UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

HUMANA INC., Plaintiff, vs. REGENERON PHARMACEUTICALS, INC., Defendant.	**Case No. 21-cv-6245** **COMPLAINT** **DEMAND FOR JURY TRIAL**

Humana Inc. ("Humana") brings this Complaint against Regeneron Pharmaceuticals, Inc. ("Regeneron") and alleges as follows.

NATURE OF THE ACTION

1. This case arises out of a scheme between a drug manufacturer and a sham charity to defraud Medicare and its contracted payors out of hundreds of millions of dollars. For years, Defendant Regeneron has inflated the price of its age-related macular degeneration drug, Eylea, and then provided illegal kickbacks disguised as donations to the Chronic Disease Foundation ("CDF"), a purported "charity", to cover the cost-sharing obligations for patients who might have otherwise chosen cheaper alternatives to Eylea.

2. This scheme has contributed to Eylea's massive success; it generates billions of dollars in revenue annually for Regeneron and is the top-selling drug of its kind in the United States. But for this scheme, Eylea's inflated price—approximately $10,000 for just one year of treatment—would be cost-prohibitive for many patients, especially as compared to one of its competitors, Avastin, which is equally as effective but costs only 3% of the price of Eylea.

3. Regeneron operated its kickback scheme as follows: to prevent patients from seeking a more cost-effective drug alternative to Eylea, Regeneron began secretly and unlawfully funneling money disguised as donations to CDF, which CDF then used to pay for the cost sharing obligations (e.g., deductibles, co-payments, and co-insurance) of patients who were enrolled in Medicare plans (including Medicare Advantage and Medicare Part D plans) and who were in need of a drug like Eylea. While Regeneron's "donations" were ostensibly to assist with the cost-sharing obligations for any patient in need of a macular degeneration drug, Regeneron engineered the scheme so that its payments to CDF would only benefit patients receiving Eylea. Thus, patients could obtain Eylea at no cost to them instead of choosing drugs offered by Regeneron's competitors which were otherwise significantly cheaper. This operation eliminated any sensitivity by patients or their physicians to the true price of Eylea and at the same time, allowed Regeneron to price Eylea well-above what the market would otherwise support. In doing so, Regeneron relied on Medicare and other payors to pay for the remaining portion, i.e., the vast majority, of the drug's inflated price.

4. Regeneron's scheme was carefully and intentionally engineered to maximize its profits. In 2012, Regeneron determined that it could increase its prices dramatically if it paid patients' cost-sharing obligations by funneling the money through a third-party charity. Regeneron subsequently began coordinating with CDF to do just that. Regeneron sought, and CDF provided, information that allowed Regeneron to determine how much it needed to "donate" to CDF to cover and eliminate the cost-sharing obligations owed by Eylea patients who were insured by Medicare. Regeneron and CDF understood that there would be a corresponding one-to-one relationship between the amounts Regeneron paid in and the amounts that CDF paid out to fund Eylea patients' cost-sharing obligations. Pursuant to this understanding, and after

determining that such payments would generate a substantial return on investment, Regeneron funneled the carefully calculated payments through CDF.

5. For many years, Regeneron's scheme worked, and it generated massive profits from Eylea sales. Since 2013, Medicare programs have paid out approximately $11.5 billion to cover the cost of Eylea, and in 2019, Eylea sales generated $4.6 billion for Regeneron. Regeneron's profits have come at the expense of both the government and payors, including Humana, who bear the cost of spending for patients enrolled in Medicare plans. Humana, alone, has paid out more than $900 million to cover the cost of Eylea for patients enrolled in its Medicare Advantage and Medicare Prescription Drug plans.

6. While Regeneron managed to conceal its scheme for years, an investigation by the United States Department of Justice ("DOJ") recently unearthed the operation. On June 24, 2020, the DOJ filed a complaint against Regeneron, laying out Regeneron's violations of federal law, putting evidence of Regeneron's unlawful scheme into the public record, and explaining how Regeneron reaped billions of dollars at the expense of the federal government and payors like Humana.

7. As evidenced by the DOJ's complaint, Regeneron's scheme violated the False Claims Act, the Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b), and various state laws that prohibit deceptive and unlawful conduct, including pharmaceutical companies paying their customers' cost-sharing obligations.

8. Regeneron's scheme has also harmed Humana in multiple ways. *First*, because the claims for Eylea submitted to Humana's Medicare plans were products of Regeneron's unlawful kickback scheme, they were not payable. Regeneron knew this, and therefore misrepresented and concealed the nature of its financial relationship with and use of CDF, to ensure that claims

continued to be paid. Specifically, Regeneron publicly stated that it did not play a role in funding CDF, and internal Regeneron emails uncovered by the DOJ show that Regeneron executives lied to company auditors who might have uncovered or outed Regeneron's unlawful conduct.

9. *Second*, Regeneron's conduct also interfered with, undermined, and defeated key provisions of Humana's Medicare plans with the individuals (called "members") enrolled in those plans. Under those plans, members are required to share in the cost of prescription drugs by paying copayments or coinsurance amounts related to those drugs. By paying kickbacks and funneling sums through CDF to eliminate Eylea patients' cost-sharing obligations, Regeneron tortiously interfered with Humana's plans with its members, and caused Humana to pay for Eylea when members had not met their required cost-sharing obligations.

10. In addition to harming insurers who offer and administer Medicare plans, Regeneron's conduct harmed the American public, by subjecting taxpayers and the programs that pay for taxpayers' healthcare costs to the inflated and excessive drug pricing of Eylea. Indeed, if patients used other drugs that were as effective as, but substantially cheaper than, Eylea, the federal government's Medicare program and taxpayers could save billions of dollars.

11. Accordingly, Humana brings this suit to recover damages and stop Regeneron's unlawful conduct.

PARTIES

12. Plaintiff Humana Inc. is a Delaware corporation with its principal place of business at 500 West Main Street, Louisville, Kentucky. Humana and its subsidiaries are providers of healthcare related services, including insuring risk for prescription drug costs for more than eight million members in all 50 states, the District of Columbia, and Puerto Rico. Among other things, Humana offers and administers Medicare Advantage health benefit plans and Medicare

Prescription Drug Plans. Humana is the second largest sponsor of these Medicare plans in the United States.

13. Defendant Regeneron Pharmaceuticals, Inc. is a New York corporation with its principal place of business in Terrytown, New York. Regeneron discovers, develops, and commercializes drugs, including the drug Eylea.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 because it arises under the Constitution, laws, or treaties of the United States. Specifically, Humana asserts claims arising under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962, *et seq*.

15. This Court also has subject matter jurisdiction over this action under 28 U.S.C. § 1332 because the matter is between citizens of different states and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

16. This Court also has supplemental jurisdiction over Humana's state law claims, including state common-law claims, under 28 U.S.C. § 1367 because those claims are so related to the federal claims that they form part of the same case or controversy.

17. This Court has personal jurisdiction over Regeneron because Regeneron is incorporated and headquartered in the State of New York.

18. Venue is proper in this district under 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because Regeneron resides in this district and because a substantial part of the events giving rise to the claims in this action have occurred in this district. Specifically, Regeneron devised, directed, and carried out the unlawful scheme described in this Complaint in and from this district.

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.