UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, Plaintiff, v. REGENERON PHARMACEUTICALS, INC., Defendant.	)	Civ. No. 20-11217

COMPLAINT

1. Since 2013, the Medicare Part B program has spent over $11.5 billion on Eylea, an injectable macular degeneration drug that typically costs over $10,000 per year. In 2013 and 2014 alone, Medicare paid $1.9 billion for the drug. Eylea's manufacturer, Regeneron Pharmaceuticals, Inc. ("Regeneron"), achieved these sales in part by funneling tens of millions of dollars through a co-pay foundation, the Chronic Disease Fund ("CDF"), to ensure that virtually no Medicare patient paid a co-pay, deductible, or co-insurance amount (collectively referred to herein as a "co-pay") on Eylea and that physicians who prescribed and purchased the drug did not have to collect Medicare co-pays from their patients.

2. Before Regeneron began selling Eylea in late 2011, it considered a price range of $1,500 to $1,950 per injection for the drug. Ultimately, the company chose a price – $1,850 – at the higher end of that range because it knew that it could eliminate any financial burden that the higher price would impose on Medicare patients and their physicians simply by paying more to a foundation that would cover the proportionately higher Medicare co-pays for Eylea. As a marketing consultant for Regeneron advised the company in the spring of 2011, "[t]he overall financial impact considering revenue of increasing price [of Eylea] . . . is largely favorable to

Regeneron, since the revenue increase will offset the increase in the budget needs to run the [foundation co-pay] program."

3. The following year, as sales of Eylea began to ramp up, Regeneron considered how much to pay Chronic Disease Fund ("CDF"), a purportedly "independent" foundation which operated a fund that covered Medicare co-pays for macular degeneration drugs. At the time, Regeneron and Genentech, which sold Lucentis, were the leading manufacturers of macular degeneration drugs. Regeneron's senior management was only willing to pay CDF enough to cover Medicare co-pays for Eylea patients; as Regeneron's former Chief Financial Officer, Murray Goldberg, put it, Lucentis patients were "Genentech's problem." Moreover, Regeneron senior management wanted assurances that the company's payments to CDF would generate return on investment, or "ROI."

4. To satisfy senior management, Regeneron employees repeatedly contacted CDF to learn the amount of money CDF would need to cover the co-pays of Eylea patients only. They then determined the Medicare revenue that Regeneron would derive from those patients and calculated that the company would earn a return of over 400% on its payments to CDF. Over the course of 2013 and through the beginning of 2014, Regeneron paid CDF exactly what CDF said it needed to cover Medicare expenses for Eylea patients only.

5. Because the anti-kickback statute, 42 U.S.C. § 1320-7b(b), prohibits such "indirect" kickbacks to subsidize the price of a drug reimbursed by Medicare, Regeneron's conduct was illegal, and senior management knew it. During 2013, company auditors twice inquired about the information Regeneron was getting from CDF about Eylea. Both times, Regeneron management, including the company's commercial chief, Robert Terifay, lied and asserted that the company was not getting Eylea-specific data from CDF. In fact, as Terifay and

others knew, the company was getting frequent Eylea-specific reports from CDF and then using that data to correlate the company's payments to CDF with the foundation's spending on co-pays for Eylea. Regeneron's payments to CDF were not charity; rather, the company intended those payments to subsidize Eylea's high price for Medicare patients and to ensure that physicians would not have to worry about collecting co-pays on Eylea from their Medicare patients.

Jurisdiction and Venue

6. This action arises under the False Claims Act ("FCA"), as amended, 31 U.S.C. §§ 3729-33. This Court has jurisdiction over this action under 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1345 and 1367(a).

7. Venue is proper in the District of Massachusetts pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

8. This Court may exercise personal jurisdiction over Regeneron pursuant to 31 U.S.C. § 3732(a) and because the company transacts business in this District.

The Parties

9. Plaintiff United States, acting through the Department of Health and Human Services ("HHS"), administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.* (Medicare).

10. Defendant Regeneron is a manufacturer and seller of pharmaceutical products, including Eylea. Regeneron has its principal place of business at 777 Old Saw Mill River Road, Tarrytown, NY 10591. Regeneron conducts business nationwide.

Legal Background

The Medicare Part B Program and Co-Pays Under Medicare Part B

11. Congress established Medicare in 1965 to provide health insurance coverage for

people aged sixty-five or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 1395 *et seq*.

12. Medicare is funded by the federal government and administered by the Centers for Medicare and Medicaid Services ("CMS"), which is part of HHS.

13. Medicare Part B primarily covers outpatient medical services and physician-administered drugs, like Eylea.

14. Once beneficiaries meet their annual deductible (currently $198), Medicare Part B pays 80 percent of the cost of prescription drugs administered by a physician in an outpatient setting. 42 U.S.C. § 1395l(a)(1). Some Medicare beneficiaries purchase a supplemental insurance product, called a Medigap plan, to cover the remaining 20 percent co-pay. Others are responsible for covering that co-pay directly.

15. Congress incorporated co-pays into Medicare to give patients an incentive to choose the most cost-effective therapy. As the Department of Health and Human Services, Office of the Inspector General observed in a 1994 Special Fraud Alert, "[s]tudies have shown that if patients are required to pay even a small portion of their care, they will be better health care consumers, and select items or services because they are medically needed, rather than simply because they are free." *Available at* https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

16. When a physician administers a drug covered by Medicare Part B, the physician typically submits a claim to Medicare for the drug. Medicare then will reimburse the physician 106 percent of the average sales price of the drug, less the applicable Medicare Part B co-pay. *See* 42 U.S.C. § 1395w–3a(b). The physician is responsible for collecting the co-pay amount from the patient.

The False Claims Act

17. The FCA provides, in pertinent part, that any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

18. For purposes of the FCA, the terms "knowing" and "knowingly" mean that a person, with respect to information: (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1).

19. The FCA defines the term "claim," in pertinent part, as

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--(I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

31 U.S.C. § 3729(b)(2).

20. For purposes of the FCA, the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* at

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