APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 17-1106

UNITED STATES OF AMERICA; STATE OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF TEXAS; COMMONWEALTH OF VIRGINIA; and STATE OF WISCONSIN, ex rel. MARK MCGUIRE, WENDY JOHNSON, and RYAN UEHLING,
Plaintiffs,

v.

MILLENNIUM LABORATORIES, INC., MILLENNIUM LABORATORIES OF CALIFORNIA, INC.; JAMES SLATTERY; HOWARD APPEL,
Defendants.

MARK MCGUIRE,
Cross-Claimant, Appellant,

ESTATE OF ROBERT CUNNINGHAM; RYAN UEHLING; OMNI HEALTHCARE INC.; AMADEO PESCE; JOHN DOE a/k/a CRAIG DELIGDISH,
Cross-Defendants, Appellees.

May 6, 2019

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS
[Hon. Nathaniel M. Gorton, U.S. District Judge]

Before

Torruella, Lynch, and Thompson, Circuit Judges.

LYNCH, **Circuit Judge**. The False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, authorizes private persons, known as relators, to "bring a civil action . . . in the name of the Government" against those who make fraudulent claims against the United States, *id.* § 3730(b)(1). When a relator brings such a qui tam suit, the government may intervene and proceed with the action, or it may decline to intervene and allow the relator to proceed. *See id.* § 3730(b)(1)-(4), (c).

The FCA encourages relators to bring qui tam suits by allowing them to share in any recovery obtained for the government. To avoid diluting this potential payout, the FCA's first-to-file rule prohibits relators other than the first to file from "bring[ing] a

related action based on the facts underlying the pending action." *Id.* § 3730(b)(5).

This case arises out of the government's successful intervention in several qui tam suits against Millennium Health (formerly Millennium Laboratories). Millennium settled with the government for $227 million, setting aside fifteen percent of that money as a relator's share. The question on appeal is who is the first-to-file relator and how that is determined.

Mark McGuire brought a crossclaim for declaratory judgment that he is the first to file and is entitled, under 31 U.S.C. § 3730(d)(1), to the fifteen-percent share. Robert Cunningham, who had brought an earlier qui tam suit against Millennium, moved to dismiss the crossclaim, arguing that he, not McGuire, was the first to file. Finding that the first-to-file rule was jurisdictional, and based on its review of extrinsic materials outside of the complaints, the district court agreed with Cunningham. *United States ex rel. Cunningham v. Millennium Labs., Inc.*, 202 F. Supp. 3d 198, 209 (D. Mass. 2016). The district court dismissed McGuire's crossclaim for lack of subject-matter jurisdiction. *Id.*

We hold, for the first time in this circuit, that the first-to-file rule is not jurisdictional, reversing earlier circuit precedent, and we hold that we have jurisdiction over McGuire's crossclaim. We then describe the appropriate method for the first-to-file analysis and hold that McGuire was the first-to-file relator and that he has stated a claim that he is entitled to the relator's share of the settlement. We reverse and remand for further proceedings consistent with this opinion.

I.

A. The False Claims Act

President Abraham Lincoln signed the FCA into law in 1863. It was originally intended "to combat rampant fraud in Civil War defense contracts." S. Rep. No. 99-345, at 8 (1986). Today, the FCA is the federal government's "primary litigative tool for combatting fraud." *Id.* at 2.

The FCA imposes liability on any person who "knowingly presents . . . a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), "to an officer, employee, or agent of the United States," *id.* § 3729(b)(2)(A)(i). A relator may enforce the FCA by bringing a civil qui tam action "in the name of the Government." *Id.* § 3730(b).

To bring such an action, the relator must file a complaint under seal and must serve the United States with a copy of the complaint and a disclosure of all material evidence. *Id.* § 3730(b)(2). After reviewing those materials, the United States may "proceed with the action, in which case the action shall be conducted by the Government." *Id.* § 3730(b)(4). Or, "[i]f the government does not exercise its right to intervene in the suit, the relator may serve the complaint upon the defendant and proceed with the action." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004), *abrogated on other grounds by Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008).

The FCA entitles the relator to a portion of any resulting judgment or settlement. Before the 1986 amendments to the FCA, the relator's share in a case in which the government had intervened was capped

at "10 percent of the proceeds of the action or settlement of the claim." S. Rep. No. 99-345, at 41. The FCA now mandates a relator award in such a case of "at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action."[1] 31 U.S.C. § 3730(d)(1).

The 1986 amendments also added a significant restriction on recoveries in qui tam suits that is relevant here: the "first-to-file" rule in paragraph 3730(b)(5). That paragraph provides, "When a person brings an action under [31 U.S.C. § 3730(b)], no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." *Id.* § 3730(b)(5). Legislative history shows that this rule was meant to "clarify in the statute that private enforcement under the civil False Claims Act is not meant to produce class actions or multiple separate suits based on identical facts and circumstances." S. Rep. No. 99-345, at 25.

B. The Complaints

Because we hold that the first-to-file issue is to be addressed under Federal Rule of Civil Procedure 12(b)(6), not Rule 12(b)(1), we confine our review to the pleadings and to facts subject to judicial notice. *Haley v. City of Bos.*, 657 F.3d 39, 46 (1st Cir. 2011). We limit

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[1] When the government declines to intervene and the relator successfully prosecutes the action, the relator may receive up to 30 percent of the payout (with the remainder to the United States). 31 U.S.C. § 3730(d)(2). That is not the situation here.

our background discussion to facts alleged in Cunningham's amended complaint, McGuire's original complaint, and in the government's complaint in intervention and settlement agreement.[2]

1. Cunningham's Amended Complaint

In late 2009 and early 2010, relator Robert Cunningham[3] filed qui tam actions against five competitors of Calloway Laboratories, his employer. One competitor he sued was Millennium.

Cunningham filed his first amended complaint[4] against Millennium on February 24, 2011. It detailed a mechanism of fraud arising from Millennium's "Physician Billing Model," the key component of which was Millennium's "multi-class qualitative drug screen," which Cunningham's complaint labels a "test kit." The test kit was a urine specimen collection cup with chemical test strips embedded in it. This kit, which "c[ould]

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[2] Cunningham's amended complaint and McGuire's original complaint are subject to judicial notice. *See Zucker v. Rodriguez*, 919 F.3d 649, 651 n.5 (1st Cir. 2019) (citing *E.I. Du Pont de Nemours & Co. v. Cullen*, 791 F.2d 5, 7 (1st Cir. 1986) (Breyer, J.)). And the government's complaint in intervention and settlement agreement are also properly before us because McGuire attached them as exhibits to his crossclaim.

[3] Cunningham died in December 2010. His estate has continued to pursue his action. For simplicity, we refer to Cunningham and his estate as "Cunningham."

[4] Cunningham's amended complaint states, "This First Amended Complaint does not add any facts to those contained in the Original Complaint; rather, it removes some of the allegations that had been contained therein." The amended complaint's allegations were the only allegations "pending" when McGuire filed his suit.

be purchased for less than" ten dollars, "use[d] a single specimen" collected at the point of care to detect "multiple drug classes."

We described the three aspects of Cunningham's allegations in *United States ex rel. Estate of Cunningham v. Millennium Labs. of Calif., Inc.*, 713 F.3d 662, 665-66 (1st Cir. 2013). Cunningham's complaint alleged that Millennium used its inexpensive point-of-care test kits to induce physicians into excessive billing (Aspect One), excessive testing (Aspect Two), and excessive confirmatory testing (Aspect Three).[5] In

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[5] We describe the first two aspects more fully. Aspect One: Cunningham alleged that Millennium told physicians that this test kit could "substantially increase his or her revenue." Because the kits performed several tests at once, Millennium told the physicians that they could "bill both government and private health insurance companies" for several drugs tests per kit. Under then-current government billing codes, the physicians should have only billed for one test per test kit. Cunningham alleged that a document distributed by Millennium "suggest[ed] each physician can bill at least 9 units per kit." And Cunningham alleged that Millennium separately informed physicians that they should bill "as many units as there are panels in the test kit." Cunningham alleged that, under this model, physicians could bill between $16.67 and $80 per unit and so extract per-kit revenues of between $173.18 to $432.

Aspect Two: Cunningham alleged that Millennium encouraged physicians to conduct excessive tests. Millennium informed physicians that, if they were to order twenty tests per day, they could earn up to $8,640 per day. The complaint stated that Millennium thus "encourage[d] the physician to order more testing than that physician would have prior to engaging in Millennium's [point-of-care] model, and increase[d] Millennium's market share by drawing other physicians to the practice with the hope and promise of greater revenues." It further alleged that participating physicians ordered "significantly more testing for their patients since

Cunningham, we held that Aspects One and Three were jurisdictionally barred by the FCA's public disclosure provision, 31 U.S.C. § 3730(e)(4)(A), because they had been "publicly disclosed" in a California state defamation suit brought by Millennium against Calloway. 713 F.3d at 671. We then vacated the district court's order dismissing Aspect Two of Cunningham's claim and remanded that claim for further proceedings. *Id.* at 676. On remand, the district court dismissed Aspect Two of Cunningham's claim for lack of particularity under Federal Rule of Civil Procedure 9(b) and for failure to state a claim under Rule 12(b)(6). *United States ex rel. Estate of Cunningham v. Millennium Labs. of Cal.*, No. 09-12209-RWZ, 2014 WL 309374, at *2 (D. Mass. Jan. 27, 2014). That decision is currently on appeal.

Only Aspect Three is potentially relevant to the first-to-file issue here.[6] Cunningham alleged that if the initial qualitative test uncovered any of the tested drugs, that test "w[ould] need to be followed up by a quantitative screen" and then "confirmed by another method." The complaint alleges that Millennium's

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entering the conspiracy than they did prior to participating in the conspiracy with Millennium." The alleged fraud consisted of Millennium's promotion of this billing model and physician defendants' misrepresentation of the medical need for the tests performed.

[6] McGuire argues, based on *Campbell v. Redding Medical Center*, 421 F.3d 817 (9th Cir. 2005), that because we found Aspect Three to be jurisdictionally barred, it does not count as a "pending" claim for first-to-file purposes. We do not address this argument because we find McGuire was the first-to-file relator even if we consider Aspect Three of Cunningham's complaint.

point-of-care model led to "significantly more testing," including "confirmatory tests."

Cunningham alleged generally that this scheme "increas[ed] the revenues of the [physician] defendants at the expense of the government and private health insurance programs" and "significantly increase[d] Millennium's revenues and market share." Cunningham's amended complaint never mentions the terms "custom profiles" or "standing orders" or describes any fraudulent schemes by Millennium associated with either.

Cunningham filed three disclosures of material evidence to the government in December 2009, September 2010, and February 2012, respectively.

2. McGuire's Original Complaint

Mark McGuire, appellant here, filed his original qui tam complaint on January 26, 2012. It focused not on point-of-care testing, the first stage of urinary drug testing, as Cunningham's complaint had done, but on confirmatory (or quantitative) testing, a later stage. McGuire alleged that after a point-of-care test discloses an unexpected drug (or shows the lack of an expected drug), a physician can order confirmatory tests. These tests, which require sophisticated equipment and so can be expensive, determine how much of the substance is present (or not).

McGuire alleged that Millennium engaged in a scheme that resulted in unnecessary *confirmatory* tests being performed and billed to the government after the point-of-care tests. Millennium persuaded physicians to execute "custom profiles," which are standing orders for a battery of confirmatory tests on *every* urine sample, regardless of whether the point-of-care

testing showed a need. McGuire alleged that "even if [a point-of-care test] comes back completely negative, . . . based on the customized profile Millennium has gotten the physician's office to sign, Millennium runs 10 confirmatory tests." Millennium profited because "[t]hese 10 unnecessary tests are then billed to Medicare, Medicaid or other federal plans." And physicians and hospitals who signed up for "custom profiles" profited because they could bill the government for the unnecessary tests.

This scheme was, according to McGuire's complaint, a matter of corporate policy. McGuire alleged that Millennium supervisors required their sales representatives to aggressively market standing orders to physicians—the representatives would return time and time again until the physicians executed custom profiles for *at least* ten confirmatory tests. Some physicians, with Millennium's participation, included up to twenty-five tests in their profiles.

McGuire also alleged that Millennium provided free point-of-care cups (test kits) to physicians to induce them to send confirmation testing orders to Millennium. This tactic helped Millennium gain market share in a highly competitive and potentially quite lucrative business.

3. The Complaint and Settlement Agreement of the United States

In December 2014, the government announced its intention to intervene in McGuire's action (as well as the actions of three other relators, none of whom were Cunningham). It filed its complaint in intervention in those actions on March 19, 2015. The complaint describes two fraudulent schemes: (1) Millennium's

submission of claims for excessive and unnecessary urine drug testing ordered by physicians through standing orders without an individualized assessment of patient need; and (2) urine drug testing referred by physicians who received free point-of-care testing supplies, in violation of the Stark Act and the Anti-Kickback Statute. Millennium used these schemes to "knowingly submit[] many millions of dollars' worth of false claims" to the government.

The United States complaint in intervention alleges that "[a] core element of Millennium's business model was the use of physician standing order forms." These standing orders led to unnecessary drug tests conducted "regardless of each patient's individualized need and condition." Millennium required physicians to use these forms or be cut off from processing specimens, set and enforced testing thresholds for standing orders, and promoted routine confirmatory testing of even negative point-of-care test results. This standing order practice generated unnecessary testing, including confirmatory testing for rarely abused drugs, even when point-of-care test results showed no need for follow-up testing.

The government's complaint also alleged that Millennium engaged in an illegal kickback scheme involving point-of-care cups. After the Center for Medicare and Medicaid Services (CMS) changed the reimbursement structure for point-of-care cups effective April 2010, "the [point-of-care] test cups were no longer a source of significant reimbursement revenue for physicians." In response, Millennium "dramatically" expanded its "Free Cup program." Under this program, Millennium distributed $5 million worth of point-of-care test cups for free to physicians in exchange for

"referrals" to Millennium. A physician "refers" a test by sending a sample for confirmatory testing. The government alleged that this program violated the Stark Law and the Anti-Kickback Statute, which require point-of-care test cups to be sold at fair market value.

On October 16, 2015, the government and Millennium reached a settlement under which Millennium agreed to pay $227 million plus interest to resolve these claims. The settlement set aside fifteen percent of the recovery as a relator's share, but did not resolve which relator was entitled to the award.[7] The agreement provided that the district court "shall retain jurisdiction as to . . . [r]elators' claims for a share of the proceeds of the Settlement Amount." The district court dismissed only the relators' claims against Millennium on March 24, 2016 and stated that the "[r]elators' respective claims, between and among themselves, for a portion of the agreed-upon 'relator share' of the Settlement Amount . . . are not dismissed and will remain pending."

C. Post-Settlement Procedural History

On October 23, 2015, McGuire filed a crossclaim for declaratory relief, asserting that he was the first to file a complaint that alleged the essential facts underlying the government's complaint in intervention and settlement agreement. He argued that he was entitled to the entire fifteen-percent relator's share because he

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[7] The settlement also preserved the relators' rights to seek reasonable costs and attorney's fees and expenses under 31 U.S.C. § 3730(d)(2) and preserved some relators' employment-retaliation claims.

was the first-to-file relator.[8] On December 7, 2015, Cunningham moved to dismiss McGuire's crossclaim, arguing that he, not McGuire, was the first to file.

The government took no position on this issue. It did, however, urge the district court to confine its first-to-file analysis to "the text of the complaints themselves, and not on any subsequent investigation by the United States of such complaints or any related communications."

On August 19, 2016, the district issued its order dismissing McGuire's crossclaim. *Cunningham*, 202 F. Supp. 3d at 209. The district court held, relying on this circuit's precedent, that the first-to-file rule was jurisdictional and that Cunningham's motion to dismiss was a factual challenge to the court's jurisdiction. *Id.* at 205-06. The district court looked beyond the complaints to extrinsic evidence and concluded that the first-to-file rule applied and barred McGuire's crossclaim. *Id.* at 206. The district court dismissed the crossclaim for lack of subject-matter jurisdiction. *Id.* at 209. The order entered on the docket three days later, on August 22, 2016.[9]

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[8] McGuire brought this crossclaim against Cunningham and several other relators but not against Wendy Johnson, Allstate Insurance Co., and Lawrence Spitz—McGuire reports that he "reached an agreement" with this last group. The cross-defendants other than Cunningham have conceded that they filed behind McGuire.

[9] There was no "separate document," Fed. R. Civ. P. 58(c)(2)(A), accompanying that order, so judgment entered 150 days later, on January 19, 2017. McGuire had 30 days from then to file his notice of appeal. McGuire's January 20, 2017 filing was timely. Cunningham's arguments to the contrary are meritless.

McGuire moved for reconsideration of the order dismissing his crossclaim. The district court denied that motion. This appeal followed.

II.

A federal appellate court normally must "satisfy itself both of its own subject-matter jurisdiction and of the subject-matter jurisdiction of the trial court before proceeding further." *Royal Siam Corp. v. Chertoff*, 484 F.3d 139, 143 (1st Cir. 2007) (citing *Bender v. Williamsport Area Sch. Dist.*, 475 U.S. 534, 541 (1986); *Irving v. United States*, 162 F.3d 154, 160 (1st Cir. 1998) (en banc)). We consider whether the first-to-file rule is jurisdictional under the Supreme Court's most recent caselaw. On de novo review, and in light of that precedent, we hold that the first-to-file rule, 31 U.S.C. § 3730(b)(5), is nonjurisdictional and that we have jurisdiction over McGuire's crossclaim.[10]

"Characterizing a rule as jurisdictional renders it unique in our adversarial system." *Sebelius v. Auburn Reg'l Med. Ctr.*, 568 U.S. 145, 153 (2013). A jurisdictional objection may be raised at any time, even after trial. And a trial court without jurisdiction lacks "all

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[10] McGuire argues that the district court erred in holding that his crossclaim for declaratory judgment under paragraph 3730(d)(1) is subject to the first-to-file rule. *Cunningham*, 202 F. Supp. 3d at 203. We need not reach this argument because even if the first-to-file rule does not apply to McGuire's crossclaim, it applies to his underlying action against Millennium. And because that action eventually gave rise to McGuire's crossclaim, we must assure ourselves of the district court's jurisdiction.

authority to hear a case."[11] *United States v. Kwai Fun Wong*, 135 S. Ct. 1625, 1631 (2015).

The Supreme Court has attempted to "ward off profligate use of the term 'jurisdiction.'" *Auburn Reg'l Med. Ctr.*, 568 U.S. at 153. As such, it has held that we must apply a "readily administrable bright line" rule and see if Congress has "clearly state[d]" that the provision under review is jurisdictional. *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 515 (2006).

In considering this issue, we do not write on a clean slate. As the district court quite properly noted, this court has several times characterized the first-to-file rule as jurisdictional. *See United States ex rel. Wilson v. Bristol-Myers Squibb, Inc.*, 750 F.3d 111, 117 (1st Cir. 2014); *United States ex rel. Heineman-Guta v. Guidant Corp.*, 718 F.3d 28, 34 (1st Cir. 2013); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 16, 33 (1st Cir. 2009).

While we are "ordinarily 'constrained by prior panel decisions directly (or even closely) on point,'" we are not so bound when "non-controlling authority that postdates the decision . . . offer[s] 'a compelling reason for believing that the former panel, in light of new developments, would change its collective mind." *Sánchez ex rel. D.R.-S. v. United States*, 671 F.3d 86, 96 (1st Cir. 2012) (quoting *United States v. Guzmán*,

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[11] So even in a case like this one, in which seven years have passed since McGuire first filed his complaint, a jurisdictional objection may result in dismissal. And that could mean "many months of work on the part of the attorneys and the court may be wasted." *Henderson ex rel. Henderson v. Shinseki*, 562 U.S. 428, 435 (2011).

419 F.3d 27, 31 (1st Cir. 2005)). There are several compelling reasons for such a belief here.

First, new developments cast serious doubt on our prior characterization of the first-to-file rule as jurisdictional. In 2015, the Supreme Court decided *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970 (2015), a qui tam case. *Carter* "addressed the operation of the first-to-file bar on decidedly nonjurisdictional terms, raising the issue *after* it decided a nonjurisdictional statute of limitations issue." *United States ex rel. Heath v. AT & T, Inc.*, 791 F.3d 112, 121 n.4 (D.C. Cir. 2015). The clear implication is that the Court did not consider the first-to-file rule to be jurisdictional. Interpreting *Carter*, the D.C. Circuit and the Second Circuit have both held that the first-to-file rule is nonjurisdictional.[12] *See United States ex rel. Hayes v. Allstate Ins. Co.*, 853 F.3d 80, 85 (2d Cir. 2017); *Heath*, 791 F.3d at 120-21.

This court has twice declined to reach the issue of whether the first-to-file rule is jurisdictional when it was not necessary to resolution of the appeal, while recognizing that *Carter* affects the analysis. *See United States ex rel. Kelly v. Novartis Pharm. Corp.*, 827 F.3d 5, 12 n.9 (1st Cir. 2016) ("We assume, but need not decide, that the first-to-file bar remains jurisdictional. This position is not without doubt."); *United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1, 6 n.2 (1st Cir. 2015) ("[W]e have no need to consider

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[12] The Fourth Circuit has, after *Carter*, based on circuit precedent, maintained that the first-to-file rule is jurisdictional. *See United States ex rel. Carter v. Halliburton Co.*, 866 F.3d 199, 203 n.1 (4th Cir. 2017).

the relator's back-up argument that the first-to-file bar is not jurisdictional in light of *Carter*.").

Second, this circuit's prior cases labeling the first-to-file rule as jurisdictional, all of which predate *Carter*, devoted no substantive analysis to this issue. *Duxbury*, the oldest case, listed the first-to-file rule among the FCA's "jurisdictional bars" only in passing as dicta. 579 F.3d at 16. But it did not ask, and no later First Circuit decision has asked, if Congress clearly stated that the first-to-file rule was jurisdictional. Because these rulings failed to apply the *Arbaugh* clear-statement test, they should be "accorded 'no precedential effect' on the question whether the federal court had authority to adjudicate the claim in suit." *Arbaugh*, 546 U.S. at 511 (quoting *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 91 (1998)).

And third, applying the bright line rule leads to only one conclusion: the first-to-file rule is nonjurisdictional. Neither statutory text nor context nor legislative history suggests otherwise. *See Kwai Fun Wong*, 135 S. Ct. at 1632-33 (looking to text, context, and legislative history to determine whether a statutory provision was jurisdictional).

As always in matters of statutory interpretation, we start with the text. *United States v. Musso*, 914 F.3d 26, 30 (1st Cir. 2019). Paragraph 3730(b)(5) provides that "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). As the D.C. Circuit recognized, this "language 'does not speak in jurisdictional terms or refer in any way to the jurisdiction of the district courts.'" *Heath*, 791 F.3d at 120 (quoting *Arbaugh*, 546 U.S. at 515).

We next look to context. Paragraph 3730(b)(5) does not speak in jurisdictional terms; nearby provisions, by contrast, explicitly do so. *Cf. Musso*, 914 F.3d at 31 (drawing a negative inference from word choices made in neighboring statutory text). For instance, paragraph 3730(e)(1) provides, "No court shall have jurisdiction over an action brought by a former or present member of the armed forces . . . against a member of the armed forces arising out of such person's service in the armed forces." 31 U.S.C. § 3730(e)(1). And paragraph 3730(e)(2) states, "No court shall have jurisdiction over an action brought . . . against a Member of Congress, a member of the judiciary, or a senior executive branch official if the action is based on evidence or information known to the Government when the action was brought." *Id.* § 3730(e)(2). So, as the D.C. Circuit recognized, "[w]hen Congress wanted limitations on False Claims Act suits to operate with jurisdictional force, it said so explicitly." *Heath*, 791 F.3d at 120.

And finally, as a check to confirm the accuracy of our textual analysis, we turn to legislative history. *See Kwai Fun Wong*, 135 S. Ct. at 1633 ("[E]ven assuming legislative history alone could provide a clear statement (which we doubt), none does so here."). Congress added the first-to-file rule when it amended the FCA in 1986. The Senate Report states that the purpose of the first-to-file rule was to clarify that "only the Government may intervene in a qui tam action" and that "private enforcement under the civil False Claims Act is not meant to produce class actions or multiple separate suits based on identical facts and circumstances." S. Rep. No. 99-345, at 25. The first-to-file rule

advances this goal even when the provision is not jurisdictional.

Finding Congress had made no clear statement that the rule was jurisdictional, the D.C. Circuit held that "the first-to-file rule bears only on whether a qui tam plaintiff has properly stated a claim." *Heath*, 791 F.3d at 121. The Second Circuit, relying heavily on *Heath*, reached the same conclusion. *Hayes*, 853 F.3d at 85-86. Given *Carter*, *Heath*, *Hayes*, and the Supreme Court's clear statement rule, there is a compelling reason to believe that prior panels would no longer view the first-to-file rule as jurisdictional. For the same reasons, we now hold that the first-to-file rule is not jurisdictional.

Because the first-to-file rule is not jurisdictional, the district court had subject-matter jurisdiction over McGuire's claim against Millennium. The district court also had subject-matter jurisdiction over McGuire's crossclaim under 28 U.S.C. §§ 1331 and 2201. And we have jurisdiction under 28 U.S.C. § 1291.

III.

The remaining question is whether, under 31 U.S.C. § 3730(d)(1), McGuire is entitled to the relator's share of the government's settlement with Millennium.[13] In assessing this question, we confine our

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[13] The district court purported to deny Cunningham's 12(b)(6) motion, but only after granting his 12(b)(1) motion. We have noted that "if the court lacks subject matter jurisdiction, assessment of the merits becomes a matter of purely academic interest." *Deniz v. Mun. of Guaynabo*, 285 F.3d 142, 150 (1st Cir. 2002).

review to the pleadings and to "facts susceptible to judicial notice."[14] *Haley*, 657 F.3d at 46.

As we demonstrate below, the crucial component of this question, as framed in this case, is whether McGuire was the first-to-file relator. Rather than remand, we address the first-to-file issue as a matter of law because it has been fully briefed, because neither party suggests that the issue requires remand, and because the basic facts are uncontested. *See G. & C. Merriam Co. v. Webster Dictionary Co.*, 639 F.2d 29, 40 (1st Cir. 1980); *see also Levy v. Lexington Cty., S.C.*, 589 F.3d 708, 716 (4th Cir. 2009); *LNC Invs., Inc. v. First Fid. Bank, N.A. N.J.*, 173 F.3d 454, 464 (2d Cir. 1999).

Subsection 3730(d), entitled "Award to qui tam plaintiff," provides in relevant part:

> If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action.

31 U.S.C. § 3730(d)(1). We look to whether the government's recovery from Millennium constitutes the

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Deciding a Rule 12(b)(6) motion after finding no subject-matter jurisdiction is "gratuitous." *Id.* at 149.

[14] The district court analyzed Cunningham's motion to dismiss as a factual challenge under Rule 12(b)(1) and so engaged its "broad authority" to look outside the pleadings "to determine its own jurisdiction." *Valentin v. Hosp. Bella Vista*, 254 F.3d 358, 363 (1st Cir. 2001).

"proceeds of the . . . settlement of the claim" McGuire brought. *See Rille v. PricewaterhouseCoopers LLP*, 803 F.3d 368, 373 (8th Cir. 2015) (en banc) ("[A] relator seeking recovery must establish that 'there exists [an] overlap between Relator's allegations and the conduct discussed in the settlement agreement.'" (quoting *United States ex rel. Bledsoe v. Cmty. Health Sys.*, Inc., 342 F.3d 634, 651 (6th Cir. 2003))).

To be entitled to the relator's share under paragraph 3730(d)(1), a relator must be a person who "br[ings]" "an action under . . . subsection [3730(b)]." 31 U.S.C. § 3730(d)(1); *Rille*, 803 F.3d at 372 ("The relators' right to recovery is limited to a share of the settlement of the claim that they brought."). The first-to-file rule bars any "person other than the Government" from "bring[ing] a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). So only the first-to-file relator can claim the relator's share of the settlement proceedings for each claim.

Nearly all courts share this conclusion. *See United States ex rel. Shea v. Cellco P'ship*, 863 F.3d 923, 927 (D.C. Cir. 2017) ("The first-to-file bar thereby ensures only one relator will share in the government's recovery . . . ."); *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 231 (3d Cir. 1998) ("[N]o qui tam plaintiff may . . . share in a government settlement if his or her allegations repeat claims in a previously filed action."); *see also United States ex rel. Merena v. SmithKline Beecham Corp.*, 205 F.3d 97, 103-06 (3d Cir. 2000) (Alito, J.) (concluding "that a relator whose claim is subject to dismissal under [the public-disclosure rule in 31 U.S.C. §] 3730(e)(4) may not receive any share of the proceeds attributable to that claim," *id.* at 106); *Fed. Recovery*

Servs., Inc. v. United States, 72 F.3d 447, 450 (5th Cir. 1995).[15]

This conclusion also aligns with the policies underlying the first-to-file rule. The rule is "part of the larger balancing act of the FCA's qui tam provision, which 'attempts to reconcile two conflicting goals, specifically, preventing opportunistic suits, on the one hand, while encouraging citizens to act as whistleblowers, on the other.'" *Wilson*, 750 F.3d at 117 (quoting *LaCorte*, 149 F.3d at 233). "The first-to-file bar operates on the recognition that, because relators can bring suit without having suffered a personal injury, countless plaintiffs in theory could file a qui tam action based on the same fraud and then share in the proceeds." *Shea*, 863 F.3d at 927. Allowing a follow-on filer to siphon off the first-filed suit's proceeds "weaken[s] the incentive to dig out the facts and launch the initial action." *United States ex rel. Chovanec v. Apria Healthcare Grp. Inc.*, 606 F.3d 361, 364 (7th Cir. 2010).

To resolve the first-to-file issue here, we ask whether Cunningham's amended complaint "contained 'all the essential facts'" of the fraud McGuire alleged.[16] *United States ex rel. Ven-A-Care of the Fla.*

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[15] *See also United States ex rel. Dhillon v. Endo Pharm.*, 617 F. App'x 208 (3d Cir. 2015) (unpublished) (summarily affirming the district court's finding that only the first-to-file relator was entitled to the relator's share of a settlement). *But see United States ex rel. Doghramji v. Cmty. Health Sys., Inc.*, 666 F. App'x 410, 418 (6th Cir. 2016) (rejecting this conclusion).

[16] Other circuits, such as the D.C. Circuit, preclude recovery from not-first-to-file relators when the first-filed complaint alleges the "material elements of fraud" at issue and "equip[s] the

Keys, Inc. v. Baxter Healthcare Corp., 772 F.3d 932, 938 (1st Cir. 2014) (quoting *Heineman-Guta*, 718 F.3d at 34). While this "essential facts" standard does not require "identity between the two complaints to trigger the first-to-file rule," *id.*, the rule still may bar a different "claim even if that claim incorporates somewhat different details," *id.* (quoting *Wilson*, 750 F.3d at 118). The essential facts test "presents a question of law about the statutorily required threshold for notifying the government of the fraud alleged in the later-filed suit." *Id.* Our review is de novo.[17] *Id.*

We apply the essential facts test by comparing Cunningham's amended complaint and McGuire's original complaint. *See Heath*, 791 F.3d at 121 ("Similarity is assessed by comparing the complaints side-by-side . . . ."); *Ven-A-Care*, 772 F.3d at 938 ("[W]e compare the Ven-A-Care complaint to the Sun and Hamilton complaint."); *In re Nat. Gas Royalties Qui Tam Litig. (CO2 Appeals)*, 566 F.3d 956, 964 (10th Cir. 2009) ("The first-to-file bar is designed to be quickly and easily determinable, simply requiring a side-by-side comparison of the complaints."). First-to-file

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government to investigate" that fraud. *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1209 (D.C. Cir. 2011). For purposes of this case, we see no difference between this standard and the essential facts test.

[17] Cunningham argues that the settlement independently reserved this issue for the district court to resolve as a matter of fact, and that we must accept the district court's findings. The premise is wrong—the settlement says nothing of the sort. It states only that the district court "retain[ed] jurisdiction" over this issue, and that the relators "reserve[d] their rights against Millennium to seek attorneys' fees, costs and expenses" under applicable provisions. It does not displace normal first-to-file law.

analysis is limited to the four corners of the relevant complaints. *See Duxbury*, 579 F.3d at 33-34 (refusing to consider allegations in a later-filed Information because the relator "had his opportunity to [include those allegations] when he filed [his] Original Complaint"). We conclude, based on those two complaints, that Cunningham and McGuire do not allege similar frauds, but allege different frauds with different mechanisms.

We proceed claim-by-claim. *Merena*, 205 F.3d at 102 ("[T]he court must conduct a claim-by-claim analysis in order to determine if section 3730(b)(5) applies."). Two claims of fraud are relevant here: (1) Millennium's custom profile fraud, and (2) Millennium's point-of-care cup kickback scheme. Cunningham's complaint lacks all the essential elements of both claims.

Cunningham argues that he was the first to file a claim against Millennium for excessive and unnecessary drug testing. But this is too general an argument. We must look to the actual mechanism (the "essential facts") of the fraud that Cunningham alleged. In his amended complaint, Cunningham alleged that Millennium's Physician Billing Model, which involved physicians billing the government for multiple tests for each point-of-care cup, led to "significantly more testing." And he alleged that this increased point-of-care testing led, in turn, to more "confirmatory tests." But CMS revised its reimbursement rules to defeat such fraud, so physicians can no longer bill for multiple tests from a single cup. And Cunningham's amended complaint never mentions "standing orders" or "custom profiles," as McGuire's does.

Cunningham's allegations do not cover the essential elements of the fraud that McGuire described in his original complaint. McGuire alleged that Millennium required physicians to execute custom profiles. And McGuire alleged that these profiles directed Millennium to automatically conduct a battery of confirmatory tests regardless of individual patient need and regardless of what the point-of-care test showed. The fraud McGuire alleged had a different mechanism (the custom profiles) and focused on a different stage of testing (the confirmatory stage) than the one Cunningham described. McGuire was the first relator to file a claim including the essential elements of Millennium's custom profile fraud, which the government then pursued.

Cunningham also argues that he alleged the essential elements of Millennium's point-of-care cup kickback scheme, the second scheme the government pursued. He says he "alleged Millennium provided test kits at a nominal cost, and encouraged doctors to bill for numerous tests rather than for just one multi-panel test." But Cunningham's amended complaint makes only one mention of cost: it says that the point-of-care cups "can be purchased for less than $10.00." Cunningham did not allege that this was less than fair market value. And he did not allege that Millennium provided the cups for free in exchange for physicians referring confirmatory testing. McGuire, by contrast, alleged that Millennium provided point-of-care cups, "a valuable diagnostic tool," to physicians *for free* to induce them to send confirmation testing orders to Millennium.

Again, Cunningham's allegations do not include the essential elements of the fraud McGuire alleged.

Further, the fraud the government pursued was that alleged by McGuire.[18] The government alleged that Millennium distributed $5 million worth of free point-of-care test cups in exchange for the doctors referring the cups to Millennium for confirmatory testing. This was an illegal kickback because, "absent an applicable statutory exception[, point-of-care] cups had to be sold at 'fair market value' to comply with the Stark Law and Anti-Kickback Statute."

The district court erred when it found that "Cunningham's materials provided the government with 'sufficient notice to initiate an investigation into [Millennium's] allegedly fraudulent practices.'" *Cunningham*, 202 F. Supp. 3d at 206 (quoting *Ven-A-Care*, 772 F.3d at 938). Mere notice—particularly of a different fraud than the government chose to pursue—is not enough. As we made clear in *Ven-A-Care*, "we must ask not merely whether the first-filed complaint provides some evidence from which an astute government official could arguably have been put on notice, but also whether the first complaint contained *all the essential facts* of the fraud it alleges." 772 F.3d at 938 (emphasis added) (internal citation and quotation marks omitted).

McGuire has established that he was the first to file a claim alleging the essential facts of Millennium's custom profile fraud and point-of-care cup kickback

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[18] McGuire attached the government's complaint in intervention to his crossclaim, so it is properly before us. In any event, the government's complaint would be subject to judicial notice. *See Zucker*, 919 F.3d at 651 n.5 (citing *E.I. Du Pont de Nemours & Co.*, 791 F.2d at 7 (Breyer, J.)).

scheme. He has also adequately pleaded that the government's recovery from Millennium constitutes the "proceeds of the . . . settlement of the claim[s]" he brought.[19] 31 U.S.C. § 3730(d)(1).

IV.

We reverse[20] and remand for further proceedings consistent with this opinion.

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[19] There is no assertion by the government or anyone else that McGuire did not plead the conduct that formed the basis of the claims the government ultimately settled. We need not address the issue decided by the Eighth Circuit in *Rille*. *See* 803 F.3d at 374 (remanding for further factual development in a case in which "[t]he government objected to [the relators'] recovery on the ground that the relators' complaint did not plead the conduct that formed the basis of the claims that the government ultimately settled," *id.* at 371).

[20] Our holding moots McGuire's appeal of the district court's denial of his motion to reconsider.

APPENDIX B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

Civil Action No. 09-12209-NMG

UNITED STATES OF AMERICA, *et al.*, *ex rel.*
ROBERT CUNNINGHAM,
Plaintiffs,

v.

MILLENNIUM LABORATORIES, INC. *et al.*,
Defendants.

Civil Action No. 12-10132-NMG

UNITED STATES OF AMERICA, *et al.*, *ex rel.*
MARK MAGUIRE,
Plaintiffs,

v.

MILLENNIUM LABORATORIES, INC. *et al.*,
Defendants.

Civil Action No. 12-10631-NMG

UNITED STATES OF AMERICA, *et al.*, *ex rel.*
RYAN UEHLING,
Plaintiffs,

v.

MILLENNIUM LABORATORIES, INC. *et al.*,
Defendants.

Civil Action No. 13-10825-NMG

UNITED STATES OF AMERICA, *et al.*, *ex rel.* OMNI HEALTHCARE, INC. and JOHN DOE,
Plaintiffs,

v.

MILLENNIUM LABORATORIES, INC. *et al.*,
Defendants.

August 19, 2016

MEMORANDUM & ORDER

GORTON, J.

Consolidated before this Court are the *qui tam* actions of six sets of relators against defendant Millennium Laboratories, Inc. (now known as Millennium Health, LLC) ("Millennium"). After the government intervened in several of the cases and reached a settlement with Millennium, relator Mark McGuire ("McGuire") filed a cross-claim against the other relators seeking a declaratory judgment that he is entitled to the relators' share of the settlement money. Pending before the Court are motions filed by four of the relators to dismiss that cross-claim, a motion to seal certain related documents and a motion to strike certain documents and statements.

I. Background

In December, 2009, Robert Cunningham ("Cunningham"), an attorney who had worked as a

compliance officer at a laboratory testing company that competed with Millennium, filed a lawsuit against Millennium pursuant to the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq*. The FCA allows whistleblowers to file lawsuits on behalf of the federal government, known as *qui tam* actions, exposing fraudulent claims charged. The whistleblower, known as a "relator", may recover damages on behalf of the government and receive a portion of those damages himself. FCA lawsuits are required to remain sealed for 60 days, unless the Court permits an extension of that time, in order to allow the government to investigate the claims before deciding whether to intervene.

Cunningham's claim alleged that Millennium had defrauded the government by submitting claims for testing that was excessive and medically unnecessary, despite its certifications to the contrary. Cunningham also alleged that Millennium caused numerous physicians to submit fraudulent claims to the government. At the time he filed his complaint and served it on the government, Cunningham also provided the government with a disclosure statement containing additional information and voluminous source materials to substantiate his allegations and to assist the government in investigating the alleged fraud.

Cunningham continued to cooperate with the government and to provide additional materials until his death in December, 2010. His estate then continued his FCA action by filing an amended complaint in February, 2011. The estate and its attorneys (hereinafter also referred to as "Cunningham") also continued to respond to requests from the government pursuant to its ongoing investigation and to provide the government with additional materials.

A few days after Cunningham filed its amended complaint, the time during which the government was permitted to intervene and keep the case sealed expired. The government entered a notice that it would not intervene in the case for the time being and later elected not to intervene at all. The case was unsealed and subsequently dismissed by the district court. After an appeal, a partial remand and a second dismissal, Cunningham's case is currently on appeal to the First Circuit for a second time, although that appeal has been stayed pending the outcome of these proceedings.

In January, 2012 Mark McGuire, a former laboratory director of operations at a medical center, filed another FCA action against Millennium. McGuire's action also alleged that Millennium submitted claims for medically unnecessary testing and caused physicians to submit fraudulent claims. The government elected to intervene in McGuire's case. All told, eight FCA cases have been filed against Millennium by different relators and the government has chosen to intervene in three.

In October, 2015 the federal government and several intervening states reached a settlement agreement with Millennium ("the Settlement Agreement") through which Millennium agreed to pay $227,000,000, plus interest, in exchange for the government's forbearance with respect to certain claims. Those claims ("the Covered Conduct") were expressly limited to the period between January 1, 2008 and May 20, 2015, and were described as:

> (1) excessive and unnecessary [urine drug testing ("UDT")] ordered by physicians without an individualized assessment of patient need . . . and

> (2) UDT referred by physicians who received free point-of-care drug testing supplies in violation of the Stark Law, 42 U.S.C. § 1395nn, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

Seven of the eight relators joined in the agreement, which requires them to dismiss their pending actions with prejudice after post-settlement proceedings have been concluded. The agreement provides that 15% of the settlement be set aside for the relators ("the Relator's Share"), but does not prescribe how the money is to be apportioned among the relators. Instead, the agreement demurs on that subject and leaves it to the Court to apportion the 15% if the relators are unable to reach an agreement among themselves.

In October, 2015, after the filing of the settlement, relator McGuire filed a cross-claim against the other relators seeking a declaratory judgment that he is entitled to the Relator's Share. Four of the other relators subsequently filed motions to dismiss his cross-claim, which motions are the subject of this memorandum and order.

II. Cunningham's Motion to Dismiss

Cunningham moves the Court to dismiss McGuire's cross-claim both for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1) and for failure to state a claim under Fed. R. Civ. P. 12(b)(6).

A. Motion to Dismiss for Lack of Subject Matter Jurisdiction

1. Legal Standard

In opposing a motion to dismiss for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1), the plaintiff bears the burden of establishing that the Court has jurisdiction. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). If the defendant mounts a "sufficiency challenge", the court will assess the sufficiency of the plaintiff's jurisdictional allegations by construing the complaint liberally, treating all well-pled facts as true and drawing all reasonable inferences in the plaintiff's favor. *Valentin v. Hospital Bella Vista*, 254 F.3d 358, 363 (1st Cir. 2001).

If, however, the defendant advances a "factual challenge" by controverting the accuracy, rather than the sufficiency, of the alleged jurisdictional facts, "the plaintiff's jurisdictional averments are entitled to no presumptive weight" and the court will consider the allegations by both parties and resolve the factual disputes. *Id.* The court has "broad authority" in conducting the inquiry and can, in its discretion, consider extrinsic evidence in determining its own jurisdiction. *Id.* at 363-64.

2. Analysis

a. Appropriateness of a Jurisdictional Inquiry

Cunningham asserts that McGuire's declaratory judgment cross-claim is jurisdictionally barred because McGuire was not the "first to file" relator in this set of FCA cases. The "first to file" rule of the FCA states that

> [w]hen a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

31 U.S.C. § 3730(b)(5). The provision precludes the filing of subsequent *qui tam* cases once a relator has notified the government of a specific fraud, preventing copycat relators from bringing claims simply to gain a portion of the relator's share. *See United States ex rel. Heineman-Guta v. Guidant Corp.*, 718 F.3d 28, 35 (1st Cir. 2013). Cunningham avers that because he filed his FCA action before McGuire filed his, McGuire's claims are barred.

The United States Court of Appeals for the First Circuit ("the First Circuit") considers the "first to file" provision to be jurisdictional. *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Baxter Healthcare Corp.*, 772 F.3d 932, 936 (1st Cir. 2014) [hereinafter "*Ven-A-Care*"] (citing *United States ex rel. Wilson v. Bristol-Myers Squibb, Inc.*, 750 F.3d 111, 117 (1st Cir. 2014)). McGuire offers, however, several reasons why this Court should not apply that rule as a jurisdictional bar in this case.

First, McGuire argues that the Court should treat his cross-claim differently because it is a claim for declaratory judgment rather than an affirmative FCA claim against Millennium. The "first to file" provision does not, however, apply by its terms only to affirmative FCA claims. Instead, it bars all "related action[s] based on the facts underlying the pending action." McGuire does not explain how his cross-claim, which by its very nature involves all of the facts underlying

not only his affirmative FCA claim but also the FCA claims of the other relators, is not a "related action."

Next, McGuire contends that the "first to file" bar should not apply because Cunningham's action is not a "pending action" for the purposes of 31 U.S.C. § 3730(b)(5). He declares that

> a final judgment, with full res judicata effect, has been entered against Cunningham that conclusively precludes it from receiving any recovery for its FCA claims against Millennium.

Although Cunningham's complaint was ultimately dismissed, his case was, nevertheless, still "pending" at all relevant times. The dismissal had not yet occurred when McGuire filed his complaint. *See United States ex rel. Bartz v. Ortho-McNeil Pharmaceutical, Inc.*, 856 F. Supp. 2d 253, 258 (D. Mass. 2012) (holding that a later-dismissed action is "pending" for the purposes of § 3730(b)(5) if it was pending when the second relator brought her claim). Furthermore, Cunningham's appeal of the dismissal was ongoing when he entered into the Settlement Agreement. *See United States ex rel. Carter v. Haliburton Co.*, No. 13-1188, 2014 WL 1767514 (E.D. Va. May 2, 2014) (holding that a *qui tam* suit is "pending" when it is on direct review). Accordingly, McGuire's second contention is also unavailing.

Finally, McGuire asserts that 28 U.S.C. § 1331 provides the Court with federal question jurisdiction over his cross-claim because it is a declaratory judgment based upon the FCA, a federal law. *See, e.g.*, *Franchise Tax Bd. of Cal. v. Construction Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 19 (1983). This

argument misses the mark. The first to file provision serves as an exception to the Court's jurisdiction. It operates, therefore, to exclude "related actions" which would normally fall within the Court's jurisdiction, including McGuire's cross-claim.

b. Materials to be Considered

Because Cunningham disputes the factual accuracy of McGuire's contention that he was the "first to file" his FCA claim, Cunningham's motion to dismiss constitutes a factual, rather than a sufficiency, challenge. Accordingly, the Court may consider evidence extrinsic to McGuire's complaint in resolving the motion. *See Valentin*, 254 F.3d at 363-64. McGuire does not dispute the Court's authority in this regard, but asserts that the materials Cunningham has provided for the Court's consideration are improper.

First, McGuire argues that the Court may consider only the complaints when determining which of the two relators was the first to file an action detailing the Covered Conduct. Cunningham does not dispute that his claim of "first to file" status is based largely on documents and information he provided the government which are not contained in his complaint. He has filed those documents with his motion as an appendix ("the Cunningham Appendix"). McGuire cites a string of cases in this and other circuits which have referred, in passing, to the fact that courts compare the relators' complaints when assessing first to file status. *See, e.g.*, *Ven-A-Care*, 772 F.3d at 937-38. None of those cases addressed, however, the question of whether documents outside the complaint may also be considered.

Indeed, contrary to McGuire's contention, the statute itself provides no basis for such a restriction.

The "first to file" provision broadly bars new actions that are "related . . . based on the facts underlying the pending action." *See* 31 U.S.C. § 3730(b)(5). It does not restrict consideration to the complaints but rather focuses more broadly on the factual content of the action itself. Moreover, the provision pertinent to the requirements for a relator to commence an FCA action (appropriately titled "Actions by private persons") mandates that

> [a] copy of the complaint and written disclosure of substantially all material and information the person possesses shall be served on the government.

Id. § 3730(b)(2). As discussed in greater detail below, the Court's "first to file" analysis focuses on whether the relator "provided the government sufficient notice that it was the potential victim of fraud worthy of investigation." *Heineman-Guta*, 718 F.3d at 33. Because written disclosures outside the complaint are a required component of the "notice" that a relator must provide for the government, the Court's analysis would be incomplete if it did not consider such documents.

McGuire attempts to bolster his argument by asserting that the First Circuit's decision in *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.* bars our consideration of materials extraneous to the complaint. *See* 579 F.3d 13 (1st Cir. 2009). *Duxbury*, however, states no such general rule. To the contrary, the *Duxbury* Court acknowledged that it is appropriate for a Court to consider extraneous materials when deciding a 12(b)(1) motion based upon the "first to file" rule. *Id.* at 33. The Court declined to review a document offered by a relator because that document was

provided to the government after the opposing relator had filed his complaint. Consequently, the document was irrelevant to the "first to file" analysis, which examines the sufficiency of the information provided by the first relator before the second relator files.

All of the materials included in the Cunningham Appendix except for the last document, Cunningham's Third Disclosure Statement, were submitted to the government before McGuire filed his FCA action. *Duxbury* does not, therefore, bar the Court's consideration of those materials. Because the Third Disclosure Statement was filed after McGuire's complaint it cannot, however, support Cunningham's claim to "first to file" status. Accordingly, the Court will not consider it.

Finally, McGuire also declares that the Court cannot consider the Cunningham Appendix because the Court may consult only "materials of evidentiary quality," *Valentin*, 254 F.3d at 363, and Cunningham's Appendix has not been authenticated pursuant to Fed. R. Evid. 901. Specifically, McGuire complains that Cunningham did not file an accompanying affidavit authenticating the documents in the Appendix. That problem was remedied, however, when Cunningham filed a signed and sworn affidavit of Robert A. Griffith on January 19, 2016 describing the documents and attesting to their authenticity (Docket No. 148). Accordingly, this argument is now moot.

c. First to File Analysis

Finally, the Court considers the merits of the "first to file" analysis. In order for a *qui tam* action that was filed first to bar a subsequently filed action, it must provide enough details

> to give the government sufficient notice to initiate an investigation into allegedly fraudulent practices.

Heineman-Guta, 718 F.3d at 36-37. Accordingly, a later-filed action is barred if it states "all the essential facts of a previously-filed claim" or "the same elements of a fraud described in an earlier suit." *Duxbury*, 579 F.3d at 32. Here, because the parties seek to claim the Relator's Share rather than to collect damages through an affirmative FCA action, the relevant "fraud" is the Covered Conduct described by the Settlement Agreement.

After considering Cunningham's complaint, first amended complaint (which was filed prior to the commencement of McGuire's action) and the documents in the Cunningham Appendix which were provided to the government prior to the filing of McGuire's complaint, the Court finds that Cunningham did sufficiently allege the Covered Conduct so as to bar McGuire's claim. Cunningham alleged that Millennium caused physicians to order excessive and unnecessary urine drug testing without an individualized assessment of patient need.

Cunningham explained that Millennium convinced doctors to use its in-office, multi-panel, qualitative screening tests, which screened for eleven commonly tested drugs, to test urine samples for multiple drugs at the same time. Millennium then convinced physicians to implement "standing orders" which dictated that urine samples would be sent to Millennium for quantitative testing to confirm the results of the in-office screening tests. That confirmation testing was reflexive, requiring samples to be re-tested for all drugs, regardless of whether there was any reason a)

to doubt the in-office results or b) to test the patient for that particular drug. Such testing without an individualized assessment of patient need was wasteful and contrary to the existing standard of care. Cunningham further alleged that Millennium profited from billing the government for such excessive drug testing.

In order to convince doctors to participate in such a scheme, Cunningham alleged, Millennium encouraged them to bill for the in-office, multi-panel test in a manner which would garner them reimbursement "far in excess of the value of the test." Cunningham asserted that Millennium provided the multi-panel test kits at a low price (less than $10) and encouraged doctors to bill for miscellaneous clinical tests when they used the kits rather than for just one multi-panel test. Such a practice was, according to Cunningham, fraudulent and abusive and a violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and the Stark Law, 42 U.S.C. § 1395nn. Millennium, nevertheless, informed doctors that it was a proper method of billing.

McGuire correctly points out that Medicare later revised its reimbursement rules so that physicians could no longer bill for multiple tests derived from a multi-panel qualitative test. Consequently, Millennium changed its incentive structure for doctors by providing the multi-panel test kits for free and encouraging them to bill insurers for the tests. This was improper because doctors were permitted to bill for such tests only if they had paid Millennium for the test kits. Accordingly, such conduct also constituted a violation of the Anti-Kickback Statute and the Stark Law. It is the latter incentive structure, and not the former,

which is included within the Covered Conduct in the Settlement Agreement.

McGuire contends that Millennium's revised incentive structure constitutes "a wholly different fraud" from the one alleged by Cunningham and, therefore, Cunningham did not sufficiently allege the Covered Conduct to claim "first to file" status. Cunningham's description of the fraud included, however, all of the essential elements of the Covered Conduct. He informed the government that Millennium was providing its multi-panel test kits to doctors and encouraging them to use the test kits to bill in excess of their permissible value. That benefitted the doctors by allowing them to collect additional revenue from payors. In exchange, Millennium required doctors to send the test results to Millennium for quantitative confirmation without regard to the medical necessity of such confirmation testing.

Although the exact method of mis-billing for the multi-panel tests changed when Medicare revised its reimbursement rules, Cunningham's materials provided the government with "sufficient notice to initiate an investigation into [Millennium's] allegedly fraudulent practices." *Ven-A-Care*, 772 F.3d at 938. Medicare's billing policies are publicly available documents and accordingly the government, through its investigation, could have discovered changes in Millennium's fraudulent incentive structure caused by those policies. As the First Circuit has noted,

> once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds.

Ven-A-Care, 772 F.3d at 942. Here, Cunningham alleged the "essential facts" of the Covered Conduct, and therefore his FCA action bars McGuire's. *Cf. Wilson*, 750 F.3d at 118 (relator's action alleging off-label drug promotion barred by earlier-filed suit alleging similar scheme involving a different off-label use).

B. Motion to Dismiss for Failure to State a Claim

1. Legal Standard

To survive a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6), a complaint must contain "sufficient factual matter" to state a claim for relief that is actionable as a matter of law and "plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 667 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). When rendering that determination, a court may not look beyond the facts alleged in the complaint, documents incorporated by reference therein and facts susceptible to judicial notice. *Haley v. City of Boston*, 657 F.3d 39, 46 (1st Cir. 2011).

2. Analysis

Cunningham also moves the Court to dismiss McGuire's cross-claim for failure to state a claim under Fed. R. Civ. P. 12(b)(6). He proposes no new arguments, but rather requests that the Court consider his "first to file" arguments under the 12(b)(6) standard. As explained above, however, Cunningham's arguments rely extensively on documents outside of McGuire's complaint. Without such support, those arguments fail. McGuire's complaint states a plausible claim that he is the "first to file" relator although, as explained above, the Court finds that once

Cunningham's submissions are considered it becomes apparent that McGuire is not. Accordingly, the motion to dismiss on 12(b)(6) grounds will be denied.

III. The Other Relators' Motions to Dismiss

Three other sets of relators, Ryan Ueling, Omni Health Care and Amadeo Pesce, filed motions to dismiss McGuire's cross-claim. Each submitted a nearly identical memorandum of law arguing that the cross-claim should be dismissed on three grounds: 1) under Fed. R. Civ. P. 12(b)(1) because McGuire was not the first to file vis-à-vis Cunningham, 2) under Fed. R. Civ. P. 12(b)(1) because McGuire was not the first to file vis-à-vis the moving relator and 3) under Fed. R. Civ. P. 12(b)(6). Because the Court has found that McGuire was not first to file vis-à-vis Cunningham, the motions will be allowed, in part. Given that McGuire's cross-claim will be dismissed on those grounds the Court need not, however, address the relators' other arguments. Accordingly, the motions to dismiss of the subject relators will be denied as moot to the extent they rely on the second and third grounds.

IV. Cunningham's Motion to Seal the Cunningham Appendix

There is a well-established presumption of public access to judicial documents. *Fed. Trade Comm'n v. Standard Fin. Mgmt. Corp.*, 830 F.2d 404, 408 (1st Cir. 1987). Non-disclosure of judicial records can be justified for "only the most compelling reasons." *Id.* District courts therefore "must carefully balance the competing interests that are at stake in the particular case." *Siedle v. Putnam Investments, Inc.*, 147 F.3d 7, 10 (1st Cir. 1998).

What constitutes sufficient cause depends on the nature of the records the parties seek to impound. *Bradford & Bigelow, Inc. v. Richardson*, No. 13-cv-11025-RWZ, 2015 WL 3819234 at *2 (D. Mass. June 19, 2015). In civil cases, interests which courts have found sufficient to justify impoundment include trade secrets, confidential business information, information covered by a recognized privilege such as the attorney-client privilege and information required by statute to be sealed. *See id.* at *2; *Baxter Int'l, Inc. v. Abbott Laboratories*, 297 F.3d 544, 546 (7th Cir. 2002). Good cause must be established "on a document-by-document basis." *Bradford & Bigelow*, 2015 WL 3819234 at *1.

Cunningham moves the Court to seal both his Appendix and his memorandum in support of his motion to dismiss, which relies extensively on materials from the Appendix. As grounds, he avers that both constitute opinion work product from his FCA action against Millennium and they are, therefore, subject to absolute or near-absolute immunity from discovery. *See, e.g.*, *Caremark, Inc. v. Affiliated Computer Services, Inc.*, 195 F.R.D. 610, 616 (N.D. Ill. 2000). In response, McGuire does not dispute that the work product privilege applies but instead argues that Cunningham has waived work product protection by placing those documents directly at issue in this dispute. *See, e.g.*, *Columbia Data Products, Inc. v. Autonomy Corp.*, No. 11-cv-12077-NMG, 2012 WL 6212898, at *16 (D. Mass. Dec. 12, 2012).

The Court agrees with McGuire that Cunningham has put the documents in issue in this case. This situation differs from the context in which the work product privilege is typically invoked, however, because

Cunningham is not attempting to conceal the documents from McGuire. Instead, by sealing the documents, Cunningham seeks to ensure that no third person obtains access to the documents. Accordingly, Cunningham does not attempt to use his disclosures "as both a sword and a shield" by invoking them against while withholding them from McGuire. *See In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 24 (1st Cir. 2003).

The Court agrees with McGuire that Cunningham has not made the requisite showing of good cause, on a document-by-document basis, as to why the presumption of public disclosure should be overruled. Although Cunningham's disclosures were clearly prepared "in anticipation of litigation," Fed. R. Civ. P. 26(b)(3), that litigation has ended. The government has negotiated a Settlement Agreement with Millennium and, upon execution of that agreement, Cunningham agreed to dismiss his FCA action against Millennium with prejudice.

Cunningham has provided no reason why ongoing secrecy is warranted, especially given the considerable resources which must be expended by the Court to process and maintain sealed documents. *Dunkin Donuts Franchised Restaurants, LLC v. Agawam Donuts, Inc.*, No. 07-cv-11444-RWZ, 2008 WL 427290, at *1 (D. Mass. Feb. 13, 2008). The motion to seal will, therefore, be denied, without prejudice.

V. McGuire's Motion to Strike the Cunningham Appendix

Finally, McGuire moves to strike the Cunningham Appendix because it lacks evidentiary foundation. He also asks the Court to strike two statements

in Cunningham's memorandum of law which he claims are false.

McGuire first declares that the Court should strike Cunningham's Appendix because the Court may not consider evidence outside the complaints when determining the "first to file" status of a relator. He also asserts that the Appendix should be stricken because Cunningham did not file an accompanying affidavit authenticating the documents in the Appendix. As explained above, neither of those arguments is availing and, therefore, the Court will not strike the Appendix.

McGuire further contends that the Court should strike two statements in Cunningham's memorandum of law which he contends are false. The first statement, on page 4 of the memorandum, proclaims that "[t]he Government never affirmatively declined Cunningham's case." McGuire argues that this statement is false because on June 28, 2011 the United States filed a notice in Cunningham's case stating that it was definitively "declining to intervene in this action." In response, Cunningham has retracted the statement. Consequently, it is no longer before the Court and it was not considered during the Court's analysis of the other pending motions.

The second disputed statement, also on page 4, avers that

> [i]t is the culmination of the ongoing investigation Cunningham's filings initiated that resulted in the $227 million settlement now before the Court.

That statement summarizes Cunningham's position that he was the first relator to file his complaint and to provide the government with the notice it needed to

commence the investigation which lead to the Settlement Agreement. Such argument about the central issue in Cunningham's motion to dismiss is neither impermissible nor improper. McGuire has provided no evidence to the contrary that the government ceased to investigate the scheme alleged by Cunningham and then, separately at a later date, commenced the investigation which lead to the Settlement Agreement based solely upon the information provided by McGuire. Accordingly, the Court finds no reason to strike the statement and McGuire's motion will be denied.

ORDER

For the foregoing reasons,

1. Cunningham's motion to dismiss (Docket No. 117) is, with respect to Fed. R. Civ. P. 12(b)(1), **ALLOWED**, but otherwise **DENIED,**
2. Uehling's motion to dismiss (Docket No. 120) is, with respect to Fed. R. Civ. P. 12(b)(1) vis-à-vis Cunningham's first to file status, **ALLOWED**, but otherwise **DENIED,**
3. Omni's motion to dismiss (Docket No. 123) is, with respect to Fed. R. Civ. P. 12(b)(1) vis-à-vis Cunningham's first to file status, **ALLOWED**, but otherwise **DENIED,**
4. Pesce's motion to dismiss (Docket No. 131) with respect to Fed. R. Civ. P. 12(b)(1) vis-à-vis Cunningham's first to file status, **ALLOWED**, but otherwise **DENIED,**
5. Cunningham's motion to seal (Docket No. 119) is **DENIED without prejudice** and

6. McGuire's motion to strike (Docket No. 142) is **DENIED**.

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated August 19, 2016

APPENDIX C

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

Civil Action No. 09-12209-NMG

UNITED STATES OF AMERICA, *et al.*, *ex rel.*
ROBERT CUNNINGHAM,
Plaintiffs,

v.

MILLENNIUM LABORATORIES, INC. *et al.*,
Defendants.

Civil Action No. 12-10132-NMG

UNITED STATES OF AMERICA, *et al.*, *ex rel.*
MARK MAGUIRE,
Plaintiffs,

v.

MILLENNIUM LABORATORIES, INC. *et al.*,
Defendants.

Civil Action No. 12-10631-NMG

UNITED STATES OF AMERICA, *et al.*, *ex rel.*
RYAN UEHLING,
Plaintiffs,

v.

MILLENNIUM LABORATORIES, INC. *et al.*,
Defendants.

Civil Action No. 13-10825-NMG

UNITED STATES OF AMERICA, *et al.*, *ex rel.* OMNI HEALTHCARE, INC. and JOHN DOE,
Plaintiffs,

v.

MILLENNIUM LABORATORIES, INC. *et al.*,
Defendants.

November 28, 2016

ORDER

GORTON, J.

Relator Mark McGuire moves this Court to reconsider its Memorandum and Order ("M&O") of August 19, 2016 (Docket No. 213) dismissing his cross-claim.

In Sections II and III of the memorandum in support of his motion, McGuire contends that the Court committed "manifest error" in its holdings in the M&O. His contentions do not, however, add anything new to the arguments he already made in his previous memoranda. McGuire is not entitled to reconsideration on such grounds. *See Palmer v. Champion Mortg.*, 465 F.3d 24, 30 (1st Cir. 2006).

McGuire also proffers several arguments in the remaining sections of his memorandum that were not raised in his earlier briefings. McGuire has thus waived those arguments. *See Cochran v. Quest Software, Inc.*, 328 F.3d 1, 11 (1st Cir. 2003).

Accordingly , the motion of relator Mark McGuire for reconsideration (Docket No . 218) is **DENIED.**

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated November 28, 2016

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 17-1106

UNITED STATES OF AMERICA; STATE OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF TEXAS; COMMONWEALTH OF VIRGINIA; and STATE OF WISCONSIN, ex rel. MARK MCGUIRE, WENDY JOHNSON, and RYAN UEHLING,
Plaintiffs,

v.

MILLENNIUM LABORATORIES, INC., MILLENNIUM LABORATORIES OF CALIFORNIA, INC.; JAMES SLATTERY; HOWARD APPEL,
Defendants.

MARK MCGUIRE,
Cross-Claimant, Appellant,

v.

ESTATE OF ROBERT CUNNINGHAM; RYAN UEHLING; OMNI HEALTHCARE INC.; AMADEO PESCE; JOHN DOE a/k/a CRAIG DELIGDISH,
Cross-Defendants, Appellees.

May 31, 2019

Before

Howard, Chief Judge,
Torruella, Lynch, Thompson,
Kayatta and Barron,* Circuit Judges.

ORDER OF COURT

The petition for rehearing having been denied by the panel of judges who decided the case, and the petition for rehearing en banc having been submitted to the active judges of this court and a majority of the judges not having voted that the case be heard en banc, it is ordered that the petition for rehearing and the petition for rehearing en banc be *denied*.

By the Court:

Maria R. Hamilton, Clerk

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* Judge Barron is recused and did not participate in the consideration of this matter.