UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BLUE CROSS AND BLUE SHIELD OF MASSACHUSETTS, INC., and BLUE CROSS AND BLUE SHIELD OF MASSACHUSETTS HMO BLUE, INC.,	**Case No. _____**
Plaintiffs,	**COMPLAINT**
v.	**DEMAND FOR JURY TRIAL**
REGENERON PHARMACEUTICALS, INC.,	
Defendant.	

Plaintiffs Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc. allege the following against Defendant Regeneron Pharmaceuticals, Inc.:

Parties

1. Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc. (collectively, "BCBSMA") are Massachusetts not-for-profit hospital and medical services corporations organized under Massachusetts General Laws chs. 176A and 176B, with headquarters at 101 Huntington Avenue, Suite 1300, Boston, Massachusetts 02199.

2. BCBSMA provides, among other things, (a) Medicare benefits through contracts with the Centers for Medicare and Medicaid Services ("CMS") for Medicare beneficiaries through various Medicare Advantage plans offered under Medicare Part C, and prescription drug benefits under Medicare Part D; and (b) private commercial health plan benefits that cover medical expenses and prescription drug costs incurred by plan beneficiaries on an individual or group basis.

3. BCBSMA, either directly or through its health plan subsidiaries, insures and administers health plan benefits for its members and group customers, including self-funded group

customers that contract with BCBSMA and its health plan subsidiaries to, among other things, administer the processing of claims on their behalf and to pursue recoveries related to those claims.

4. Regeneron Pharmaceuticals, Inc. ("Regeneron") is a New York corporation with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591. Regeneron is a publicly traded pharmaceutical company with a market capitalization of more than $66 billion (as of December 17, 2021).

Summary

5. Regeneron manufactures and sells Eylea (aflibercept), a prescription drug administered by injection for the treatment of wet age-related macular degeneration ("wet AMD"), an eye disease that can render patients legally blind. From 2012 to at least June 2020, Eylea cost $1,850 per treatment.

6. Although a competing and equally effective drug, Avastin, cost only about $55 per treatment during the same period, Eylea's sales have far exceeded the sales of Avastin or any other alternative drug. Regeneron has reaped billions of dollars in annual revenue from Eylea's sales.

7. Since 2012, Regeneron has built Eylea's market dominance and maintained its exorbitant price through an illegal scheme that directly injured BCBSMA and other healthcare plans. On a regular basis, Regeneron transferred funds to a so-called "charity," the Chronic Disease Fund, Inc. ("CDF"), to provide financial assistance to patients for their out-of-pocket share of Eylea's costs. Pursuant to a secret arrangement between Regeneron and CDF, the funds provided by Regeneron were calculated to cover patients' out-of-pocket costs for Eylea but not for competing drugs. Regeneron's arrangement with CDF made Eylea cheaper for patients—but not for the Medicare program or for private healthcare plans—in comparison with alternative drugs.

8. As a result, Regeneron gained an unfair advantage over its competitors by distorting the cost of Eylea in the view of patients and their prescribers, while increasing the costs

borne by Medicare and private healthcare plans. The payments funneled by Regeneron through CDF operated as kickbacks to patients who otherwise had a contractual incentive to choose an equally effective but lower-cost drug. Regeneron's scheme thus violated the federal Anti-Kickback statute, among other laws.

9. Regeneron concealed its illegal scheme from the public, including BCBSMA and other healthcare plans, until the scheme was exposed by an action against Regeneron filed by the U.S. Department of Justice in June 2020 (the "DOJ Action"). *United States v. Regeneron Pharms, Inc.*, No. 20-CV-11217-FDS (D. Mass.).

10. To date, BCBSMA has paid more than $100 million to cover patients' costs with respect to Eylea. Regeneron's illegal scheme targeted claims for Eylea paid by BCBSMA and other healthcare plans.

11. Because BCBSMA was directly injured by Regeneron's scheme, BCBSMA brings this action under the federal Racketeer Influenced and Corrupt Organizations ("RICO") Act, the Massachusetts Consumer Protection Law, and state law governing fraudulent concealment, tortious interference with contractual relationships, and unjust enrichment.

Background

12. The U.S. Food and Drug Administration approved Eylea as a treatment for wet AMD in 2011. Soon thereafter, Regeneron developed a covert pricing strategy for Eylea: by paying patients' out-of-pocket costs through a supposedly independent "charity," Regeneron could neutralize the incentive systems used by Medicare and private healthcare plans to guide covered patients to lower-cost but equally effective drugs.

13. By reducing or even eliminating patients' and prescribers' cost-sensitivity, Regeneron's scheme increased market demand for Eylea over less expensive alternative drugs, maintained Eylea's exorbitant price, and shifted a higher percentage of Eylea's net cost to

healthcare plans, including BCBSMA. Pursuant to this scheme, Regeneron gained far more in sales revenue than it paid to the supposed "charity."

14. Regeneron implemented its scheme in close coordination with CDF. On a regular basis, Regeneron and CDF discussed the amount of funds needed to cover the anticipated cost-sharing obligations of patients using Eylea. Regeneron then transferred the necessary funds to CDF with the understanding and agreement that the funds would be used solely for the benefit of Eylea patients, as opposed to patients using alternative drugs.

15. Regeneron's scheme rendered Eylea cost-free in the view of patients and their prescribing physicians, while healthcare plans paid Eylea's entire net cost. In effect, Regeneron's scheme covertly funneled illegal kickbacks to patients through CDF, giving patients and their prescribers a powerful financial incentive to choose Eylea over alternative drugs. When choosing among alternative drugs, patients naturally prefer drugs that are cheaper or even cost-free. Similarly, prescribers naturally favor alternative drugs that their patients can more easily afford.

16. Regeneron widely advertised to patients and physicians the availability of CDF's financial assistance for Eylea's out-of-pocket costs. Regeneron did so through a program called "EYLEA4U," which Regeneron implemented in concert with CDF and The Lash Group LLC (the "Lash Group"), a pharmaceutical industry consulting firm. The EYLEA4U program connected patients and prescribers with CDF, assisted them in submitting claims to healthcare plans such as BCBSMA, and facilitated the plans' payment of claims tainted by Regeneron's illegal kickbacks.

17. Regeneron, CDF, and the Lash Group never disclosed to BCBSMA and other healthcare plans, or to the public at large, the illegal aspects of Regeneron's relationship with CDF. In particular, they concealed the fact that Regeneron's funding of CDF was designed to cover anticipated demand by Eylea patients exclusively. Moreover, as recently disclosed in the DOJ Action, Regeneron executives concealed from the company's own auditors the nature of

Regeneron's relationship with CDF.

18. Regeneron's scheme was remarkably successful. Despite its exorbitant cost, Eylea quickly became the best-selling treatment for wet AMD in the United States, far outstripping any competing product. In 2020 alone, Eylea generated almost $5 billion in sales revenue for Regeneron.[1] Eylea is by far Regeneron's best-selling product.

19. Medicare programs have spent over $14 billion to cover the cost of Eylea from 2013 through 2019. CMS Drug Spending, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs. Medicare Part B spent more for Eylea than any other drug in 2019. Medicare Part B Drug Spending Dashboard, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB. CMS, the agency that administers Medicare, recently singled out Eylea as illustrating the nation's drug-pricing problems, stating: "[T]he top-selling Medicare Part B drug—a common eye drug (Eylea) —was approximately two times as expensive in Medicare Part B as in comparison countries." The government thus cited Eylea as a prime example of the need to reform a dysfunctional and "anti-competitive" system that "leaves taxpayers and American seniors on the hook for paying the highest drug costs in the world." Centers for Medicare & Medicaid Services, FACT SHEET: Most Favored Nation Model for Medicare Part B Drugs and Biologicals Interim Final Rule with Comment Period (Nov. 20, 2020), https://www.cms.gov/newsroom/fact-sheets/fact-sheet-most-favored-nation-model-medicare-part-b-drugs-and-biologicals-interim-final-rule#_ftn5.

20. BCBSMA pays for Eylea both as a Medicare Part C (or Medicare Advantage) Plan sponsor and as a provider of private commercial health plans.

[1] In addition, Eylea is sold by Bayer outside the U.S. and generated approximately $3 billion in foreign 2020 sales.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.