UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services,

CENTERS FOR MEDICARE AND MEDICAID SERVICES, and

SEEMA VERMA, in her official capacity as the Administrator of the Centers for Medicare and Medicaid Services,

Defendants.

Case No. 20-10488

ECF Case

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Regeneron Pharmaceuticals, Inc. (Regeneron) brings this complaint for declaratory and injunctive relief against Defendants United States Department of Health and Human Services (HHS); Alex M. Azar II, in his official capacity as Secretary of HHS; Centers for Medicare & Medicaid Services (CMS); and Seema Verma, in her official capacity as Administrator of CMS. In support thereof, Regeneron states the following:

NATURE OF THIS ACTION

1. The U.S. pharmaceutical industry is one of the marvels of the modern world. Every year the industry develops new treatments for diseases that have afflicted humans for millennia.

Even now, during a worldwide pandemic, U.S. pharmaceutical companies have been working around-the-clock in an unprecedented effort to discover vaccines, therapies, and other products to combat SARS-CoV-2, the virus that causes COVID-19.

2. The success of the U.S. pharmaceutical industry and the scientific advances that benefit patients have not come about by chance. A new drug can cost years of time and literally billions of dollars to develop. To encourage the pharmaceutical industry to incur those extraordinary costs, Congress has provided intellectual property protections but left drug pricing largely to the law of supply and demand, thus creating incentives for drug developers to expend the resources necessary for cutting-edge innovation. The resulting access that patients have to life-saving medicines is a testament to Congress' wisdom.

3. Many other countries, by contrast, have taken a different path, thus depriving patients access to innovative medicines. Because the pharmaceutical industry is characterized by enormous "sunk" costs (namely, the prior costs of discovering and developing new drugs) but low "marginal" costs (namely, the ongoing costs of manufacturing existing drugs), foreign governments—especially those with less innovative pharmaceutical industries—often dictate drug pricing that allows drug companies to recoup marginal costs but not sunk costs. Yet the only reason many drugs even exist is because they were developed in the United States, which rewards innovation and allows drug companies to charge prices that reflect *total* costs. If every country, including the United States, gave short shrift to sunk costs, there would be few innovative drugs to price as the incentives to develop new drugs would decrease if not disappear outright. Congress thus has repeatedly rejected proposals to model U.S. drug pricing on other countries' approaches.

4. Despite Congress' considered and consistent judgment not to follow foreign countries' approaches to drug pricing, on July 24, 2020, the President announced four executive

orders addressing pharmaceutical drug pricing. According to the President, "the four orders … will completely restructure the prescription drug market"—and the fourth is "the granddaddy of them all." This fourth order, "the order on favored nations," would be "transformative" and require Medicare to "purchase drugs at the same price as other countries pay." According to the President, the effect of the orders would be "very dramatic," "very shocking," and "sweeping"—resulting in "the most far-reaching prescription drug reforms ever issued."

5. The Administration released the text of the first three orders alongside the President's July 24 announcement. But it elected to "hold" the "transformative" fourth order out of public view, only issuing it on September 13. That order directed HHS to "implement" a rule whereby Medicare would, for certain drugs, pay "no more than the most-favored-nation price."

6. On November 20, 2020, HHS, acting through CMS, issued the rule previewed in July and September: a "Most Favored Nation (MFN) Model" for Medicare Part B drug pricing (the "MFN Rule"). The 258-page MFN Rule establishes an "MFN Model" under which, for the 50 drugs generally making up the highest levels of Medicare Part B spending, the federal government will reimburse a healthcare provider for the sale of a drug not at the average sale price for that drug in the United States—as Congress has directed by statute—but only at the lowest price paid for that drug by any other country that is a member of the Organisation for Economic Cooperation and Development (OECD) with a GDP per capita at least sixty percent of the U.S. GDP per capita. The "MFN Model" applies nationwide, is mandatory for all providers and suppliers in the Medicare program, and will be in effect for seven years beginning January 1, 2021.

7. In announcing the MFN Rule, the President called the rule "groundbreaking," "unprecedented," and a rule that "will transform the way the U.S. government pays for drugs."

The President acknowledged that "[n]obody has ever done this" before.

8. Upon issuance of the MFN Rule, it became clear why "[n]obody has ever done this" before: the MFN Rule, while certainly "transformative," "groundbreaking," and "the granddaddy" of "the most far-reaching prescription drug reforms ever issued," is also unlawful.

9. First, the 258-page "transformative," "groundbreaking," and "unprecedented" MFN Rule was issued without the notice-and-comment process required by the Administrative Procedure Act and the Medicare Act. Despite the fact that the MFN Rule, by design, will have sweeping effects on millions of stakeholders in the American healthcare system—including healthcare providers, patients, and pharmaceutical manufacturers—and impact the Nation's economy by billions of dollars, Defendants did not properly invite, much less consider, public input before issuing the rule. Defendants have instead claimed that they need not comply with the notice-and-comment requirement, an assertion that does not withstand scrutiny.

10. Second, the lone source of statutory authority Defendants have invoked to issue the MFN Rule is an obscure provision created by the Affordable Care Act. But the United States is currently telling the Supreme Court that the *entire* Affordable Care Act should be struck down. If Defendants stand by the arguments that the Solicitor General has made to the Supreme Court, then there is no conceivable statutory authority whatsoever for the MFN Rule. Regardless, the cited provision does not remotely support Defendants' effort to "transform" the Nation's pharmaceutical drug market. It merely establishes the Center for Medicare and Medicaid Innovation (CMMI) and provides that CMMI may "test" new "payment and service delivery models." Nothing in that limited statutory mousehole begins to justify the elephantine and "transformative" MFN Rule or otherwise permit Defendants to unilaterally replace the Nation's longstanding, congressionally mandated, market-driven methodology for pharmaceutical pricing.

11. Third, the MFN Rule is arbitrary and capricious. In their quest to force a nationwide pricing regimen, Defendants failed to create a control group to assess the effects of the MFN "model," and they failed to address critical considerations, including the rule's adverse effects on innovation, the pharmaceutical industry's reliance on longstanding drug pricing law, and the fact that some companies—like Regeneron—do not control the foreign pricing of products affected by the MFN Rule. The MFN Rule is also arbitrary and capricious because Defendants' *real* motivation for issuing the rule was animus against the pharmaceutical industry.

12. Fourth, interpreting the modest provision invoked by Defendants as authorizing the Executive Branch to "transform" the pricing of prescription drugs by overriding the congressionally established pricing system violates constitutional separation-of-powers principles. The MFN Rule also violates the First Amendment, the nondelegation doctrine, due process, and the Foreign Commerce Clause, and constitutes a taking without just compensation.

13. Because the MFN Rule was issued without following proper procedure, is in excess of Defendants' statutory and constitutional authority, and is arbitrary and capricious, it is unlawful and this Court should enjoin it. As Congress has recognized on numerous occasions, the pharmaceutical industry's long-term ability to innovate and find new cures and treatments for disease depends on the existence of a domestic pricing system that allows drug developers to recoup the *full* costs of drugs, including their development costs. Because the MFN Rule, by design, will prevent that from happening, judicial review is essential to protect the future of this important industry and the billions of people it serves.

PARTIES

14. Plaintiff Regeneron is a New York corporation with its headquarters in Tarrytown, New York. Regeneron was founded in 1988 as a biopharmaceutical company committed to developing new medicines for people with serious and rare diseases. The physician-scientists that

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