

United States Court of Appeals
for the Fifth Circuit

United States Court of Appeals
Fifth Circuit

FILED

July 7, 2021

Lyle W. Cayce
Clerk

No. 19-40906

UNITED STATES OF AMERICA, EX REL., HEALTH CHOICE ALLIANCE, L.L.C., *on behalf of* UNITED STATES OF AMERICA AND 31 STATES (AR; CA; CO; CT; DE; DC; FL; GA; HI; IL; IN; IA; LA; MD; MA; MI; MN; MT; NV; NH; NJ; NM; NY; NC; OK; RI; TN; TX; VT; VA; WA),

Plaintiffs—Appellants,

versus

ELI LILLY AND COMPANY, INCORPORATED; VMS BIOMARKETING; COVANCE, INCORPORATED; UNITED BIOSOURCE CORPORATION; HEALTHSTAR CLINICAL EDUCATION SOLUTIONS, L.L.C.; COVANCE MARKET ACCESS SERVICES, INCORPORATED,

Defendants—Appellees,

UNITED STATES OF AMERICA,

Appellee,

UNITED STATES OF AMERICA, EX REL., HEALTH CHOICE GROUP, L.L.C., *on behalf of* UNITED STATES OF AMERICA AND 31 STATES (AR; CA; CO; CT; DE; DC; FL; GA; HI; IL; IN; IA; LA; MD; MA; MI; MN; MT; NV; NH; NJ; NM; NY; NC; OK; RI; TN; TX; VT; VA; WA),

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Plaintiff—Appellant,

versus

BAYER CORPORATION; AMGEN, INCORPORATED; ONYX
PHARMACEUTICALS, INCORPORATED; AMERISOURCEBERGEN
CORPORATION; LASH GROUP,

Defendants—Appellees,

UNITED STATES OF AMERICA,

Appellee.

Appeals from the United States District Court
for the Eastern District of Texas
USDC No. 5:17-CV-123
USDC No. 5:17-CV-126

Before HIGGINBOTHAM, ELROD, and HAYNES, *Circuit Judges*.

JENNIFER WALKER ELROD, *Circuit Judge*:*

The appellants Health Choice Alliance and Health Choice Group brought *qui tam* actions under the False Claims Act on behalf of the United States alleging violations of the Anti-Kickback Statute by pharmaceutical companies. The United States moved to dismiss the actions, and the district court granted the motion. Because the actions were properly dismissed, we AFFIRM.

I.

Health Choice Alliance and Health Choice Group (collectively Health Choice) are both entities created by the National Health Care Analysis Group

* Judge Haynes concurs in the judgment only.

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for the purpose of filing *qui tam* actions alleging instances of fraud in medicine and pharmaceuticals. Health Choice and affiliated entities brought eleven *qui tam* actions under the False Claims Act against a total of thirty-eight defendants alleging similar violations of the Anti-Kickback Statute. 31 U.S.C. § 3730(b); 42 U.S.C. § 1320a-7b(b). This appeal concerns two of those *qui tam* cases, against Eli Lilly and Company and Bayer Corporation.¹ The complaints in both the Eli Lilly and Bayer cases allege that the defendants illegally provided patient-education services to providers before a prescription had been written in violation of the Anti-Kickback Statute and certain state laws.

Health Choice filed two similar complaints against Eli Lilly and (initially) four other defendants and against Bayer and four other defendants

¹ The nine cases which are not at issue in this appeal are: *United States ex rel. CIMZNHCA v. UCB, Inc.*, 970 F.3d 835, 852, 854 (7th Cir. 2020) (remanding and instructing the district court to dismiss the case on the government's motion and stating that "[w]herever the limits of the government's power lie, this case is not close to them"), *remanded to* No. 3:17-CV-765 (S.D. Ill. Sept. 28, 2020), *cert. denied*, No. 20-1138, 2021 WL 2637991 (June 28, 2021); *United States ex rel. SMSPF, LLC v. EMD Serono, Inc.*, 370 F. Supp. 3d 483, 491 (E.D. Pa. 2019) (granting government's motion to dismiss); *United States ex rel. NHCA-TEV, LLC v. Teva Pharm. Prods. Ltd.*, No. 17-CV-2040, 2019 WL 6327207, at *6 (E.D. Pa. Nov. 26, 2019) (granting government's motion to dismiss); *United States ex rel. SAPF, LLC v. Amgen, Inc.*, No. 16-CV-5203 (E.D. Pa. Feb. 11, 2019) (dismissing case on voluntary consent of the government and relators); *United States ex rel. SCEF, LLC v. AstraZeneca PLC*, No. 17-CV-1328, 2019 WL 5725182, at *4 (W.D. Wash. Nov. 5, 2019) (granting government's motion to dismiss); *United States ex rel. Miller v. AbbVie, Inc.*, No. 16-CV-2111 (N.D. Tex. May 09, 2019) (dismissing case on voluntary consent of relator and the government); *United States ex rel. Carle v. Otsuka Holdings Co.*, No. 17-CV-966 (N.D. Ill. Jan. 29, 2019) (dismissing case on voluntary consent of the government and relators); *United States ex rel. SMSF, LLC v. Biogen, Inc.*, No. 16-CV-11379 (D. Mass. Dec. 17, 2018) (granting defendant's unopposed motion to dismiss for failure to state a claim); *United States ex rel. Health Choice Advocates, LLC v. Gilead, et al.*, No. 5:17-CV-121 (E.D. Tex. July 27, 2018) (dismissing case on voluntary consent of relator and the government).

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in the United States District Court for the Eastern District of Texas.² Prior to filing these complaints, Health Choice submitted pre-filing notices to and met with attorneys from the United States Attorney's Office for the Eastern District of Texas. After filing the complaints, Health Choice met with officials at the Department of Justice Civil Division in Washington, D.C. The United States declined to intervene in either case.

Health Choice then amended each of its complaints. Shortly thereafter, Eli Lilly, Bayer, and the other defendants filed motions to dismiss for failure to state a claim. *See* Fed. R. Civ. P. 9(b), 12(b)(6). The magistrate judge held a consolidated hearing on the motions to dismiss in both cases. The magistrate judge recommended the motions be denied in part and granted in part, and the district court adopted these recommendations. Health Choice amended its complaints once more to address the pleading deficiencies identified by the district court.

In October of 2018, approximately a year after declining to intervene in the Eli Lilly and Bayer cases, the government sent notice to Health Choice that it intended to move to dismiss the complaints. *See* 31 U.S.C. § 3730(c)(2)(A). Over the next two-and-a-half months, Health Choice and the government conferred by meeting, letter, and teleconference to discuss the government's stated concerns about the case. During a teleconference with Health Choice, the government identified four specific concerns about

² In its negotiations with the government, Health Choice agreed to voluntarily dismiss its claims against the non-pharmaceutical defendants in the Eli Lilly case in order to "streamline" the case and reduce the administrative burden on the government. In January of 2019, Health Choice dismissed its claims, without prejudice, against all the defendants except Eli Lilly in the Eli Lilly case. Health Choice did not voluntarily dismiss any claims in the Bayer case. Amgen, Inc., Onyx Pharmaceuticals, Inc., AmerisourceBergen Corp., and Lash Group remain codefendants in the Bayer case. For simplicity, we refer only to Eli Lilly and Bayer.

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the Eli Lilly and Bayer cases: “(1) whether there [was] sufficient factual and legal support to prove violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (AKS); (2) the substantial costs and burdens for the United States if the *qui tam* actions were to continue; (3) certain policy interests of Medicare and other federal healthcare programs; and (4) the investigative methods employed by ‘National Healthcare Analysis Group,’” Health Choice’s parent organization.

On December 17, 2018, the government notified Health Choice that it intended to proceed with its motions to dismiss, and it filed those motions the same day. In its notice to Health Choice, the government cited to its own two-year investigation and the supplemental information provided by Health Choice—including documents purportedly supporting Health Choice’s theory of the cases and letters from Health Choice concerning the merits and costs and benefits of the cases—as the basis of its decision to seek dismissal.

In response to the government’s motions to dismiss, Health Choice first asserted that the government supported its motions primarily with “*ad hominem* attacks” against Health Choice. Health choice then argued that the district court should not afford the government unfettered discretion to dismiss and instead should hold that the government has not made the “proper showing” to warrant dismissal.

In reply, the government said it had “concluded that, not only do the allegations lack factual and legal support, but further litigation will impose burdens and costs on the government that are not justified and will undermine practices that benefit federal healthcare programs by providing patients with greater access to product education and support.”

On May 14, 2018, the magistrate judge held a consolidated hearing on the government’s motions to dismiss both cases. The magistrate judge recommended that the district court grant both motions. The district court

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