NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 09-2341

UNITED STATES OF AMERICA, ex rel.
JEFFREY D. FELDSTEIN, M.D.,

v.

ORGANON, INC.; a corporation, and
SCHERING-PLOUGH, INC.; a corporation

Jeffrey D. Feldstein,
Appellant

On Appeal from the United States District Court
for the District of New Jersey
District Court No. 2-07-cv-02690
District Judge: The Honorable Dennis M. Cavanaugh

Submitted Pursuant to Third Circuit L.A.R. 34.1(a)
January 15, 2010

Before: SCIRICA, *Chief Judge*, SMITH, and COWEN, *Circuit Judges*

(Filed: February 2, 2010)

OPINION

SMITH, *Circuit Judge.*

Jeffrey D. Feldstein, M.D., brought this qui tam action under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, against appellees Organon and Schering Plough, claiming that Organon's failure to disclose the harmful side effects of the pharmaceutical drug Raplon resulted in the submission of false claims to Medicare and Medicaid.[1] The District Court dismissed Feldstein's complaint for lack of jurisdiction, and, in the alternative, for failure to comply with the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure. We will affirm.

I.

Because we write only for the parties, who are familiar with the record, we recount only those facts which are essential to our decision. Organon developed, manufactured, and sold Raplon, which was approved by the FDA on August 18, 1999. Raplon was a neuromuscular blocking agent used during surgery and other medical procedures. After Raplon entered the market, there were reports of episodes of an adverse side effect known as bronchospasm, and in some cases a severe form of bronchospasm known as "cement lung," in patients who were treated with the drug. These conditions made breathing difficult and led to severe injuries in certain patients, and in some cases, death. These harmful side effects also spawned lawsuits against Organon, several of which alleged that

[1] Schering-Plough acquired Organon in 2007, which was several years after the fraud described in Feldstein's complaint allegedly took place. According to Feldstein, Schering-Plough succeeded to Organon's liabilities and is jointly and severally liable with Organon under the FCA.

Organon fraudulently concealed safety information about Raplon's potential to cause bronchospasm and cement lung, both before and after the FDA approved the drug. Organon voluntarily withdrew Raplon from the market in March of 2001.

In May of 2000, Organon hired Feldstein to serve as its Associate Director of Medical Services for Antithrombotics. His duties included assisting with the launch of the anticoagulant drug Arixtra. A disagreement soon arose between Feldstein and his superiors. Feldstein complained that Organon personnel were concealing instances of bleeding associated with Arixtra, and that his supervisor, Dr. Jonathan Deutsch, attempted to coerce Feldstein into disseminating false information about such bleeding. Organon fired Feldstein in May of 2001.

During his tenure at Organon, Feldstein did not work on Raplon, nor was he involved in obtaining FDA approval for the drug. He makes no claim that he was part of, or personally observed, any fraud related to Raplon. Before he left Organon, however, Feldstein voiced his concerns about Deutsch and Arixtra to Dr. Daniel Sack, Organon's Associate Director of Anesthesiology. Sack informed Feldstein that Raplon, with which Deutsch was also involved, had caused multiple deaths since its approval. Sack then showed Feldstein an email concerning Raplon that he had discovered on his laptop computer. The email was written by Deutsch and sent to Dr. Deborah Shapse, Organon's Vice President of Medical Services. It predated Raplon's FDA approval. In the email, Deutsch described bronchospasm as "a potential problem that needed to be addressed prior to launch" and stated that "Michael may be correct in not wanting to draw attention

to bronchospasm." Feldstein claims that "Michael" was Michael Novinsky, Organon's Vice President of Marketing. He describes this email as a "smoking gun" because he claims that it proves that Organon knew of the respiratory dangers posed by Raplon before it was approved, but failed to disclose those dangers to the FDA and otherwise attempted to withhold safety information about Raplon from the medical community.

Later, Feldstein reviewed Organon's submissions to the FDA concerning Raplon and concluded that Organon had inadequately disclosed Raplon's risk of serious adverse events (SAEs). He also spoke with Robert Plona, Organon's former Brand Manager for Anesthetics. Plona had been involved with Raplon marketing efforts, and he supplied Feldstein with more details about events referenced in the "smoking gun" email. Feldstein's conversation with Plona reinforced his belief that the email from Sack to Shapse was evidence of fraud.

In April of 2002, Feldstein filed a qui tam complaint against Organon pursuant to the FCA. After the government declined to intervene in June of 2006, *see* 31 U.S.C. § 3730(b)(4)(B), Feldstein filed an amended, one-count complaint in the United States District Court for the District of New Jersey on April 14, 2008. The complaint alleged that Organon concealed the respiratory dangers of Raplon and contended that Raplon's regulatory approval was "invalid" because it was obtained through fraud on the FDA. The consequence of this fraud, Feldstein alleged, was that hospitals, physicians and patients submitted "false claims" to Medicare and Medicaid, because those programs "would not have reimbursed . . . for the use of Raplon had [they] known that the FDA

approved Raplon without the benefit of adequate disclosures" regarding Raplon's potential for harmful side effects.

The District Court dismissed Feldstein's complaint for lack of jurisdiction because it concluded that Feldstein's claim was foreclosed by the FCA's public disclosure bar. *See* 31 U.S.C. § 3730(e)(4)(A). As an alternative holding, the District Court concluded that Feldstein's "false claims" allegations were generalized and speculative, and thus dismissed the complaint for failure to comply with Rule 9(b).

Feldstein filed this timely appeal. Jurisdiction in this court arises under 28 U.S.C. § 1291. We exercise plenary review of the District Court's dismissal under Rule 12(b)(1). *United States ex rel Paranich v. Sorgnard*, 396 F.3d 326, 331 (3d Cir. 2005).[2]

II.

The FCA's public disclosure bar provides that "[n]o court shall have jurisdiction" over a qui tam action brought by a private plaintiff if that action is "based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing," certain government reports, or "the news media, unless the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A). In other words, if Feldstein's complaint is "based upon" allegations that were previously disclosed in certain qualifying public sources, his claim is barred unless he is an original source of those allegations. The list of qualifying sources includes certain government reports and

[2] The same standard applies to the District Court's dismissal for failure to comply with Rule 9(b), *see In re Westinghouse Securities Litigation*, 90 F.3d 696, 706 (3d Cir. 1996), but as we explain, we need not reach the District Court's dismissal on that ground.

the news media. *See id.* It also includes allegations contained in civil complaints. *United States ex rel. Stinson, Lyons, Gerlin & Bustamante P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1157 (3d Cir. 1991).

A. Feldstein's Claim Was "Based Upon" Publicly Disclosed Allegations

A "qui tam action is 'based upon' a qualifying disclosure if the disclosure sets out *either* the allegations advanced in the qui tam action *or* all of the essential elements of the qui tam action's claims." *United States ex rel Mistick PBT v. Hous. Auth. of City of Pittsburgh*, 186 F.3d 376, 388 (3d Cir. 1999) (emphasis added). "To be 'based upon' the publicly revealed allegations or transactions," the allegations in the relator's complaint need not be "actually derived from" the publicly disclosed allegations. *United States ex rel. Atkinson v. Pa. Shipbldg. Co.*, 473 F.3d 506, 519 (3d Cir. 2007). Rather, they "need only be 'supported by' or 'substantially similar to' the disclosed allegations and transactions." *Id.* Substantial similarity exists where there is "substantial identity" between the publicly disclosed allegations and the allegations in the relator's complaint. *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 514 (6th Cir. 2009).

We conclude that the allegations in Feldstein's complaint are substantially similar to allegations that were publicly disclosed in earlier Raplon-related personal injury lawsuits against Organon. The central premise of Feldstein's false claims theory is the allegation that Organon concealed the harmful side effects of Raplon, both before and after its FDA approval. For example, Feldstein alleged that Organon:

- "[F]ailed to disclose to the FDA instances and the severity of the SAEs associated with Raplon both before and after obtaining FDA approval";

- "[N]ever advised doctors or patients of the potential for SAEs in any labeling or package insert and never had a treatment protocol in place prior to or even after launch";

- "[N]ever informed the FDA, hospitals, physicians or patients that Raplon posed a serious threat to public health and safety" before it withdrew the drug from the market;

- "[K]nowingly misrepresented and/or concealed relevant information from the FDA in order to obtain, and subsequently retain, regulatory approval for Raplon"; and

- "[K]nowingly failed to warn hospitals, physicians and patients of the dangers posed by Raplon" from August 1999 through March 2001.

Substantially similar allegations of concealment of the harmful side effects of Raplon–specifically its potential to cause bronchospasm and cement lung–were asserted in the complaint filed in *Rogers v. Organon, Inc.*, No. 190698B, in Texas state court in February of 2002. The complaint in *Rogers* alleged that Raplon "causes and contributes to severe and disabling medical conditions including severe bronchospasm which can result in death or 'cement lung'" and that "[p]rior to marketing Raplon, . . . Organon knew or should have known that Raplon could cause death or cement lung as a result of severe bronchospasm." It further alleged that Organon failed "to ascertain and report the existence, nature, and extent of the risk of severe bronchospasm posed by Raplon"; failed to "give an adequate, meaningful warning regarding the significant risk of bronchospasm and/or cement lung related dysfunctions of Raplon"; and "[r]ecklessly, falsely, and/or deceptively represented or knowingly omitted, suppressed, or concealed facts of such materiality regarding the safety and efficacy of Raplon from prescribing physicians and the consuming public." At a minimum, there is "substantial identity" between these

allegations and the allegations of fraud in Feldstein's complaint. *Poteet*, 552 F.3d at 514.[3]

Feldstein contends that his allegations are not "based upon" the allegations in *Rogers* because that complaint sounded in negligence, failure to warn, and breach of warranty, and made no reference to Medicare, Medicaid, or false claims. This distinction is unavailing. Feldstein's identification of one specific legal consequence of the alleged fraud–the possible submission of false claims to Medicare and Medicaid–does not change the substantially similar nature of the underlying allegations of fraud and concealment in each action. *See United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 688 (D.C. Cir. 1997) (noting that a "relator's ability to recognize the legal consequences of a publicly disclosed fraudulent transaction does not alter the fact that the material elements of the violation already have been publicly disclosed"); *Kennard v.*

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[3] Several of our cases use the following algebraic representation to explain the public disclosure bar:

> If X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed. To draw an inference of fraud, both a misrepresented [X] and a true [Y] state of facts must be publicly disclosed. So, if *either* Z (fraud) or both X (misrepresented facts) and Y (true facts) are disclosed by way of a listed source, then a relator is barred from bringing suit under § 3730(e)(4)(A) unless he is an original source.

Atkinson, 473 F.3d at 519 (emphasis added, internal citations and alterations omitted). Our conclusion, stated in these terms, is that the "Z" (fraud) component of the equation was publicly disclosed before Feldstein filed his complaint. Therefore, we need not analyze the X and Y components.

Comstock Res., Inc., 363 F.3d 1039 (10th Cir. 2004) (same); *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1245 (9th Cir. 2000) (noting that the "mere fact that [the relator's] own expertise . . . enabled it to formulate its novel legal theory of fraud is irrelevant to the question of whether the material transactions giving rise to the alleged fraud were already disclosed in the public domain in the first place").

The allegations of fraud in Feldstein's complaint are substantially similar to allegations that were publicly disclosed in the *Rogers* complaint. Therefore, the District Court correctly held that the allegations in Feldstein's complaint were "based upon" those publicly disclosed allegations for purposes of the public disclosure bar.

B. Feldstein Was Not an "Original Source"

Because Feldstein's allegations were "based upon" public disclosures, the District Court lacked jurisdiction over his claim unless he was an "original source" of the allegations in his complaint. To qualify as an "original source," the private plaintiff must have "direct and independent knowledge of the information on which the allegations are based and . . . voluntarily provide[] the information to the Government before filing" the action. 31 U.S.C. § 3730(e)(4)(B). "Direct" knowledge means knowledge that is "immediate" and "marked by absence of an intervening agency[.]" *Stinson*, 944 F.2d at 1160. The "independent" knowledge requirement means that "knowledge of the fraud cannot be merely dependent on a public disclosure." *Paranich*, 396 F.3d at 336.

We conclude that Feldstein lacked "direct" knowledge of Organon's alleged fraud. To be direct, Feldstein's knowledge must have arisen from his "own efforts, . . . not by

the labors of others, and . . . [must not be] derivative of the information of others." *Id.* (quoting *United States ex rel Hafter v. Spectrum Emergency Care, Inc.*, 190 F.3d 1156, 1162 (10th Cir. 1999)). It is undisputed that Feldstein was not involved in the FDA approval process for Raplon; he could not have been, for Raplon's FDA approval predated Feldstein's employment with Organon. Once employed by Organon, Feldstein did no work related to Raplon. He describes no fraud concerning Raplon that he personally witnessed or in which he participated. His knowledge concerning Organon's alleged fraud was acquired through "intervening agenc[ies]," *see Stinson*, 944 F.2d at 1160, such as his receipt of the "smoking gun" email from Dr. Sack and his conversation with Plona. This is not the kind of "immediate," first-hand knowledge required by our precedents. *Id.* Accordingly, we conclude that Feldstein lacked "direct and independent knowledge of [Organon's] allegedly fraudulent statements" concerning Raplon, and thus was not an original source. *See Mistick*, 186 F.3d at 389.

Feldstein's FCA claim is based on publicly disclosed allegations and Feldstein was not an original source of those allegations. Therefore, the public disclosure bar of 31 U.S.C. § 3730(e)(4)(A) forecloses his claim.

III.

Because the public disclosure bar applies, we conclude that the District Court lacked jurisdiction over Feldstein's claim. On that basis, we will affirm the District Court's judgment. We do not reach the District Court's alternative holding that Feldstein's complaint failed to satisfy the heightened pleading requirements of Rule 9(b).