78] Indeed, the very definition of "covered outpatient drugs" in the

[76] 42 U.S.C. §§ 1396b(i)(10)(A), 1396r-8(a)(1).

[77] *See* 42 U.S.C. §§ 1396a-(a)(10), 1396d-(a)(12), 1396r-8(d)(4) ("include[] the covered outpatient drugs of any manufacturer which has entered into and complies with [a rebate agreement]"); *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1327 (S.D. Fla. 2006) ("[T]the Medicaid Act *requires* a state paying for outpatient prescription drugs to reimburse for 'medically accepted indications,'. . . ."); *see also* Exc. 281 ("The statute *requires* coverage of off-label uses of FDA-approved drugs for indications that are supported . . . in the compendia specified in section 1927(g)(1)(B)(II)).") (emphasis added).

[78] The rebate law was enacted in 1990. States have been allowed to cover "prescribed drugs" since the Medicaid program's inception in 1965. *See* Pub.L. 89-97, Title I, § 121(a), 79 Stat. 379.

rebate law shows that "covered outpatient drugs" are a subset of "prescribed drugs:"

> Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means --
>
> (A) *of those drugs which are treated as prescribed drugs* for purposes of section 1396d(a)(2) of this title, a drug which . . .[79]

In other words, "covered outpatient drugs" are among the drugs that are "treated as prescribed drugs" for purposes of the Medicaid benefit, but they are not the *only* drugs that are so treated.

Although "prescribed drugs" is not defined in the Medicaid statutes, it has been defined in CMS Medicaid regulations since at least 1978, twelve years before the rebate law was enacted. That definition, which Congress is presumed to have been aware of when it enacted the rebate law, defines "prescribed drugs" broadly:

> "Prescribed drugs" means simple or compound substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are --
>
> (1) Prescribed by a physician or other licensed practitioner of the healing arts within the scope of this professional practice as defined and limited by Federal and State law;
>
> (2) Dispensed by licensed pharmacists and licensed authorized practitioners in accordance with the State Medical Practice Act; and

[79] 42 U.S.C. § 1396r-8(k)(2) (emphasis added).

> (3) Dispensed by a licensed pharmacist or practitioner on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records. [80]

This definition was not revised after enactment of the rebate law and makes no reference to the rebate law or to "covered outpatient drugs."[81]

Moreover, the rebate statute is "carefully constructed" in such a way as to "precisely circumscribe the only methods by which a state may remove" a drug from coverage.[82] A state "may subject to prior authorization any covered outpatient drug," but only if the state's preauthorization program complies with detailed requirements.[83]

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[80] 42 C.F.R. § 440.120(a). The definition appears in 42 C.F.R. Part 440, Subpart A, which "interprets and implements" specified sections of the Medicaid title of the Social Security Act, including section 1905(a) [42 U.S.C. 1396d] Services included in the term "medical assistance." 42 C.F.R. § 440.01. The rebate law's legislative history quotes the regulation verbatim, so it is clear Congress knew of the definition at the time. (Supp. Exc. 62-75.) *See also* Dkt. 120-1 at 12.

[81] The rebate law's requirements are implemented by a different part of the CMS regulations, 42 C.F.R. § 447.500-520. Those regulations likewise offer no support for Relators' interpretation of the law. They do not limit the prescription drug benefit to covered outpatient drugs, they refer both to "covered outpatient drugs" and to "prescription drugs," and they do not use those terms interchangeably. *Compare* 42 C.F.R. § 447.502 ("'Multiple source drug' means, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which . .. [i]s rated as therapeutically equivalent ....") *with* 42 C.F.R. § 447.518(a) ("The State plan must describe comprehensively the agency's payment methodology for prescription drugs.").

[82] *Edmonds*, 417 F. Supp. 2d at 1330-31.

[83] 42 U.S.C. §§ 1396r-8(d)(1)(A), (5).

Notably, CMS recognizes that "covered outpatient drugs" and "prescribed drugs" are not synonymous, and has reassured State Medicaid Program Directors that the rebate law "made no changes to a State's previous ability to cover" drugs that "do not meet the definition of covered outpatient drug" in the Act, including "experimental" drugs. (Supp. Exc. 59.)

Other provisions in the Social Security Act show that the provisions cited by Relators establish a "floor" for reimbursements of medications by Medicaid programs, not a "ceiling" as Relators claim. Indeed, Relators ignore other provisions that establish that Medicaid *must* cover all "covered outpatient drugs," but *may* cover FDA-approved drugs for any indication. For example, the Act provides that "[a] state *may exclude or otherwise restrict coverage* of a covered outpatient drug *if the prescribed use is not for a medically accepted indication* (as defined in subsection (k)(6) of this section)."[84] It would make no sense for the Act to permit states to "exclude or otherwise restrict coverage" of FDA-approved medication for indications not listed as supported in the drug compendia if, as Relators contend, another section prohibits Medicaid from covering drugs for those indications. Alaska, like most states, has chosen to pay claims for FDA-approved medications regardless of whether they are listed as "supported" in the compendia.

[84] 42 U.S.C. § 1396r-8(d)(1)(B)(i) (emphasis added).

Finally, even if Defendants' (and the Alaska Medicaid program's and CMS's) interpretation of the Social Security Act is ultimately found to be incorrect, Relators' claims would still fail. Relators rely on the theory that the Medicaid claims at issue were false because, according to Relators' interpretation of the Social Security Act, Federal Medicaid law does not cover the claims and Defendants had certified to be in compliance with federal law. (Exc. 118-123.) That theory fails as a matter of law, however, because "[f]or a certified statement to be 'false' under the Act, it must be an intentional, palpable lie. Innocent mistakes . . . and differences in interpretation are not false certifications under the Act."[85]

XI. CONCLUSION

For the foregoing reasons, the Court should affirm the district court's dismissal with prejudice.

XII. STATEMENT OF RELATED CASES

There are no known related cases pending in this Court.

[85] *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996) (citing *United States ex rel. Hagood v. Sonoma Cnty. Water Agency*, 929 F.3d 1416, 1478 (9th Cir. 1991)).

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XIII. CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the enlargement of brief size permitted by Ninth Circuit Rule 28-4. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6). This brief is 14,884 words, excluding the portions exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

/s/ Eric P. Berlin
Eric P. Berlin

Dated: This 2nd day of March, 2011.

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 2, 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, within 3 calendar days to the following non-CM/ECF participants:

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