UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *et al.* *ex rel*. ROBERT E. MANCHESTER, Plaintiff, v. PURDUE PHARMA, L.P., PURDUE PHARMA, INC., PURDUE FREDERICK CO., MCKESSON CORP., CARDINAL HEALTH INC., and AMERISOURCEBERGEN CORP., Defendants.	**REDACTED** No. 1:16-cv-10947 MLW **Leave to File Granted August 24, 2018**

MEMORANDUM OF LAW IN SUPPORT OF THE UNITED STATES' MOTION TO DISMISS RELATOR'S COMPLAINT

Pursuant to Fed. R. Civ. P. 12(b)(1) and (6), the United States moves to dismiss this declined False Claims Act ("FCA") *qui tam* action for three reasons. First, the relator, Robert Manchester bases his allegations only on publicly available information, and the FCA's public disclosure bar precludes relators from pursuing any FCA action that is premised on "substantially the same allegations or transactions" as those that were publicly disclosed prior to the filing of the complaints unless the action or claim is brought by an "original source." 31 U.S.C. § 3730(e)(4). Mr. Manchester, an attorney in Vermont, has no inside information concerning any of the defendants and is not an original source.

[redacted]

[redacted]

Finally, Mr. Manchester does not have standing to bring his non-FCA claims on behalf of the United States or the named plaintiff states.[2]

I. FACTUAL AND PROCEDURAL BACKGROUND

A. The Defendants and Prior Public Scrutiny of Their Conduct

Purdue Pharma, L.P., Purdue Pharma, Inc., and Purdue Frederick Co. (collectively "Purdue") manufacture and market pharmaceuticals, including OxyContin. McKesson Corp., Cardinal Health, Inc., and Amerisource Bergen Corp. are major distributors of pharmaceuticals, including Purdue products. The nationwide opioid epidemic and defendants' manufacturing, sale and distribution of OxyContin were the subject of intense public scrutiny since well before the filing of the instant lawsuit.

In 2007, as Mr. Manchester recognizes in his own complaint, Purdue and certain of its officers and affiliates pled guilty to criminal charges and paid over $600 million to resolve federal civil and criminal allegations that they "fraudulently misbranded OxyContin as being less

---

[1] For ease of reference, true and correct copies of documents referenced in this motion are appended to the Declaration of Steven Sharobem ("Sharobem Decl.").

[2] The government also respectfully submits that, pursuant to 31 U.S.C. § 3730(c)(2)(A), it has the unilateral right to dismiss this or any other *qui tam* action, even over the relator's objection. *See Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003) ("Reading § 3730(c)(2)(A) to give the government an unfettered right to dismiss an action is. . .consistent with the Federal Rules of Civil Procedure."); *United States ex rel. Nasuti v. Savage Farms, Inc.*, 2014 WL 1327015, at *10 (D. Mass. Mar. 27, 2014) (expressing favor for the "unfettered right" standard for dismissal under Section 3730(c)(2)(A)), *aff'd on other grounds*, No. 14-1362, 2015 WL 9598315 (1st Cir. Mar. 12, 2018); *but see United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1146 (9th Cir. 1998) (applying a valid governmental purpose test under Section 3730(c)(2)(A)). Because other strong grounds exist to dismiss this *qui tam*, the government is not relying on Section 3730(c)(2)(A) here.

addictive and less subject to abuse and diversion than other pain medications." Sharobem Decl., Ex. B; *see* Third Amended Complaint, Dkt. No. 31, Att. 12. At or around that time, many states publicly filed suit against Purdue. *See, e.g.,* Dkt. No. 31, Att. 26 (discussing Kentucky lawsuit); Sharobem Decl., Ex. C (noting that Purdue "agreed to pay $19.5 million to twenty-six states and the District of Columbia").

Even after resolution of those investigations, as Mr. Manchester has recognized, OxyContin remained the subject of news reports and media scrutiny. Some of the media attention has focused on the abuse deterrent formulation of OxyContin, which the Food and Drug Administration ("FDA") approved in 2010. *See* Dkt. No. 31, Att. 7. In 2011, the New York Times reported comments by a Massachusetts state senator who queried why Purdue had waited so long to develop an abuse-deterrent formulation. Sharobem Decl., Ex. D. In 2013, the FDA announced that it would not accept applications for generic, non-abuse-deterrent formulations of OxyContin. *Id.*, Ex. E. Shortly thereafter, Purdue filed a patent lawsuit related to its abuse-deterrent formulation. *Id.* In 2015, the court in the patent case issued its findings of fact and conclusions of law detailing Purdue's development of its abuse-deterrent formulation and finding certain of its patents invalid. *Id.*; *see* Dkt. No. 31, Att. 2.

The media has also reported on allegations that Purdue misrepresented the risks of OxyContin and marketed the drug to overprescribing physicians. In 2012, the Wall Street Journal published an article contending that a key opinion leader linked to Purdue "and other pain doctors who promoted the drugs say they erred by overstating [opioids'] benefits and glossing over risks." Sharobem Decl., Ex. F. And, in 2013 and 2016, as Mr. Manchester has pointed out, the Los Angeles Times published articles suggesting that Purdue knowingly failed to report, and cease marketing OxyContin to, prescribers engaged in diversion, and some of

Purdue's distributors continued making deliveries of OxyContin to pharmacies that they suspected of filling suspicious orders. Dkt. No. 31, Att. 16, 17.

In 2014, the City of Chicago filed suit against several opioids manufacturers, including Purdue, alleging that they caused the opioid epidemic by, among other things, misrepresenting the risks and benefits of prescription painkillers. Sharobem Decl., Ex. G. Hundreds of suits by, *inter alia*, states, counties, municipalities and Native American tribes against manufacturers and distributors, including the defendants in this action, have followed. Sharobem Decl., Ex. H. In late 2017, a multi-district panel was created to consolidate certain of the federally filed actions. Sharobem Decl., Ex. I. The lawsuits were widely reported by the media.

In 2016, Cardinal Health agreed to pay $44 million to resolve federal allegations that, among other things, it failed to report suspicious orders of controlled substances, including oxycodone in certain jurisdictions. Sharobem Decl., Ex. J. In January 2017, McKesson agreed to pay $150 million to resolve similar allegations. Sharobem Decl., Ex. K. In May 2017, a federal Congressional committee opened an investigation concerning, among other things, the distribution of opioids in West Virginia by all three distributors named in this suit. Sharobem Decl., Ex. L.

B. Relator and His Qui Tam Actions Against Purdue and Its Distributors

Mr. Manchester is a Vermont attorney. He does not allege that he ever worked for any of the defendants in any capacity; nor does he allege any insider or non-public information concerning them. Nevertheless, he has filed a series of *qui tam* complaints, [redacted] alleging that Purdue and its distributors have violated the FCA in their manufacturing, sale and distribution of OxyContin.

On May 25, 2016, Mr. Manchester filed his initial *qui tam* complaint in this Court against Purdue. *See* Dkt. No. 1. This complaint alleged, *inter alia*, that Purdue (1) should have implemented an abuse-deterrent formulation of OxyContin earlier than 2010, when it received FDA approval, and (2) failed to report healthcare providers engaged in diversion. In support of his allegations, Mr. Manchester cited only to information available in the public domain. In November of 2016, the United States and all of the 29 named states, including the District of Columbia, declined to intervene. Dkt. Nos. 12, 14. On December 19, 2016, the Court unsealed the complaint and ordered Mr. Manchester to serve it on Purdue. Dkt. No. 15. Mr. Manchester, however, never served his initial complaint and did not make any further filings in this matter for approximately a year and a half.

[redacted]

On May 23, 2018, still not having served his initial complaint, Mr. Manchester filed a First Amended Complaint in this Court. Dkt. Nos. 20, 26. The First Amended Complaint contained no new factual allegations. *See id.* Mr. Manchester simultaneously filed a "Notice of Voluntary Dismissal Without Prejudice as to Certain Non-resident Co-Plaintiffs" that purported to dismiss the claims he had brought in his initial complaint on behalf of all of the named

[redacted]

plaintiff states except for the claim on behalf of the Commonwealth of Massachusetts. *See* Dkt. No. 25. The First Amended Complaint sought relief under the federal FCA and the Massachusetts FCA, and it asserted certain statutory and common law causes of action that do not contain *qui tam* provisions. Dkt. Nos. 20 and 26.

On July 12, 2018, Mr. Manchester filed a Second Amended Complaint in this Court on behalf of the United States, "twenty-nine Co-Plaintiff States," and "Local Government intervenors who subsequently elect to intervene in the pending action under FFCA section 3730(b)." Dkt No. 28 at 1, 14. Similar to his previous Massachusetts complaints [redacted], Mr. Manchester's Second Amended Complaint did not cite to, or rely upon, any non-public or independently obtained information in support of his allegations.

On August 3, 2018, Mr. Manchester filed a Third Amended Complaint. Dkt. No. 31. His factual allegations in the pending Third Amended Complaint largely reiterate allegations in his prior complaints here [redacted]. He again alleges that the defendants knowingly failed to report providers who were engaged in diversion, and that Purdue should have introduced an abuse-deterrent formulation earlier but failed to do so until it was approved by the FDA in 2010. In addition, Mr. Manchester contends that Purdue knowingly failed to report adverse events pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). Relator seeks a declaratory judgment (Count I), along with damages and penalties under federal and state FCAs (Count II), the Restatement (Second) of Torts (Count III), the common law theory of unjust enrichment (Count IV), the Massachusetts Consumer Protection Act (Counts V and VI), and common law theories of fraud, fraudulent concealment and willful non-disclosure (Counts VII and VIII). In essence, the primary differences between the Third Amended Complaint and the first complaint Mr. Manchester filed here are causes of action that

are premised on similar factual allegations derived from publicly available sources of information.

II. ARGUMENT

A. Mr. Manchester's Case Should Be Dismissed In Its Entirety Under the Public Disclosure Bar.

1. Each Of Relator's Allegations Was Previously Disclosed By The News Media Or Federal Reports.

This action should be dismissed under the public disclosure bar provision of the FCA because Mr. Manchester's allegations are wholly dependent upon information acquired from publicly available sources. The FCA's public disclosure bar provides that courts "shall dismiss" a *qui tam* complaint if "substantially the same allegations or transactions" are "publicly disclosed" in a "[f]ederal report, hearing, audit, or investigation," or by the "news media." 31 U.S.C. § 3730(e)(4)(A).[4] The purpose of the public disclosure bar is to accommodate the twin goals of the False Claims Act: "encouraging private citizens to expose fraud and avoiding opportunistic actions by opportunists who attempt to capitalize on public information without seriously contributing to the disclosure of the fraud." *United States ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 321 (2d Cir. 1992).

"[A] public disclosure occurs when the essential elements exposing the particular transaction as fraudulent find their way into the public domain." *CVS Caremark*, 827 F.3d at 208 (citation omitted). When evaluating dismissal under the public disclosure bar, courts examine (1) "whether the allegations or transactions identified in the relator's complaint have already been publicly disclosed"; (2) "whether that disclosure occurred through one of the

[4] Where the public disclosure bar is raised, courts "may consider matters of public record and facts susceptible to judicial notice." *United States ex rel. Winkelman v. CVS Caremark Corp.,* 827 F.3d 201, 208 (1st Cir. 2016).

statutorily prescribed methods"; and (3) "whether the allegations or transactions on which the relators' suit rests are substantially the same as the publicly disclosed allegations or transactions." *Id.* "These sets of facts may originate in different sources, as long as they 'lead to a plausible inference of fraud' when combined." *Id.* The public disclosures need not "use magic words or specifically label disclosed conduct as fraudulent." *Id.* at 209.

In this case, and as set forth in detail below, each of Mr. Manchester's allegations was publicly disclosed in prior articles in the news media and federal reports, and every exhibit attached to his complaints is a matter of public record. *See, e.g.*, Dkt. No. 31, Appx. A. Accordingly, each of these allegations should be dismissed.

Abuse-Deterrent Formulation. In his initial complaint filed on May 25, 2016, Mr. Manchester alleged that Purdue should have released an abuse-deterrent formulation of OxyContin earlier than 2010. Dkt. No. 1. He repeated this allegation in his three amended complaints here. Dkt. Nos. 20, 26, 28, 31. However, all of the essential facts upon which Mr. Manchester relies were widely reported in the news media and in federal reports before he filed his initial complaint. For example, in 2011 – nearly five years before Mr. Manchester filed this lawsuit – the New York Times reported allegations by a Massachusetts state senator that "Purdue Pharma should have reformulated OxyContin sooner." Sharobem Decl., Ex. D ("These people are scientists. Why didn't they do this years ago?"). In 2013, online articles discussed at length the key patent on which Purdue's abuse-deterrent formulation relies and Purdue's early research. *See id.*, Exs. M-O. In 2015 and early 2016, legal news outlets published articles regarding, and in at least one instance appended, the court's findings in Purdue's OxyContin antitrust litigation on which Mr. Manchester heavily relies. *See id.*, Exs. E, P; Dkt. No. 31, Att. 2. Beyond those findings, all other documents cited by Mr. Manchester are public federal documents, including

United States patents and FDA approval letters, issued between 1997 and 2013, which pre-date this lawsuit and fall within the public disclosure bar. *See* Dkt. No. 31, Appx. A, Atts. 5-10.

Diversion. In his initial complaint here, Mr. Manchester also contended that Purdue failed to report diversion and continued marketing OxyContin to providers engaged in diversion. Dkt. No. 1. His allegations concerning diversion mirror news articles predating his initial complaint. For example, in 2013, the Los Angeles Times published an article that noted suggestions made during a 2001 federal hearing that Purdue should "use sales data to 'weed out' bad doctors"; discussed Purdue's internal data and allegations regarding its suspicious prescriber database; and suggested that Purdue failed to report suspicious prescribers. Dkt. No. 31, Att. 17.

Mr. Manchester added similar diversion-related allegations against Purdue's distributors in the Second and Third Amended Complaints he filed earlier this year. Dkt. Nos. 28, 31. In support of these allegations, he cited to a Los Angeles Times article published two years earlier, in July 2016, which stated that Purdue discussed its data and evidence concerning potential diversion with its distributors. *See* Dkt. No.31, Att. 16. The Los Angeles Times article also explained that Purdue's distributors possessed evidence of potential diversion at "pill mill"; neither Purdue nor its distributors timely reported the pill mill; and only one of Purdue's distributors cut off shipments of OxyContin to the pill mill. *Id.* Additionally, an October 2017 report by 60 Minutes stated: "This is an industry that allowed millions and millions of drugs to go into bad pharmacies and doctors' offices that distributed them out to people who had no legitimate need for those drugs. . . . The three largest distributors are Cardinal Health, McKesson, and Amerisource Bergen." Sharobem Decl. Ex. Q. This 60 Minutes report predated the Second and Third Amended Complaints by nine months.

Indeed, the diversion allegations against the defendants were widespread and the subject of publicly reported Congressional investigations and state and municipal led litigations throughout the country. In December 2016 and January 2017, respectively, the Department of Justice settled analogous allegations against Cardinal Health and McKesson under the Controlled Substances Act. *See id.*, Ex. J, K. In May 2017, Congress sent publicly available letters to all three distributors stating: "[D]istributors have databases and other analytical tools to help identify and respond to suspicious order trends for addictive opioids that appear problematic or excessive. Distributors also have the ability to hold suspicious orders instead of sending them out immediately." *Id.*, Ex. R; *see also id.*, Ex. S (April 12, 2018 Washington Post article discussing Congressional investigation of Distributors). Media coverage of lawsuits and investigations led by states and municipalities has been extensive. *See id.*, Exs. G-I, T, U.

Adverse Events. In his Second and Third Amended Complaints, Mr. Manchester added cursory allegations concerning Purdue's alleged failure to report adverse events, including addiction and overdoses, in violation of the FDCA. As he notes, from approximately 2007 through 2009, Purdue resolved certain state and federal investigations regarding allegations that, among other things, Purdue improperly downplayed the risk of OxyContin addiction. *See, e.g.,* Dkt. No. 31 and Atts. 15 (2007 Consent Judgment between Purdue and Massachusetts), 19 (2007 Corporate Integrity Agreement between the United States Department of Health and Human Services and Purdue), 22 (2009 Plea Bargain between the United States and Purdue); Sharobem Decl., Exs. B, C. Over the next few years, but before Mr. Manchester filed his initial complaint here, various news outlets continued reporting allegations that Purdue misrepresented the risk of addiction. In 2012, the Wall Street Journal published an article contending that a key opinion leader linked to Purdue "and other pain doctors who promoted the drugs say they erred by

overstating [opioids'] benefits and glossing over risks." Sharobem Decl., Ex. F. Likewise, in 2013, another news outlet reported that Purdue downplayed the risk of addiction in studies. *Id.*, Ex V. In 2015, the Pacific Standard published an article discussing Kentucky's lawsuit against Purdue, originally filed in 2007, alleging, among other things, that Purdue downplayed the risk of OxyContin addiction and abuse. *Id.*, Ex. W; *see also* Dkt. No. 31, Att. 26. As is the case with his other allegations, Mr. Manchester's other primary sources of support for his allegations are federal reports that pre-dated his initial complaint, including a 2005 Congressional hearing regarding "FDA's Role in Preventing Prescription Drug Abuse" and a 2009 General Accountability Office report entitled "Medicaid Fraud and Abuse Related to Controlled Substances Identified in Selected States." Dkt. No. 31, Atts. 18, 28.

In sum, none of Mr. Manchester's allegations are new. The essential elements of each of his allegations were widely available in the public domain before he filed any of his complaints here.

2. Mr. Manchester Does Not Meet the Original Source Exception to the Public Disclosure Bar.

Mr. Manchester's dependence on publicly disclosed information and lack of connection to any of the defendants preclude him from contending that he qualifies for the "original source" exception to the public disclosure bar. 31 U.S.C. § 3730(e)(4)(A)(iii) and (B). To be deemed an "original source," a relator must have either (i) "voluntarily disclosed to the Government the information" before the public disclosure, or (ii) have "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions." 31 U.S.C. § 3730(e)(4)(B). *C.f. United States ex rel. Ondis v. City of Woonsocket,* 587 F.3d 49, 59 (1st Cir. 2009) ("Virtually by definition, a relator whose knowledge is dependent upon the public disclosure of allegedly fraudulent transactions cannot be said to have independent knowledge of the fraud.").

In effect, the public disclosure bar and original source provisions of the FCA were "designed to preclude *qui tam* suits based on information that would have been equally available to strangers to the fraud transaction had they chosen to look for it as it was to the relator." *United States ex rel. Poteet v. Bahler Medical, Inc.*, 619 F.3d 104, 110 (1st Cir. 2010) (citation omitted); *see CVS Caremark Corp.*, 827 F.3d at 203 ("[T]he FCA forbids private suits once the sun has shone on the essential features of the alleged misconduct."). The FCA is intended to provide for "incentives for whistle-blowing insiders with genuinely valuable information" to become relators. *Graham Cty. Soil and Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 294 (2010).

Mr. Manchester does not, and cannot, allege that he is an original source. *See* Dkt. No. 31; *United States ex rel. Bartz v. Ortho-McNeil Pharma., Inc.*, 856 F. Supp. 2d 253, 268 (D. Mass. 2012) (dismissing complaint on several grounds, including under the public disclosure bar: "Noticeably missing from this recital is any evidence that [relator] was in fact an original source of the claims made in his initial complaint, much less the revisionist claims set out in the Third Amended Complaint."). He does not qualify under the first prong of the original source exception since he did not file his complaint prior to the public disclosures. Nor can he qualify under the second prong since he does not have "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions." 31 U.S.C. § 3730(e)(4)(B). Mr. Manchester is precisely the type of "stranger" that the public disclosure bar was intended to prohibit from bringing a *qui tam* action. Indeed, the supplements to his complaints – all of which are public materials – underscore his lack of independent information about the alleged fraud. *See, e.g.*, Dkt. No. 31, App. A.

There is nothing "independent" about Mr. Manchester's knowledge. He is not an insider and never worked for any of the defendants in any capacity. Instead, his complaint is based entirely on information that can be obtained by any member of the public. Accordingly, the public disclosure bar mandates dismissal of Mr. Manchester's case here in its entirety.

[redacted]

[redacted]

C. Mr. Manchester Lacks Standing to Pursue Non-FCA Claims On Behalf of the United States.

In addition to his allegations under the FCA, Mr. Manchester has filed claims seeking a declaratory judgment, along with common law claims and a claim under the Massachusetts Consumer Protection Act ("93A"), M.G.L. c. 93A, *et seq*. "While the FCA conveys standing on the relator to bring claims pursuant to the FCA, 'the FCA does not give relators the right to assert common law claims on behalf of the United States.'" *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257, 2007 WL 4287572, at *5 (D. Mass. Dec. 6, 2007) (citation omitted);

see United States ex rel. Walsh v. Eastman Kodak Co., 98 F. Supp. 2d 141, 149 (D. Mass. 2000) (dismissing relator's fraud, payment under mistake of fact, and unjust enrichment claims for lack of standing). Nor does a relator have standing to bring claims under federal and state statutes that do not contain *qui tam* provisions, including the FDCA, the Controlled Substances Act, and 93A. *See, e.g., Bowling v. Haas*, No. 3:07-032, 2010 WL 3825467 (E.D. Ky. Sept. 23, 2010).[6] Accordingly, all non-FCA claims brought by Mr. Manchester on behalf of the United States or any state should be dismissed.

V. CONCLUSION

For the reasons set forth above, this Court should dismiss this action with prejudice solely as to Mr. Manchester[7] and without prejudice as to the United States and the named states pursuant to 31 U.S.C. § 3730(e)(4)(A) [redacted] and Fed. R. Civ. P. 12(b)(1) and (b)(6).

Respectfully submitted,

CHAD A. READLER
Acting Assistant Attorney General,
Civil Division

ANDREW E. LELLING
United States Attorney

Dated: August 24, 2018

By: /s/ *Steven Sharobem*
STEVEN SHAROBEM (BBO #664583)
Assistant United States Attorney

[6] Sections 9 and 11 of Chapter 93A confer standing on a private litigant "who has been injured" or has or will suffer "any loss of money or property." *See* M.G.L.c. 93A, §§ 9, 11. Mr. Manchester has not made allegations of personal harm or injury.

[7] Dismissal should be without prejudice to the United States and named states. A non-merits dismissal, if dismissed with prejudice as to the United States and named states, could be argued by a defendant to have the preclusive *res judicata* effect of preventing future actions against defendants. This would not be in accord with the purpose of the FCA *qui tam* provisions, *i.e.*, assisting the United States in pursuing fraud, not hindering it. *See United States ex rel. Pilon v. Martin Marietta Corp.*, 60 F.3d 995, 1000 n. 6 (2d Cir. 1995).

John Joseph Moakley Courthouse
One Courthouse Way, Suite 9200
Boston, Massachusetts 02210
Tel: (617) 748-3355
steven.sharobem@usdoj.gov

MICHAEL D. GRANSTON
EDWARD C. CROOKE
KRISTEN M. MURPHY
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
202-616-3041
202-307-3852 (fax)
Kristen.M.Murphy@usdoj.gov