NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 24-1807

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CHARLES BENNETT,
Ex Rel,
Appellant

v.

BAYER CORPORATION, An Indiana Corporation;
JOHNSON & JOHNSON, a New Jersey Corporation;
MERCK & CO., INC., a New Jersey Corporation*;
JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT,
L.L.C.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS

(*Dismissed pursuant to Clerk's Order dated 06/21/2024)

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On Appeal from the United States District Court
for the District of New Jersey
(District Court No. 2:17-cv-04188)
District Judge: Honorable James B. Clark, III

Argued January 17, 2025

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Before: PHIPPS, FREEMAN, and CHUNG, Circuit Judges

(Filed: April 10, 2025)

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OPINION[1]

CHUNG, Circuit Judge.

Relator Dr. Charles Bennett filed this *qui tam* action under the False Claims Act ("FCA") against pharmaceutical companies Bayer, Johnson & Johnson, and others. Bennett asserts that the defendants fraudulently induced the Food and Drug Administration ("FDA") to approve certain antibiotic drugs, and thus are liable under the FCA for the ensuing prescription costs paid by federal healthcare programs. Defendants moved to dismiss for failure to state a claim and the District Court granted their motion.

We will affirm.

I. BACKGROUND[2]

This *qui tam* action concerns two fluoroquinolone-class antibiotic drugs used to treat a wide variety of conditions. Ciprofloxacin was developed by Bayer and approved

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[1] This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

[2] Because we write for the parties, we recite only facts pertinent to our decision.

by the FDA in 1987. Levofloxacin was developed by Johnson & Johnson and approved by the FDA in 1996.

In his complaint, Bennett alleged that the defendants knew that both drugs caused serious side effects, including neurological and psychiatric damage, but omitted or misrepresented information about these side effects to the FDA during and after the New Drug Application ("NDA") process. According to Bennett, the defendants "fraudulently induced [the FDA] to grant its approval to these drugs without appropriate warning labels that would otherwise have been required," and were therefore "marketed to, prescribed for, and used by patients who should not have used the[] drugs." Br. at 6. Prescriptions for these drugs, in turn, caused "the submission of millions of claims a year to federal" healthcare programs that would "have never been reimbursed by the government" had the defendants been truthful. App. at 294.

The District Court dismissed Bennett's complaint on two independent grounds. First, it held that Bennett's fraudulent inducement theory of FCA liability was not viable because the government was not induced to enter into a contract with the defendants. The District Court next concluded that, even if Bennett's theory of liability were viable, Bennett failed to plead falsity, a necessary element of an FCA claim. Specifically, the District Court concluded that Bennett failed to allege that the defendants "misrepresented or omitted any required disclosures" or knowingly made any false or fraudulent statements to the FDA. App. at 20.

Bennett timely appealed.

II. DISCUSSION[3]

A. Standard of Review

We review *de novo* the dismissal of a complaint under Rule 12(b)(6). U.S. ex rel. Petratos v. Genentech Inc., 855 F.3d 481, 486 (3d Cir. 2017). Because this Court's "review is plenary, we may affirm on any ground supported by the record." Hassen v. Gov't of Virgin Islands, 861 F.3d 108, 114 (3d Cir. 2017) (internal quotations omitted).

To survive a motion to dismiss, Bennett's 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 (2009) (internal quotations omitted). Moreover, because Bennett's FCA claim alleges that the defendants committed fraud, his complaint is subject to the heightened pleading standards of Fed. R. Civ. P. 9(b). See U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC, 812 F.3d 294, 306-07 (3d Cir. 2016). Under Rule 9(b), Bennett must allege "with particularity the circumstances constituting fraud or mistake," including "the who, what, when, where and how of the events at issue." Id. at 307 (citations omitted).

B. Bennett Failed to Sufficiently Plead an FCA Violation

"A False Claims Act violation includes four elements: falsity, causation, knowledge, and materiality." Petratos, 85 F.3d at 487 (citations omitted). Bennett failed to plead falsity and materiality.[4]

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[3] The District Court had jurisdiction under 28 U.S.C. §§ 1331 and 1345. We have jurisdiction under 28 U.S.C. § 1291.

[4] We do not address whether fraudulent inducement liability under the FCA is limited

Bennett asserts two ways that the defendants misled the FDA into approving the drugs. First, the defendants allegedly withheld clinical data on the prevalence and severity of the drugs' side effects. According to Bennett, the defendants "had to have known" about "the adverse neurological and psychiatric effects of their…drugs" after conducting "human and animal studies" as part of the NDA process in the 1980s and 1990s. Br. at 9-10 (emphasis omitted). The defendants were allegedly on notice about the adverse side effects in 2014, at the latest, after Bennett filed two Citizen Petitions with the FDA concerning the drugs' side effects.

Second, the defendants allegedly disaggregated data concerning the drugs' side effects, "camouflaging the safety issues." Br. at 11. Specifically, this "disaggregation" allegedly allowed the defendants to report relatively low rates of multiple side effects instead of grouping them together as manifestations of a broader condition that Bennett refers to as "fl[uo]roquinolone-associated disability" or "FQAD."[5] App. at 256. Had defendants appropriately aggregated the symptoms, Bennett asserts, the FDA would have had "a true picture of FQAD" incidence. App. at 274.

Neither of these allegations satisfy the heightened pleading standard under Rule

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to situations where the government is induced to enter a contract, as Bennett's claim fails under any theory.

[5] Dr. Deborah Boxwell, an FDA official studying the side effects of fluoroquinolone-class drugs, defined FQAD as a "disability" resulting from "adverse events reported from two or more…body systems" that lasts "30 days or longer after stopping the fluoroquinolone." App. at 484 n.2. According to the FDA, however, FQAD "is not accepted medical terminology" and the term "is not used in clinical practice."

9(b).

1. Omission of Prevalence Data

Bennett fails to allege what, if anything, the defendants knew or withheld from the FDA during the NDA process. At most, Bennett asserts that the defendants "*had to have known*" about the adverse side effects based upon studies defendants were required to conduct. Br. at 10. This is a textbook Rule 9(b) pleading deficiency in the form of speculation. See City of Warren Police and Fire Ret. Sys. v. Prudential Fin., Inc., 70 F.4th 668, 680 (3d Cir. 2023); Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 155 (3d Cir. 2014).

Nor are we persuaded by Bennett's assertion that the defendants failed to disclose relevant side-effect data in reports to the FDA after the NDA was approved. As Bennett notes, the defendants acknowledged the new data but "denied that their drugs had any linkage to" the side effects or any need to change their labeling at hearings before the Joint Meeting of the Antimicrobial Drugs Advisory Committee and the Drug Safety Risk Management Advisory Committee, both of which are run by the FDA. Br. at 10 (emphasis omitted). Simply stated, although Bennett asserts that the defendants falsely claimed the drugs did not cause the side effects,[6] the defendants' conduct cannot be said

[6] Bennett's allegation that the defendants "denied the connection between [the drugs] and their side effects," App. 287, is similarly undeveloped. Bennett fails to specify what denials were false and the only possible identifiable such statement was made at the 2015 Joint Meeting. Bennett does not allege, though, that the defendants knew the data established causation at that time. See Dist. Ct. ECF 71-7 at 10 (identifying "*emerging* safety issues" with fluoroquinolone-class antibiotics (emphasis

to be an "omission" of any kind, as they neither hid, nor denied, the existence of the data.

2. Disaggregating Side-Effect Data

Bennett's second allegation of fraud relies on the defendants' use of disaggregated side-effect data in their NDA. He argues that the defendants "intentionally disaggregated individual symptomatic components" that would have revealed a higher incidence of FQAD. Br. at 31-32. In Bennett's view, the use of disaggregated data was therefore misleading.

We disagree. Bennett does not allege that the data itself was false, only that its organization or presentation was misleading. Even assuming that slicing and dicing otherwise accurate data can amount to a false or fraudulent statement, the central problem with Bennett's contention is that he fails to allege such aggregated data would be material. Bennett fails to plausibly allege with specificity that the FDA would have recognized FQAD as a diagnosis and that aggregated data would have led the FDA to deny the NDA or take other action. This is especially true given that it appears that the FDA did in fact have aggregated data, as shown in the drug approval letters. Stated simply, Bennett's disaggregated-data theory fails to plausibly allege the necessary element of materiality.

We therefore conclude that Bennett failed to plausibly allege an FCA violation.

III. CONCLUSION

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added)); United States v. Care Alternatives, 952 F.3d 89, 95 (3d Cir. 2020) (noting that "the plain language of the FCA denotes scienter as an element independent of falsity").

For the reasons set forth above, we will affirm.