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, in his official capacity as the Secretary of the United States Department of Health and Human Services, CENTERS FOR MEDICARE & MEDICAID SERVICES, and SEEMA VERMA, in her official capacity as the Administrator of the Centers for Medicare & Medicaid Services,

Defendants.

Case No. _____

DECLARATION OF JENNIFER L. OLEKSIW

DECLARATION OF JENNIFER L. OLEKSIW

I, Jennifer L. Oleksiw, being duly sworn, depose and state 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 the Vice President-Consumer Experience at Eli Lilly and Company ("Lilly"). The information set forth below is based on my personal knowledge, and the facts stated in this declaration are true to the best of my knowledge, information, and belief.

3. Founded more than 140 years ago, Lilly is a pharmaceutical company. Lilly has developed and currently manufactures for sale across the United States a number of life-saving and life-enhancing pharmaceutical products.

4. Lilly's fundamental, innovation-driven strategy is predicated on discovering and manufacturing new medicines. As one of the largest pharmaceutical companies in the United States, Lilly looks for answers to some of the world's most urgent medical needs. Lilly discovers and develops products through rigorous testing and in accordance with the highest scientific and ethical standards. Lilly's mission is to make medicines that help people live longer, healthier, more active lives.

5. Lilly educates consumers about its prescription drugs, including its biologic products, through a number of channels, including through direct-to-consumer ("DTC") advertising. 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.

6. In my capacity as Vice President-Consumer Experience at Lilly, I have responsibility for media operations and placement for Lilly. I am also familiar with the United States Food & Drug Administration's (FDA) regulation of pharmaceutical advertising.

7. I have read 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 a statement specifying that "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."

8. The Rule defines the "list price" of a drug as the Wholesale Acquisition Cost ("WAC") "for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate." WAC, in turn, is defined by the Rule as "[t]he manufacturer's list price for the prescription drug or biological product to *wholesalers or direct purchasers* in the United States, not including prompt pay or other discounts, rebates or reductions in price . . . as reported in wholesale price guides or other publications of drug or biological product pricing data." The Rule specifies that when the typical course of treatment varies based on the indication for which a 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.

9. 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.

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

11. 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 Lilly 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. To educate consumers about its products, Lilly utilizes a mixture of media, including television, print, and the internet. Lilly believes that utilizing different forms of media allows it to most effectively convey its message to consumers.

14. Lilly believes that DTC television advertising is a particularly important avenue for educating consumers about medical conditions and potential treatments. Such advertising educates patients about medical conditions and treatments, empowers patients to discuss their healthcare needs with their healthcare providers, and promotes better healthcare outcomes.

15. Lilly believes that the Rule's mandated disclosure of list prices in DTC advertisements, without full context, may intimidate and confuse consumers while deterring them from seeking needed medical treatment. Lilly believes that it is unlikely that many patients understand what the "list price" of a prescription drug or biological product is, as defined by the Rule, and believes that many who see a statement like the one required by the Rule could believe that a drug's list price is, or bears a close relationship to, the out-of-pocket cost that most consumers would pay if they filled a prescription for the prescription drug or biological product in question. As CMS itself points out in the preamble to the Rule, "consumers, intimidated and confused by high list prices, may be deterred from contacting their physicians about drugs or medical conditions. Consumers might believe they are being asked to pay the list price rather than a co-pay or co-insurance and wonder why they are paying so much when they already paid a premium for their drug plan. This could discourage patients from using beneficial medications, reduce access, and potentially increase total cost of care."

16. "List price," as defined by the Rule, is the price at which Lilly sells its medications to wholesalers or direct purchasers, not including discounts or rebates; it is not a price that is directed at consumers, nor one that Lilly charges to them. The list price of a medication is generally much higher than the out-of-pocket cost that a particular consumer may pay for a prescription drug or biological product at the pharmacy, which is based on the terms of a consumer's insurance coverage. Indeed, many prescription drugs or biological products with list prices of thousands of dollars are available for little or no cost to many because their

insurance requires them to pay a small, flat co-pay at the pharmacy. Consumers' actual out-of-pocket costs for medications can vary considerably based on their access to insurance coverage and how that coverage is structured.

17. Among other things, this means patients who are familiar with the out-of-pocket costs of their currently prescribed drugs may conclude, based on the statement required by the Rule, that other advertised prescription drugs or biological products treating the same medical condition are significantly more expensive than their current treatments, even though the advertised products may be equivalent in cost or even less expensive for that patient. Lilly believes the Rule's requisite disclosure of list price in DTC advertising, without full context, could discourage many patients from taking the initiative to discuss such drugs or biological products with their health care providers, and for that reason, could lead to less-informed health care decisions and worse healthcare outcomes. Adriana Samper & Janet A. Schwartz, *Price Inferences for Sacred versus Secular Goods: Changing the Price of Medicine Influences Perceived Health Risk*, 39 J. Consumer Res. 1343, 1349 (2013) ("[A]wareness of higher prices has the potential to reduce the likelihood of seeking necessary care," which "portends detrimental effects on consumers and may ultimately increase future treatment costs").

18. In addition, Lilly believes the Rule's requisite disclosure of list price in DTC advertising, without full context, may discourage many patients from filling prescriptions given to them by their healthcare providers. *See, e.g.*, Peter A. Ubel, *Beyond Costs and Benefits: Understanding How Patients Make Health Care Decisions,* 15 The Oncologist Supp. 5, 9 (2010) ("Giving patients information about the costs and benefits of health-related choices won't always lead to optimal decisions. Clinicians need to be aware of the subtle contextual factors that can influence the way people perceive the costs and benefits of health care interventions, and thereby influence the health care choices people make").

19. As a result, Lilly is concerned that the Rule's requisite disclosure of list price in DTC advertising, without full context, could harm patients, as they may be discouraged from seeking or complying with treatments important or necessary to their health.

20. Lilly also believes that the Rule could increase the overall costs of many patients' health care. Failure to take preventive medicine often leads to increased risk of hospitalization or other deleterious health consequences that necessitate more expensive interventions. CMS itself appears to understand this. It admits that the Rule "could discourage patients from using beneficial medications, reduce access, and potentially increase total of care." Fed. Reg. 20,732, 20,756 (May 10, 2019). Although the Rule requires the inclusion of a statement that "[i]f you have health insurance that covers drugs, your cost may be different," Lilly does not believe that caveat will be sufficient to ameliorate the confusion caused by the statement required by the Rule.

21. Lilly believes that the statement required by the Rule could also mislead patients about their out of pocket costs in additional respects. For instance, the Rule mandates that advertisements display a single list price for a typical 30-day regimen or a typical course of treatment of the advertised prescription drug or biological product. But the typical course of treatment for different patients may vary substantially based on the dosage required for that particular patient's weight, age, or baseline test results, as well as whether administration of the drug at a particular time requires a titration period or continual dosing adjustments. Providing a single list price for a particular drug despite the significant differences in individual patients' treatment needs may cause some patients to overestimate, and even some to underestimate, their own out-of-pocket costs.

22. Providing patients with information that confuses them and could inhibit them from seeking medical care that could improve their health care outcomes is fundamentally inconsistent with Lilly's mission.

23. Lilly's DTC advertisements are intended to provide patients with truthful information about medical conditions and available treatments, encourage patients to discuss

such treatments with their healthcare providers when applicable, and improve healthcare outcomes. Lilly believes that the statement required by the Rule, without full context, could frustrate those goals.

24. Additionally, one of the main public health benefits of DTC advertising, reducing rates of under treated disease, could be jeopardized by the Administration's approach. Ultimately, health outcomes could worsen and the total cost of care may rise as a result of incorporating a drug's list price directly into DTC television advertisements without the proper context.

25. Most broadcasters sell advertising in 15-, 30-, or 60-second slots. To comply with the rule, Lilly will already be required to devote a portion of time in each slot to displaying CMS's required message.

26. To help ameliorate the most misleading and confusing aspects of the Rule's required statement, Lilly ideally would explain (i) what "list price" is, *i.e.*, the actual price at which Lilly sells its medications to wholesalers and direct purchasers, not including any discounts or rebates, (ii) the reasons why out-of-pocket cost is generally different from list price, and (iii) how patients can determine what their out-of-pocket cost would be depending on their insurance and treatment needs. In the context of a brief advertisement, any attempt to present that sort of detailed pricing discussion may undermine Lilly's intended message about the benefits and risks associated with a particular prescription drug or biological product, and supplant it with an essay about a product's list price, the meaning of that term, and the pricing implications for different patients.

27. In addition to the risk of confusing patients and potentially discouraging them from inquiring about and seeking out promising treatments, inclusion of the statement required by the Rule will make DTC television advertisements more expensive to Lilly. Although Lilly will still be required to pay for 100% of its advertisements, the Rule will enable CMS to co-opt a portion of every covered DTC advertisement purchased by Lilly for its own message, at Lilly's expense. For example, Lilly will be required to devote one percent of the screen space and four

seconds of a 75-second commercial, and a proportional amount of time and space for shorter commercials. Rule. 84 Fed. Reg. 20732, 20756 (May 10, 2019).

28. For all of these reasons, Lilly 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 pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.

Jennifer L. Oleksiw

Executed on June 14, 2019 in Indianapolis, Indiana.