In the

United States Court of Appeals

For the Seventh Circuit

No. 24-3121

JEFFREY LEWIS,

Plaintiff-Appellant,

v.

ABBVIE INC., f/k/a/ ALLERGAN,

Defendant-Appellee.

Appeal from the United States District Court for the
Northern District of Indiana, South Bend Division.
No. 3:20-cv-00956 — **Damon R. Leichty,** *Judge*.

ARGUED MAY 15, 2025 — DECIDED SEPTEMBER 3, 2025

Before RIPPLE, KIRSCH, and KOLAR, *Circuit Judges*.

KOLAR, *Circuit Judge*. Jeffrey Lewis sued AbbVie under the False Claims Act for retaliating against him as a whistle-blower. Lewis had become alarmed by how the company marketed one of its drugs, Vraylar, as an effective treatment for non-approved uses. The gist of the alleged fraud rests on connecting several premises. One, government insurance usually does not cover prescriptions for non-approved uses. Two, the government insures roughly 40% of Americans. And

three, by pushing Vraylar to medical providers for off-label uses, AbbVie caused at least one provider to submit a false claim—reimbursement for unapproved use of Vraylar—for a government-insured patient. The district court found this theory implausible and dismissed Lewis's claim.

At this early stage of litigation, we ask only whether the alleged facts give rise to a plausible, not probable, claim for relief. Still, because Lewis only complained of regulatory, rather than fraudulent, violations in his internal communications with AbbVie, the company had no reason to think Lewis's concerns revolved around the False Claims Act. More simply, AbbVie could not have retaliated against Lewis as a fraud whistleblower because he never blew the whistle on fraud. We affirm.

I. Background[1]

This case stems from Jeffrey Lewis's experience as a sales representative for AbbVie, a global pharmaceutical manufacturer, in 2019 and 2020. As a salesman, Lewis marketed AbbVie's drugs to medical providers to increase prescriptions, and thus, revenue for AbbVie. We focus on one type of advertising practice—"off-label" marketing.

A medical provider can prescribe a drug for either (1) its Food and Drug Administration (FDA) approved use on the label or (2) its unapproved "off-label" use. The Food, Drug, and Cosmetic Act (FDCA) and accompanying regulations generally prohibit pharmaceutical companies like AbbVie

[1] Because the district court dismissed Lewis's claim at the pleadings stage, we recite the well-pled facts according to the complaint and view them in the light most favorable to Lewis. *Emerson v. Dart*, 109 F.4th 936, 941 (7th Cir. 2024).

from promoting off-label uses to the public or medical providers. 21 C.F.R. §202.1(e)(6)–(7). Providers are free to prescribe drugs for off-label use, but drug companies cannot be the ones to suggest the idea.[2]

Another rule of thumb important to this case: Medicare and Medicaid do not reimburse off-label prescriptions unless one of three medical compendia have sanctioned the use. During his employment with AbbVie, Lewis was "regularly made to re-certify [his] awareness and understanding" that off-label marketing was unlawful and told that non-compliance with these regulations "constitute[d] a personal and corporate risk" of "state and federal anti-fraud statutes."

Vraylar is one of AbbVie's drugs. It is an antipsychotic medication the FDA has approved for treating schizophrenia, bipolar mania, and bipolar I depression. Bipolar depression is medically distinct from major depression disorder (MDD) because MDD patients do not experience mania and mixed emotion episodes, a necessary feature of a bipolar diagnosis.[3] As

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[2] A helpful illustration. The FDA has only approved Ozempic for its on-label use to treat Type II Diabetes. However, because of its efficacy at helping individuals lose weight, many physicians prescribe it for weight loss, which is off-label. Carley Prendergast, *Ozempic For Weight Loss: Is It Safe and What Do Experts Say?*, FORBES (Aug. 7, 2025), https://perma.cc/9EU3-KUV4.

[3] MDD is also far more common than bipolar depression, affecting roughly three times as many Americans. NAT'L. CTR. HEALTH STATISTICS, CTR. FOR DISEASE CONTROL AND PREVENTION, No. 528, CHARACTERISTICS OF ADULTS AGE 18 AND OLDER WHO TOOK PRESCRIPTION MEDICATION FOR DEPRESSION: UNITED STATES, 2023 at 1 (1 in 10 adults took prescription medication for major depressive episodes in 2023); *Bipolar Disorder*, Nat'l Inst. of Health: Mental Health Info., https://perma.cc/3N22-VDEG (last

such, the FDA has approved different medicines and therapies for bipolar depression and MDD. Specifically, there are only three approved antipsychotic drugs for treating MDD; Vraylar is not one of them.

Any use of Vraylar to treat MDD is off-label. The only way a provider could deploy Vraylar on-label in MDD treatment is when they believe the patient actually presents with bipolar depression, in addition or alternate to MDD.

But according to Lewis, after the FDA approved Vraylar for bipolar depression treatment, AbbVie began aggressively peddling the drug to providers for off-label uses. From 2019 to 2020, AbbVie pushed Vraylar as an effective medicine for (1) substance abuse and (2) MDD.

Regarding substance abuse treatment, AbbVie identified practitioners who were known to prescribe Vraylar for addiction treatment and paid them to speak at AbbVie's lecture series. At these events, the speakers encouraged the audience, comprised of other providers, to follow their lead of using Vraylar to combat substance abuse. After several of these talks, some audience members told Lewis they took that advice. AbbVie also had Lewis convey the results of a "study" purporting to show that Vraylar was an effective addiction treatment drug on provider visits. The "study" consisted of one clinician's experience.

AbbVie's MDD off-label campaign was more extensive. Beginning in 2019, the company trained its sales representatives to pitch Vraylar as an early treatment option for patients

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visited June 12, 2025) (roughly 3% of Americans suffer from bipolar disorder).

with MDD, premised on the notion that bipolar depression and MDD were hard to distinguish. The message to providers was to eschew standardized protocol for diagnosing MDD and immediately turn to Vraylar.

The campaign came amid an ambitious sales target for employees like Lewis. Every representative was to recruit 200 new Vraylar prescribers, each writing 7 to 10 prescriptions per week, by year's end. To do so, AbbVie pushed representatives to position Vraylar as a Selective Serotonin Reuptake Inhibitor (SSRI) replacement, which it was not. SSRIs constitute an important part of many MDD treatment plans. But because Vraylar was not an SSRI, characterizing it as one was off-label. Nonetheless, if questioned by providers, Lewis was to assure them not to worry about labels. Internal documents reflected the same guidance. Vraylar was a "Great Antidepressant," and providers should avoid labeling.

The company advanced a full-court press strategy. In addition to honing the SSRI-substitute message, AbbVie propagated a study—also to be used in pitches—to falsely claim Vraylar must be used earlier in MDD treatment plans. Moreover, as with the substance abuse playbook, the firm utilized its paid speaking program to reward and incentivize providers who prescribed Vraylar for MDD. These opportunities compensated speakers $1,500 to $2,500 per hour. And, AbbVie directed its Vraylar message to "mid-level" providers, like nurse practitioners or internist doctors, rather than psychiatrists, because they were easier to persuade than those with greater bipolar and MDD expertise.

The campaign seemed to pay off. Anecdotally, specific providers told Lewis they began to prescribe Vraylar for MDD treatment. Stepping back, Vraylar sales increased 88%

in the first three fiscal quarters after AbbVie began the off-label project, and revenue from Vraylar sales increased 70% in the second quarter of 2020 alone. Critically for the claims Lewis brought, Medicare and Medicaid account for roughly 40% of annual prescription drug spending in the United States.

Despite AbbVie's ongoing success, Lewis faced blowback for refusing to push Vraylar's off-label use. When he did not comply with company messaging, he was told to hammer practitioners harder about Vraylar as a MDD drug or else risk replacement by a "bolder" representative. He dug in, and complained to his direct supervisor and the Human Resources Department about the off-label initiative. By the summer of 2020, he was emailing HR that he worried about being "noncompliant" when pitching Vraylar off-label and related issues of "corp policy." He alleges to have raised concerns over the program's "illegality," but never framed his internal grievances as related to defrauding the government through the off-label campaign. Instead, he complained of regulatory risks. As a result of his whistleblowing, Lewis claims to have lost a promotion and received excessive work.

In November 2020, Lewis brought a False Claims Act (FCA) *qui tam* action against AbbVie. Relevant to this appeal, Lewis argued that AbbVie violated the FCA by (1) causing the government to pay fraudulent insurance claims, 31 U.S.C. §3729, and (2) retaliating against him for whistleblowing. 31 U.S.C. §3730(h). The government investigated for four years before deciding not to intervene. Shortly after, AbbVie filed a motion to dismiss.

In response, Lewis amended his complaint and dropped his §3729 FCA allegation. Only his §3730(h) retaliation claim

remained. AbbVie moved to dismiss again for failure to state a claim. Lewis countered on the merits, and argued in the alternative that the district court allow him an opportunity to amend rather than dismiss with prejudice. In support of his pleading, Lewis attached an exhibit rife with internal AbbVie documents and his communications to management. The district court considered the additional facts but granted AbbVie's motion with prejudice. It found that Lewis's theory of fraud against the government was not objectively reasonable. Lewis now appeals.

II. Analysis

We review a district court's motion to dismiss for failure to state a claim *de novo*. *Kilborn v. Amiridis*, 131 F.4th 550, 556 (7th Cir. 2025). To survive dismissal, a complaint must "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A plausible claim is one with more than "a sheer possibility" of succeeding, *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), and it cannot rely on mere speculation. *Twombly*, 550 U.S. at 555. Yet it is a decidedly lower threshold than probable. *Smith & Wesson Brands, Inc. v. Estados Unidos Mexicanos*, 605 U.S. 280, 291 (2025). For most claims governed by Federal Rule of Civil Procedure 8(a)(2), including 31 U.S.C. §3730(h), the complaint simply needs "enough details about the subject matter to present a story that holds together." *Russell v. Zimmer, Inc.*, 82 F.4th 564, 570–71 (7th Cir. 2023) (citation omitted). We may affirm on any ground supported by the record, so long as the losing party had a fair opportunity to be heard on the issue. *Gonzalez v. McHenry County, Illinois*, 40 F.4th 824, 828 n.2 (7th Cir. 2022).

Under 31 U.S.C. §3730(h), an employer cannot retaliate against an individual in any matter "because of lawful acts

done by the employee ... in furtherance of an [FCA enforcement] action under this section or other efforts to stop 1 or more violations" of the FCA. That extrapolates into three elements: (1) the employee's actions were in furtherance of a FCA action or preventing a FCA violation (protected conduct requirement); (2) the employer knew the employee engaged in protected conduct (notice requirement); and (3) the employer took a retaliatory action in response. *United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 715 (7th Cir. 2014). We focus on the second element—notice. Because Lewis's internal complaints to AbbVie never suggested that *his* concern was fraud-based, rather than rooted in regulatory violations, AbbVie was not on notice that Lewis sought to prevent any FCA violations.[4] This deficiency is fatal to his claim.

A. Lewis's Theory of Fraud

While Lewis only advances a retaliation theory under §3730 after abandoning his §3729 fraud claim, the viability of his fraud theory is still relevant to understanding our disposition. Lewis needed to put AbbVie on notice that he reasonably suspected AbbVie was defrauding the government, or, in other words, that he held an objectively plausible belief that a §3729 violation was occurring. *United States ex rel. Sibley v. Univ. of Chicago Med. Ctr.*, 44 F.4th 646, 662 (7th Cir. 2022). And an entity violates §3729 when it "knowingly presents, *or causes to be presented*, a false or fraudulent claim for payment

[4] AbbVie advanced this notice argument in its motion to dismiss, and on appeal. Thus, Lewis had a fair opportunity to respond below and again before us. *See Bradley Hotel Corp. v. Aspen Specialty Ins. Co.*, 19 F.4th 1002, 1006 (7th Cir. 2021).

or approval" or "knowingly makes, uses, or *causes to be made or used*, a false record or statement material to a false or fraudulent claim" to the government. 31 U.S.C. §3729(a)(1)(A)–(B) (emphasis added).

So, we move to Lewis's theory of fraud. He argues AbbVie caused providers to present false claims to the government because they prescribed Vraylar for an off-label use at AbbVie's insistence, to at least one government-insured patient, and submitted a claim for reimbursement. Lewis's complaint does not name the providers that may have submitted false claims. Instead, AbbVie is the alleged engine of malfeasance for designing and executing a deceptive off-label campaign that led third parties (the providers) to consummate the fraud. This theory includes a layer of insulation—the providers—between the purported fraudster and the government often absent in FCA cases, which AbbVie suggests creates an "unusually attenuated" chain of causation. *Ibanez v. Bristol Myers Squibb Co.*, 874 F.3d 905, 917 (6th Cir. 2017).

Notwithstanding AbbVie's objection, FCA suits against drug manufacturers for deceptive off-label marketing campaigns are not novel. They emerged in the late 1990s and have continued since.[5] *See United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 147 F. Supp. 2d 39, 51 (D. Mass. 2001) (first off-label FCA claim). The debate over when a third-party action "breaks the chain of causation" to relieve an individual of liability is "familiar to American civil

[5] Joan H. Krause, *Truth, Falsity, and Fraud: Off-Label Drug Settlements and the Future of the Civil False Claims Act*, 71 Food & Drug L.J. 401, 426–27 (2016) (discussing history of off-label FCA cases).

jurisprudence." *United States v. King-Vassel*, 728 F.3d 707, 714 (7th Cir. 2013) (citing *Palsgraf v. Long Island R.R. Co.*, 248 N.Y. 339 (1928)). While the claims submission process in Medicaid is "dense," it does not necessarily create a "proximate cause problem" because it is "eminently foreseeable" that a false prescription will result in a false claim. *Id.* at 714–15.

B. Notice

We affirm because regardless of Lewis's theory of fraud, no facts suggest AbbVie was "on notice" of these concerns. *Fanslow v. Chicago Mfg. Ctr., Inc.*, 384 F.3d 469, 483 (7th Cir. 2004). The notice requirement is not particularly onerous, but it is essential. All it asks is that the employee convey to his employer that he suspects fraud. *United States ex rel. Barrick v. Parker-Migliorini Int'l, LLC*, 79 F.4th 1262, 1272 (10th Cir. 2023). He need not have knowledge of the FCA, nor utter any magic words like "False Claims Act," but he must make it clear that his complaints were "aimed at preventing the [employer's] submission of false or fraudulent claims" to the government. *Singletary v. Howard*, 939 F.3d 287, 300 (D.C. Cir. 2019). "[M]erely informing an employer it is not complying with a statutory, regulatory, or contractual requirement" is not sufficient. *United States ex rel. Sorenson v. Wadsworth Bros. Constr. Co., Inc.*, 48 F.4th 1146, 1160 (10th Cir. 2022).

We have held the same, and find wide agreement among our sister circuits. *See, e.g.*, *Brandon v. Anesthesia & Pain Mgmt. Assocs., Ltd.*, 277 F.3d 936, 945 (7th Cir. 2002) ("[T]rying to convince shareholders to comply with Medicare billing regulations ... usually does not put an employer on notice of FCA litigation."); *United States ex rel. Strubbe v. Crawford County Mem'l Hosp.*, 915 F.3d 1158, 1167–68 (8th Cir. 2019) (holding employees failed to provide notice because they only alleged

employer was violating licensing requirements without connecting it to fraud or potential FCA liability); *McKenzie v. BellSouth Telecommunications, Inc.*, 219 F.3d 508, 517–18 (6th Cir. 2000) (same); *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 951 (5th Cir. 1994) (same); *but see United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 908 (9th Cir. 2017) (holding that even "vague" reference to "civil violations" is sufficient to put employer on notice).

And that is exactly what Lewis did here. According to his complaint and attached exhibits, Lewis complained about being "noncompliant" and "corp[orate] policy" without once suggesting he feared defrauding the government.

The logic of the notice requirement is clear: "only if the employer is aware that its employee is engaging in … the protected conduct" of the FCA "can the employer fire the employee 'because of' the employee's protected conduct." *United States ex rel. Schweizer v. Oce N.V.*, 677 F.3d 1228, 1238 (D.C. Cir. 2012). It is especially important in light of the stringency of FCA claims. The Supreme Court has repeatedly cautioned that "[t]he False Claims Act is not an 'all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 194 (2016) (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)). Its goal is to prevent actors from defrauding the government. *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 750 (2023). Indeed, courts often dismiss §3729 fraud claims related to off-label theories noting FDA regulatory violations are simply not enough to suggest fraud on the government has occurred. *See, e.g., United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 620 (2d Cir. 2016); *Campie*, 862 F.3d at 899 ("It is

not enough to allege regulatory violations."); *United States ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 60 (1st Cir. 2017).

In the typical FCA fraud case where an employee whistle blows on the firm directly submitting false claims, satisfying notice is practically co-extensive with the protected conduct element. *Accord United States ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 742 (D.C. Cir. 1998) (holding when plaintiff informs superiors of fraudulent conduct, "the kind of knowledge the defendant must have mirrors the kind of [protected] activity in which the plaintiff must be engaged"). For instance, an employee who complains about his boss submitting false invoices to the government for payment need say little more to satisfy notice because the conduct is so obviously linked to fraud. *See United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 239 (1st Cir. 2004) (holding that reporting to employer that staff were knowingly submitting "claims [to the government] for medical treatments [the employer] knew were not provided" put employer on notice).

But the longer the chain of causation, the less related protected conduct and notice become. Here, AbbVie is purportedly causing third parties to defraud the government by subscribing to a marketing pitch. The marketing scheme does not imply any of these fraud concerns on its face, so an individual complaining about it is not plausibly "convey[ing] a connection to the FCA" or unlawful claims for government payment. *Barrick*, 79 F.4th at 1270–71 (quotation omitted). Instead, the "obvious alternative explanation" that proves fatal for Lewis, is that AbbVie risked violating the FDA's regulations about off-label marketing, wholly unrelated to the FCA. *Twombly*,

550 U.S. at 567. Nothing in Lewis's communications would steer AbbVie toward the FCA.

C. Denial of Motion to Amend

Finally, we address Lewis's alternative argument that the district court erred by dismissing his complaint without affording him an opportunity to amend. Rule 15(a) directs districts courts to "freely give leave [to amend] when justice so requires," and "favors amendment as a general matter." *Allen v. Broad Advisory, LLC*, 41 F.4th 843, 853 (7th Cir. 2022). But that principle has limits. "Where a plaintiff repeatedly fails to cure deficiencies, the district court enjoys 'broad discretion' to deny leave to amend." *Knowlton v. City of Wauwatosa*, 119 F.4th 507, 520 (7th Cir. 2024) (quoting *Arreola v. Godinez*, 546 F.3d 788, 796 (7th Cir. 2008)). So, we review the district court's decision for abuse of discretion and will reverse "only if no reasonable person could agree with that decision." *Freeman v. Ocwen Loan Servicing, LLC*, 113 F.4th 701, 707 (7th Cir. 2024) (citation omitted).

When a plaintiff does not propose how they would cure a deficient complaint, a district court can "quite reasonably" find an amendment "would suffer the same flaws as the one before it." *James Cape & Sons Co. v. PCC Const. Co.*, 453 F.3d 396, 401 (7th Cir. 2006); *cf. Foster v. DeLuca*, 545 F.3d 582, 584–85 (7th Cir. 2008) (holding abuse of discretion when district court "made no determination regarding the sufficiency of the amended complaint nor did it provide any explanation for why it denied the motion to amend"). Rather, "[g]ranting leave to amend is pointless when the plaintiff fails to 'suggest to the court the ways in which [he] might cure the defects.'" *Fosnight v. Jones*, 41 F.4th 916, 924–25 (7th Cir. 2022) (quoting *Haywood v. Massage Envy Franchising, LLC*, 887 F.3d 329, 335

(7th Cir. 2018)); *Indep. Tr. Corp. v. Stewart Info. Servs. Corp.*, 665 F.3d 930, 943 (7th Cir. 2012) (same, collecting cases).

Lewis "never has attempted to explain how [he] would amend h[is] complaint to state a claim for relief," either during the proceedings below or on appeal. *Gonzalez-Koeneke v. West*, 791 F.3d 801, 808–09 (7th Cir. 2015). The district court said as much when denying amendment. *See Stewart Info.*, 665 F.3d at 943 (holding "most important" reason district court properly denied amendment was because plaintiff "did not offer any meaningful indication of how it would plead differently"). After four years of litigation, and a prior amendment, we agree with the district court that if Lewis had communicated a fraud concern, "he would have alleged it by now."

III. Conclusion

For the foregoing reasons, we AFFIRM.