United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 12, 2021 Decided July 20, 2021

No. 20-7062

UNITED STATES OF AMERICA,
EX REL. ELIZABETH W. KENNEDY, ET AL.,
PLAINTIFF-APPELLEES

AND

ELIZABETH W. KENNEDY,
PLAINTIFF-APPELLANT

v.

NOVO A/S, ET AL.,
DEFENDANTS

Appeal from the United States District Court
for the District of Columbia
(No. 1:13-cv-01529)

Nicolas F. Mendoza argued the cause for appellant. With him on the briefs were *Ann Lugbill*, *Michael T. Anderson*, *Mark Hanna*, *Joel M. Androphy*, and *Sarah Frazier*.

Andrea Gold was on the brief for *amicus curiae* Taxpayers Against Fraud Education Fund in support of appellant.

Karen Schoen, Attorney, U.S. Department of Justice, argued the cause for appellee. With her on the brief were *Brian M. Boynton*, Acting Assistant Attorney General, and *Charles W. Scarborough*, Attorney.

Before: MILLETT, KATSAS, and RAO, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* MILLETT.

MILLETT, *Circuit Judge*: The False Claims Act authorizes the federal government to obtain treble damages for false and fraudulent claims for money or property that are submitted to it. 31 U.S.C. § 3729(a)(1). The Act also authorizes private persons to help obtain such recoveries for the government by filing *qui tam* lawsuits against those who engaged in such false or fraudulent behavior. *Id.* § 3730(b). If successful, those private plaintiffs receive a share of the damages awarded. *Id*. § 3730(d).

Yet the same misconduct that underlies false and fraudulent claims may also run afoul of other federal statutes for different reasons. As a result, the government may sometimes choose to pursue relief under the False Claims Act. Other times, on the same set of facts, it might prioritize the enforcement of a different law. Still other times, it might do both.

The question in this case is whether a private plaintiff who has filed a False Claims Act case is also entitled to a share of the monetary relief that the government obtains in its own separate enforcement action just because the underlying facts are similar to those in the earlier-filed *qui tam* lawsuit. The answer is No. The plain text of the False Claims Act confines *qui tam* plaintiffs to recoveries only for claims seeking relief based on the type of fraud or falsehoods covered by that statute.

The government's separate enforcement action in this case did not involve the type of claim cognizable under the False Claims Act, nor did it allege a false or fraudulent effort to obtain money or property from the United States. In addition, the *qui tam* plaintiff, Elizabeth Kennedy, received an agreed-upon False Claims Act payment with knowledge of the government's separate action. So she is not entitled to any further recovery.

I

A

The False Claims Act, 31 U.S.C. § 3729 *et seq*., broadly makes individuals liable for a civil penalty and treble damages if they submit "[f]alse claims" to the federal government concerning money or property. More specifically, the False Claims Act prohibits individuals from (i) knowingly presenting to the federal government a false or fraudulent claim for payment, (ii) knowingly making or using a false statement material to a false or fraudulent claim, (iii) knowingly failing to deliver money or property that is to be used by the federal government, (iv) knowingly buying or receiving public property from an unauthorized government worker in payment of a debt or obligation, (v) knowingly making or using a false record or otherwise improperly avoiding or decreasing a debt or obligation owed to the government, (vi) making or delivering a document that certifies the receipt of property for governmental use without knowledge that the information in the receipt is true and with the intent to defraud the government, or (vii) conspiring to violate any of the preceding provisions. 31 U.S.C. § 3729(a)(1).

Under Section 3729, a false "claim" means "any request or demand * * * for money or property" in which the United States has a legal interest that is either "presented to an officer, employee, or agent of the United States" or is "made to a

contractor, grantee, or other recipient" who has authority to use that money or property on the government's behalf. *See* 31 U.S.C. § 3729(b)(2).

Section 3730 then authorizes the Attorney General to bring "[c]ivil actions for false claims" for any violation of those Section 3729 prohibitions. 31 U.S.C. § 3730(a) (bold omitted).

To strengthen enforcement and to protect taxpayers' money, the False Claims Act also authorizes private persons to bring civil *qui tam* lawsuits in the name of the United States for violations of Section 3729's prohibitions. 31 U.S.C. § 3730(b)(1).[1] When suing in the name of the United States, those private plaintiffs are referred to as "relators." *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769 (2000). If a False Claims Act suit is successful, the relator may receive up to 30% of the damages recovered, as well as reasonable attorneys' fees and costs. 31 U.S.C. § 3730(d)(1) & (2).

Since Congress amended the False Claims Act in 1986, *qui tam* suits under Section 3730 have saved the government over $45 billion. *See* DEPARTMENT OF JUSTICE, FRAUD STATISTICS—OVERVIEW: OCTOBER 1, 1986–SEPTEMBER 30, 2019, at 3 (Jan. 21, 2020), https://www.justice.gov/opa/press-release/file/1233201/download (last accessed July 19, 2021); *see also* False Claims Amendment Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153.

A relator must initially file her False Claims Act lawsuit *in camera* and under seal and serve the government with a copy of the complaint, along with any material information or

[1] The False Claims Act imposes a number of limitations on who may qualify as a *qui tam* plaintiff, but they are not at issue in this case. *See* 31 U.S.C. § 3730(e).

evidence in her possession. 31 U.S.C. § 3730(b)(2). The statute then affords the federal government at least 60 days to investigate the claims. *Id.* After the time for its review ends, the government must either intervene and assume primary responsibility for prosecuting the action, *id*. § 3730(c)(1), or "notify the court that it declines to take over the action," *id.* § 3730(b)(4)(B). If the government chooses not to intervene, then the relator litigates the action herself. *Id.* § 3730(c)(3).[2]

Subsection 3730(c)(5) of the statute separately allows the government to "pursue its claim" through an "alternate remedy" if it does not wish to press an action under the False Claims Act. As relevant here, that subsection provides:

> Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section.

31 U.S.C. § 3730(c)(5).

[2] The government may choose to intervene in the case later, but its delay may deprive it of the opportunity to oversee the lawsuit. 31 U.S.C. § 3730(c)(3).

B

1

In January 2009, Elizabeth Kennedy began working for Novo Nordisk, a pharmaceutical company, as a sales representative. False Claims Act Complaint ¶ 4, *United States ex rel. Kennedy v. Novo Nordisk Inc.*, No. 13-cv-01529-RBW (D.D.C. Oct. 15, 2010), ECF No. 1, J.A. 26–27. Kennedy was tasked with helping to promote Novo Nordisk's new diabetes drug, Victoza. *Id.* Victoza was designed to improve "glycemic control"—that is, maintain safe levels of blood sugar—in adults with type-2 diabetes.

The Food and Drug Administration's approval of Victoza for sale in 2010 came with specific conditions.

First, the drug had to be labeled with a warning that its use created an "unknown risk" of contracting a specific type of thyroid cancer.

Second, Novo Nordisk had to maintain a "Risk Evaluation and Mitigation Strategy" for Victoza. The point of that strategy was to warn healthcare providers about the possible risk of thyroid cancer so that providers could monitor their patients appropriately.[3]

Third, Novo Nordisk was not allowed to promote the drug for use by adults with type-2 diabetes.

---

[3] The Secretary of Health and Human Services may impose a Risk Evaluation and Mitigation Strategy when doing so "is necessary to ensure that the benefits of the drug outweigh the risks of the drug[.]" 21 U.S.C. § 355–1(a)(1).

According to the allegations in Kennedy's complaint, in the lead-up to Victoza's commercial launch, Kennedy's supervisors directed her to market the drug in ways that ran afoul of those FDA limitations. False Claims Act Complaint ¶ 98, *Kennedy*, No. 13-cv-01529-RBW (D.D.C. Oct. 15, 2010), ECF No. 1 ("Kennedy was directed at the launch meeting, at district meetings, and in ride-a-longs with her manager, to make a number of off-label claims about Victoza."), J.A. 63. Kennedy alleged that, among other violations, Novo Nordisk marketed the drug for use by pre-diabetics, who outnumber patients with diabetes two to one in the United States According to Kennedy's allegations, selling Victoza as a treatment to pre-diabetics could potentially triple the market for the drug. *Id.* ¶ 105. The problem was that the FDA had not approved Victoza for the treatment of pre-diabetics. J.A. 573 ¶ 11.

Kennedy also alleged that Novo Nordisk instructed sales representatives not to mention the "unknown risk" of thyroid cancer to doctors. False Claims Act Complaint ¶ 117, *Kennedy*, No. 13-cv-01529-RBW (D.D.C. Oct. 15, 2010), ECF No. 1, J.A. 70. In fact, according to her complaint (and to Novo Nordisk's own admissions), "Novo Nordisk trained sales representatives to downplay these safety issues and side effects * * * during calls with doctors." *Id.* ¶ 119, J.A. 71; *see also* J.A. 438 ¶ (D)(1)–(5) (Novo Nordisk admitting that it "trained its sales representatives that * * * they were permitted to inform physicians that there were no cases of [thyroid cancer] in the clinical trials for Victoza[,]" and that certain Novo Nordisk sales representatives "suggested to or told prescribers that * * * Victoza[] only posed a risk of [thyroid cancer] to rats or rodents and posed no risk to humans.").

Armed with this information, Kennedy filed a False Claims Act complaint in the United States District Court for the Southern District of Texas in October 2010. Kennedy alleged, among other things, that Novo Nordisk had violated the False Claims Act by causing people to submit to the federal government millions of dollars in false claims for payment under federal health care programs like Medicare and Medicaid. False Claims Act Complaint ¶¶ 164–165, *Kennedy*, No. 13-cv-01529-RBW (D.D.C. Oct. 15, 2010), ECF No. 1 (Kennedy alleged that Novo Nordisk made millions of dollars by selling Victoza to "Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, and other federal healthcare program patients[.]"), J.A. 85–86; *id.* ¶ 171, J.A. 88. Other relators across the country subsequently filed similar lawsuits. All of those *qui tam* cases were then transferred to and consolidated in the United States District Court for the District of Columbia.

In July 2017, the United States filed a formal notice of intervention in the district court. In the notice, the government advised that the United States, Novo Nordisk, and Kennedy had reached a settlement in the case in which Novo Nordisk agreed to pay $46.5 million to resolve the matter. J.A. 352, 406 ¶ 1.

The United States explained that it was intervening only "as to the Covered Conduct as that term is defined in Paragraph K of the Settlement Agreement, to the extent that the Complaint contains such claims." J.A. 352. That covered conduct was (i) Novo Nordisk's training of its sales representatives to imply that the "risk message was erroneous, irrelevant, or unimportant," J.A. 404, and (ii) Novo Nordisk's knowing promotion of Victoza for sale to and use by adults

who did not yet have type-2 diabetes, J.A. 405. The district court subsequently approved the voluntary dismissal of Kennedy's remaining False Claims Act claims. *See* False Claims Act Complaint ¶¶ 185–190, *Kennedy*, No. 13-cv-01529-RBW (D.D.C. Oct. 15, 2010), ECF No. 1 (alleging conspiracy and retaliation claims under the Act), J.A. 91–92.

Four days later, the government filed in the same court a separate complaint against Novo Nordisk. This case pressed claims not under the False Claims Act, but under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. J.A. 571 ¶ 1. The government alleged that Novo Nordisk introduced Victoza into interstate commerce as an unlawfully "misbranded" drug because it "failed to comply with the Victoza Risk Evaluation and Mitigation Strategy[.]" J.A. 571 ¶ 1 (citing 21 U.S.C. § 331). The government accused Novo Nordisk of providing its sales force with "certain messages and tactics" that created the "false or misleading impression" that the warning about thyroid cancer on Victoza's label was "erroneous, irrelevant, or unimportant." J.A. 571–572 ¶ 1. The government sought "an equitable disgorgement of $12,150,000[.]" J.A. 578 ¶ 28(a).

At the same time that it filed the complaint, the government disclosed that it had already settled the FDCA claims with Novo Nordisk. As part of the FDCA Settlement, Novo Nordisk admitted that it had trained its employees to undermine the Risk Evaluation and Mitigation Strategy. J.A. 438. Novo Nordisk also agreed to pay the government $12,150,000. Although the government entered into the FDCA Settlement only a few days after the False Claims Act Settlement, Kennedy was not a party to the FDCA litigation or to its settlement. At the government's request, the district court dismissed the FDCA case shortly thereafter.

Following those settlements, Kennedy filed a motion claiming that, as a *qui tam* relator, she was entitled to a fair share of the False Claims Act settlement. Relator Kennedy's Motion for Immediate Award of Relator's Share, *United States ex rel. Kennedy v. Novo A/S*, No. 13-cv-01529-RBW (D.D.C. Oct. 27, 2017), ECF No. 96. Kennedy also mentioned in a footnote that, as a relator, she believed that she had a right to a share of the FDCA Settlement as well. *Id.* at 5 n.6.

Twenty months later, Kennedy separately moved the district court to award her a share of the FDCA Settlement. Relator Kennedy's Motion for Relator's Share of Award, *United States ex rel. Kennedy v. Novo A/S*, No. 13-cv-01529-RBW (D.D.C. June 12, 2019), ECF No. 116. Kennedy argued that the FDCA Settlement was an "alternate remedy" under the False Claims Act, 31 U.S.C. § 3730(c)(5), and so she was statutorily entitled to a share of that recovery too. Relator Kennedy's Motion for Relator's Share of Award at 9, *United States ex rel. Kennedy v. Novo A/S*, No. 13-cv-01529-RBW (D.D.C. June 12, 2019), ECF No. 116.

In May 2020, the district court agreed with Kennedy that she was entitled to a relator's share of the False Claims Act settlement.[4] The court awarded her 18% of the recovery, which

[4] None of the other relators who had filed *qui tam* suits in other courts were awarded any share of the federal recovery because Kennedy's suit was the first in time. *See United States ex rel. Ferrara v. Novo Nordisk, Inc.*, Nos. 11-cv-74, 11-cv-1596, 11-cv-1662, 13-cv-221, 13-cv-1529, 17-cv-791, 2019 WL 4305503, at *3 (D.D.C. Sept. 11, 2019); *see also* 31 U.S.C. § 3730(e)(4)(A) ("The court shall dismiss an action or claim under this section [3730]" if the allegations are publicly disclosed, "unless the action is brought

was roughly $7.8 million plus interest. Kennedy Br. 24 n.4; Gov't Br. 27–28. But the court denied her request for a share of the FDCA Settlement proceeds. *United States ex rel. Kennedy v. Novo A/S*, No. 13-cv-01529-RBW, 2020 WL 2552947, at *7 (D.D.C. May 19, 2020). Following similar decisions of the Third, Sixth, and Ninth Circuits, the district court ruled that Kennedy could not recover any share of the government's FDCA Settlement because the government had intervened in her False Claims Act lawsuit. *Id.* (citing *United States ex rel. Bledsoe v. Community Health Sys., Inc.*, 342 F.3d 634, 649 (6th Cir. 2003); *United States ex rel. Barajas v. United States*, 258 F.3d 1004, 1010 (9th Cir. 2001); *United States ex rel. Dunleavy v. County of Delaware*, 123 F.3d 734, 739 (3d Cir. 1997)).

Kennedy filed a timely notice of appeal.

II

The district court had federal subject-matter jurisdiction under 28 U.S.C. § 1331. We have jurisdiction under 28 U.S.C. § 1291.

The meaning of the False Claims Act's provision governing alternate remedies is a question of statutory construction that we review *de novo*. *See Allegheny Defense Project v. FERC*, 964 F.3d 1, 11 (D.C. Cir. 2020).

III

The question in this case is whether the government's FDCA lawsuit against and settlement with Novo Nordisk was an "alternate remedy," within the meaning of the False Claims

---

by the Attorney General or the person bringing the action is an original source of the information.").

Act, 31 U.S.C. § 3730(c)(5), from which Kennedy was entitled to receive a relator's share of the settlement, or whether it was instead an independent action outside of subsection 3730(c)(5)'s compass. In other words, what types of governmental enforcement actions count as an "alternate remedy" and which do not? We hold that, regardless of the government's decision to intervene in the False Claims Act litigation, the FDCA Settlement was not an "alternate remedy" because it did not involve the type of claim covered by the False Claims Act.

A

In deciding whether the False Claims Act's alternate-remedy provision applies to the government's FDCA lawsuit and settlement, we begin and end with the plain text of the False Claims Act, because its terms confine the *qui tam* relator to recoveries arising from the type of fraud claims that could have been brought in a *qui tam* action under the False Claims Act.

By way of reminder, the alternate-remedy provision of the False Claims Act provides in relevant part:

> Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the [False Claims Act] action shall have the same rights in such proceeding as such person would have had if the action had continued under this section.

31 U.S.C. § 3730(c)(5).

In three ways, that statutory text allows a relator to recover a share only when the claim pursued in the alternate remedy is of the type that could have been pressed under the False Claims Act.

First, while subsection 3730(c)(5) does not define alternate remedy, the opening clause "[n]otwithstanding subsection (b)" signifies that the alternate remedy is an alternative that the government can choose instead of its intervention, participation, and pursuit of a remedy in a private *qui tam* lawsuit—the subject of subsection (b). After all, an "alternate" remedy must be in place of something else. That is, there must be a default choice for which the alternate remedy is a different option.

Here, the "notwithstanding" clause tells us that the default choice is the remedy the government could have pursued under the *qui tam* provision of the False Claims Act. Section 3730(c)(5), in other words, gives the government options for resolving the types of false and fraudulent claims that are the *raison d'etre* of the False Claims Act, 31 U.S.C. § 3729. *See* S. REP. NO. 345, 99th Cong., 2d Sess. at 1 (1986) (The purpose of the False Claims Act is to "enhance the Government's ability to recover losses sustained as a result of fraud against the Government."); *United States ex rel. Totten v. Bombardier Corp.*, 286 F.3d 542, 546 (D.C. Cir. 2002) ("The statute's *qui tam* provision is a powerful tool that augments the government's limited enforcement resources by creating a strong financial incentive for private citizens to guard against efforts to defraud the public fisc.").[5]

[5] The meaning of an "alternate" remedy as an alternative to an already identified remedy seems well within the public ken, and in fact is not disputed by Kennedy. But if dictionary definitions from

Second, to understand when subsection 3730(c)(5) applies, one has to ask: "Alternate remedy for what?"

Again, the statutory text answers that question: The alternate remedy must be used to pursue the government's "claim." 31 U.S.C. § 3730(c)(5). Within the context of legal proceedings, which is what Section 3730 addresses, a "claim" is a "[c]ause of action," and the "[m]eans by or through which [a] claimant obtains possession or enjoyment of [a] privilege or thing." *Claim*, BLACK'S LAW DICTIONARY 224 (5th ed. 1979).

But subsection 3730(c)(5) does not refer to just any legal claim or cause of action that the government has. The statute does not, for example, say that the relator can recover if the government pursues any alternate cause of action. Instead, the remedy is tied to the single referenced "claim." 31 U.S.C. § 3730(c)(5). That claim is only the one that otherwise could be prosecuted through a *qui tam* suit under subsection 3730(b) of the False Claims Act. It is for those specified claims of falsity or fraud that Congress felt a need to give express permission for the government to pursue alternative recourse "notwithstanding" a relator's initiation of a *qui tam* lawsuit under "subsection (b)." *Id.*

---

the time of enactment are desired, see *Alternate*, RANDOM HOUSE UNABRIDGED DICTIONARY 61 (defs. 11 & 12) (2d ed. 1993) (defining "alternate" as "constituting an alternative" and "alternative (defs. 4, 6)"); *Alternative*, *id.* (defs. 4 & 6) (defining "alternative" as "affording a choice of two or more things, propositions, or courses of action" and "employing or following nontraditional or unconventional ideas, methods, etc."); *see also* WEBSTER'S NEW INT'L DICTIONARY 63 (def. 1-5) (3d ed. 1981) (defining "alternate" as an "alternative" or "substitute").

More specifically, the legal claims that the False Claims Act vests in the government are for "violation[s] under section 3729." 31 U.S.C. § 3730(a). Section 3729, in turn, spells out seven grounds of liability based on the use of falsity or fraud to obtain money or property in which the United States has a legal interest. *Id.* § 3729(a)(1)(A), (B), (C), (D), (E), (F) & (G). The statute is all about those species of false and fraudulent claims. *Id.* § 3729 (entitled "False claims"); *id.* § 3730 (entitled "Civil actions for false claims"); False Claims Amendments Act of 1986, Pub. L. No. 99-562, § 2, 100 Stat. 3153, 3153 (1986). And those claims are the only type for which the statute authorizes a *qui tam* lawsuit. 31 U.S.C. § 3730(b)(1) (*qui tam* plaintiff "may bring a civil action *for a violation of section 3729*") (emphasis added).

All of that is a long way of saying that Section 3730's alternate-remedy provision authorizes the government, when confronted with a *qui tam* complaint, to choose to vindicate its legal claim arising from the fraud and falsity that Section 3729 proscribes through either (i) the *qui tam* action, or (ii) an alternate remedy for that same type of false or fraudulent claim. 31 U.S.C. § 3730(a), (b) & (c)(5).

Reading "claim" in subsection 3730(c)(5) as referring to the types of falsity and fraud that the False Claims Act identifies is not just textually compelled; it is commonsensical. Why would Congress need to expressly authorize the use of alternative legal remedies for a claim unless it is the same type of claim that the statute otherwise addresses and remediates?

Third, subsection 3730(c)(5) provides that, if the government pursues an alternate remedy, the relator "shall have the same rights in such proceeding as" she "would have had if the action had continued under this section." 31 U.S.C. § 3730(c)(5). That means that the type of claim the

government pursues through the alternate remedy must be the same type of claim that a relator could have initiated and "continued" through a *qui tam* False Claims Act suit. *Id*. After all, those are the only types of claims that give rise to "rights" for *qui tam* relators and the only claims that relators can pursue through "action[s] * * * under this section"—that is, the False Claims Act cause of action. *Id.* (indicating that the action must have been able to "continue[] under [Section 3730]," which prescribes the rules for civil actions for false claims).

In short, from every angle, the text of the alternate-remedy provision establishes that the alternative remedial proceedings from which a relator can recover a share must redress the same type of falsity and fraud claims that otherwise could be pursued by a private relator's *qui tam* lawsuit under the False Claims Act. That could include, for example, an administrative proceeding for the remediation of false or fraudulent money claims. *See* 31 U.S.C. § 3730(c)(5).

By the same token, if the alternate proceeding seeks recompense for some other type of claim that the relator could not have brought, then the proceeding is not covered by subsection 3730(c)(5) because it is not "alternate" to the False Claims Act *qui tam* remedy. It is a different legal claim altogether, arising beyond the False Claims Act's borders.[6]

[6] Given the statutory text and structure, we doubt that the district court was correct in holding that the permissibility of an alternate remedy recovery turns on the government's intervention decision. *See United States v. L-3 Communications EOTech, Inc.*, 921 F.3d 1, 26–27 (2d Cir. 2019). So we exercise our prerogative to affirm on another ground. *See United States ex rel. Heath v. AT&T, Inc.*, 719 F.3d 112, 123 (D.C. Cir. 2015).

B

1

Given subsection 3730(c)(5)'s text, the alternate-remedy provision forecloses Kennedy's argument that she is also entitled to a share of the FDCA Settlement.

In the FDCA lawsuit, the government charged Novo Nordisk with misbranding its drug in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 352(y), and shipping that misbranded drug in interstate commerce in violation of 21 U.S.C. § 331. *See* FDCA Complaint ¶ 1, *United States v. Novo Nordisk Inc.*, No. 17-cv-01820-RBW (D.D.C. Sept. 5, 2017), ECF No. 1 (alleging that the defendant received "ill-gotten gains" because it "introduced Victoza into interstate commerce while such drug was misbranded"), J.A. 571. But misbranding bears little resemblance to the types of fraudulent behavior that the False Claims Act identifies and proscribes. *See* 31 U.S.C. § 3729(a)(1).

Most critically, a misbranding claim seeks to protect the *public* from being misled by the drug company's marketing tactics. And it does so by pursuing equitable relief and penalties or fines. *See* 21 U.S.C. § 333 (defining civil and criminal penalties for violations of Section 331); *id.* § 355a (allowing debarment as a punishment for individuals convicted of federal felonies related to abbreviated new drug applications); *cf. United States v. Rx Depot, Inc.*, 438 F.3d 1052, 1062 (10th Cir. 2006) (restitution under the FDCA is different from traditional damages because it is "directly traceable to * * * illegal conduct and the *harm it caused consumers*" rather than the United States itself) (emphasis added).

So a misbranding claim does not seek to recover damages for any use of falsity or fraud to deprive the *government* of its money or property, which is the hallmark of a claim litigable under the False Claims Act. 21 U.S.C. § 333; *see* FDCA Complaint, *Novo Nordisk*, No. 17-cv-01820 (D.D.C. Sept. 5, 2017), ECF No. 1 (no allegation that Novo Nordisk used falsity or fraud in submitting claims to the government or otherwise to obtain money or property in which the government held a legal interest), J.A. 571–579.

That means that the FDCA Settlement did not resolve the type of claim that could have been litigated under the False Claims Act. Kennedy agrees. She admits that she would never have been able to bring a *qui tam* lawsuit against Novo Nordisk for misbranding. Oral Argument Tr. at 9:23–10:1, *United States ex rel. Kennedy v. Novo A/S*, No. 20-7062 (D.C. Cir. May 24, 2021), ECF No. 1899779. Nor is the misbranding lawsuit the type of action that could have been initiated by a *qui tam* relator, let alone "continued[,]" under subsection 3730(b) of the False Claims Act. Yet that is a prerequisite for obtaining a relator's share under the alternate-remedy provision. 31 U.S.C. § 3730(c)(5).

2

Kennedy argues that she nevertheless is entitled to recover under subsection 3730(c)(5) because the FDCA claim arose from the same underlying facts identified in her *qui tam* lawsuit.

The problem is that Congress wrote a different statute than the one that Kennedy envisions. Congress provided for the relator to share in the recovery if and when the government pursues an "alternate remedy" specifically for a false or fraudulent taking of governmental money or property. 31 U.S.C. § 3730(c)(5). The statute does not reward relators any

time the government pursues any "alternate claim or cause of action" arising from the same facts and circumstances. In other words, it is the nature of the legal claim—the fraudulent or false deprivation of a monetary or property interest—and not the commonality of facts that determines a relator's right to share in an alternative recovery.

To that same point, if Congress had wanted the relator's recovery for an alternate remedy to turn on whether the government's action arose out of the same facts, it would have used the language that it employed in the immediately preceding subsection. Subsection 3730(c)(4) addresses discovery matters when the government prosecutes "a criminal or civil matter arising out of the same facts[.]" 31 U.S.C. § 3730(c)(4). But Congress did not draw that same line in subsection 3730(c)(5). Instead, Congress changed course and tied the relator's recovery of an alternate remedy to the nature of the claim pursued by the government, not to the facts from which the claim arose. That is a textual distinction that makes a difference. *Salinas v. United States R.R. Retirement Board*, 141 S. Ct. 691, 698 (2021) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)).

Kennedy's proposed reading of the statute also overlooks that the "claim" pursued through an alternate remedy must be one that could have continued instead under the False Claims Act. 31 U.S.C. § 3730(c)(5). The misbranding claim plainly could not have. So Kennedy's atextual focus on just the underlying facts would vastly expand a relator's right to recover beyond the type of injury that the False Claims Act addresses.

Neither of the cases on which Kennedy relies for her "factual overlap" theory works. *See* Kennedy Br. 19 (citing *Rille v. PricewaterhouseCoopers LLP*, 803 F.3d 368, 373–374 (8th Cir. 2015) (en banc); *Bledsoe*, 342 F.3d at 650–651). Both cases state only that factual overlap is *necessary* for an alternative proceeding to be an "alternate remedy" within the meaning of subsection 3730(c)(5). *See Rille*, 803 F.3d at 373; *Bledsoe*, 342 F.3d at 649. But neither case holds that factual overlap alone is *sufficient* to allow a relator to share in the recovery.

To be sure, factual similarity can be important. It can, for example, ensure that the claim for which recovery is sought is one that the relator herself actually brought to the government's attention. 31 U.S.C. § 3730(e)(4)(A). And common facts may, for claim preclusion reasons, sometimes make it difficult for the government to pursue an alternate remedy after intervening in the *qui tam* lawsuit. But for present purposes, that is neither here nor there. The issue in this case is not what the government can do, but whether and when a relator may share in the proceeds after the government has successfully obtained a recovery through an alternative proceeding. Factual symmetry alone is not enough to seal that deal.

3

Kennedy also worries that resting a relator's right to recover under the alternate-remedy provision on the character of the claim rather than the similarity of the underlying facts will allow the government to reap all the benefit of the relator's work and yet avoid compensating her as the False Claims Act contemplates.

But the False Claims Act has built-in mechanisms to protect against such abuse. Most relevantly, a relator can object to the government's settlement of its False Claims Act

qui tam suit. 31 U.S.C. § 3730(c)(2)(B). If the relator raises an objection to the settlement, the district court must determine, after first holding a hearing, whether "the proposed settlement is fair, adequate, and reasonable under all the circumstances[.]" *Id.*

In any event, this case does not implicate Kennedy's concern. Kennedy received an 18% share (approximately $7.8 million) of the False Claims Act settlement. And importantly, Kennedy never objected to the fairness of her settlement even though the government gave her advance notice of its separate settlement under the Food, Drug, and Cosmetic Act. *See* J.A. 447–448 ¶¶ 9, 12–14; *see also* Oral Argument Tr. at 34:21–22, *Kennedy*, No. 20-7062 (D.C. Cir. May 24, 2021), ECF No. 1899779. If Kennedy had feared that she would be short-changed, she could have raised that concern in a motion prior to the district court's dismissal of her *qui tam* action.

Given all of that, we have no occasion to decide in this case what the consequences (if any) would be were the government to use a relator's information in a separate proceeding without fairly compensating the relator in the *qui tam* litigation, or what would happen if the government failed to disclose the existence of such a separate proceeding to the relator and the district court before the district court approves settlement of the action as fair, adequate, and reasonable. For purposes of the case before us, it suffices to say that the claim pursued by the government through an alternate remedy here was not of the type that Kennedy could ever have pursued in a False Claims Act *qui tam* action and that no claim of governmental manipulation has been raised.

IV

Subsection 3730(c)(5) limits a relator's recovery from an alternate remedy pursued by the government to those types of

false or fraudulent claims that the False Claims Act recognizes and for which a *qui tam* action could have been litigated. For that reason, we affirm the judgment of the district court declining to disburse to Kennedy a share of the FDCA settlement.

So ordered.