No. _____

IN THE
# Supreme Court of the United States

OMNI HEALTHCARE INC.,

*Petitioner*,

-v-

U.S. ONCOLOGY, INC.,

*Respondent.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit**

## PETITION FOR A WRIT OF CERTIORARI

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## QUESTIONS PRESENTED

1. Is a qui tam relator barred by the "public disclosure" of its own prior complaint? No other circuit court has so held.

2. Does the public-disclosure bar apply to the unsealing of a first-filed complaint after the relator filed its first complaint, but before it re-filed its second complaint? No other circuit court has so held.

3. Was the Second Circuit correct in interpreting the False Claims Act in a way that bars any relator from being an "original source"? Other circuit courts have expressly interpreted the act to hold the opposite.

## PARTIES TO THE PROCEEDINGS

Petitioner is Omni Healthcare, Inc., which was plaintiff-relator-appellabt below.

Respondent is U.S. Oncology, Inc., which was defendant-appellee below.

## CORPORATE DISCLOSURE STATEMENT

Petitioner Omni Healthcare, Inc., has no parent corporations, and no publicly held company owns 10% or more of their stock.

## STATEMENT OF RELATED CASES

This case arises from the following proceedings:

- *United States v. U.S. Oncology, Inc.*, No. 23-1334 (2d Cir. Nov. 12, 2024) (affirming lower court decisions).
- *United States of America et al. v. McKesson Corporation et al.*, No. 1:19-cv-5125 (E.D.N.Y. Sept. 8, 2023) (granting motion to dismiss).
- *United States of America et al. v. McKesson Corporation et al.*, No. 1:19-cv-5125 (E.D.N.Y. July 21, 2022) (granting motion to dismiss).
- *United States of America et al. v. McKesson Corporation et al.*, No. 1:12-cv-6440 (E.D.N.Y. Feb. 4, 2019) (granting in part and denying in part motion to dismiss).

There are no other proceedings in state or federal trial or appellate courts, or in this Court, directly related to this case within the meaning of this Court's Rule 14.1(b)(iii).

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## PETITION FOR A WRIT OF CERTIORARI

The Petitioner, Omni Healthcare, Inc., respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit in this case.

## OPINIONS BELOW

The opinion of the Second Circuit is unpublished and is reproduced in the Appendix ("App.") as App. A. It is also available at 2024 WL 4751635 (2d Cir. Nov. 12, 2024).

The order of the Second Circuit denying rehearing is unpublished and is reproduced in the Appendix at App. E.

The orders of the district court are unpublished and are reproduced in the Appendix at Apps. B, C, and D. They are also available at 2019 WL 438357 (Feb. 4, 2019); 2022 WL 17685383 (E.D.N.Y. July 21, 2022); and 2023 WL 5831140 (E.D.N.Y. Sept. 8, 2023).

## JURISDICTION

The Second Circuit issued its decision on November 12, 2024. The court denied a timely rehearing petition on December 27, 2024. This Petition is timely filed. This Court has jurisdiction under 28 U.S.C. § 1254(1).

## STATUTORY PROVISIONS INVOLVED

31 U.S.C. § 3730(b)(2), reproduced in App. F, provides in relevant part:

> A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) [1] of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

31 U.S.C. § 3730(e)(4), reproduced in App. F, provides in relevant part:

> (A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—
>
> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
>
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
>
> (iii) from the news media,
>
> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

> (B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) 3 who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

31 U.S.C. § 3730(e)(4) (2006), reproduced in App. F, provides in relevant part:

> (A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

## INTRODUCTION

This Petition gives this Court the opportunity to address a split among the circuit courts concerning whether the public-disclosure rule under the False Claims Act ("FCA") is intended to prevent parasitic lawsuits. In the decision below, the Second Circuit held that petitioner Omni Healthcare, Inc.'s ("Omni") was barred by the "public disclosure" of its own original complaint. A second complaint was filed only because the first complaint was barred by a then-sealed complaint that made bare-bones allegations against U.S. Oncology. Consistent with this Court's ruling in *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970 (2015), Omni re-filed after the first-filed case was dismissed. The Second Circuit's holding is contrary to the clear intent of the FCA and creates a circuit split with every other circuit court, which have ruled that the purpose of the FCA's public-disclosure bar is to weed out parasitic relators who learn of information through public channels. It also contravenes this Court's holdings in *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 413 (2011), and *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 294–95 (2010), wherein this Court found that the public-disclosure rule seeks to weed our parasitic relators and that parasitic relators are "those who learn of the fraud through public channels and seek remuneration although they contributed nothing to the exposure of the fraud." *Graham Cnty.*, 559 U.S. at 296 n.16.

Omni is not a parasitic relator, and defendant U.S. Oncology, Inc. ("U.S. Oncology") does not argue that it is one. Therefore, the public-disclosure bar should not

apply in these circumstances. Prior to this case, no circuit or district court has held that a party is barred under the public-disclosure rule simply because, like here, it had to re-file its action after being dismissed under the first-to-file bar. Here, it is undisputed that U.S. Oncology learned all of the relevant facts by its own investigation and not as a result of any public disclosure. Indeed, the first-filed action was under seal at the time Omni filed its first action, so it could not have obtained any information from that first-filed action, nor was there any other public disclosure. The Second Circuit's holding eviscerates this Court's holding in *Kellogg* because, under its reasoning, any re-filed complaint would, as a matter of law, be barred by by public disclosure. The bar would also be absolute because the Second Circuit interpreted the statute's definition of "original source" to bar literally every relator from meeting that definition.

For the same reason, the Second Circuit's holding that the unsealing of the previously sealed, first-filed complaint (the "*Underwood*" complaint) was a public disclosure should be rejected. Again, U.S. Oncology filed its initial action (the "*Omni 2012 Action*") before *Underwood* was unsealed. U.S. Oncology did not rely on any prior public disclosure. The unsealing of *Underwood* after U.S. Oncology filed its initial complaint, but before it re-filed its new complaint (the "*Omni 2019 Action*"), did not make Omni's action parasitic. Indeed, the complaint in the *2019 Omni Action* had more detail than the unsealed *Underwood* complaint, which makes mere pro forma conclusory allegations about U.S. Oncology among numerous other defendants.

Equally unprecedented and illogical is the Second Circuit's conclusion that no relator can be an original source under 31 U.S.C. § 3730(e)(4). This is the inevitable result of the Second Circuit's conclusion that any disclosure to the government is, by definition, involuntary because any relator must make a disclosure to the government under 31 U.S.C. § 3730(b)(2). No other circuit has read the statute in this manner. Nor is the Second Circuit's holding consistent with the legislative history. The clear legislative history indicates that the term "voluntary" was meant to exclude original sources who were under some independent compulsion or requirement to make a disclosure, such as a government employee who, as part of her employment, was required to make such disclosures, or an individual who receives a government subpoena or is questioned during a government investigation. Other circuits expressly so held.

The Petition should be granted.

## STATEMENT OF THE CASE

### I. FACTUAL BACKGROUND

Petitioner Omni Healthcare Inc. ("Omni") is a physician group practice specializing in hematology and oncology, among other specialties. FAC ¶ 24. In the course of his medical practice, Omni's principal came to learn of a fraudulent scheme carried out by Respondent U.S. Oncology Inc. ("U.S. Oncology") by

which U.S. Oncology advocated that its network practices harvest and pool the "overfill"[1] of certain oncology drugs, create additional dosages with the harvested overfill, administer those newly-created overfill dosages to unsuspecting patients, then claim reimbursement from government payers (including Medicare and state and local healthcare programs) and private insurers for the overfill injections without revealing that they had manipulated and contaminated the drugs. FAC ¶¶ 25–26; FAC ¶¶ 112–21. U.S. Oncology's network practices profited by billing payers for overfill and U.S. Oncology received a percentage of its network practices' profits. FAC ¶ 130. Overfill harvesting is illegal and unsafe, and claiming reimbursement for overfill while certifying compliance with applicable laws and regulations is fraudulent. FAC ¶¶ 42–66. In December 2010, U.S. Oncology was acquired by McKesson Corporation and is now a wholly owned subsidiary of McKesson.[2] FAC ¶ 28.

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[1] "Overfill" denotes the portion of liquid medication contained in a vial that exceeds the labeled dose amount. FAC ¶ 4. Overfill is included in the vial to ensure the administering physician is able to draw the full amount needed for a given injection; overfill ordinarily comprises between 10 to 20 percent of the volume of the vial. *Id.*; FAC ¶ 79. Overfill is meant to be discarded when a full dosage has been drawn from the vial into the administering syringe. FAC ¶ 105. Health care providers do not pay for overfill, and they are prohibited from claiming reimbursement for overfill. FAC ¶¶ 91, 93.

[2] McKesson Corporation is a defendant in a related lawsuit. *See* Case No. 1:12-cv-6440 (E.D.N.Y.).

## II. PROCEDURAL HISTORY

### a. The *Omni 2012 Action*

In the months leading up to formally filing a qui tam lawsuit, Omni repeatedly disclosed information to the government about the overfill scheme perpetrated by U.S. Oncology and others. Omni discussed with government officials the overfill practices of AmerisourceBergen in early 2012. Omni filed its complaint against AmerisourceBergen in March 2012. *See* Declaration of J. Marc Vezina ("Vezina Declaration" or "Vezina Decl.") ¶ 14. In the spring and summer of 2012, Omni's counsel discussed adding U.S. Oncology and others as parties. Vezina Decl. ¶¶ 7–15. Omni then drafted a revised disclosure statement in July 2012, which it provided to the government on or about August 24, 2012, detailing allegations against McKesson Corporation, Oncology Therapeutic Network, and U.S. Oncology. Vezina Decl. ¶¶ 16, 18.

On October 9, 2012, Omni amended its existing complaint to add U.S. Oncology, among other defendants. No. 1:12-cv-1178, Dkt. 5 (E.D.N.Y. Oct. 9, 2012) (the "*Omni 2012 Action*").[3]

Unbeknownst to Omni, a different relator had already made some similar, but meaningfully fewer, allegations against U.S. Oncology in another case: *United States ex rel. Underwood v. Amgen*, No. 1:10-cv-2441 (E.D.N.Y. filed May 28, 2010) ("*Underwood*");

[3] On March 28, 2018, the claims against U.S. Oncology and others were severed from the claims against AmerisourceBergen and related entities. The claims against AmerisourceBergen were settled.

see Complaint, *Underwood*, Dkt. 1 ¶¶ 6(C), 7, 10, 76. The *Underwood* case was pending under seal at the time Omni filed its complaint. *Underwood* was voluntarily dismissed without prejudice on August 5, 2016, about three months after the complaint in that case was unsealed. *Underwood*, Dkt. 23 (May 11, 2016), Dkt. 26 (Aug. 5, 2016). Omni was unaware of the *Underwood* case when it filed its 2012 complaint and did not become aware of *Underwood* until it was raised by the defendants in May 2018 prior to their motion to unseal in the *Omni 2012 Action*.

In the *Omni 2012 Action*, Omni filed a Second Amended Complaint on April 3, 2018. The action was unsealed on June 20, 2018. Defendants moved, *inter alia*, to dismiss the claims against U.S. Oncology on the grounds that the *Underwood* action was a first-filed case. That motion was granted under the FCA first-to-file bar as it had recently been construed by this Court in *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 172 (2d Cir. 2018); *see* 31 U.S.C. § 3730(b)(5). Pursuant to *Wood*, Omni's 2012 complaint had to be dismissed because, even though *Underwood* had since been dismissed, the *Underwood* complaint was pending (under seal) at the time Omni's complaint was initially filed. *Omni 2012 Action*, Dkt. 66.[4]

**b. The *Omni 2019 Action***

Because *Underwood* had since been dismissed, however, in accordance with *Kellogg*, the first-to-file

[4] The *Omni 2012 Action* has continued against two other defendants—McKesson Corporation and Oncology Therapeutics Network—and discovery in that matter is continuing. *See United States v. McKesson Corp.*, No. 1:12-cv-06440-NG-ST (E.D.N.Y.).

bar posed no impediment to Omni persisting with its allegations under a new case caption. 575 U.S. at 663–64. Omni re-filed its complaint against U.S. Oncology on September 9, 2019, Dkt. 1, No. 1:19-CV-05125 (NG) ("*Omni 2019 Action*"), making substantially similar allegations as to U.S. Oncology that it had made almost seven years earlier in the *Omni 2012 Action*.

U.S. Oncology moved to dismiss the new complaint, and the district court granted that motion on July 21, 2022 on the basis that "the public disclosure bar is applicable to Omni's re-filed action," (Pet. App. 33a) notwithstanding the fact that the Omni 2012 Action had pleaded the elements of the fraud before there was any public disclosure. The district court found that Omni's own complaint in the *Omni 2012 Action* was a "public disclosure" and that the Underwood complaint, unsealed in 2016, after Omni had filed its initial complaint but before it filed its complaint in the *Omni 2019 Action*, was also a "public disclosure."

Furthermore, the district court held Omni did not qualify for the pre-2010 "original source" exception to the public-disclosure bar because it had not alleged facts showing "direct and independent knowledge of the information on which the allegations are based.'" (Pet. App. 54a) (quoting 31 U.S.C. § 3730(e)(4) (2006)). The district court further held that Omni did not qualify for the post-2010 original source definition because the *Omni 2019 Action* complaint did not "materially add" to either the *Omni 2012 Action* complaint or the *Underwood* complaint.

The district court granted Omni's leave to amend its complaint to further allege a factual basis for its

claim as an original source and, on August 19, 2022, Omni moved to file a third complaint, i.e., the FAC. This FAC substantially added to the allegations in the original complaint with respect to how Omni learned of the overfill harvesting scheme at U.S. Oncology.

On September 8, 2023, the district court held that Omni's allegations in the FAC did not meet the definition of an "original source" under either the pre-2010 or post-2010 versions of the public-disclosure bar, dismissing Omni's claims. With respect to the pre-2010 version of the public-disclosure bar, the district court held Omni did not establish that it had "direct and independent" knowledge of the fraud. (Pet. App. 20a-22a).[5] With respect to the post-2010 public-disclosure bar, the district court determined that Omni met neither of the "two avenues" to meet the definition of an original source. (Pet. App. 23a). First, the district court held that Omni did not "voluntarily disclose[] to the Government the information on which allegations or transactions in a claim are based." *Id*. Second, the district court held Omni did not possess "knowledge that . . . materially adds to the publicly disclosed allegations." *Id*.

The Second Circuit agreed with the district court on each issue and denied Omni's petition for a rehearing or rehearing *en banc*. Omni now submits to this Court its petition for a writ of certiorari.

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[5] Although the district court's holding regarding "involuntary" § 3730(b)(2) disclosures was limited to the post-2010 statute, the word "voluntarily" also appears in the pre-2010 statute and, therefore, the following discussion applies to both pre-2010 and post-2010 versions of the statute.

## REASONS FOR GRANTING THE PETITION

The decision below concerns a key issue concerning the application of the public-disclosure bar under the False Claims Act ("FCA"). The effect of the Second Circuit's decision is to significantly misconstrue the policy purpose and legislative history of the public-disclosure bar embodied in 31 U.S.C. § 3730(e)(4)(A); to dramatically narrow the scope of the original-source exception to the public-disclosure bar; and to punish good-faith, non-parasitic relators who doggedly pursue independent investigations and fastidiously comply with qui tam procedure. Furthermore, the Second Circuit's decision creates a circuit split with every other circuit and contravenes this Court's own precedent, which holds that the public-disclosure bar is to weed on parasitic relators, which Omni is indisputably not.

### I. THE SECOND CIRCUIT'S RULING CREATES A CIRCUIT SPLIT WITH EVERY OTHER CIRCUIT AND CONTRAVENES THIS COURT'S HOLDING THAT THE PUBLIC-DISCLOSURE BAR IS INTENDED TO WEED OUT PARASITIC RELATORS.

#### a. Under the Rulings of Every Other Court to Have Considered the Public-Disclosure Bar, There Is No Authority for the Position That an Earlier Action, Dismissed Under the First-to-File Bar, Is a "Public Disclosure."

The Second Circuit erred in holding that a relator's first complaint can be a public disclosure when the need for a second complaint only arises when the first complaint is dismissed under the first-to-file bar. The

Second Circuit's decision that the *Omni 2012 Action* bars the *Omni 2019 Action* as a public disclosure depends on a logical impossibility, i.e., that a relator's re-filed allegations are "parasitic" on its own earlier allegations. That position is not tenable, and it obviously contravenes this Court's holding in *Kellogg*. The Second Circuit (unsurprisingly) cites not a single case that supports it.

This Court has recognized in its holdings in *Schindler Elevator* and *Graham County* that the purpose of the public-disclosure bar is to "root out fraud and stifling parasitic lawsuit." *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 413 (2011) (citing *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 294–95 (2010). Parasitic lawsuits are "by those who learn of the fraud through public channels and seek remuneration although they contributed nothing to the exposure of the fraud." *Graham Cnty.*, 559 U.S. at 296 n.16. Omni's allegations were not based on information learned through public channels; U.S. Oncology does not contest this, and the Second Circuit di dnot rule otherwise. Indeed, Omni implicated U.S. Oncology on October 9, 2012, more than three and a half years before the *Underwood* complaint was unsealed and any such "public channels" were available. *See infra* Section II(a). Therefore, Omni cannot be a parasitic relator, and thus the principles motivating the public-disclosure bar are irrelevant here.

In dismissing Omni's claims, the Second Circuit created a circuit split with every other circuit, which each has found the FCA's purpose to be rooting out parasitic relators. Every circuit has held that the pub-

lic-disclosure rule is intended to prevent parasitic lawsuits. *See, e.g.*, *United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104 (1st Cir. 2010); *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149 (3d Cir. 1991); *United States ex rel. Wilson v. Graham Cnty. Soil & Water Conservation Dist.*, 777 F.3d 691 (4th Cir. 2015); *United States ex rel. Schweizer v. Canon, Inc.*, 9 F.4th 269 (5th Cir. 2021); *United States ex rel. Holloway v. Heartland Hospice, Inc.*, 960 F.3d 836 (6th Cir. 2020); *United States v. Emergency Med. Assocs. of Ill., Inc.*, 436 F.3d 726 (7th Cir. 2006); *Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032 (8th Cir. 2002); *United States v. Allergan, Inc.*, 46 F.4th 991 (9th Cir. 2022); *In re Nat. Gas Royalties Qui Tam Litig.* (CO2 Appeals), 566 F.3d 956 (10th Cir. 2009); *Cho on behalf of States v. Surgery Partners, Inc.*, 30 F.4th 1035, 1040 n.2 (11th Cir. 2022); *United States ex rel. Oliver v. Philip Morris USA Inc.*, 763 F.3d 36 (D.C. Cir. 2014). This Court has held the same. *See Graham Cnty.*, 559 U.S. at 285; *Schindler Elevator*, 563 U.S. at 413. While none of these cases have addressed Omni's precise situation here—where a relator's first complaint was dismissed under the first-to-file bar and subsequently re-filed—all these cases nevertheless rely on an understanding of the statutory purpose of the FCA and a definition of the "parasitic" relator that would incontrovertibly excludes Omni.

In support of its position, the Second Circuit does not cite a single case because none exists. Instead, the Second Circuit relies on an inaccurate reading of the plaint text of the FCA: "The court shall dismiss an action or claim under this section . . . if substantially the

same allegations or transactions as alleged in the action or claim were publicly disclosed." 31 U.S.C. § 3730(e)(4)(A). The Second Circuit interpreted the statute as follows: "The referent 'action or claim' is the present litigation before a court. Because a court cannot exercise jurisdiction over, nor dismiss, an action or claim not before it." (Pet. App. 8a). The Second Circuit does not support its interpretation with any common understanding of the words "action" or "claim," nor any case that would interpret these words so narrowly.

More egregiously, the Second Circuit's interpretation of the public-disclosure bar is flatly inconsistent with the FCA's statutory purpose. The FCA is intended to encourage people to blow the whistle on fraud, and the public-disclosure bar is intended to root out parasitic relators. Here, Omni's second complaint was filed only because the first complaint was barred by a first-filed action. Whether this situation makes a relator parasitic is an issue of first impression in this Court, and the Court should grant the Petition to uphold the principles undergirding the public-disclosure bar.

**b. The District Court's Ruling Contravenes the Objective of the First-to-File Bar.**

After *Kellogg*, the question arose of whether subsequent relators need only amend or supplement their complaint after the dismissal of the first-filed case, or whether they must re-file the action anew. In *United States ex rel. Wood v. Allergan*, Inc., 899 F.3d 163, 172 (2d Cir. 2018), the Second Circuit held that relators must re-file anew. 899 F.3d at 173–74. If the Second Circuit permitted relators' re-filed actions to succeed,

that would uphold the principle of of *Kellogg*. However, the Second Circuit's decision below has foreclosed the possibility that any re-filed action will pass the public-disclosure bar. The combination of *Wood* and the decision below means that, within the Second Circuit, there can be no relator who can take advantage of the principle of *Kellogg*; in every case, the second-filed action would be barred by the first as a "public disclosure."

The Second Circuit's decision is also inconsistent with its own holding in *Wood*. *Wood* confirmed that a relator whose complaint is dismissed on first-to-file grounds will ordinarily "be able to re-file her action . . . ." *Wood*, 899 F.3d at 174. It is also has created a circuit split with the Eleventh Circuit, who held in *Cho* that "the first-to-file bar will not prevent relators from bringing a new action once the earlier-filed action is no longer pending." *Cho*, 30 F.4th at 1040 n.2 (citing *Wood*, 899 F.3d at 174). Now, the Second Circuit has imposed on every re-filed action a public-disclosure bar. If *Kellogg* countenanced successfully re-filed or amended actions after dismissal on first-to-file grounds, the Second Circuit subsequently dashed those hopes. As a result, the Second Circuit's decision cannot stand.

**c. The District Court's Holding Produces Perverse Policy Effects.**

By treating complaints dismissed under the first-to-file bar as prior public disclosures, courts would encourage relators to withhold fraud allegations in their first qui tam complaint. Fearful that an unknown and then-sealed complaint from a different relator would upend their action months or years down the road

when unsealed, savvy relators would hedge against this risk by only partially disclosing a fraudulent scheme. Partial disclosure would increase the likelihood that a re-filed second qui tam complaint, which now would include the previously-withheld revelations, could "materially add" to the relator's own prior complaint, thereby qualifying as an original sources. Relators would be incentivized, then, to disclose information to the government stingily, saving a "material" amount of information for a rainy day when the relator may need to pass the public-disclosure bar once again.

## II. THE UNSEALING OF THE *UNDERWOOD* COMPLAINT DOES NOT SERVE AS A PUBLIC DISCLOSURE BARRING THIS ACTION.

The Second Circuit ruled that the unsealed *Underwood* complaint was a "public disclosure" barring the *Omni 2019 Action* (Pet. App. 7a), affirming the lower court's decision that it was "in the public domain before Omni filed [the *Omni 2019 Action*]" and "available to any member of the public that wanted to review [the] publicly accessible docket[]." (Pet. App. 51a). The Second Circuit errs in conducting its analysis from the vantage point of the date the *Omni 2019 Action* was filed (i.e., September 9, 2019) rather than the date the *Omni 2012 Action* was filed (i.e., October 9, 2012). In its decision below, the Second Circuit again becomes the only circuit or district court to have held thus.

Omni initially filed its complaint alleging fraud by U.S. Oncology on October 9, 2012, more than three and a half years before the *Underwood* complaint was unsealed on May 11, 2016. See *Underwood*, Dkt. 23. The overfill scheme had not been publicly disclosed on

October 9, 2012, as a sealed court document such as the *Underwood* complaint cannot be "publicly disclosed." *Cf. United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1157–58 (2d Cir. 1993) (finding a public disclosure because "the [court] record was not sealed . . . . Thus, the information was publicly disclosed *because it was available to anyone who wished to consult the court file*." (emphasis added)); *John Doe*, 960 F.2d at 322 ("Potential accessibility by those not a party to the fraud [is] the touchstone of public disclosure."). It is illogical to assert that Omni's allegations, which preceded Underwood's unsealing, are "based in any part upon publicly disclosed allegations or transactions." *Kreindler*, 985 F.2d at 1158 (quoting *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548, 553 (10th Cir. 1992)).

The Second Circuit cites no case in which an earlier-filed but still sealed complaint operates as a public disclosure under 31 U.S.C. § 3730(e)(4)(A), and it is inconsistent with the Fourth Circuit's opinion in *United States ex rel. Beauchamp v. Academi Training Ctr.*, 816 F.3d 37, 43 (4th Cir. 2016). In *Beauchamp*, defendants argued that the qui tam complaint was barred by the public-disclosure rule because, between the filing of the original complaint and the amended complaint, a news article disclosed the fraud. The Fourth Circuit rejected that argument, noting that the relator alleged the basic underlying facts in the initial complaint before the news article was published. 816 F.3d. at 45–46. Thus, the *Beauchamp* relator was not being parasitic, and allowing the case to proceed was consistent with the public-disclosure rule's legislative purpose.

Neither the Second Circuit nor the district court addressed *Beauchamp* in their decisions below or explained why Omni should be considered parasitic where the *Beauchamp* relator was not. Rather, the public-disclosure bar "applies only when information exposing the fraud has already entered the public domain prior to the relator's suit." *Beauchamp*, 816 F.3d at 43. And "the determination of when a plaintiff's claims arise for purposes of the public-disclosure bar is governed by the date of the first pleading to particularly allege the relevant fraud and not by the timing of any subsequent pleading." *Id.* at 46. Omni's claims thus "arose" in October 2012, when it first "allege[d] the relevant fraud" against U.S. Oncology. This was long before *Underwood* was unsealed.

## III. OMNI IS AN ORIGINAL SOURCE BECAUSE ITS PRE-FILING DISCLOSURE WAS VOLUNTARY.

### a. A Pre-filing Disclosure, Even if Made Pursuant to § 3730(b)(2), Can Be Voluntary.

Because the Second Circuit found that the *Omni 2019 Action* was subject to the public-disclosure bar by virtue of Omni's own prior complaint, Omni was required to show that it was an " original source" under both the pre- and post-2010 versions of the statute. The Second Circuit found that Omni could meet neither definition of original source. In particular, the court held that Omni never made a "voluntary" disclosure to the government pursuant to § 3730(e)(4) because the disclosure it made was required by the qui tam statute itself and thus, under § 3730(b)(2), all relators are per se "involuntary." The Second Circuit reasoned Omni's § 3730(b)(2) disclosure was involuntary specifically because Omni stated in pleadings

that the disclosure complied with § 3730(b)(2). (Pet. App. 11a). Again, the Second Circuit is now the only circuit or district court to have held thus, and this Court should grant the Petition to decide this issue of first impression.

The Second Circuit is incorrect for multiple reasons. First, the Second Circuit clearly misconstrues the intent of the statute. As several other circuits have recognized, the legislative history reveals that the archetypal instance of involuntary disclosure was compliance with a subpoena—i.e., fulfillment of a legal obligation outside the FCA itself. The following is an excerpt from the floor statement by Senator Chuck Grassley, the principal sponsor of the 1986 amendments to the FCA that created the public-disclosure bar:

> In the definition of "original source," the requirement that the individual "voluntarily" informed the Government or news media is meant to preclude the ability of an individual to sue under the qui tam section of the False Claims Act when his suit is based solely on public information and the individual was a source of the allegations only because the individual was subpeonaed [sic] to come forward. However, those persons who have been contacted or questioned by the Government or the news media and cooperated by providing information which later led to a public disclosure would be considered to have "voluntarily" informed the Government or media and therefore considered eligible qui tam relators.

132 Cong. Rec. 20,536 (Aug. 11, 1986).

Several other circuits have recognized this distinction between voluntary and involuntary disclosures. For example, the Third Circuit held that disclosure after receiving a subpoena are not voluntary. *See United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 341 (3d Cir. 2005). Similarly, in *Little v. Shell Expl. & Prod. Co.*, 690 F.3d 282 (5th Cir. 2012), the Fifth Circuit posits a definition of voluntariness based in choice, not obligation: voluntary disclosures are those "produced in or by an act of choice." *Id.* at 294 (quoting Webster's Third New Int'l Dictionary 1836 (1993)). Further, the Ninth Circuit in *United States ex rel. Fine v. Chevron, USA Inc.*, 72 F.3d 740 (9th Cir. 1995), held that "a salaried government employee, compelled to disclose fraud by the very terms of his employment" could not make a "voluntary" disclosure when it was his job to do so. Other courts concur. *See United States ex rel. LeBlanc v. Raytheon Co., Inc.*, 913 F.2d 17, 20 (1st Cir. 1994) (as quality assessor of government contracts, "[i]t was [relator]'s responsibility, a condition of his employment, to uncover fraud"); *Prather v. AT&T, Inc.*, 847 F.3d 1097, 1106–07 (9th Cir. 2017) (state prosecutor was not volunteer); *United States ex rel. Biddle v. Bd. of Trs. of Leland Stanford, Jr. Univ.*, 161 F.3d 533, 540, 542–44 (9th Cir. 1998) (relator, an officer for the Office of Naval Researcher at Stanford University, could not meet voluntariness requirement because he "had a duty . . . to disclose fraud" as part of his job); *Hagood v. Sonoma Cnty. Water Agency*, 81 F.3d 1465 n.19 (9th Cir. 1996) (disclosure was voluntary because "[relator]'s job was not to expose fraud,

but to draft contracts and perform other legal services for the [Army] Corps [of Engineers]").[6]

Courts also have found reporting involuntary when the relator discloses as part of an ongoing government investigation. *See United States ex rel. Barth v. Ridgedale Elec., Inc.*, 44 F.3d 699 (8th Cir. 1995) (provision of information was initiated by HUD investigator); *City of Chicago ex rel. Rosenberg v. Redflex Traffic Sys. Inc.*, 884 F.3d 798, 806 (7th Cir. 2018) (relator disclosed only after city investigation initiated).[7] Neither applies here. Here, in contrast, the relator is neither a government employee nor subject to an ongoing investigation.

The Second Circuit gives no reason why the same disclosure cannot satisfy both § 3730(b)(2) and § 3730(e)(4)(A), and the text of the statute does not supply one. In any event, the Vezina Declaration demonstrates that Omni made multiple disclosures before filing the complaint, only the last of which was specifically designated as a § 3730(b)(2) disclosure: on or about January 19, 2012, *see* Vezina Decl. ¶¶ 7–9; on or about February 9, 2012, *see id.* ¶ 13; on or about

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[6] *See also United States ex rel. Hendrickson v. Bank of America, N.A.*, 343 F. Supp. 3d 610, 630 (N.D. Tex. 2018) (relator worked for Office of the Inspector General "employed specifically to disclose fraud").

[7] *See also United States ex rel. Stone v. AmWest Savings Ass'n*, 999 F. Supp. 852, 857 (N.D. Tex. 1997) (business executive relator disclosed only after federal government initiated an investigation into the business, in exchange for criminal immunity).

August 24, 2012, and finally on October 9, 2012 (the day of the filing) *see id*. ¶¶ 15, 16, 18.[8]

Omni's § 3730(b)(2) disclosure was made before filing, making the disclosure definitionally voluntary. Inexplicably, the Second Circuit takes special pains to note that Omni's "*prefiling* disclosure statement" and its "meeting with the [government] *in anticipation of* filing a lawsuit" can never be voluntary, even if done months or years before filing. (Pet App. 12a n.3) (emphases added). If Omni had spoken to an Assistant U.S. Attorney, say, a year before filing its complaint, how is that not voluntary? Apparently not, according to the Second Circuit. The Second Circuit provides no guidance on how, then, a relator would comply with § 3730(b)(2) and submit a "voluntary" disclosure. Apparently, Omni's actions—i.e., inform the government months before filing its complaint—are insufficient. What should Omni have done instead? Should Omni have mailed two identical pre-filing disclosures to the government: one to comply with § 3730(b)(2) and one to qualify as a "voluntary" disclosure? This is an absurd reading of the FCA. Given that Omni had not yet initiated an FCA action when it made its § 3730(b)(2) disclosure, Omni had no "obligation" at the time to do anything, and its disclosure was voluntary.

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[8] The Second Circuit did not rule on whether the district court was permitted to consider the Vezina Declaration on the motion to dismiss, despite the district court's ruling that "[t]he declaration sets forth facts that are not alleged in the [Third] Complaint." (Pet. App. 28a). The district court's exclusion of the Vezina Declaration was clearly wrong due to reasons articulated in the briefing below. *See* Appellant's Brief and Special Appendix, *United States v. U.S. Oncology*, No. 23-01334, ECF No. 45, at 36-38 (2d Cir. Jan. 5, 2024).

The "obligat[ion]" to serve the § 3730(b)(2) disclosure is created by the FCA itself. This is distinguishable from all other circumstances where courts have found a § 3730(b)(2) disclosure to be outside of the FCA and thus involuntary.

In contrast, where there is no independent legal duty to report the fraud, the disclosure is considered voluntary. In *United States v. Kinetic Concepts, Inc.*, No. CV 08-6403-GHK, 2016 WL 11688143 (C.D. Cal. Aug. 30, 2016), the court described its "commonsense reading to the term 'voluntary'" as "acting or done without any present legal obligation to do the thing done or any such obligation that can accrue from the existing state of affairs." *Id.* at *9–10 (quoting Webster's Third New Int'l Dictionary 2564 (1981)).

The Second Circuit's circular logic defeats the policy objectives of the FCA: disclosing fraud pursuant to the FCA's own requirements cannot automatically render the disclosure involuntary. The Second Circuit's decision bars a relator who complies with the statutory requirement to serve the complaint and the material information the relator possesses pursuant to § 3730(b)(2), even when that relator makes the disclosure before filing suit, and even if made weeks or months before filing, thereby giving the government ample time to act on the allegations. The Second Circuit thus precisely punishes the whistleblowing behavior the FCA's statutory regime was designed to encourage.

## CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

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MARCH 2025

# APPENDIX

## TABLE OF APPENDICES

**APPENDIX A — SUMMARY ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT, DECIDED NOVEMBER 12, 2024**

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

No. 23-1334-cv

OMNI HEALTHCARE INC.,

*Plaintiff-Relator-Appellant,*

UNITED STATES OF AMERICA, EX REL. OMNI HEALTHCARE, STATE OF CALIFORNIA, EX REL. OMNI HEALTHCARE, STATE OF COLORADO, EX REL. OMNI HEALTHCARE, STATE OF CONNECTICUT, EX REL. OMNI HEALTHCARE, STATE OF DELAWARE, EX REL. OMNI HEALTHCARE, STATE OF DISTRICT OF COLUMBIA, EX REL. OMNI HEALTHCARE, STATE OF FLORIDA, EX REL. OMNI HEALTHCARE, STATE OF GEORGIA, EX REL. OMNI HEALTHCARE, STATE OF HAWAII, EX REL. OMNI HEALTHCARE, STATE OF ILLINOIS, EX REL. OMNI HEALTHCARE, STATE OF INDIANA, EX REL. OMNI HEALTHCARE, STATE OF IOWA, EX REL. OMNI HEALTHCARE, STATE OF LOUISIANA, EX REL. OMNI HEALTHCARE, STATE OF MARYLAND, EX REL. OMNI HEALTHCARE, STATE OF MASSACHUSETTS, EX REL. OMNI HEALTHCARE, STATE OF MICHIGAN, EX REL. OMNI HEALTHCARE, STATE OF MINNESOTA, EX REL. OMNI

*Appendix A*

HEALTHCARE, STATE OF MONTANA, EX REL. OMNI HEALTHCARE, STATE OF NEVADA, EX REL. OMNI HEALTHCARE, STATE OF NEW HAMPSHIRE, EX REL. OMNI HEALTHCARE, STATE OF NEW JERSEY, EX REL. OMNI HEALTHCARE, STATE OF NEW MEXICO, EX REL. OMNI HEALTHCARE, STATE OF NEW YORK, EX REL. OMNI HEALTHCARE, STATE OF NORTH CAROLINA, EX REL. OMNI HEALTHCARE, STATE OF OKLAHOMA, EX REL. OMNI HEALTHCARE, STATE OF RHODE ISLAND, EX REL. OMNI HEALTHCARE, STATE OF TENNESSEE, EX REL. OMNI HEALTHCARE, STATE OF TEXAS, EX REL. OMNI HEALTHCARE, STATE OF VERMONT, EX REL. OMNI HEALTHCARE, STATE OF VIRGINIA, EX REL. OMNI HEALTHCARE, STATE OF WASHINGTON, EX REL. OMNI HEALTHCARE, STATE OF WISCONSIN, EX REL. OMNI HEALTHCARE, THE CITY OF CHICAGO, EX REL. OMNI HEALTHCARE, THE CITY OF NEW YORK, EX REL. OMNI HEALTHCARE,

*Plaintiffs,*

v.

U.S. ONCOLOGY, INC.,

*Defendant-Appellee.*

Decided November 12, 2024

*Appendix A*

**SUMMARY ORDER**

RULINGS BY SUMMARY ORDER DO NOT HAVE PRECEDENTIAL EFFECT. CITATION TO A SUMMARY ORDER FILED ON OR AFTER JANUARY 1, 2007, IS PERMITTED AND IS GOVERNED BY FEDERAL RULE OF APPELLATE PROCEDURE 32.1 AND THIS COURT'S LOCAL RULE 32.1.1. WHEN CITING A SUMMARY ORDER IN A DOCUMENT FILED WITH THIS COURT, A PARTY MUST CITE EITHER THE FEDERAL APPENDIX OR AN ELECTRONIC DATABASE (WITH THE NOTATION "SUMMARY ORDER"). A PARTY CITING A SUMMARY ORDER MUST SERVE A COPY OF IT ON ANY PARTY NOT REPRESENTED BY COUNSEL.

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 12th day of November, two thousand twenty-four.

Present:

EUNICE C. LEE,
MARIA ARAÚJO KAHN,
*Circuit Judges,*
MARGARET M. GARNETT,
*District Judge**

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* Judge Margaret M. Garnett, of the United States District Court for the Southern District of New York, sitting by designation.

*Appendix A*

Appeal from a September 11, 2023 judgment of the United States District Court for the Eastern District of New York (Gershon, *J.*).

**UPON DUE CONSIDERATION, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED** that the judgment of the district court is **AFFIRMED**.

Plaintiff-Relator-Appellant Omni Healthcare Inc. ("Omni"), a Florida medical company specializing in oncology and hematology treatment, appeals from the district court's dismissal of its amended *qui tam* complaint filed on August 19, 2022, against Defendant-Appellee U.S. Oncology Inc. ("U.S. Oncology"), a Delaware corporation providing specialty pharmacy services to physicians who treat cancer patients, claiming violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, violations of various state and municipal FCA analogs, and unjust enrichment. Specifically, Omni alleges U.S. Oncology harvested the "overfill" of injectable oncology drugs to fill and sell unapproved syringes to other medical providers, and profited from providers' administration of these overfill drugs to patients by submitting fraudulent reimbursement claims to the Center for Medicare and Medicaid Services, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).[1]

1. "Overfill" is the excess volume of a drug contained in a vial to guard against loss during extraction and ensure proper dosage. Under the applicable commercial good manufacturing practices and FDA regulations, this excess volume cannot be recycled, reused, or adulterated in any way.

Omni first brought FCA claims against U.S. Oncology in 2012 as part of a *qui tam* action filed against multiple defendants (the "*Omni I*" action). In February 2019, the district court dismissed the claims pertaining to U.S. Oncology without prejudice, finding that the claims were precluded by the FCA's "first-to-file bar," 31 U.S.C. § 3730(b)(5). Omni then initiated the current lawsuit against U.S. Oncology when it filed a new complaint in September 2019 ("*Omni II* Complaint"). In July 2022, the district court dismissed the *Omni II* Complaint, this time holding that the FCA's "public disclosure bar" applied, *see* 31 U.S.C. § 3730(e)(4), and that Omni's allegations did not satisfy the bar's "original source exception," *see* 31 U.S.C. § 3730(e)(4)(B). Upon the district court's grant of leave to amend, Omni subsequently filed the operative amended complaint ("*Omni II* Amended Complaint") in hopes of satisfying that exception. In September 2023, the district court found that Omni's amended allegations failed to meet the original source exception's requirements and granted U.S. Oncology's renewed motion to dismiss for lack of subject-matter jurisdiction and failure to state a claim. Omni appeals both the 2022 and 2023 dismissals.

We assume the parties' familiarity with the remaining underlying facts, the procedural history, and the issues on appeal, to which we refer only as necessary to explain our decision to affirm.

## DISCUSSION

"We review dismissal of a cause of action under Fed. R. Civ. P. 12(b)(1) or 12(b)(6) *de novo*." *Jaghory v. N.Y.*

*State Dep't of Educ.*, 131 F.3d 326, 329 (2d Cir. 1997). "Under these rules, the court must accept all factual allegations in the complaint as true and draw inferences from those allegations in the light most favorable to the plaintiff." *Id.* "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (internal quotation marks omitted).

## I. The Public Disclosure Bar

The district court dismissed the *Omni II* Complaint as precluded by the public disclosure bar, which prohibits *qui tam* actions that allege misconduct already disclosed to the public where no statutory exception applies. On appeal, Omni argues that the district court erred because the allegations against U.S. Oncology were not public when Omni began pursuing its claims in 2012. However, by the time *Omni II* was filed in September 2019, two federal actions had publicized U.S. Oncology's alleged role in harvesting overfill: *Omni I*, initially filed in 2012 with a second amended complaint publicly filed in April 2018, and *United States ex rel. Underwood v. Amgen, Inc.* ("*Underwood*"), No. 10-CV-2441 (E.D.N.Y.), initially filed in 2010 and unsealed in 2016. Because Omni never contested that the public allegations from *Omni I* and *Underwood* are "substantially the same" as *Omni II*'s allegations, the district court held that both actions qualified as prior public disclosures. *United States ex rel. Omni Healthcare Inc. v. U.S. Oncology, Inc.*, No. 19-CV-5125 (NG) (LB), 2022 U.S. Dist. LEXIS 226026, 2022 WL 17685383, at *7–8 (E.D.N.Y. July 21, 2022). We agree.

Since Omni's allegations relate to U.S. Oncology's conduct from 2003 to 2014, we are obliged to consider the FCA's public disclosure provisions before and after the 2010 amendment. Both the pre-2010 and post-2010 public disclosure bars apply to this action if substantially the same allegations in the *Omni II* Complaint and Amended Complaint were publicly disclosed by the time of filing.[2] *See* 31 U.S.C. § 3730(e)(4)(A); 31 U.S.C. § 3730(e)(4)(A) (2000). As relevant here, public disclosures include the publicly accessible dockets of federal civil cases. *See* 31 U.S.C. § 3730(e)(4)(A)(i); 31 U.S.C. § 3730(e)(4)(A) (2000).

Omni's primary contention is that applying the bar to the *Omni II* action would be unfair and inconsistent with the FCA's purposes. The public disclosure bar is intended to "stifl[e] parasitic lawsuits" that are predicated on already-known information. *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 295, 130 S. Ct. 1396, 176 L. Ed. 2d 225 (2010). Omni insists that is not the case here. In its view, Omni has pursued its claims in good faith since 2012, and its previous *Omni I* action was dismissed only because the

2. The post-2010 bar applies to actions involving "substantially the same" allegations as those publicly disclosed, while the pre-2010 version applies to actions "based upon public disclosures." 31 U.S.C. § 3730(e)(4)(A); 31 U.S.C. § 3730(e)(4)(A) (2000). Because this Circuit has interpreted "based upon" to mean "the same [allegations] as those" publicly disclosed, the 2010 amendment did not alter the bar's applicability. *United States ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 324 (2d Cir. 1992); *see United States ex rel. Patriarca v. Siemens Healthcare Diagnostics, Inc.*, 295 F. Supp. 3d 186, 196 (E.D.N.Y. 2018).

first-to-file bar required it. *See United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 172 (2d Cir. 2018). Since Omni is not a "parasitic relator," but instead reviving its own earlier claims, it contends *Omni II* should be treated as the "continuation of [*Omni I*], re-filed under a new caption." Appellant's Br. at 21, 24. Following this logic, *Omni II* should be viewed as if initially filed in October 2012, when *Omni I* was amended under seal to include allegations against U.S. Oncology prior to any public disclosures.

This relation-back argument is both unpersuasive and contrary to the FCA's plain text. While it is true that *Omni I* was dismissed pursuant to the first-to-file bar, and so Omni had to file *Omni II* in order to continue pursuing its claims, Omni's contention that the public disclosure bar does not or should not apply in such instances seeks to carve out a new exception. The FCA does not treat two separate actions, filed under different captions, as a continuation. The pre-2010 and post-2010 text of the public disclosure bar both reference "an action or claim," which cannot proceed if substantially similar allegations have already been publicly disclosed. 31 U.S.C. § 3730(e)(4)(A) (2000); 31 U.S.C. § 3730(e)(4)(A). The referent "action or claim" is the present litigation before a court. Because a court cannot exercise jurisdiction over, nor dismiss, an action or claim not before it, the *Omni II* action filed in 2019 is the relevant "action or claim" for the purposes of this appeal, not *Omni I*. Since *Omni I* publicly disclosed allegations against U.S. Oncology when Omni filed a publicly accessible second amended complaint in April 2018, and it is uncontested that the later-filed *Omni II*

Complaint and Amended Complaint include allegations substantially similar to *Omni I*, the public disclosure bar applies. Moreover, even if, as Omni insists, applying the public disclosure bar to actions dismissed under the first-to-file bar creates perverse incentives or stymies the FCA's legislative purpose, this Court is not entitled to rewrite the FCA's text to decide the policy stakes for Congress. *Cf. Bartenwerfer v. Buckley*, 598 U.S. 69, 81, 143 S. Ct. 665, 214 L. Ed. 2d 434 (2023) ("No statute pursues a single policy at all costs, and we are not free to rewrite this statute (or any other) as if it did.").

Omni also suggests that the *Underwood* complaint does not serve as a separate public disclosure because *Omni I* was filed prior to *Underwood*'s unsealing. This argument is meritless. The *Underwood* complaint was filed on May 28, 2010 (before the *Omni I* action) and unsealed on May 11, 2016, well before the *Omni II* Complaint was filed and, as Omni concedes, *Underwood* alleged substantially similar conduct as *Omni II*. As a result, *Underwood* also triggers the public disclosure bar.

## II. Original Source Exception

Because the public disclosure bar applies, Omni must satisfy the original source exception to proceed. The district court dismissed the *Omni II* Amended Complaint because Omni failed to plead sufficient allegations to qualify as an original source. In particular, the district court found that Omni did not sufficiently allege direct and independent knowledge of U.S. Oncology's involvement in the overfill-harvesting fraud, a voluntary disclosure to

the government, nor a material addition to prior public disclosures. We agree.

The pre-and post-amendment definitions of an "original source" are distinct. Pre-amendment, a relator must have "direct and independent knowledge of the information on which the allegations are based" and "voluntarily provided the information to the Government before filing an action" to qualify. 31 U.S.C. § 3730(e)(4)(B) (2000). Post-amendment, a relator can qualify as an original source if it either (1) "voluntarily disclosed" the information underlying its claim to the government, prior to a public disclosure; or (2) has "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions" and has "voluntarily provided the information to the Government before filing an action." 31 U.S.C. § 3730(e)(4)(B)(i), (2).

For the pre-amendment definition, Omni argues that it has plausibly alleged direct and independent knowledge, because the *Omni II* Amended Complaint avers that its allegations "are based upon the personal knowledge Relator's principal [Dr. Deligdish]" gained through his work as an oncologist. J. App'x at 285–86. However, Omni claims that Dr. Deligdish found out about the overfilling scheme through "conversations" with oncologists affiliated with U.S. Oncology. *Id.* at 306–07. This Court has held that "if a third party is the source of the core information upon which the *qui tam* complaint is based," the relator does not satisfy the pre-amendment bar's direct and independent knowledge requirement. *United States v. N.Y. Med. Coll.*, 252 F.3d 118, 121 (2d Cir. 2001) (per curiam) (internal

quotations omitted). Because Dr. Deligdish's knowledge is predicated on conversations with third parties, Omni has failed to plead direct knowledge of U.S. Oncology's fraudulent conduct. Therefore, Omni is not an original source under the pre-amendment definition.

For the first prong of the post-amendment definition, Omni alleges it "voluntarily" disclosed information regarding U.S. Oncology's fraudulent activity, satisfying 31 U.S.C. § 3730(e)(4)(B)(i), by submitting a disclosure statement to the government, "as required by 31 U.S.C. § 3730(b)(2)," weeks prior to filing *Omni I* and before any public disclosures. J. App'x at 284. The district court concluded that Omni did not allege *voluntary* disclosure because Omni's pleading explicitly references the FCA's mandatory disclosure provision, which obligates a relator to serve on the government a "[a] copy of the complaint and written disclosure of substantially all material evidence," 31 U.S.C. § 3730(b)(2). The district court rejected Omni's argument, repeated before us, that this mandatory disclosure may simultaneously be voluntary if a relator discloses information to the government prior to public disclosures. We agree with the district court that Omni's argument "reads the voluntary requirement out of [31 U.S.C. § 3730(e)(4)(A)(i)]," which requires both "voluntarily" disclosing information and doing so "prior to a public disclosure." *United States ex rel. Omni Healthcare Inc. v. U.S. Oncology, Inc.*, No. 19-CV-5125 (NG) (LB), 2023 U.S. Dist. LEXIS 159434, 2023 WL 5831140, at *5 (E.D.N.Y. Sept. 8, 2023). The timing of disclosures, alone, is insufficient to conclude that a disclosure is voluntary; to hold otherwise would erase the provision's

voluntariness requirement. *See United States. ex rel. Beauchamp v. Academi Training Ctr., Inc.*, 933 F. Supp. 2d 825, 846 (E.D. Va. 2013) ("Courts that have addressed whether these mandatory disclosures under § 3730(b)(2) also qualify as voluntary disclosures under § 3730(e)(4) have held that they do not, as these are mandatory disclosures rather than voluntary disclosures."), *vacated and remanded on other grounds sub nom.* 816 F.3d 37 (4th Cir. 2016). In addition, Omni's inclusion of the word "voluntarily" in its complaint to describe its disclosure is a legal conclusion that we do not accept as true without plausible substantiating factual assertions.[3] *See Iqbal*, 556 U.S. at 678–81. Consequently, Omni is not an original source under 31 U.S.C. § 3730(b)(4)(B)(i).

Finally, for the second prong of the post-amendment definition, Omni contends that its averments regarding Dr. Kolodziej, a physician at U.S. Oncology who can "attest to the company's scienter," materially add to publicly disclosed allegations, thus satisfying one requirement of 31 U.S.C. § 3730(e)(4)(B)(2). Appellant's Br. at 45. But here,

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3. Omni attached the declaration of J. Marc Vezina, its former counsel, with its brief opposing U.S. Oncology's motion to dismiss the *Omni II* Amended Complaint, as evidence that Omni made a voluntary disclosure to the government months before filing *Omni I*. Appellant's Br. at 4 n.3, 35; *see also* J. App'x at 370–76. Assuming *arguendo* the declaration may be considered, the declaration does not help Omni show voluntariness. Mr. Vezina's declaration details a "prefiling disclosure statement" and meetings with the U.S. Attorney's Office in anticipation of filing a lawsuit. *See* J. App'x at 373–76. Such efforts are consistent with Omni's mandatory disclosure obligation under 31 U.S.C. § 3730(b)(2).

*Omni I* already publicly disclosed that "[U.S. Oncology] knew that [its] conduct was illegal." J. App'x at 139. The identification of specific individuals "aware of, or complicit in," U.S. Oncology's overfilling fraud does not "materially add to the already robust universe of publicly-available information." *Ping Chen ex rel. United States v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 300 (S.D.N.Y. 2013) (emphasis omitted). Therefore, Omni does not satisfy 31 U.S.C. § 3730(e)(4)(B)(2).

## III. Statute of Limitations

Because we conclude that the public disclosure bar applies and Omni is not an original source under any definition, we do not reach whether Omni's action is nonetheless precluded by the FCA's statute of limitations, 31 U.S.C. § 3731(b).

* * *

We have considered Omni's remaining arguments and conclude they are without merit. Accordingly, for the reasons set forth above, we **AFFIRM** the judgment of the district court.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk of Court

/s/ Catherine O'Hagan Wolfe

**APPENDIX B — OPINION & ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, FILED SEPTEMBER 8, 2023**

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

19-cv-5125 (NG) (LB)

UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, WISCONSIN, THE CITY OF CHICAGO, AND THE CITY OF NEW YORK ex rel. OMNI HEALTHCARE INC.,

*Plaintiffs,*

-against-

U.S. ONCOLOGY, INC.,

*Defendant.*

Filed September 8, 2023

*Appendix B*

**OPINION & ORDER**

**GERSHON, United States District Judge**:

## I. Background

Relator Omni Healthcare Inc. ("Omni") filed a *qui tam* action on behalf of the United States, 30 states, the District of Columbia, and the cities of New York and Chicago against U.S. Oncology, Inc. ("U.S. Oncology"), alleging violations of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, analogous state statutes, and the common law. U.S. Oncology moved to dismiss the original complaint in its entirety, under Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure, principally arguing that the FCA's "public disclosure bar" barred the action.

I agreed and dismissed the original complaint. I rejected Omni's argument that the public disclosure bar does not apply to an action filed against a defendant that was previously dismissed from a relator's own prior action by reason of the first-to-file bar. Turning to the "original source" exception, I found that Omni had not established that it met the pre-or post-amendment public disclosure bar's definition for an "original source of the information." Familiarity with my prior decision, including the relevant procedural history, facts as alleged in the original complaint, and my rulings regarding the public disclosure bar, is presumed. *See U.S. ex rel. Omni Healthcare Inc. v. U.S. Oncology, Inc.* ("*U.S. Oncology I*"), 2022 U.S. Dist. LEXIS 226026, 2022 WL 17685383 (E.D.N.Y. July 21, 2022).

Following the dismissal of the original complaint, I granted Omni's unopposed motion for leave to file an amended complaint, and Omni filed its First Amended Complaint (the "Complaint"). The Complaint's allegations are largely the same as those alleged in the original complaint, but Omni adds factual allegations to support an argument that it satisfies the public disclosure bar's original source exception. U.S. Oncology now moves again to dismiss the Complaint, under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), arguing that Omni's amended allegations do not establish that it meets the original source exception.

For the reasons set forth below, U.S. Oncology's motion to dismiss the Complaint is granted.

## II. The Complaint's Amended Allegations

The following facts are drawn from the Complaint and are assumed to be true for purposes of this motion. Below, I primarily discuss the newly alleged facts that Omni has added to the Complaint, as compared to the original complaint that it filed in this action.

Relator's principal and owner is Dr. Craig Deligdish. Dr. Deligdish served as CEO of Oncology Resource Networks, which had a strategic partnership with McKesson Corporation, the current owner of Defendant. Dr. Deligdish also served on the Executive Board of the Florida Society of Clinical Oncology and on the editorial board of Value Based Cancer Care. In these roles, Dr. Deligdish served with multiple medical directors of

oncology practices within the U.S. Oncology Network as well as other employees of U.S. Oncology. Put differently, Dr. Deligdish "regularly interfaced with and supervised employees of and medical directors of member-practices of Defendant." Complaint ¶ 116. These individuals included oncologists Dr. Barry Berman, Dr. Linda Bosserman, and Dr. Michael Kolodziej. Dr. Berman currently practices with Florida Cancer Specialists, but previously practiced oncology with U.S. Oncology Network practice Cancer Centers of Florida. Dr. Bosseman was, for ten years, the president and managing partner of Wilshire Oncology, a member of the U.S. Oncology Network. Dr. Kolodziej practiced oncology at U.S. Oncology Network practice New York Oncology/Hematology and served as National Medical Director of the U.S. Oncology Network.

In a conversation with Dr. Kolodziej, at a meeting in Florida, Dr. Deligdish learned that U.S. Oncology kept a record of the average overfill in each different oncology medication vial because different medications contained different amounts of overfill, and documents with these overfill amounts were distributed regularly to members of the US Oncology Network between 2003 and 2014 to encourage and facilitate physicians to administer overfill to patients. Through subsequent unidentified "investigation" and "conversations" with Dr. Berman, Dr. Bosserman, Dr. Kolodziej, and "others," Dr. Deligdish learned that U.S. Oncology advocated that its physicians utilize "overfill billing" for the Oncology Drugs administered to patients. *Id.* ¶ 119. "As part of his investigation," Dr. Deligdish learned that physicians throughout the U.S. Oncology Network harvested overfill and billed government payors

for it. *Id.* ¶ 121. Dr. Kolodziej also informed Dr. Deligdish that U.S. Oncology was aware that it was illegal to bill Medicare for overfill.

Nancy Payne provided additional information to Dr. Deligdish. Dr. Deligdish learned from her that the harvesting of the overfill was done either by the pharmacists or the technicians at each office in the U.S. Oncology Network who were either employed by U.S. Oncology or acted under its direction and that the overfill was billed to government and private payers by staff employed by U.S. Oncology. Nancy Payne is the Executive Director of Cancer Centers of Florida, which was a member of the U.S. Oncology Network from 2001-2010.

The Complaint also alleges the following:

> On or about September 13, 2012, as required by 31 U.S.C. § 3730(b)(2), Relator voluntarily submitted prior to the filing of the initial complaint in this action a confidential written disclosure statement (subject to the attorney-client privilege) to the United States Government, containing materials, evidence, and information in its possession pertaining to the allegations contained in this Complaint. Relator also voluntarily submitted a confidential written disclosure statement and this Complaint to the District of Columbia, as well as the states and cities under whose FCAs this action is partially brought. The

> disclosure contained the information on which the allegations in this Complaint are based.

*Id.* ¶ 23.

## III. Discussion

### A. The FCA's Public Disclosure Bar

As I noted in *U.S. Oncology I*, the public disclosure bar was enacted in 1986 and amended in 2010. In its original, pre-amendment form, the public disclosure bar was "jurisdictional;" if the bar applied, it divested the court of its subject matter jurisdiction over an action. *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 467, 127 S. Ct. 1397, 167 L. Ed. 2d 190 (2007). Post-amendment, the current version of the bar is no longer jurisdictional. Instead, it serves as a ground for dismissal, such "as an affirmative defense or in connection with [a] motion to dismiss." *U.S. ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 80 (2d Cir. 2017). Because Omni alleges that U.S. Oncology's conduct occurred "from 2003 through at least October 2014," both versions of the bar are relevant. Complaint ¶ 122; *U.S. Oncology I*, 2022 U.S. Dist. LEXIS 226026, 2022 WL 17685383, at *6 (explaining that the pre-amendment bar applies to conduct that occurred prior to the amendment and the post-amendment bar applies to conduct that occurred after the effective date of the amendment).

Under either version, the public disclosure bar requires a two-step inquiry. "First, courts look to whether the substance of a relator's claim had been disclosed prior

to the filing of his suit; second, courts look to whether, if such disclosures had been made, the relator can be considered an 'original source.'" *See U.S. ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.*, 2022 U.S. App. LEXIS 35101, 2022 WL 17818587, at *2 (2d Cir. Dec. 20, 2022) (internal quotation marks omitted). The only dispute, for purposes of this motion, concerns step two, namely, whether Omni's amended allegations establish that it meets the pre-and post-amendment's original source exception.

**i. Original Source of the Information**

**1. Pre-amendment "Original Source"**

The pre-amendment public disclosure bar defines an "original source" as "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B) (2006). U.S. Oncology argues that Omni has not established that it has direct and independent knowledge.

The pre-amendment original source exception "impose[s] a conjunctive requirement" on *qui tam* plaintiffs, which requires them to show that their "knowledge of the information on which the allegations are based" is both "direct *and* independent." *U.S. Oncology I*, 2022 U.S. Dist. LEXIS 226026, 2022 WL 17685383, at *9.

As I noted in *U.S. Oncology I*, knowledge is not direct "if a third party is the source of the core information upon which the *qui tam* complaint is based." *United States v. N.Y. Med. Coll.*, 252 F.3d 118, 121 (2d Cir. 2001) (internal quotation marks omitted). Courts regularly find that knowledge gained through conversations with third parties is not direct. *U.S. Oncology I*, 2022 U.S. Dist. LEXIS 226026, 2022 WL 17685383, at *9. Indeed, the Second Circuit relied on this principle in two recent decisions, affirming dismissals of complaints on the ground of the public disclosure bar. In *Piacentile v. U.S. Oncology, Inc.*, 2023 U.S. App. LEXIS 7314, 2023 WL 2661579 (2d Cir. Mar. 28, 2023), the Second Circuit held that the relator's knowledge was "indirect" when the information that he used to craft his FCA complaint was obtained from "third parties," namely, through an "investigation" that consisted of interviews with defendants' executives. 2023 U.S. App. LEXIS 7314, [WL] at *3. Similarly, in *United States ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.*, 2022 U.S. App. LEXIS 35101, 2022 WL 17818587 (2d Cir. Dec. 20, 2022), the relator, CKD Project, LLC, which was an entity formed for the litigation, acquired its information from a third party, who was an "inside participant" to the fraud. 2022 U.S. App. LEXIS 35101, [WL] at *3. The Second Circuit explained that, while the "inside participant might possess direct knowledge," CKD Project did not. *Id.*; *accord U.S. ex rel. Oliver v. Philip Morris USA Inc.*, 826 F.3d 466, 478, 423 U.S. App. D.C. 302 (D.C. Cir. 2016) (examining cases and concluding that "in order to have 'direct' knowledge for purposes of the original source exception, a relator must have some first-hand knowledge that would lead him to believe that a fraud had been committed").

*Appendix B*

As in *Piacentile* and *CKD Project*, Omni's amended allegations do not plead that it has direct knowledge of the information on which the allegations are based. The Complaint alleges that Omni's principal, Dr. Deligdish, learned of the fraud through conversations with third parties, namely, Dr. Berman, Dr. Bosserman, Dr. Kolodziej, and Nancy Payne.

Omni's allegation that Dr. Deligdish also learned of the fraud through his own "investigation," likewise, does not plead that his knowledge is direct. Complaint ¶ 119. Omni does not allege any details about the investigation and whether it consisted of anything more than speaking with the aforementioned third parties. An allegation that the relator undertook an "investigation" is insufficient. *Piacentile*, 2023 U.S. App. LEXIS 7314, 2023 WL 2661579, at *3.

Omni relies on *United States ex rel. Banigan v. PharMerica, Inc.*, 950 F.3d 134 (1st Cir. 2020), and *Kennard v. Comstock Resources, Inc.*, 363 F.3d 1039 (10th Cir. 2004). In *Banigan*, the relator "was a corporate insider . . . who learned of the fraudulent scheme in which his own company and department participated while he was employed there" and "gained knowledge of the fraud from emails and conversations with . . . the architects and primary perpetrators of the fraudulent scheme." *Banigan*, 950 F.3d at 146. In *Kennard*, the dramatic drop in royalty payments, which the relator had been paid for more than twenty-five years, for gas wells located on his own property, prompted the investigation that revealed the fraud. In contrast to these cases, and as in *Piacentile* and

*CKD Project*, Omni alleges that it obtained its knowledge entirely secondhand through conversations with, or documents provided to it by, third parties.

Accordingly, Omni has not shown that it meets the pre-amendment public disclosure bar's original source exception.

### 2. Post-amendment "Original Source"

Post-amendment, an individual has two avenues to meet the definition of an "original source." Under the first avenue, an individual who "prior to a public disclosure . . . has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based" is an original source. 31 U.S.C. § 3730(e)(4)(B)(i). Under the second avenue, an individual qualifies as an original source if the individual possesses "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions" and has "voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B)(2).

#### a. Voluntary Disclosure to the Government Prior to a Public Disclosure

As to the first avenue, Omni relies on the following allegation:

> On or about September 13, 2012, as required by 31 U.S.C. § 3730(b)(2), Relator voluntarily

> submitted prior to the filing of the initial complaint in this action a confidential written disclosure statement (subject to the attorney-client privilege) to the United States Government, containing materials, evidence, and information in its possession pertaining to the allegations contained in this Complaint.

Complaint ¶ 23. The referenced 31 U.S.C. § 3730(b)(2) provides:

> A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4[i] of the Federal Rules of Civil Procedure.

U.S. Oncology contends that, because Omni alleges that its disclosure to the government was "required by 31 U.S.C. § 3730(b)(2)," its disclosure was not made voluntarily. U.S. Oncology is correct. While Omni alleges that its disclosure was made "voluntarily," that is a legal conclusion, which is insufficient. *Ashcroft v. Iqbal*, 556 U.S. 662, 680–81, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009). The further allegation that the disclosure was made "as required by 31 U.S.C. § 3730(b)(2)" dooms Omni's argument that it made a voluntary disclosure. Complaint ¶ 23.

As the court explained in *United States ex rel. Beauchamp v. Academi Training Center, Inc.*, 933 F. Supp. 2d 825, 846 (E.D. Va. 2013), such a mandatory disclosure is not a voluntary disclosure. *Beauchamp* relied on the Tenth and Seventh Circuits' decisions in *United*

*States ex rel. King v. Hillcrest Health Center, Inc.*, 264 F.3d 1271 (10th Cir. 2001), and *United States v. Bank of Farmington*, 166 F.3d 853 (7th Cir. 1999), *overruled on other grounds by Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009). These cases construed the pre-amendment original source definition, which also contained a requirement that the relator "voluntarily" provide information to the government to qualify as an original source. 31 U.S.C. § 3730(e)(4)(B) (2006). They explained that a disclosure that is made pursuant to § 3730(b)(2) is not voluntary. *King*, 264 F.3d at 1280 ("It is also clear from the statutes that compliance with the disclosure requirements of § 3730(b)(2) at the time of filing does not satisfy the pre-filing disclosure requirement of § 3730(e)(4)."); *Farmington*, 166 F.3d at 866 (same).[1] Like the court in *Beauchamp*, I see no reason to depart from this reasoning in construing the identical word in the post-amendment definition.

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1. Omni argues that *King* and *Farmington* mean only that the timing of the disclosure matters. Specifically, Omni contends that, if made adequately in advance of filing, rather than post-filing, disclosures qualify as voluntary under *King* and *Farmington*, even if they were made to comply with the § 3730(b)(2) disclosure obligation. However, I read *King* and *Farmington* as standing for a broader proposition that any disclosure that is made to comply with § 3730(b)(2) is not a voluntary disclosure. *Farmington*, for example, contrasted § 3730(b)(2) disclosures with examples of how a relator might satisfy the statutory requirement, such as "by notifying the United States Attorney, the FBI, or other suitable law enforcement office of the information which is the basis for the action, or by informing the agency or official responsible for the particular claim." 166 F.3d at 866. Thus, in my view, these cases treated § 3730(b)(2) disclosures as distinct from voluntary disclosures.

Omni's arguments to the contrary are unpersuasive. It contends that "[i]t is clear from the post-2010 statute that the only requirement is that the disclosure to the government come before the public disclosure." Relator's Opp'n 6. But this argument reads the voluntary requirement out of the statute. The disclosure must come not only "prior to a public disclosure," but it also must be made "voluntarily." 31 U.S.C. § 3730(e)(4)(B)(i). Omni also argues that I should not rely on authority construing the pre-amendment original source definition because the pre-amendment statute "spoke of disclosure to the government before *filing*," whereas post-amendment, the statute "requires disclosure to the government before *public disclosure*." Relator's Opp'n 7. But Omni offers no explanation as to why this distinction should matter when construing the identical word—voluntarily—in the post-amendment statute.

This conclusion is supported by cases addressing the voluntariness requirement in contexts other than § 3730(b)(2) disclosures. In *United States ex rel. Fine v. Chevron, U.S.A., Inc.*, 72 F.3d 740 (9th Cir. 1995), the Ninth Circuit held that a salaried government employee who was compelled to disclose the fraud as part of his job responsibilities "was no volunteer." *Id.* at 743. He "acted in exchange for valuable consideration—his salary—and under an employment-related obligation to do the very acts he claims were voluntary." *Id.* at 744. Similarly, in *United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326 (3d Cir. 2005), the Third Circuit determined that disclosures made in response to a subpoena were not voluntary. They were "precipitated by a subpoena and sustained by [the

relator's] self-interest," namely, to obtain a favorable outcome in the government's investigation. *Id.* at 341. Like *Fine* and *Paranich*, Omni was no mere volunteer. Omni's disclosures were made pursuant to a legal obligation and in return for valuable consideration in the form of a possible *qui tam* award. By contrast, for example, courts have found disclosures to be voluntary where apparently unconnected to a *qui tam* lawsuit the relator wrote a letter to the Department of Justice requesting an investigation, *Cause of Action v. Chi. Transit Auth.*, 815 F.3d 267 (7th Cir. 2016), or met with Department of Defense officials, *U.S. ex rel. Lujan v. Hughes Aircraft Co.*, 162 F.3d 1027 (9th Cir. 1998).[2]

In sum, since the Complaint does not allege facts showing that Omni "voluntarily" disclosed information to the Government before the relevant public disclosures, its allegations do not meet the post-amendment original source exception's first avenue.

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2. *United States ex rel. Godecke v. Kinetic Concepts, Inc.*, 2016 U.S. Dist. LEXIS 200425, 2016 WL 11688143 (C.D. Cal. Aug. 30, 2016), relied upon by Omni, provides no persuasive authority in Omni's favor. *Godecke* held that disclosures made in a meeting with the U.S. Attorney's Office, before the relator amended her complaint to add a new claim, were voluntary. The court in *Godecke*, however, apparently was not presented with, and did not address, the issue presented here, namely, whether § 3730(b)(2) disclosures are voluntary disclosures. Additionally, adopting the definition of voluntary that Omni argues *Godecke* used—"[a]cting, or done, of one's own free will without valuable consideration; acting or done without any present legal obligation to do the thing done or any such obligation that can accrue from the existing state of affairs," 2016 U.S. Dist. LEXIS 200425, [WL] at *9 (quoting *Fine*, 72 F.3d at 744)—Omni would not succeed.

Finally, Omni requests that I consider the declaration of J. Marc Vezina, relator's former counsel, which it attaches to its opposition brief. The declaration sets forth facts that are not alleged in the Complaint, relating to Mr. Vezina's discussions with the government prior to the filing of Omni's 2012 complaints. Such a declaration cannot be considered in ruling on a Rule 12(b)(6) motion to dismiss. *Gray Gables Corp. v. Arthur*, 2022 U.S. App. LEXIS 8194, 2022 WL 905393, at *2 (2d Cir. Mar. 29, 2022); *Faulkner v. Beer*, 463 F.3d 130, 134 n.1 (2d Cir. 2006). However, in the interest of avoiding further motion practice on this issue, I note that were I to consider it, it would not suffice. Mr. Vezina describes all of these disclosures as part and parcel of Omni's § 3730(b)(2) mandatory disclosure obligation. For the reasons discussed above, the declaration does not show that these disclosures were voluntary. On the contrary, it shows the opposite.[3]

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3. Mr. Vezina states the following in his declaration: in late 2011, after Omni retained Mr. Vezina, Mr. Vezina "reached out" to the U.S. Attorney's Office in Boston and his "law firm prepared a prefiling disclosure statement in this matter," which was provided to the government. Vezina Decl. ¶ 6. After a meeting with Mr. Vezina and Dr. Deligdish, the U.S. Attorney's Office in Boston informed Mr. Vezina that the case "would have to be filed" in Brooklyn and to contact the U.S. Attorney's Office in Brooklyn. *Id.* ¶ 10. Subsequently, Mr. Vezina and Dr. Deligdish met with government attorneys, including from the U.S. Attorney's Office in Brooklyn, and, at the meeting, "Relator conveyed his intention to file the case in that District." *Id.* ¶ 12. Mr. Vezina's office then set up a "Sharepoint site" with the government and "all documents relating to the matter were uploaded, including the disclosure statement." *Id.* ¶ 13. The original complaint in the case was filed shortly thereafter. Following that filing, in July 2012, Mr. Vezina

### b. Material Addition to the Public Disclosures

With respect to the second avenue for meeting the post-amendment original source exception, U.S. Oncology argues that Omni does not materially add to the prior public disclosures. To begin with, much of Omni's opposition brief, with respect to 31 U.S.C. § 3730(e)(4)(B)(2), merely repeats arguments that it made in its opposition to the motion to dismiss its original complaint and expresses its disagreement with the *U.S. Oncology I* decision. Since all of Omni's now repeated arguments were fully considered in that decision and rejected, I do not address them again. I consider here only the newly added allegations.

In order "for new allegations to 'materially add' to public disclosures, they must 'substantially' or 'considerably' add to information that is already public." *Vierczhalek v. MedImmune Inc.*, 803 F. App'x 522, 526 (2d Cir. 2020). Prior public disclosures had disclosed that U.S.

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"began preparing a new disclosure statement as to McKesson, OTN, and U.S. Oncology" and "notified the government" "of the intent to amend the complaint in EDNY to add against McKesson, OTN, and U.S. Oncology, as well as the reasons for the amendment." *Id.* ¶¶ 16–17. In August 2012, Mr. Vezina's law firm "finished the new disclosure statement and provided it to the government." *Id.* ¶ 18. Mr. Vezina's subsequent discussions with the government in September and October 2012 concerned the "substance of the new disclosure statement" and the "imminent filing of the amended complaint." *Id.* ¶¶ 21, 23. The amended complaint was then filed.

Oncology harvested overfill and billed the Government for it, and that it knew this practice to be illegal. Omni contends that the Complaint materially adds to such disclosures because it now names specific individuals who can attest to the fact that U.S. Oncology harvested overfill and billed the Government for it, and it names one physician, Dr. Kolodziej, who can attest to the fact that U.S. Oncology knew this practice to be illegal.

Generally, "the 'materially adds' requirement . . . focuses on the *substance* of the allegations, not the *source*." *U.S. ex rel. Reed v. KeyPoint Gov't Sols.*, 923 F.3d 729, 760 (10th Cir. 2019). For example, in *Ping Chen ex rel. United States v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282 (S.D.N.Y. 2013), the court rejected the relator's argument that alleging that his "colleagues professed to him that they too were aware of, or complicit in, a fraud" materially added "to the already robust universe of publicly-available information regarding [the] schemes." *Id.* at 300. The relator identified some of his colleagues by name and others by the name of their current employer. *Id.* at 288–89. As in *EMSL*, Omni's identification of individuals with knowledge of an already publicly disclosed fraud does not materially add to prior public disclosures.

Omni argues that, by identifying Dr. Kolodziej, it alleged evidence of scienter, and "[c]ourts have found that evidence of scienter 'materially adds'" to the public disclosures. Relator's Opp'n 12. However, except for the identification of Dr. Kolodziej, the prior public disclosures already alleged that U.S. Oncology knew that it was unlawful to bill Medicare for the overfill, so this allegation cannot materially add to them. By contrast, in the case

relied on by Omni, *United States ex rel. Mitchell v. CITBank, N.A.*, 2022 U.S. Dist. LEXIS 6960, 2022 WL 135438 (E.D. Tex. Jan. 13, 2022), which found that the relator's "specific detail[ed]" scienter allegations were a material addition, the prior public disclosures had contained "no hint" that Defendants' "actions were taken *knowingly*." 2022 U.S. Dist. LEXIS 6960, [WL] at *8.

In sum, the Complaint does not meet the post-amendment original source exception's second avenue.

Omni's FCA claims are dismissed.

**B. State and Local Law Claims**

Having dismissed Omni's FCA claims, I decline to exercise supplemental jurisdiction over its state, local, and common law claims. *See* 28 U.S.C. § 1367(c)(3); 31 U.S.C. § 3732(b).

**IV. Conclusion**

For the reasons set forth above, U.S. Oncology's motion to dismiss the Complaint is granted.

**SO ORDERED**.

**/s/ NINA GERSHON**
**NINA GERSHON**
**United States District Judge**

September 8, 2023
Brooklyn, New York

**APPENDIX C — OPINION & ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, FILED JULY 21, 2022**

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

19-cv-5125 (NG) (LB)

UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, WISCONSIN, THE CITY OF CHICAGO, AND THE CITY OF NEW YORK ex rel. OMNI HEALTHCARE INC.,

*Plaintiffs,*

-against-

U.S. ONCOLOGY, INC.,

*Defendant.*

Filed July 21, 2022

*Appendix C*

## OPINION & ORDER

**GERSHON, United States District Judge**:

### I. Introduction

Relator Omni Healthcare Inc. ("Omni") brings this *qui tam* action on behalf of the United States, 30 states, the District of Columbia, and the cities of New York and Chicago against U.S. Oncology, Inc. ("U.S. Oncology"), alleging violations of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, analogous state statues, and the common law. U.S. Oncology moves to dismiss the action in its entirety under Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure, principally arguing that the FCA's "public disclosure bar" bars the action.

This case raises the question whether a relator's *qui tam* action against a defendant, that was previously dismissed from an action brought by the same relator by reason of the FCA's first-to-file provision, is subject to the public disclosure bar, and if so, whether the relator may, nonetheless, proceed with the action because it qualifies under the public disclosure bar's exception for an "original source of the information." For the following reasons, I find that the public disclosure bar is applicable to Omni's re-filed action and that Omni has not established that it is an "original source of the information." Accordingly, the motion is granted.

*Appendix C*

## II. Relevant Procedural History

### A. The Underwood Action

On May 28, 2010, relator John Underwood filed a complaint in this district under seal (the "Underwood Complaint"). Underwood brought FCA and analogous state law claims against 50 defendants, including the drug manufacturer Amgen, Inc., 12 other drug manufacturers, 23 drug repackagers, and 14 health care providers, including U.S. Oncology. The allegations in the Underwood Complaint were based on the observation of the relator during his employment with one of the defendant drug manufacturers between 1986 and 2005. The Underwood Complaint summarized its allegations as follows:

> Although expansive in scope, the fraudulent scheme is straightforward. With the knowledge and participation of Defendant Health Care Providers and Manufacturers, Defendant Repackagers unlawfully manipulated the licensed biologic drugs by repeatedly entering single-use and multi-use vials, extracting and/or pooling the overfill, and repackaging the product into smaller doses that are re-labeled and placed in interstate commerce for delivery to health care providers. . . . [f]urther, the manipulation of the drugs in violation of approved labeling adulterates and misbrands the products under the [Federal Food, Drug & Cosmetic Act (the "FDCA")], [the Public Health Services Act (the "PHS Act")], and violates

the requirements that licensed biologic drugs comply with commercial good manufacturing practices ("CGMP") and [Food and Drug Administration ("FDA")] regulations set forth at 21 C.F.R. § 600 *et seq.* . . .

Defendant Manufacturers have participated in the scheme. Driven by competition and the desire to increase market share, Defendant Manufacturers routinely fill containers of licensed biologic product . . . in amounts greater than the FDA labeled quantity or the dose to be administered to a patient. . . . Defendant Manufacturers illegally market the overfill to health care providers as an excess, free biologic product that had been recaptured, repackaged, administered to patients, and billed to the Federal Payer Programs. With the assistance of Defendant Repackagers or through in-house pharmacies, providers pool the overfill amount from one or more doses to create additional doses, as well as divide and re-manufacture the single-use vials to create smaller doses that are administered to patients. . . .

Defendant Health Care Providers were encouraged to and in fact did seek reimbursement from the Federal Payer Programs for the repackaged drugs. In so doing, providers have billed the Federal Payer Programs for the repackaged product by, for example, purchasing one single-use dose, but billing for more than one dose by illegally repackaging

> the finished product. The conduct results in illegal kickbacks and price concessions concealed from federal and state governments. The conduct violates the FDCA, PHS Act, and the requirement that licensed biologic drugs comply with commercial good manufacturing practices and FDA regulations set forth at **21 C.F.R.** § **600** *et seq.*

Underwood Complaint ¶¶ 7–10. The relator further alleged that the health care provider defendants, including U.S. Oncology, "unlawfully remanufacture the drugs in-house . . . administer them to patients, and bill them to the Federal Payer Programs." *Id.* ¶ 159(D). With respect to U.S. Oncology specifically, it alleged that "US Oncology knowingly purchases repackaged biologic drugs for administration to patients and/or manipulates and repackages licensed finished biologic drugs internally in violation of the FDCA and PHS Act." *Id.* ¶ 76. The relator alleged that the fraudulent scheme affected a long list of "biologic drugs," which "include, but are not limited to," certain oncology drugs. *Id.* ¶ 14.

On April 29, 2016, the United States declined to intervene in Underwood. The action was unsealed on May 10, 2016, and it was voluntarily dismissed without prejudice on September 7, 2016.

### B. The Omni I Action

On March 9, 2012, after the Underwood Complaint was filed, but before it was unsealed and voluntarily dismissed,

Omni filed a *qui tam* complaint (the "Omni I Complaint") under seal alleging FCA and analogous state law violations against AmerisourceBergen Corporation ("ABC") and three affiliated companies (collectively "ABC defendants"). On October 9, 2012, Omni filed, also under seal, its First Amended Complaint (the "Omni I FAC"), which added as defendants McKesson Corporation ("McKesson"), Oncology Therapeutics Network Corporation ("OTN"), and U.S. Oncology. The Omni I FAC characterized each of these defendants as a "Defendant Manufacturer/ Distributors." Omni I FAC ¶ 31. The Omni I FAC summarized its allegations as follows:

> Beginning in 2001, Defendant Manufacturer/ Distributors have taken certain injectable oncology drugs . . . which come already packaged by the original manufacturer in single dose and/or multi-dose vials and remove and pool the oncology liquid from those vials to be placed into Defendant Manufacturer/ Distributors' own pre-filled syringes which are then distributed to the provider/physicians for patient treatment. It is this conduct, the removal and pooling of Oncology Drugs into Defendant Manufacturer/Distributors' own pre-filled syringes through their own Pre-filled Syringe Program, which forms the basis of the Complaint.

*Id.* ¶ 32.

The United States intervened with respect to certain claims against the ABC defendants. Upon Omni's

motion, Omni's claims against McKesson, OTN, and U.S. Oncology were severed. The United States declined to intervene in the severed action. On April 3, 2018, Omni publicly filed a Second Amended Complaint (the "Omni I SAC"), adding five additional McKesson subsidiaries as defendants: McKesson Specialty Care Distribution Corporation, McKesson Specialty Distribution LLC, McKesson Specialty Care Distribution Joint Venture, L.P., Oncology Therapeutics Network Joint Venture, L.P., and US Oncology Specialty, L.P. On December 6, 2018, all filings in the action made on or after April 3, 2018, including a copy of the Omni I FAC, were unsealed.

The Omni I SAC's allegations are described in detail in my order dismissing that action by reason of the first-to-file bar as against U.S. Oncology, *United States ex rel. Omni Healthcare Inc. v. McKesson Corp.*, 2019 U.S. Dist. LEXIS 17574, 2019 WL 438357 (E.D.N.Y. Feb. 4, 2019), familiarity with which is presumed. Notably, with respect to U.S. Oncology, the Omni I SAC alleged that "apart from those physicians purchasing the Oncology Drugs in prefilled syringes from U.S. Oncology's distribution network, U.S. Oncology's affiliated physician offices, vis-à-vis their staff, harvested overfill when administering the Oncology Drugs to their patients." Omni I SAC ¶ 146. It also alleged that U.S. Oncology-affiliated physician's offices "would not properly record that overfill, and would subsequently bill government reimbursement programs for that overfill." *Id.*

In opposing dismissal, Omni agreed that Underwood was "pending" when it filed Omni I, but contended that the

first-to-file bar did not apply because Underwood alleged a different fraudulent scheme and, thus, was not "related" to Omni I. *McKesson*, 2019 U.S. Dist. LEXIS 17574, 2019 WL 438357, at *7. I concluded that Underwood was related to Omni I only as to defendant U.S. Oncology:

> The FAC, like the complaint in Underwood, alleges that US Oncology, Inc. engaged in specific fraudulent conduct concerning overfill of injectable cancer drugs. Both describe how US Oncology, Inc. harvested overfill from sterile vials and repackaged the overfill in prefilled syringes in violation of the CGMPs and [United States Pharmacopeia] standards. The two cases allege that this conduct occurred during overlapping periods of time and with respect to overlapping groups of drugs. However, there need not be perfect identify between every factual element of related frauds. All that is required is that the cases 'rely on the same essential facts.' I conclude that, because Underwood disclosed that defendant US Oncology, Inc. engaged in the same fraudulent conduct, with respect to injectable oncology drugs, during an overlapping time period, Omni's claims against US Oncology, Inc. are related to Underwood, and consequently barred by it.

2019 U.S. Dist. LEXIS 17574, [WL] at *8 (internal citations omitted).[1] Although I based my decision on the relatedness

1. I held that, in assessing relatedness, the Underwood Complaint should be compared to the Omni I FAC, rather than

of the Underwood Complaint and the Omni I FAC, I noted that the Omni I SAC reinforced my conclusion. 2019 U.S. Dist. LEXIS 17574, [WL] at *8 n.5. The Omni I SAC alleged that U.S. Oncology itself administered prefilled syringes containing overfill to patients and filed false claims; those allegations also appeared in the Underwood Complaint. *Id.*

Concluding that the first-to-file bar barred Omni's federal claims against U.S. Oncology, I dismissed Omni's claims against U.S. Oncology without prejudice. *Id.* at *13.[2]

### C. Omni Files the Omni II Complaint

Following U.S. Oncology's dismissal from Omni I, Omni filed the instant complaint against U.S. Oncology (the "Omni II Complaint").

## III. The Omni II Complaint's Allegations

The following facts are drawn from the Omni II Complaint and are assumed to be true for purposes of this motion.

Relator Omni is a professional medical company primarily based in Florida. Omni II Complaint ¶ 24. Through physicians in central Florida, Omni practices hematology and oncology and regularly treats cancer

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the Omni I SAC. *McKesson*, 2019 U.S. Dist. LEXIS 17574, 2019 WL 438357, at *8 n.4.

2. I also dismissed the common law claims and declined to exercise supplemental jurisdiction over the remaining state law claims against U.S. Oncology.

patients. *Id.* Omni also regularly purchases drugs from various distributors and wholesalers to treat its patients. *Id.* Omni alleges that it is an "original source" of the facts and information in Omni II.[3] *Id.* ¶ 25. Omni's sole allegation in support of its original source status is that the "facts averred herein are based upon the personal knowledge [of] Relator's principal, and documents and information in his possession, which were acquired by him in connection with his work as an oncologist treating patients with cancer." *Id.*

Defendant U.S. Oncology is a Delaware corporation with its principal place of business in The Woodlands, Texas, and a wholly owned subsidiary of McKesson. *Id.* ¶ 26. U.S. Oncology operates more than 450 cancer treatment center locations nationwide, with more than 1,400 affiliated physicians in a network called the U.S. Oncology Network (the "Network"). *Id.* ¶ 1. Beginning in 2005, U.S. Oncology also distributed pharmaceutical drugs to the Network through U.S. Oncology Specialty, LP. *Id.*

The Omni II action "arises from Defendant's unlawful conduct in connection with its harvesting of overfill from certain cancer drugs and administering the overfill to cancer patients and other immune-compromised patients."

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3. As discussed below, if the FCA's public disclosure bar applies, qualifying as an "original source" is the statutory standard that Omni must meet for this action to proceed. Of course, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009).

*Id.* ¶ 3. Omni alleges that the fraudulent scheme involved all cancer drugs that come packaged "by the original manufacturer in single dose and/or multi-dose vials." *Id.* Omni describes the drugs at issue as the "Oncology Drugs." *Id.* U.S. Oncology sold the Oncology Drugs to U.S. Oncology physicians in the Network. *Id.* ¶ 113.

The central allegation in Omni II is that pharmacists or technicians at each office in the Network, who were employed by U.S. Oncology or acting under its direction, "punctured original, sterile glass vials more than once and pooled the overfill from the Oncology Drugs, transferring overfill from multiple sources into syringes for delivery to unsuspecting patients." *Id.* ¶¶ 114, 117. By doing so, U.S. Oncology violated nine CGMP standards, rendering the drugs adulterated. *Id.* ¶ 116.

According to the Omni II Complaint, U.S. Oncology "advocated that its physicians utilize 'overfill billing' for the Oncology Drugs administered to patients." *Id.* ¶ 113. U.S. Oncology "kept a record of the average overfill in each different oncology medication vial as different medications contained different amounts of overfill and documents with these overfill amounts were distributed regularly to members of the U.S. Oncology Network between 2003 and 2014 to encourage and facilitate physicians to administer overfill to patients." *Id.* ¶ 112. Staff employed by U.S. Oncology, then, submitted false and fraudulent claims for reimbursement to the federal and state government and private payers for the overfill. *Id.* ¶ 114. U.S. Oncology

engaged in this conduct from 2003 through at least October 2014. *Id.* ¶ 115.

U.S. Oncology certified that it complied with "all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law)" when it submitted claims to Medicare Part B for professional services, filed annual cost reports to federal and state health care programs, and, as part of provider agreements with the Center for Medicare & Medicaid Services ("CMS"), which administers Medicare and works in partnership with state governments to administer Medicaid. *Id.* ¶¶ 53, 133–135. But these certifications were false because U.S. Oncology submitted claims for reimbursement for overfill, which is not reimbursable under Medicare or Medicaid. *Id.* ¶¶ 100, 117. Adulterated and compounded drugs also are not reimbursable by any governmental health program or private insurance company. *Id.* ¶ 147.

Omni alleges that U.S. Oncology's overfill scheme also violated the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), artificially inflated the drugs's Average Sales Price ("ASP") and led to removal of the drugs's "pedigree." *Id.* ¶¶ 113, 117, 127–28, 141.

As an Exhibit to the Omni II Complaint, Omni attached examples of false claims that had been filed. *Id.* ¶ 120; *id.*, Ex. 1.

## IV. Discussion

### A. FCA FRAMEWORK

The FCA imposes liability on "any person who 'knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval' to the Government or any person who 'knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.'" *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 166 (2d Cir. 2018) (quoting 31 U.S.C. § 3729(a)(1)(A)-(B)). "Rather than rely solely on federal enforcement of these provisions, Congress decided to deputize private individuals, encouraging them to come forward with claims on behalf of the Government in the form of *qui tam* suits." *Id.* The FCA's *qui tam* provisions allow a private party, called the relator, to challenge fraudulent claims against the Government on the Government's behalf, ultimately sharing in any recovery. *Id.* The Government may intervene in any *qui tam* action, "in which case the action shall be conducted by the Government," and the relator's recovery thereby reduced, or it may decline to take over the action, in which case the relator "shall have the right to conduct the action." 31 U.S.C. § 3730(b)(4)(A)-(B), (d)(1).

### B. The Public Disclosure Bar

The FCA includes several limiting provisions. Relevant to this motion is the provision known as the "public disclosure bar," which was enacted as part of the 1986 amendments to the FCA, and amended in 2010, as

part of the Patient Protection and Affordable Care Act (the "PPACA"). Congress's purpose in amending the FCA in 1986 was to strike "the golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own." *Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 294, 130 S. Ct. 1396, 176 L. Ed. 2d 225 (2010). As part of these amendments, Congress enacted the public disclosure bar in an apparent "effort to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits." *Id.* at 295. Following the 1986 FCA amendments, the bar provided as follows:

> (A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, 'original source' means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4) (2006). In this, its original form, the public disclosure bar was "jurisdictional;" if the bar applied, it divested the court of its subject matter jurisdiction over an action. *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 467, 127 S. Ct. 1397, 167 L. Ed. 2d 190 (2007).

Congress's use of the phrase "based upon" in the public disclosure bar led to a disagreement among the Circuit Courts of Appeals. The minority view, held by the Fourth Circuit, was that "based upon" meant that the bar applied only when the relator's allegations were "derived from" public disclosures. *U.S. ex rel. Siller v. Becton Dickinson & Co. By & Through Microbiology Sys. Div.*, 21 F.3d 1339, 1348 (4th Cir. 1994). The majority view, held by all other Courts of Appeals, was that a lawsuit is "based upon" public disclosures when the relator's allegations are "substantially similar" to publicly disclosed allegations or transactions, *U.S. ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 324 (2d Cir. 1992); *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 915, 920 (7th Cir. 2009), even if the relator obtained its information from a different source. *John Doe*, 960 F.2d at 324.

In 2010, Congress again amended the FCA, including the public disclosure bar, as part of the PPACA. *See Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 293 (S.D.N.Y. 2013). Following the 2010 amendments, which became effective on March 23, 2010, the public disclosure bar provides as follows:

> (4)(A) The court shall dismiss an action or claim under this section, unless opposed by

> the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—
>
> > (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
> >
> > (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
> >
> > (iii) from the news media,
>
> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, 'original source' means an individual who either (i) prior to a public disclosure under subsection (e)(4)(A), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

31 U.S.C. § 3730(e)(4). Thus, Congress made several changes to the bar's text, although "no direct legislative

history seems to exist." *U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 299 (3d Cir. 2016).

The current version of the bar is no longer jurisdictional. Instead, it serves as a ground for dismissal, such "as an affirmative defense or in connection with [a] motion to dismiss." *U.S. ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 80 (2d Cir. 2017). Congress's use of the phrase "substantially the same allegations or transactions" has been read to adopt the majority view of the Circuit Courts, which construed the words "based upon" as "substantially similar" to public disclosures. *EMSL Analytical*, 966 F. Supp. 2d at 297 n.11. Accordingly, pre-PPACA cases determining whether substantially similar allegations or transactions were publicly disclosed prior to the relator's filing of its complaint remain instructive for interpreting the current version of the bar. *Id.*

Because U.S. Oncology's conduct occurred "from 2003 through at least October 2014," both versions are relevant. "The pre-2010 version of the public disclosure bar applie[s] to any conduct that occurred prior to the amendment and [] the post-2010 version applie[s] to any conduct that occurred after the effective date of the 2010 amendment." *U.S. ex rel. Patriarca v. Siemens Healthcare Diagnostics, Inc.*, 295 F. Supp. 3d 186, 195 (E.D.N.Y. 2018) (first and third alterations in original) (collecting cases).

Under both the pre-and post-PPACA versions, courts in the Second Circuit employ a two-step approach. *Id.* at 196. At step one, courts consider whether substantially

the same allegations or transactions have been publicly disclosed via an enumerated source prior to the filing of the action. *See id.* If so, courts look to whether the suit may, nonetheless, go forward because the relator is an "original source of the information" underlying the allegations. *See id.*

### i. Public Disclosures

Omni does not contend, at step one, that Underwood or Omni I did not publicly disclose substantially the same allegations or transactions as Omni II. Omni, instead, argues that the public disclosure bar is not applicable at all. It contends that the public disclosure bar does not apply to a *qui tam* complaint filed against a defendant that was dismissed from a relator's own prior action by reason of the first-to-file bar, if the prior action was filed before any public disclosure. For several reasons, this argument is not persuasive.

By the pre-amendment bar's plain terms, "[n]o court shall have jurisdiction over an action" and, by the post-amendment bar's plain terms, the "court shall dismiss an action or claim," if substantially the same allegations or transactions were publicly disclosed via an enumerated source. The FCA's plain language deprives courts of jurisdiction over "an action," or mandates dismissal of an "action or claim", once there has been such a public disclosure. The public disclosure bar provides for only two exceptions: if "the action is brought by the Attorney General or the person bringing the action is an original source of the information." Omni seeks to carve out its

own exception: if the person bringing the action had previously brought an action against the defendant, who was dismissed by application of § 3730(b)(5). But that exception is not provided for in the text.[4]

As the Second Circuit has held, the public disclosure bar is applicable regardless of "where the relator obtained [its] information," once the "information on which a *qui tam* suit is based is in the public domain." *John Doe*, 960 F.2d at 324. This rule applies even if the relators's own earlier filed state-court complaint, setting forth many of the same allegations, was the public disclosure barring the later filed federal *qui tam* action. *See United States v. N.Y. Med. Coll.*, 252 F.3d 118 (2d Cir. 2001). Numerous courts outside of this circuit have, similarly, considered a relator's *qui tam* complaint, filed in a prior action, as a public disclosure that could bar its own later *qui tam* action. *E.g., U.S. ex rel. Schweizer v. Canon, Inc.*, 9 F.4th 269, 275–76 (5th Cir. 2021); *U.S. ex rel. Folliard v. Comstor Corp.*, 308 F. Supp. 3d 56, 74–77, 77 n.13 (D.D.C. 2018); *U.S. ex rel. Bly-Magee v. Premo*, 470 F.3d 914, 916–17 (9th Cir. 2006); *see also U.S. ex rel. Atkinson v. PA. Shipbuilding Co.*, 473 F.3d 506, 521 (3d Cir. 2007) (explaining that filing a *qui tam* complaint before any public disclosure does not "insulate [a relator's subsequent *qui tam*] action from normal public disclosure analysis").

4. Nor does the text of the statute support Omni's argument that Omni II is merely a "continuation of" Omni I. Opp. 3. The public disclosure bar deprives a court of jurisdiction over an "action" or requires dismissal of an "action or claim." Clearly, the "action" that must be considered is the one that is before the court on the instant motion to dismiss, not a prior action from which U.S. Oncology was dismissed.

While these cases did not involve a defendant that had been dismissed from a relator's prior action by reason of the first-to-file bar, there is no basis in the text or Second Circuit precedent to distinguish these decisions on that ground alone. Here, both Underwood and Omni I were "in the public domain" before Omni filed Omni II.

Applying the public disclosure bar in this case also comports with the purposes that the public disclosure bar serves. The public disclosure bar has been said to have been "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." *John Doe*, 960 F.2d at 322 (quoting *U.S. ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1155–56 (3d Cir. 1991)). Here, before Omni II was filed, the information in the Underwood Complaint and Omni I SAC was available to any member of the public that wanted to review those publicly accessible dockets.

Other Courts of Appeals have explained that the public disclosure bar seeks "to prevent suits by those other than an 'original source' when the government already has enough information to investigate the case or where the information could at least have alerted law-enforcement authorities to the likelihood of wrongdoing." *U.S. ex rel. Doe v. Staples, Inc.*, 773 F.3d 83, 86, 413 U.S. App. D.C. 208 (D.C. Cir. 2014) (internal quotation marks omitted); *see Glaser*, 570 F.3d at 913. No party contends that Underwood and Omni I did not already alert the government to substantially the same allegations or

transactions as are alleged in Omni II. Finally, the First Circuit made a similar point in rejecting an argument that a relator's subsequent *qui tam* action could not be parasitic of its own prior *qui tam* action:

> Such an exception strikes us as unnecessary. The qui tam mechanism is intended to encourage people to blow the whistle on fraud. If they have already done so, whether to take advantage of a qui tam reward or for other reasons, there seems to be little need to encourage them to give the whistle a second toot. Furthermore, the "original source" exception already ensures that the most valuable relators—typically insiders with direct and independent knowledge of fraud—will not be barred by prior public disclosures, whether made by the relators themselves or others.

*U.S. ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 113 (1st Cir. 2010).

Omni urges that the Supreme Court's decision in *Kellogg Brown & Root Servs. Inc. v. U.S. ex rel. Carter*, 575 U.S. 650, 135 S. Ct. 1970, 191 L. Ed. 2d 899 (2015), "expressly sanctioned" a relator's ability to file a new action, against a defendant that was dismissed on first-to-file grounds, once the related action that was the basis for the defendant's dismissal is no longer "pending." Opp. 5. But *Kellogg* merely held that, for purposes of the first-to-file bar, a *qui tam* suit "ceases to be 'pending' once it is dismissed." *Kellogg*, 575 U.S. at 664.

Omni also cites *U.S. ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163 (2d Cir. 2018) in support of its position. But *Wood*, like *Kellogg*, concerned the first-to-file bar, not the public disclosure bar, and held that "a first-to-file violation cannot be cured by amending or supplementing a complaint." *Wood*, 899 F.3d at 175. Omni refers to dicta in *Wood* that "in many circumstances, absent a statute of limitations issue, the relator will be able to re-file her action," but Omni omits the rest of the sentence, which states "without violating the first-to-file bar." *Id.* at 174.

Indeed, *Wood* even recognized that the first-to-file bar poses risks for would-be relators. In that case, the Second Circuit explained that the "FCA's scheme is difficult for relators, who may substantially invest in claims, only to find out that a recently unsealed complaint blocks their action, months if not years down the road," but that "is how Congress designed the statutory scheme, and it is carefully calibrated." *Id.* at 174.

Finally, I recognize Omni's argument that U.S. Oncology's position could subject many "refiled *qui tam* complaints to the public-disclosure bar after an initial dismissal without prejudice." Opp. 6. But Congress made no exception for actions against defendants that had been previously dismissed under the first-to-file rule. The only exception provided for is when the relator is the "original source of the information."[5]

5. Omni's reliance on *U.S. ex rel. Beauchamp v. Academi Training Ctr.*, 816 F.3d 37 (4th Cir. 2016), is also misplaced. *Beauchamp* stands for the proposition that the public disclosure bar will not bar a relator from adding "further detail about a claim

### ii. Original Source of the Information

Because the public disclosure bar applies, I turn to whether Omni's action may, nonetheless, go forward on the ground that Omni is an "original source of the information." U.S. Oncology contends that Omni does not meet the "original source" exception. I agree. Omni has not alleged facts from which it can be inferred that it meets this exception under either the pre-or post-amendment version of the bar.

#### 1. Pre-amendment "Original Source"

Under the pre-amendment bar, which, as discussed above, was jurisdictional, to qualify as an original source, an individual must have "direct and independent knowledge of the information on which the allegations are based" and have "voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4) (2006). U.S. Oncology contends only that Omni has not shown that it has "direct and independent" knowledge.

Direct and independent knowledge "impose[s] a conjunctive requirement—direct *and* independent—on *qui tam* plaintiffs," *U.S. ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 656, 304 U.S. App. D.C. 347 (D.C. Cir. 1994), and the relator bears the burden of proving the existence of subject matter jurisdiction. *See Malik v. Meissner*, 82 F.3d 560, 562 (2d Cir. 1996).

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already alleged." *Id.* at 45. It has no bearing on how the public disclosure bar should operate with respect to a newly filed action.

*Appendix C*

The "paradigmatic" example of a relator with direct knowledge "is a whistleblowing insider," who was a "close observer[] or otherwise involved in the fraudulent activity." *E.g., Stinson*, 944 F.2d at 1161. In contrast, a relator's knowledge is not direct "if a third party is the source of the core information upon which the *qui tam* complaint is based." *N.Y. Med. Coll.*, 252 F.3d at 121 (internal quotation marks omitted). "Courts must be mindful of suits based only on 'secondhand information, speculation, background information or collateral research.'" *U.S. ex rel. Oliver v. Philip Morris USA Inc.*, 826 F.3d 466, 479, 423 U.S. App. D.C. 302 (D.C. Cir. 2016) (quoting *Atkinson*, 473 F.3d at 523).

For example, a relator does not have "direct" knowledge merely because he learned of the fraud through conversations with third parties. In *U.S. ex rel. Piacentile v. Amgen, Inc.*, 2021 U.S. Dist. LEXIS 230133, 2021 WL 5631958, 2021 WL 5631958 (E.D.N.Y. Dec. 1, 2021), a physician, who operated a website that sought to partner with individuals who have information about frauds perpetrated against the U.S. government, lacked direct knowledge of an alleged scheme between the drug manufacturer Amgen and U.S. Oncology. The relator alleged that U.S. Oncology agreed to purchase drugs in exchange for illegal incentives, such as kickbacks, but obtained his knowledge from detailed interviews with top executives at both companies, as part of an "extensive undercover investigation." 2021 U.S. Dist. LEXIS 230133, [WL] at *11; *see also Oliver*, 826 F.3d at 478–80.

And likewise, mere possession of documents that may evidence the fraud is insufficient. For example, in *U.S.*

*ex rel. Kirk v. Schindler Elevator Corp.*, 437 F. App'x 13 (2d Cir. 2011), a relator lacked direct knowledge that his former employer obtained government contracts while falsely representing that it had filed certain reports with the Secretary of Labor. *Id.* at 15. His knowledge was gained through Freedom of Information Act responses indicating that reports were not found for certain years. *Id.* at 18. Similarly, in *U.S. ex rel. Devlin v. California*, 84 F.3d 358 (9th Cir. 1996), relators possessed "ledger cards and sheets" allegedly documenting a fraudulent scheme by the Social Services Department of Mariposa County ("SSD") to obtain increased federal funding. *Id.* at 361 n.5. But they lacked direct knowledge, because the documents, along with other information, were provided to them by an SSD employee, who had participated in the scheme. *Id.* at 361 & n.5.

There are, of course, countless factual variations between, on the one hand, being a corporate insider, who is a close observer of or participant in the fraud and, on the other hand, an individual, who gained his knowledge from third party sources, and courts have reached different conclusions about how far removed from the paradigmatic case can still qualify a relator as having "direct" knowledge.[6]

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6. For example, some courts have suggested that only relators that fall into the paradigmatic case have "direct" knowledge, while others have rejected a bright-line requirement that only a corporate insider, who has participated in or observed an ongoing fraud has direct knowledge. *Compare U.S. ex rel. Schumann v. Astrazeneca Pharms. L.P.*, 769 F.3d 837, 847-48 (3d Cir. 2014), *with U.S. ex rel. Banigan v. PharMerica, Inc.*, 950 F.3d 134, 145 & n.15 (1st Cir. 2020).

But it is not necessary to decide how far removed from the paradigmatic case is sufficient, because Omni's allegations fall far short, *i.e.*, into the category that courts have routinely found do not establish direct knowledge. Omni alleges only that it is an "original source" because of its principal's "personal knowledge" and "documents and information in his possession, which were acquired by him in connection with his work as an oncologist treating patients." Omni II Complaint ¶ 25. From this lone allegation, there is simply no basis from which I can infer that the source of Omni's core information did not come entirely secondhand through conversations with, or documents provided to it by, third parties. Omni has, accordingly, not met its burden of establishing that it is an "original source" under the pre-amendment bar.

In its opposition, Omni argues that it must be an original source because there had been "no public disclosure of any kind" when it brought Omni I. Opp. 13. But a relator does not have "direct and independent" knowledge merely because it was itself the party that "publicly disclosed the information by filing" a lawsuit. *N.Y. Med. Coll.*, 252 F.3d at 122. Omni's argument conflates the distinct requirements that the relator's knowledge be "direct *and* independent." 31 U.S.C. § 3730(e)(4) (2006) (emphasis added). "Independent knowledge" has been defined as "knowledge that is not itself dependent on public disclosure." *Springfield Terminal*, 14 F.3d at 656. While Omni's knowledge may be "independent" of any public disclosure, given that it earlier filed Omni I, that does not render Omni an "original source" when it has

not also alleged that its knowledge is "direct." *See, e.g.*, *Devlin*, 84 F.3d at 361 n.5.[7]

### 2. Post-amendment "Original Source"

As noted above, Congress amended the definition of "original source" as part of the 2010 PPACA amendments. Post-amendment, an individual has two alternative avenues to meet the definition of an "original source." Under the first avenue, an individual who, "prior to a public disclosure . . . has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based" is an original source. 31 U.S.C. § 3730(e)(4)(B)(i). Omni does not argue that it meets this definition.

Under the second avenue, argued by Omni, an individual qualifies as an original source if the individual possesses "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions" and has "voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B)(2). U.S. Oncology contends that Omni has not "materially added" to the publicly disclosed allegations or transactions. Since, as discussed above, the public disclosure bar is now a ground for dismissal, Omni

7. In the same vein, Omni argues that it is an "original source" because it derived all its information from its own investigation. But as the D.C. Circuit explained in rejecting the same argument, a relator's undertaking of an investigation to gain knowledge of a fraud does not in and of itself confer original source status. *Oliver*, 826 F.3d at 477; *see Piacentile*, 2021 U.S. Dist. LEXIS 230133, 2021 WL 5631958, at *11.

must plead "sufficient factual matter . . . to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (internal quotation marks omitted).

In order "for new allegations to 'materially add' to public disclosures, they must 'substantially' or 'considerably' add to information that is already public." *Vierczhalek v. MedImmune Inc.*, 803 F. App'x 522, 526 (2d Cir. 2020). Conversely, "a relator who merely adds detail or color to previously disclosed elements of an alleged scheme is not materially adding to the public disclosures." *U.S. ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 213 (1st Cir. 2016). The relator must add new "value" to the information already in the public domain. *See U.S. ex rel. Maur v. Hage-Korban*, 981 F.3d 516, 527 (6th Cir. 2020); *U.S. ex rel. Hastings v. Wells Fargo Bank, NA, Inc.*, 656 F. App'x 328, 332 (9th Cir. 2016).

Omni contends that Omni II "materially adds" to the information made public by Underwood, but it makes no argument that Omni II "materially adds" to Omni I. Instead, Omni concedes that Omni II makes "the same allegations as to U.S. Oncology that it had made" in Omni I. Opp. 3. For this reason alone, Omni does not qualify as an original source under the post-PPACA public disclosure bar. *See Vierczhalek*, 803 F. App'x at 526 (affirming district court's dismissal of relator's complaint because it did not "materially add" to allegations in publicly disclosed complaint).

Omni I aside, Omni's various arguments that Omni II "materially adds" to Underwood are not persuasive. First, Omni argues that Omni II "extends the relevant timeframe," as compared to Underwood. Opp. 14. In Underwood, the relator alleged fraudulent conduct, occurring between 1986 and 2005, during his employment with Genentech, Inc. But Omni does not argue that the Underwood Complaint suggested a reason to think that U.S. Oncology's fraudulent conduct ended once the relator no longer worked for one of the defendants. That Omni alleges that U.S. Oncology's fraudulent conduct continued—from 2003 through at least October 2014, including after Mr. Underwood left his employment at Genentech, Inc., in 2005—does not substantially add to the information already publicly disclosed. *See Winkelman*, 827 F.3d at 212; *Maur*, 981 F.3d at 528. Indeed, Mr. Underwood did not file the complaint until May 28, 2010, and the government declined to intervene on April 29, 2016 and was presumably investigating those allegations until after the period alleged in Omni II.

Omni's remaining arguments—that it alleges that U.S. Oncology "kept a record of the average amounts of overfill" and "distributed [such records]" to members of the Network in order to "facilitate physicians to administer overfill to patients," "advocated that its physicians utilize 'overfill billing,'" failed to comply with at least nine CGMP standards, named additional oncology drugs, and attached examples of false claims—all merely add "detail or color" to the fraudulent scheme in Underwood. The Underwood Complaint alleged that U.S. Oncology harvested overfill

in violation of CGMP standards, administered overfill to patients, and billed the government for the overfill by filing false claims. It also alleged that the biologic drugs affected, "include, but are not limited to," a long list of drugs, including certain oncology drugs. Underwood Complaint ¶ 14. In short, Omni II merely adds some details to "what is already known in outline." *U.S. ex rel. Ckd Project LLC v. Fresenius Med. Care Holdings Inc.*, 551 F. Supp. 3d 27, 47, 551 F. Supp. 3d 27, 47 (E.D.N.Y. 2021); *see Winkelman*, 827 F.3d at 212–13.

For these reasons, Omni has not alleged that it is an "original source" under either the pre-or post-amendment versions of the public disclosure bar, and its FCA claims are dismissed.

### C. State and Local Claims

Having dismissed Omni's FCA claims, I decline to exercise supplemental jurisdiction over its state, local, and common law claims. *See* 28 U.S.C. § 1367(c)(3); 31 U.S.C. § 3732(b); *see U.S. ex rel. Mohajer v. Omnicare, Inc.*, 525 F. Supp. 3d 447, 461–63 (S.D.N.Y. 2021).

### D. Leave to Amend

Omni requests leave to amend its complaint if it is deemed deficient for any reason. Omni is given 30 days to file a motion for leave to amend.

## V. Conclusion

For the reasons set forth above, U.S. Oncology's motion to dismiss the Omni II Complaint is granted. Omni is given 30 days to file a motion for leave to amend.

**SO ORDERED**.

**/s/ NINA GERSHON**
**NINA GERSHON**
**United States District Judge**

July 21, 2022
Brooklyn, New York

**APPENDIX D — OPINION & ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, FILED FEBRUARY 4, 2019**

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

12-CV-6440 (NG) (LB)

UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, WISCONSIN, THE CITY OF CHICAGO, and THE CITY OF NEW YORK ex rel. OMNI HEALTHCARE INC.,

*Plaintiffs*,

v.

MCKESSON CORPORATION, MCKESSON SPECIALTY CARE DISTRIBUTION CORPORATION, MCKESSON SPECIALTY DISTRIBUTION LLC, MCKESSON SPECIALTY CARE DISTRIBUTION JOINT VENTURE, L.P., ONCOLOGY THERAPEUTICS NETWORK

*Appendix D*

CORPORATION, ONCOLOGY THERAPEUTICS NETWORK JOINT VENTURE, L.P., US ONCOLOGY, INC., and US ONCOLOGY SPECIALTY, L.P.,

*Defendants.*

February 4, 2019, Decided;
February 4, 2019, Filed

**OPINION & ORDER**

**GERSHON, United States District Judge**:

Relator Omni Healthcare Inc. ("Omni") brings this *qui tam* action on behalf of the United States, 30 states, the District of Columbia, and the cities of New York and Chicago against McKesson Corporation ("McKesson") and 7 of McKesson's corporate subsidiaries (collectively "defendants") alleging violations of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, analogous state statues, and the common law. Defendants move to dismiss the Second Amended Complaint ("SAC") in its entirety under Federal Rule of Civil Procedure 12(b)(6), principally arguing that the FCA's "first-to-file" provision bars the action. Secondarily, defendants argue that any claims involving submissions of false claims by an entity another than Omni should be dismissed as not plead with sufficient particularity, as required under Rule 9(b). Finally, defendants argue that certain claims should be dismissed because they fail to state a claim for relief, and/or are time barred, and/or Omni lacks standing to assert them. For

the following reasons, defendants' motion is granted in part and denied in part.

## I. Factual Allegations

The following facts are drawn from the SAC and are assumed to be true for the purposes of this motion.

### 1. General Nature of the Action

Relator Omni alleges that the defendants have engaged in misconduct in the use of "overfill" in vials of injectable drugs intended for the treatment of cancer patients. "Overfill" is the amount of a drug in excess of the amount indicated on the label. Manufacturers of injectable drugs must include some amount of overfill to ensure that the medical provider administering the drug is able to withdraw a full dose from the vial. The central allegation in this action is that defendants intentionally broke into vials of injectable drugs, harvested the dosage and overfill, and then sold syringes, including the overfill, to non-defendant medical providers who wrongfully billed government programs for the overfill. As detailed below, relator Omni alleges that the defendants' conduct not only caused the submission of fraudulent claims, including by Omni itself, but also had negative consequences for patient safety, resulted in the distribution of adulterated and misbranded drugs, and provided an unlawful kickback to medical providers who purchased prefilled syringes. The drugs at issue in this case include Aloxi, Procrit, Aranesp, Neupogen, Taxotere, and Kytril in both the brand and generic forms (the "Oncology Drugs"). Defendants engaged in this conduct from 2001 through at least 2010.

**2. Parties**

Relator Omni is a professional medical company based in Florida. Through its principals, who are physicians, Omni practices internal medicine with subspecialties in hematology and oncology and regularly treats cancer patients. In connection with its treatment of cancer patients, Omni purchases injectable drugs from pharmaceutical distributors and wholesalers.

Defendant McKesson is a Delaware corporation headquartered in California. McKesson is one of the largest pharmaceutical distributors in North America.

Defendant US Oncology, Inc. is a Delaware corporation headquartered in Texas that provides drug distribution and specialty pharmacy services. McKesson purchased US Oncology, Inc. and its subsidiary, US Oncology Specialty, L.P. in December 2010. US Oncology Specialty, L.P., is a pharmaceutical distributor specializing in oncology drugs.

The remaining defendants are other subsidiaries of McKesson. McKesson Specialty Care Distribution Corporation ("McKesson Specialty") is a health care services company that distributes medical supplies and pharmaceutical products to the health care industry, including to specialty medical providers such as oncologists. McKesson Specialty is the successor to defendant McKesson Specialty Care Distribution Joint Venture, L.P., which is itself the successor-in-interest to defendant Oncology Therapeutics Network Joint Venture, L.P. Defendant Oncology Therapeutics Network

Corporation ("OTN") was a specialty pharmaceutical distribution corporation that acted as a general partner of Oncology Therapeutics Network Joint Venture, L.P. In October 2007, McKesson acquired all outstanding shares of OTN and integrated OTN with its existing businesses.

### 3. Pharmaceutical Distribution, Regulation, and Reimbursement

Each of the Oncology Drugs was manufactured by an original manufacturer, whose conduct in producing, handling, packaging, and labeling its drug products was subject to a comprehensive regime of regulation. The following companies manufactured the drugs at issue in this case: Aloxi was manufactured by Eisai, Inc.; Aranesp and Neupogen were manufactured by Amgen, Inc.; Procrit was manufactured by Ortho Biotech, Inc.; Kytril was manufactured by Roche Pharmaceuticals; and Taxotere was manufactured by Sanofi Aventis.

In general, the original manufacturers sold the Oncology Drugs they produced to wholesale distributors who provided the operational infrastructure—such as warehouse facilities, distribution vehicles, and inventory control systems—necessary to distribute the drugs further. The wholesale distributors sold the drugs either to pharmacies or directly to health care providers.

As wholesale distributors and specialty pharmacies in the oncology industry, defendants purchased the Oncology Drugs from the manufacturers and provided the Oncology Drugs to health care providers who administered them

to patients and sought reimbursement from government programs. Defendant US Oncology, Inc. maintained affiliations with physicians and submitted its own claims for reimbursement on behalf of those physicians.

The government programs that reimbursed the claims included various federal medical assistance and health care programs and state-administered Medicaid programs. The state-administered programs were financed with a combination of federal and state funds. Although detailed in the SAC, the specifics of each program are not relevant to the resolution of the present motion. For all of the programs at issue, medical services and supplies were reimbursable only if they represented expenses actually incurred by a health care provider. Because health care providers incurred no costs for overfill, it was not reimbursable. Additionally, only FDA-approved drugs were reimbursable. Adulterated or misbranded drugs were not reimbursable.

The Oncology Drugs were subject to regulation by the U.S. Food and Drug Administration ("FDA"), which administers the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.* and promulgates regulations relating to the approval, manufacture, labeling, and distribution of drugs. Before a new drug may be marketed in the United States, the FDA must approve the drug as safe and effective for its intended use. The sponsor of a new drug makes a formal application to the FDA to approve the new drug for use in the United States by submitting, in the case of conventional drugs, a New Drug Application ("NDA"), under 21 U.S.C. § 355(b)

(1), or, in the case of biologic drugs, a Biologics License Application ("BLA"), under 42 U.S.C. § 262(a). An NDA must include a description of the methods used in, and the facilities and controls used for, the drug's manufacture, processing, and packaging. The FDA also reviews a new drug's labeling information and container closure system as part of an NDA. Similarly, a BLA must include information concerning manufacturing methods and a sample of the product's label, container, and closure. 21 C.F.R. § 601.2(a). Once it approves a product for marketing, the FDA requires that manufacturers notify it of changes in the conditions established in the NDA or BLA.

The FDA publishes Current Good Manufacturing Practices ("CGMPs") which set forth minimum requirements for processing, packing, and holding drugs. The CGMPs provide standards for, among other things, the personnel engaged in quality control, the maintenance of manufacturing facilities and equipment, and the testing of in-process drugs. Drug manufacturers demonstrate compliance with the CGMPs through written documentation subject to FDA review. Drugs that are not manufactured in compliance with the CGMPs are deemed to be adulterated.

The FDA also regulates repackaging of drugs. Repackaging differs from drug compounding practiced by licensed pharmacists, which is the practice of mixing a drug to create a medication tailored to an individual patient. Drug repackagers must register with the FDA and repackaged drugs are generally subject to the regulations described above, including the CGMPs. When

repackagers manipulate drugs beyond the approved intended uses, it results in new products whose safety and effectiveness have not been established, and thus the new drug lacks whatever approval the original drug may have had.

The United States Pharmacopeial Convention is a scientific non-profit organization that publishes the United States Pharmacopeia ("USP"). The USP establishes professional standards for the identity, strength, quality, and purity of drugs, as well as professional standards for compounding drugs identified as sterile. The USP requires that vials of injectable drugs contain overfill in slight excess of the labeled volume to permit withdrawal and administration of the label amount. The USP recommends that vials of the Oncology Drugs contain up to an additional .1 milliliter, or 10% overfill. Many manufacturers, however, include additional overfill to ensure that patients receive the proper amount from the vial.

Drugs are identified and reported using a National Drug Code ("NDC"), a unique, ten-digit, three-segment number that identifies a drug's labeler, product, and trade package size. The FDA publishes NDC numbers and the corresponding information in a national directory. A drug is considered misbranded if its labeling is false or misleading in any way or if use in accordance with the labeling would be dangerous to a patient's health. Additionally, the USP requires that sterile drugs bear an expiration date derived from tests conducted on samples stored in the immediate container closure system in which the drug is marketed.

*Appendix D*

Federal regulations set minimum requirements for drug storage, handling, and associated recordkeeping. Facilities used for drug storage must meet certain structural requirements, be maintained appropriately, and be secure. When required by a drug's labeling or the USP, the regulations also require that the drug be stored at the proper temperature. When not otherwise indicated, a drug may be held at controlled room temperature.

**4. Allegations of Defendants' Wrongdoing**

**a. Manufacturing, Repackaging, and Distribution of Injectable Oncology Drugs**

Defendants developed an intentional scheme (the "Prefilled Syringe Program") under which FDA requirements, as well as the CGMPs and USP guidelines, for manufacturing, processing, labeling, packing, and holding drugs were intentionally disregarded. Defendants acquired the Oncology Drugs in FDA-approved packaging from the original manufacturers. In at least two facilities, in Frisco, Texas and Memphis, Tennessee, defendants removed the Oncology Drugs from the sterile, preservative-free glass vials, pooled the drugs and their overfill, and transferred the drugs into plastic syringes. Defendants then relabeled the now-prefilled plastic syringes with altered NDC numbers, and then packaged and shipped the syringes. One of Omni's principals witnessed defendants engaging in this conduct at the Frisco, Texas facility during a meeting with several OTN executives on or about August 28, 2007. Additionally, the staff of physicians affiliated with defendant US Oncology,

Inc., engaged in similar pooling and transferring of the Oncology Drugs and their overfill at the offices of those physicians.

Defendants' "repackaging" facilities and personnel, whether licensed or not, did not comply with the relevant CGMPs for: personnel engaged in quality control; the construction, cleaning, and maintenance of equipment; the storage, inspection, and testing of drug components and containers; the control of production and process, including in-process product testing; control of packaging, labeling, storage, and distribution; laboratory controls; recordkeeping; and procedures for handling of returned and salvaged product. Similarly, defendants' facilities and personnel did not comply with USP standards for: cleaning and disinfecting areas; clean room surfaces and air filtration; action levels for microbial contamination; training of personnel; and gloved fingertip sampling. Defendants' facilities concealed issues that would have led the government to deny or withdraw registration.

On information and belief, defendants did not store the Oncology Drugs at appropriate temperatures or under appropriate conditions as specified on the labeling of the drugs, or in the then-current editions of the USP. Additionally, on information and belief, defendants did not use appropriate equipment, maintain records, or perform testing to ensure the safety, identity, strength, quality, or purity of the Oncology Drugs repackaged into prefilled syringes.

In many cases, the Oncology Drugs were originally packaged without preservatives in sterile, single-use vials.

The single-use vials were designed to be punctured once and the drug dose extracted and administered in a single injection. Puncturing a vial more than once exposed the drug to a risk of contamination. The package insert for Procrit, as an example, stated: "Use only one dose per vial; do not re-enter the vial. Discard unused portions. Contains no Preservatives." (SAC ¶ 157). Relatedly, in 2001, the Centers for Disease Control and Prevention issued recommendations warning: "Intravenous medication vials labeled for single use ... should not be punctured more than once. Once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed. Residual medication from two or more vials should not be pooled into a single vial." (SAC ¶ 164).

Defendants' practice of de-capping the vials in a non-aseptic environment, entering a single-use vial multiple times, and pooling the Oncology Drugs into larger syringes exposed the drugs to potential contamination and destroyed the documented sterility of the original vials. Additionally, by pooling drugs from myriad vials to make a series of prefilled syringes, defendants destroyed the pedigree of the drugs. As a result, the source of an infection from a prefilled syringe could not be traced. Defendants concealed the nature of the drugs from providers on both the invoice and the pedigree. The invoice for a single-dose vial and a prefilled syringe each stated that the specific unit was obtained directly from the manufacturer.

Defendants' practices also compromised the Oncology Drugs' expiration date information. Defendants distributed the prefilled syringes either without expiration dates or

with fabricated expiration dates that did not correspond with the expiration dates on the original vials. Further, because defendants distributed the Oncology Drugs in plastic syringes not designed for storage, the conditions relevant to a drug's expiration date were altered. For example, Aloxi when drawn into a syringe is safe and effective for only forty-eight hours at room temperature.

Health care providers ordered prefilled syringes from defendants by emailing or faxing a specific order form. The order form did not allow health care providers to include patient-specific information when ordering prefilled syringes. Relator Omni placed orders for prefilled syringes up until 6:00 pm on a given day and received the syringes the following day. Omni infers that this quick turnaround time reflected defendants' practice of mass producing prefilled syringes in advance of orders and without a valid prescription for a specific patient.

Defendants' Prefilled Syringe Program resulted in "major changes" to the repackaged Oncology Drugs such that FDA approval would have been required to distribute the drugs. As no such approval was obtained, defendants' distribution of the prefilled syringes was unapproved. Further, as defendants represented the prefilled syringes to be the same as the drug in the original vial, the drugs were misbranded.

**b. Payment of Kickbacks and Manipulation of the Average Sales Price**

Defendants sold prefilled syringes to health care providers through contractual agreements that provided

discounts to the providers in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b). For example, in or around September 2007, defendants charged $327.42 for a prefilled syringe of Procrit, whereas a vial of Procrit cost $346.99. This discount was made possible through the "free" overfill, for which defendants had not paid the original manufacturers. The discount amounted to a kickback to the health care providers; however, defendants advised health care providers that this practice was legal.

Defendants' conduct also had the effect of artificially inflating the Average Sales Price ("ASP") of the Oncology Drugs. The Centers for Medicare and Medicaid, an agency of the U.S. Department of Health and Human Services, bases its reimbursement rates for injectable drugs on the ASP. The ASP represents the drug manufacturer's total sales divided by the total number of units sold during a particular quarter. The total sales figure is adjusted to account for any price concessions, discounts, or rebates. The total units figure is calculated based on the amount of product as reflected on a product's FDA-approved label; thus overfill is not included in the ASP calculation.

Defendants skewed the ASP "by introducing into commerce drug product specifically excluded from the calculation of the ASP, namely, overfill, and failing to report the lower prices that defendants charged for drug product in pre-filled syringes." (SAC ¶ 23). The SAC provides a hypothetical example demonstrating how the sale of overfill would skew the ASP but does not provide any specific figures regarding the ASPs for any of the Oncology Drugs during the period of time defendants operated the Prefilled Syringe Program.

**5. Exhibits**

Omni attached the following exhibits to the SAC: 1) an undated letter from Amgen, Inc. to health care providers describing an outbreak of bacteremia among patients receiving Epogen; 2) invoices from December 2007 to March 2010 showing Omni's purchase of Oncology Drugs from OTN; 3) McKesson "Prefilled Syringe Order Forms" showing orders by Omni of Procrit and Aloxi between September 2009 and March 2010; 4) an email dated September 4, 2009 from a "McKesson Specialty Care Solutions" representative to an Omni principal explaining how to order prefilled syringes; 5) an email dated November 5, 2007 from an OTN employee stating that manufacturer contract prices for Procrit and Aloxi had changed; 6) Eisai's product price list, effective July 20, 2012; 7) twenty-four Medicare claims submitted by Omni between January 2007 and December 2010.

**6. The Federal Claims**

Omni bring four federal claims under the FCA. First, Omni alleges that defendants, for the purpose of defrauding the government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicare, Medicaid, and other government health programs in violation of 31 U.S.C. § 3729(a)(1) (1994).[1] Second, Omni alleges that

1. Citations in the SAC refer to the version of 31 U.S.C. § 3729 in effect until amended on May 20, 2009 by the Fraud Enforcement and Recovery Act of 2009. Although some of the conduct described in the SAC occurred after the amendment, the parties have cited

defendants knowingly made, used or caused to be made or used, false records or statements to get a false claim paid in violation of 31 U.S.C. § 3729(a)(2). Third, Omni alleges that defendants knowingly made, used, or caused to be made or used false records or false statements to conceal an obligation to refund the government in violation of 31 U.S.C. § 3729(a)(7); a claim of this nature is often called a "reverse false claim." Fourth, Omni alleges that defendants conspired to violate the FCA, including by jointly marketing prefilled syringes, in violation of 31 U.S.C. § 3729(a)(3).

**7. The State Law Claims**

Omni brings 35 state law claims concerning 30 states, 2 cities, and the District of Columbia alleging violation of various FCA analogs. Omni brings one claim under the law of each jurisdiction, except for New Mexico and Tennessee, for which Omni brings two under each state's law. Each of the state law claims contains a similar allegation, namely, that defendants knowingly presented and/or caused to be presented false claims for payment under the applicable state-funded program and that defendants knowingly made and/or caused to be made false records or statements in connection with the false claims.

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only to the earlier version of the statute in their papers. As the amendment does not appear to affect the issues discussed in this opinion—and the parties do not argue otherwise—I also cite to the pre-2009 statute.

### 8. The State Common Law Claims

Omni brings two claims under the common law of unidentified states for payment under mistake of fact and unjust enrichment. The mistake of fact claim alleges that the governments (federal, state, and local) made payments for prefilled syringes under a mistake of fact, caused by defendants, that the claims were for the FDA-approved drugs contained in vials. The unjust enrichment claim alleges that defendants unjustly enriched themselves at the expense of the governments "under circumstances where it would be inequitable ... to retain the benefits conveyed." (SAC ¶ 259).

## II. Procedural History

On March 9, 2012, Omni filed a *qui tam* Complaint under seal alleging FCA violations by AmerisourceBergen Corporation ("ABC") and three affiliated companies (collectively "ABC defendants"). On October 9, 2012, Omni filed, also under seal, its First Amended Complaint ("FAC") making the same substantive allegations as the Complaint and adding as defendants McKesson, OTN, and US Oncology, Inc. The United States later intervened with respect to certain claims against the ABC defendants. Upon relator's motion, this action was severed from the ABC action on March 28, 2018. On April 3, 2018, Omni publicly filed the SAC adding two new federal claims, two new state statutory claims (under Vermont and Washington law), and five additional McKesson subsidiaries as defendants: McKesson Specialty, McKesson Specialty Care Distribution LLC,

McKesson Specialty Care Distribution Joint Venture, L.P., Oncology Therapeutics Network Joint Venture, L.P., and US Oncology Specialty, L.P. [2]

## III. Discussion

### 1. FCA Framework

The FCA imposes liability on any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government ... a false or fraudulent claim for payment or approval" or any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a)(1)-(2). "Rather than rely solely on federal enforcement of these provisions, Congress decided to deputize private individuals, encouraging them to come forward with claims on behalf of the Government in the form of *qui tam* suits." *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 166 (2d Cir. 2018). The FCA's *qui tam* provisions allow a private party, called the relator, to challenge "fraudulent claims against the Government on the Government's behalf, ultimately sharing in any recovery." *Id.* (internal citations and alterations omitted).

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2. On June 20, 2018, I issued a limited unsealing order allowing defendants to review the Complaint and the FAC. On December 7, 2018, I granted Omni's unopposed motion to unseal all entries on this case's docket filed after April 3, 2018. Because the parties had filed copies of the Complaint and the FAC as sealed exhibits to their memoranda of law concerning this motion, my order operated to unseal those documents.

The government may intervene in any *qui tam* action, "in which case the action shall be conducted by the Government," and the relator's recovery thereby reduced, or it may decline to take over the action, in which case the relator "shall have the right to conduct the action." 31 U.S.C. § 3730(b)(4)(A), (d)(1), (b)(4)(B).

The FCA includes several limiting provisions. Relevant to this motion is the provision known as the "first-to-file bar," which provides that "[w]hen a person brings an action under [the FCA], 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). "The command is simple: as long as a first-filed complaint remains pending, no related complaint may be filed." *Wood*, 899 F.3d at 167 (quoting *United States ex rel Batiste v. SLM Corp.*, 659 F.3d 1204, 1210, 398 U.S. App. D.C. 110 (D.C. Cir. 2011)). The rule "ensures that only one relator shares in the Government's recovery and encourages potential relators to file their claims promptly." *Id.* (citing *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998)).

**2. First-to-File Bar**

Defendants argue that this entire action should be dismissed under the first-to-file bar because Omni's allegations are "indistinguishable" from an earlier filed *qui tam* action, *United States ex rel. Underwood v. Amgen, Inc.*, 10-cv-2441 (SLT)(SMG). Omni agrees that *Underwood* was pending when this action was filed but

argues that the first-to-file bar is inapplicable because *Underwood* alleged a different fraudulent scheme and thus is not related to this action.

In the recent case *United Stales ex rel. Wood v. Allergan, Inc.*, the Court of Appeals for the Second Circuit discussed the standard for evaluating whether actions are related for purposes of the first-to-file bar:

> A second action is "related," within the meaning of Section 3730(b)(5), if the claims incorporate the same material elements of fraud as the earlier action, even if the allegations incorporate additional or somewhat different facts or information. In other words, to be related, the cases must rely on the same essential facts. If the first-filed complaint ensures that the Government would be equipped to investigate the fraud alleged in the later-filed complaint, then the two cases are related within the meaning of Section 3730(b)(5).

*Wood*, 899 F.3d at 169 (internal quotation marks, alterations, and citations omitted).

The first-to-file bar "bears on the merits of whether a plaintiff has stated a claim" and thus must be analyzed under Federal Rule of Civil Procedure 12(b)(6). *United States ex rel. Hayes v. Allstate Ins. Co.*, 853 F.3d 80, 85 (2d Cir. 2017). Under this rule, the court must accept as true all well-pleaded factual allegations and must draw all inferences in plaintiff's favor. *Swiatkowski v. Citibank*, 446 Fed. Appx. 360, 360-61 (2d Cir. 2011). To survive a

motion to dismiss, a complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)). Facial plausibility exists when a plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* In considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), a district court may consider the facts alleged in the complaint and documents attached to the complaint as exhibits. *See Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002).

Keeping in mind the Second Circuit's direction that an action is related if it "incorporate[s] the same material elements of fraud as the earlier action," I review the *Underwood* complaint. *Wood*, 899 F.3d at 169. That complaint, filed under seal on May 28, 2010 in this district, brought FCA and analogous state laws claims against 50 defendants, including the drug manufacturer Amgen, Inc., 12 other drug manufacturers, 23 drug repackagers, and 14 health care providers.[3] The only *Underwood* defendant who is also a defendant in this action is US Oncology, Inc. The allegations in *Underwood* were based on the observation of the relator in that action during his employment with one of the defendant drug manufacturers between 1986 and 2005. The complaint summarized its allegations as follows:

3. On April 29, 2016, the United States declined to intervene in *Underwood*. The case was unsealed on May 11, 2016 and voluntarily dismissed without prejudice on September 7, 2016.

*Appendix D*

Although expansive in scope, the fraudulent scheme is straightforward. With the knowledge and participation of Defendant Health Care Providers and Manufacturers, Defendant Repackagers unlawfully manipulated the licensed biologic drugs by repeatedly entering single-use and multi-use vials, extracting and/or pooling the overfill, and repackaging the product into smaller doses that are re-labeled and placed in interstate commerce for delivery to health care providers. (*Underwood* Compl. ¶ 7).

Defendant Manufacturers have participated in the scheme. Driven by competition and the desire to increase market share, Defendant Manufacturers routinely fill containers of licensed biologic product... in amounts greater than the FDA labeling quantities or the dose to be administered to a patient . . . . Defendant Manufacturers illegally market the overfill to health care providers as an excess, free biologic product that had been recaptured, repackaged, administered to patients, and billed to the Federal Payer Programs. With the assistance of Defendant Repackagers or through in-house pharmacies, *providers pool the overfill amount from one or more doses to create additional doses, as well as divide and re-manufacture the single-use vials to create smaller doses that are administered to patients. Id.* ¶ 8-9 (emphasis added).

*Appendix D*

> Defendant Health Care Providers were encouraged to and in fact did seek reimbursement from the Federal Payer Programs for the repackaged drugs. In so doing, *providers have billed the Federal Payer Programs for the repackaged product by, for example, purchasing one single-use dose, but billing for more than one dose by illegally repackaging the finished product.* The conduct results in illegal kickbacks and price concessions concealed from federal and state governments. *Id.* ¶ 10 (emphasis added).

Because US Oncology, Inc. is categorized in *Underwood* as a health care provider defendant, all of the allegations against that group of defendants are applicable to it, including, that it "unlawfully remanufacture[s] the drugs in-house . . ., administer[s] them to patients, and bill[s] them to the Federal Payer Programs." (*Id.* ¶ 159(D)). Additionally, the *Underwood* complaint specifically alleged that "US Oncology knowingly purchases repackaged biologic drugs for administration to patients and/or manipulates and repackages licensed finished biologic drugs internally in violation of the FDCA and [Public Health Services] Act." (*Id.* ¶ 76).

Defendants here argue that this case must be dismissed in its entirety because *Underwood*'s allegations "were more than sufficient to enable the Government to investigate *any entity* that created, distributed, or used pre-filled syringes of injectable drugs." (Defs.' Mem. at 3 (emphasis added)). Although counsel for defendants moderated

this position under questioning at oral argument, it is important to reject this overbroad argument, which potentially immunizes unrelated defendants from *qui tam* liability. Instead, I must compare the specific allegations in this case to the *Underwood* complaint, and having done so, I conclude that the allegations are related only as to defendant US Oncology, Inc.

The FAC, like the complaint in *Underwood*, alleges that US Oncology, Inc. engaged in specific fraudulent conduct concerning overfill of injectable cancer drugs.[4] Both describe how US Oncology, Inc. harvested overfill from sterile vials and repackaged the overfill in prefilled syringes in violation of the CGMPs and USP standards.[5] The two cases allege that this conduct occurred

4. In assessing relatedness, I compare *Underwood* to the FAC because that is the earliest filed complaint in this action bringing claims against any of the present defendants. *See United States ex rel. Hanks v. Amgen, Inc.*, 336 F. Supp. 3d 90, 116 (E.D.N.Y. 2018) (citing *Wood*, 899 F.3d at 172). Although at oral argument both parties agreed that the FAC is the operative complaint for the issue of relatedness, the parties' papers took different positions. Defendants assumed, without analysis, that I should compare the SAC. Omni argued in a footnote to its memorandum of law that I should use the original Complaint, which did not name any of the present defendants, yet discussed the SAC in its above-the-line argument.

5. Although I base my decision as to relatedness on the FAC, I note that the SAC reinforces the conclusion that this action and *Underwood* describe the same conduct by US Oncology, Inc. The SAC adds that US Oncology, Inc. administered prefilled syringes containing overfill to patients and itself filed false claims. (SAC ¶ 146). These same allegations appear in *Underwood.* (*Underwood* Compl. ¶ 159(D)).

during overlapping periods of time and with respect to overlapping groups of drugs.[6] However, there need not be perfect identify between every factual element of related frauds. *See, e.g., U.S. ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Baxter Healthcare Corp.*, 772 F.3d 932, 940 (1st Cir. 2014) (additional drugs); *U.S. ex rel. Chovanec v. Apria Healthcare Grp. Inc.*, 606 F.3d 361, 365 (7th Cir. 2010) (differing time periods). All that is required is that the cases "rely on the same essential facts." *Wood*, 899 F.3d at 169. I conclude that, because *Underwood* disclosed that defendant US Oncology, Inc. engaged in the same fraudulent conduct, with respect to injectable oncology drugs, during an overlapping time period, Omni's claims against US Oncology, Inc. are related to *Underwood*, and consequently barred by it.[7]

Although I conclude that the claims against US Oncology, Inc. are related to *Underwood*, I reach the

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6. Three of the six Oncology Drugs in this action were expressly identified in *Underwood*, which in total identified twenty-one biologic drugs.

7. I note that the FAC might allow for a reading that would distinguish some of its claims against US Oncology, Inc. from those in *Underwood*. That reading is that the claims against US Oncology, Inc. only begin in December 2010 when it was acquired by McKesson. In that case, the FAC would cover a different set of facts from *Underwood*, namely, US Oncology, Inc's participation, in concert with McKesson and other affiliates, in an intra-McKesson fraud concerning overfill. *See U.S. ex rel. Hampton v. Columbia/HCA Healthcare Corp.*, 318 F.3d 214, 219, 355 U.S. App. D.C. 23 (D.C. Cir. 2003). However, on oral argument, Omni expressly disclaimed this reading of the FAC and made clear that it was suing US Oncology, Inc. for conduct that occurred before it was acquired by McKesson. (Tr. 32:10-34:6, Jan 10, 2019).

opposite conclusion with respect to the claims against the other defendants. *Underwood* did not name any of those defendants or provide any facts that might associate them with the conduct described. The identity of the defendant is a crucial fact bearing on whether two fraud claims are related. *In re Natural Gas Royalties ex rel. United States v. Exxon Co., USA*, 566 F.3d 956, 962 (10th Cir. 2009). Consequently, the first-to-file bar would not reach a subsequent *qui tam* action otherwise alleging the same material elements of fraud, but alleging those elements concerning different defendants. *See id.* ("Two complaints can allege the very same scheme to defraud the very same victim, but they are not the same claim unless they share common defendants.). Omni asserts, and defendants have not refuted, that there is indeed no authority that holds that a *qui tam* complaint alleging a particular fraudulent scheme bars all other cases in which other unrelated defendants commit an entirely independent fraud involving the same elements.

Defendants argue, however, that McKesson's 2010 acquisition of US Oncology, Inc. associates McKesson with US Oncology, Inc. such that *Underwood* implicated McKesson. But the factual and procedural timeline contradicts that conclusion. *Underwood* concerned conduct that its relator observed between 1986 and 2005. McKesson purchased US Oncology, Inc. years later in December 2010, months after the complaint in *Underwood* was filed. While the government may well have continued its investigation of US Oncology, Inc. past the period ending in 2005, it is not reasonable to conclude that *Underwood's* allegations against US Oncology, Inc.

"ensure[d] that the Government 'would be equipped to investigate'" a separate fraud by McKesson. *Wood*, 899 F.3d at 169 (quoting *United States ex rel, Health v. AT&T, Inc.*, 791 F.3d 112, 121, 416 U.S. App. D.C. 289 (D.C. Cir. 2015)).

Finally, I address defendants' argument that the recently unsealed case, *United States ex rel. Mullen v. AmerisourceBergen Corp.*, 10-cv-4856 (NG) (ST), filed in this district on October 21, 2010, supplies the missing link to associate McKesson and OTN with the conduct described in *Underwood*.[8] Defendants argue that federal authorities could have read *Mullen* and *Underwood* together to conclude that McKesson and its subsidiaries were engaged in the fraud described in this action—and thus the government was "equipped to investigate" McKesson. *Mullen* alleged FCA violations against ABC, a drug wholesaler that is a McKesson competitor. None of the defendants in this action was a defendant in *Mullen*, nor were they identified as unnamed co-conspirators. Yet, defendants argue that *Mullen* should have alerted the government to McKesson's alleged fraud because the corporate-parent defendant in *Mullen*, ABC, operates a similar business with a similar business structure to McKesson.

I reject defendants' argument. To be "equipped" to investigate a fraud, the government must know whom to

8. Although defendants first raised *Mullen* in their reply, I do not fault them for doing so as the complaint in that case was under seal at the time they filled their moving memorandum of law. I allowed Omni to file a surreply on the issue.

investigate. Certainly, there are cases where unnamed parties were so closely linked to named defendants that the government had notice to investigate. *See CO2 Appeal*, 566 F.3d at 962; *Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1280 n.4 (10th Cir. 2004). Here, no connection is alleged between any *Mullen* defendant and McKesson other than that they were similarly situated in terms of their business structures. The allegations against ABC thus reveal nothing related to this case. *See United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 373 (5th Cir. 2009) (rejecting the notion that within an industry "suit as to one is suit as to all"). Accordingly, I conclude that the first-to-file bar does not prevent this action from proceeding as to any defendant other than US Oncology, Inc.

**3. Rule 9(b)**

Defendants move to dismiss Omni's claims under § 3729(a)(1) and § 3729(a)(2) on the ground that they were not pled with the particularity required by Federal Rule of Civil Procedure 9(b). "*Qui tam* complaints filed under the FCA, because they are claims of fraud, are subject to Rule 9(b)," which requires a plaintiff to plead fraud claims with particularity. *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017). Generally, to comply with Rule 9(b), a complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Id.* (citations omitted). However, an FCA complaint "can satisfy Rule 9(b)'s particularity requirement by making plausible allegations

creating a strong inference that specific false claims were submitted to the government and that the information that would permit further identification of those claims is peculiarly within the opposing party's knowledge." *Id.* at 86. Rule 9(b) permits scienter to be averred generally, but a relator must "plead the factual basis which gives rise to a strong inference of fraudulent intent." *United States ex rel. Tessler v. City of New York*, 712 F. App'x 27, 29 (2d Cir. 2017) (quoting *O'Brien v. Nat'l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991)).

To state a claim under § 3729(a)(1) a relator must show that the defendant "(1) made [or caused to be made] a claim, (2) to the United States government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury." *Bishop v. Wells Fargo & Co.*, 823 F.3d 35, 43 (2d Cir. 2016) (quoting *Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001)), *abrogated on other grounds by Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. —, 136 S. Ct. 1989, 195 L. Ed. 2d 348 (2016). To state a claim under § 3729(a)(2) a relator must show that defendants "knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim." *United States ex rel. Piacentile v. Amgen, Inc.*, 336 F. Supp. 3d 119, 135 (E.D.N.Y. 2018) (quoting *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 335 (9th Cir. 2017)).

Defendants argue that allegations about false claims submitted by any entity other than Omni itself fail because the SAC contains no information about the content of such claims, who submitted them, and when they were submitted. However, such information is not required where, as here,

the relator's allegations create a strong inference that specific false claims were submitted. *Chorches*, 865 F.3d at 82. Omni has detailed an extensive scheme whereby defendants caused health care providers to submit claims to government health programs for drugs that were not eligible for reimbursement.[9] Omni has described how defendants marketed their fraudulent "Prefilled Syringe Program" to health care providers, identified the six drugs that were part of the scheme, and provided an approximate timeframe. The information that would permit further identification of the false claims is the identity of the healthcare providers who ordered prefilled syringes. This information is within defendants' knowledge. Thus, Omni has satisfied the particularity requirement.

It is also worth emphasizing that "[i]t is not the purpose of Rule 9(b), as applied to FCA *qui tam* actions, to render the FCA toothless as to particularly clever fraudulent schemes." *Id.* at 86. Given the structure of the fraud in this case, requiring relator to plead the content of the false claims is unnecessary.

**4. Failure to State a Claim**

The allegation under § 3729(a)(7) for "reverse false claims" fails, as the basis for this claim is exactly the same

9. Contrary to defendants' assertions, Omni has pled sufficient facts, which are assumed to be true for purposes of this motion, to show that claims for prefilled syringes containing overfill would have been false and that defendants' actions could have inflated the ASP. It is not necessary that Omni plead what the ASP would have been if not for defendants' actions.

as the basis for the claim under § 3729(a)(1) for presentation of false claims.[10] Characterizing the receipt and retention of federal money as two different claims is "redundant—two ways of describing the same transaction." *U.S. ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d 313, 339 (S.D.N.Y. 2004). Omni does not allege any conduct that would have resulted in the retention of federal money that is not the same conduct that caused the payment of false claims. Accordingly, the claim under § 3729(a)(7) is dismissed.

The claim for civil conspiracy under § 3729(a)(3) is also dismissed. A parent corporation and its wholly owned subsidiaries are "legally incapable of forming a conspiracy with one another." *U.S. ex rel. Brooks v. Lockheed Martin Corp.*, 423 F. Supp. 2d 522, 528 (D. Md. 2006), *aff'd in part, dismissed in part*, 237 F. App'x 802 (4th Cir. 2007) (citing *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 104 S. Ct. 2731, 81 L. Ed. 2d 628 (1984)). On that basis, there can be no conspiracy among any of the remaining defendants after October 2007 when McKesson acquired OTN. Prior to that time, a conspiracy claim might lie if the relator had plead, as to McKesson and OTN, "an agreement to defraud the government . . . coupled with any act to get a false or fraudulent claim allowed or paid." *Taylor*, 345 F. Supp. 2d. at 331 (citations and internal quotations omitted). However, this is not alleged in the SAC. Rather, the SAC describes only that McKesson acquired OTN for the purpose of more efficiently operating the fraudulent

10. "A reverse false claim is any fraudulent conduct that results in no payment to the government when a payment is obligated." *Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73, 88 (D.D.C. 2014) (citations and internal quotations omitted).

Prefilled Syringe Program. (SAC ¶ 26). The SAC does not describe any joint conduct by McKesson and OTN prior to the acquisition that might show an implicit agreement to defraud the government. Accordingly, the claim under § 3729(a)(3) is dismissed.

**5. Statute of Limitations**

In general, a relator must bring an FCA *qui tam* action within six years of a violation.[11] 31 U.S.C. § 3731(b)(1). Defendants argue that the claims and defendants added in the SAC are time barred. (Defs.' Mem. at 22). Omni concedes that its SAC will be timely only if it relates back to the FAC. And, as I have already concluded that the newly asserted FCA claims, reverse false claims and conspiracy, fail under Rule 12(b)(6), I need not consider whether those claims would relate back under Rule 15(c)(1)(B). I consider only whether Omni's claims against five McKesson subsidiaries, who were first added as defendants in the SAC, relate back to the FAC.[12]

An amended complaint adding a new party must meet the following criteria under Rule 15(c)(1)(C) to relate back:

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11. The FCA offers a potentially longer statute of limitations in 31 U.S.C. § 3731 (b)(2). Here, neither party argues that this provision is applicable.

12. Defendants raise no objection to two name changes in the caption. The FAC named "Oncology Therapeutics Network" and "U.S. Oncology." The SAC changed those names to "Oncology Therapeutics Network Corporation" and "US Oncology, Inc."

> (1) the claim must have arisen out of conduct set out in the original pleading; (2) the party to be brought in must have received such notice that it will not be prejudiced in maintaining its defense; (3) that party should have known that, but for a mistake of identity, the original action would have been brought against it; and (4) the second and third criteria are fulfilled within [90] days of the filing of the original complaint and the original complaint was filed within the limitations period.

*Hogan v. Fischer*, 738 F.3d 509, 517 (2d Cir. 2013) (citations and alterations omitted). The application of this rule to an FCA action presents a paradox because "[b]y design, the seal provision of § 3730(b) deprives the defendant in an FCA suit of the notice usually given by a complaint." *United States v. Baylor Univ. Med. Ctr.*, 469 F.3d 263, 270 (2d Cir. 2006). Even the defendants who were actually named in the FAC did not receive notice of it until I ordered its limited unsealing, which was after the SAC itself had been served. Thus, one might argue, the new defendants were not deprived of any notice they might have received had they been named in the FAC.

However, the statute expressly allows a timely complaint to satisfy the statute of limitations with respect to named defendants although those defendants are deprived of notice. *See* 31 U.S.C. § 3730(b)(2) ("[T]he complaint... shall not be served on the defendant until the court so orders."). As the court in *Hayes v. Department of Education of New York* explained, "[N]o claim actually

pleaded in the Amended Complaint would be time-barred, if timely when the original sealed complaint was filed." 20 F. Supp. 3d 438, 445 (S.D.N.Y. 2014). There is no such provision in the statute that supports depriving a party not named in the filed complaint of notice. On the contrary, the Second Circuit stated, although in the context of amending claims under Rule 15(c)(1)(B), that the secrecy requirements of the FCA's sealing provision are incompatible with relation back because "the touchstone for relation back ... is notice." *Baylor*, 469 F.3d at 270. Therefore, the claims asserted against McKesson Specialty Care Distribution Corporation, McKesson Specialty Care Distribution LLC, McKesson Specialty Care Distribution Joint Venture, L.P., Oncology Therapeutics Network Joint Venture, L.P., and US Oncology Specialty, L.P. are dismissed as untimely. I note that my conclusion here is consistent with my focus, in my analysis of the first-to-file bar, on whether the earlier filed complaint identified the defendant at issue. The statute of limitations, like the first-to-file bar, encourages relators to come forward promptly with information to help the government uncover fraud. *Cf. United States ex rel Shea v. Cellco P'ship*, 863 F.3d 923, 932 (D.C. Cir. 2017). This purpose would be undermined if a relator were permitted to add additional defendants years later—and potentially after the government has declined to intervene.

**6. State Law Claims**

The briefing on this motion almost exclusively addresses the federal FCA. However, Omni also brings 35 state-law claims alleging violations of different state

laws analogous to the FCA. Although these statutes in general mirror the FCA, they are not identical. However, defendants argue that I should treat the state statutes as identical and dismiss the state law claims "for the same reasons" that I dismiss any federal claim. (Defs.' Mem. at 22). However, I cannot simply transfer my reasoning concerning the federal statute to different statutes, particularly when defendants, who are the movants, have provided me with no information concerning those statutes. I cannot assume those statutes' limitations periods and pleading standards. Therefore, I deny the motion to dismiss as to all state claims.

### 7. Common Law Claims

Lastly, defendants argue that Omni's common law claims for payment under mistake of fact and unjust enrichment must be dismissed because Omni lacks standing to assert claims to recover damages allegedly suffered by governments. *See U.S. ex rel. Phipps v. Comprehensive Cmty. Dev. Corp.*, 152 F. Supp. 2d 443, 452 (S.D.N.Y. 2001). There being no argument in opposition by Omni, the common law claims are dismissed.

## IV. Conclusion

Defendants' motion to dismiss the Second Amended Complaint is granted in part and denied in part.

All federal claims (counts 1-4) against US Oncology, Inc. are dismissed without prejudice under the first-to-file bar.

The reverse false claims (count 3), conspiracy (count 4), and common law (counts 5 and 6) claims are dismissed as to all defendants.

All federal claims (counts 1-4) against McKesson Specialty Care Distribution Corporation, McKesson Specialty Care Distribution LLC, McKesson Specialty Care Distribution Joint Venture, L.P., Oncology Therapeutics Network Joint Venture, L.P., and US Oncology Specialty, L.P. are dismissed on statute of limitations grounds. I decline to exercise supplemental jurisdiction over the state law claims asserted against those defendants and US Oncology, Inc. and dismiss those claims without prejudice. The Clerk of Court shall terminate these defendants as parties.

The motion to dismiss is otherwise denied. In sum, the remaining claims are those brought under § 3729(a)(1) for false claims (count 1) and § 3729(a)(2) for false statements (count 2), and all state statutory claims (counts 7-41). The remaining defendants are McKesson Corporation and Oncology Therapeutics Network Corporation.

**SO ORDERED**.
/s/ Nina Gershon
NINA GERSHON
United States District Judge

Dated: February 4, 2019
Brooklyn, New York

**APPENDIX E — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT, FILED DECEMBER 27, 2024**

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

Docket No: 23-1334

OMNI HEALTHCARE INC.,

*Plaintiff-Relator-Appellant,*

UNITED STATES OF AMERICA,
EX REL. OMNI HEALTHCARE, *et al.*,

*Plaintiffs,*

v.

U.S. ONCOLOGY, INC.,

*Defendant-Appellee.*

Filed November 27, 2024

**ORDER**

Appellant, Omni Healthcare, Inc., filed a petition for panel rehearing, or, in the alternative, for rehearing *en banc*. The panel that determined the appeal has considered the request for panel rehearing, and the active members of the Court have considered the request for rehearing *en banc*.

*Appendix E*

IT IS HEREBY ORDERED that the petition is denied.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk

/s/ Catherine O'Hagan Wolfe

## APPENDIX F — STATUTORY PROVISION INVOLVED

### § 3730. Civil actions for false claims

* * *

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4)[1] of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

* * *

(4)(A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—

> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
>
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
>
> (iii) from the news media,

1. So in original. Probably should be a reference to Rule 4(i).

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has[3] knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

* * *

3. So in original. Probably should be "or (ii) has".

*Appendix F*

**§ 3730. Civil actions for false claims**

* * *

(4)(A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—

> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
>
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
>
> (iii) from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

* * *