UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC., ELI LILLY AND COMPANY, AMGEN INC., and ASSOCIATION OF NATIONAL ADVERTISERS, INC.

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX M. AZAR II, CENTERS FOR MEDICARE & MEDICAID SERVICES, and SEEMA VERMA,

Defendants.

Case No. _____

DECLARATION OF RIAD EL-DADA

I, Riad El-Dada, state and declare as follows:

1. I am an adult over the age of eighteen, and if called to testify in this matter, I could and would testify as follows:

2. I am Riad El-Dada, a Senior Vice President at Merck Sharp & Dohme Corp. (either "Merck" or the "Company"), a subsidiary of Merck & Co., Inc. The information set forth below is based on my personal knowledge and is true to the best of my knowledge, information, and belief.

3. For more than a century, Merck has been a leading global biopharmaceutical company bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies, we work with customers to deliver innovative health solutions.

4. Merck educates consumers about its prescription drugs and biologic products through a number of media channels, including direct-to-consumer television advertising. Direct-to-consumer ("DTC") advertising enhances patients' knowledge of medical conditions and treatments, stimulates productive conversations between doctors and patients, and empowers patients to take more responsibility regarding their healthcare.

5. In my capacity as Senior Vice President of Regional Marketing at Merck, my responsibilities include overseeing the teams responsible for, and making decisions about, the promotion of our products in the U.S. I have personal knowledge about Merck's DTC advertising operations and am familiar with the United States Food & Drug Administration's (FDA) regulation of pharmaceutical advertising.

6. I understand CMS-4187-F, published at 84 Fed. Reg. 20,732 (May 10, 2019) (the "Rule"), which amends regulations for the Medicare Parts A, B, C, and D programs, as well as the Medicaid program, to require DTC television advertisements of prescription drugs and biological products for which payment is available through or under Medicare or Medicaid ("covered drugs") to include the required statement, "The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different."

7. The Rule defines list price as the Wholesale Acquisition Cost ("WAC") "for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate." The Rule specifies that when the typical course of treatment varies based on the indication for which the drug or biological product is prescribed, the list price should represent the typical course of treatment associated with the primary indication addressed in the advertisement.

8. The Rule exempts prescription drugs or biological products that have a list price of less than $35 per month for a 30-day supply or typical course of treatment.

9. Manufacturers will face serious consequences if they fail to comply with the Rule.

10. First, the Rule specifies that the Secretary of the United States Department of Health and Human Services ("HHS") shall maintain and publish a public list of all prescription drugs and biological products being "advertised in violation" of the Rule. If Merck drugs and/or biological products are included on such a list, Merck will suffer reputational harm and resulting economic injury.

11. Second, the preamble to the Rule states that "[f]ailure to disclose the list price in a DTC advertisement, if required to do so by [the Rule], makes that advertisement false and misleading." Accordingly, the preamble anticipates that companies who fail to comply with the Rule will be subject to private lawsuits and civil liability under the Lanham Act, 15 U.S.C. 1125(a), for unfair competition in the form of false or misleading advertising. If Merck fails to comply with the Rule, it will face a credible threat of civil lawsuits.

12. The Rule was published in the Federal Register on May 10, 2019, with an effective date of 60 days after publication. As a result, absent an injunction, the Rule will take effect on July 9, 2019.

13. As part of its efforts to educate consumers about its products, Merck utilizes a mixture of media, including television, print, and the internet. Merck believes that utilizing different forms of media allows it to most effectively convey information about its products to consumers.

14. Merck believes that DTC television advertising is an important avenue for educating consumers about medical conditions and potential treatments. Such advertising helps to empower

patients to discuss their healthcare needs with their healthcare providers, which promotes better healthcare outcomes.

15. Merck believes that, if the Rule is not enjoined, the statement required by the Rule will confuse patients in a manner that will harm them.

16. As such, Merck would not voluntarily include a prescription drug or biological product's list price in its DTC television advertisements if it were not compelled by the Rule to do so.

I declare under penalty of perjury that the foregoing is true and correct.

Riad El-Dada

Executed on June 13, 2019