UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

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 DAVID MAREK

I, David Marek, 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 set forth in this declaration. The information herein is based on my personal knowledge and experience, and may in part be informed by input from others at Amgen with relevant personal knowledge. The information herein is true to the best of my knowledge, information, and belief.

2. I began my career at Eli Lilly and Company, where I worked in marketing and sales positions from 1988 to 1997. This was followed by two years in Marketing roles at Zeneca and AstraZeneca Pharmaceuticals. Over approximately the next 15 years, I held various

positions where I led or advised commercialization and marketing efforts predominantly in the healthcare industry.

3. Headquartered in Thousand Oaks, California, Amgen is a biotechnology company that discovers, develops, manufactures, markets and delivers medications that treat a broad range of illnesses. Amgen has developed and currently manufactures for sale across the United States a number of such products. I started at Amgen in 2015 as Vice President of Marketing. In that role, I led Amgen's marketing efforts and strategy to healthcare provider and consumer audiences for Amgen's inflammation, nephrology and, later, neuroscience therapeutic areas. In mid-2017, I began my current role at Amgen, Vice President and General Manager of Neuroscience. In this role, I am responsible for all U.S. commerical aspects of Amgen's neuroscience therapeutic area, including marketing. I also continue to provide strategic advice and leadership on Amgen's DTC efforts more broadly, including with respect to the "Pricing Transparency" rule that was published in the Federal Register on May 10, 2019.

4. For Amgen, direct-to-consumer ("DTC") television advertising is an important means by which we educate consumers about our products. DTC television advertising has the potential to reach a broad audience, educating viewers about medical conditions and potential treatments, and to empower patients to discuss their medical needs with their healthcare providers, which in turn promotes better health outcomes. Amgen currently utilizes DTC television advertising for its products Neulasta®, Prolia®, Enbrel®, Repatha® and Aimovig®.

5. I am aware that federal regulations provide that the Food and Drug Administration ("FDA") maintains "primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising." 36 Fed. Reg. 18,539, 18,539 (Sept. 16, 1971). I am also aware that, among other things, FDA regulations provide that DTC advertisements must include a "[t]rue statement of information in brief summary relating to side effects, contraindications and effectiveness," and "present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug." 21 C.F.R. 202.1(e); 202.1(e)(5)(ii). I am also aware that the mission of the FDA's Office of

Prescription Drug Promotion ("OPDP"), as set forth on its website, is "[t]o protect the public health by ensuring that prescription drug information is truthful, balanced, and accurately communicated."[1]

6. Truth and accuracy are especially important in the medical advertising space, where advertisements may help viewers understand and decide on important issues related to their health and medical treatment. Truth and accuracy in advertising are also consistent with Amgen's core mandate to "do the right thing" in all aspects of its business.

The Department of Health and Human Services Rule

7. I am aware that, on May 10, 2019, a "Drug Pricing Transparency" rule (the "Rule") was published in the Federal Register. It is my understanding that the Rule will require certain DTC television advertisements of prescription drugs and biological products to include the price for a 30-day supply or typical course of treatment of the product being advertised. I also understand that the Rule will require a "caveat" statement that,"[i]f you have health insurance that covers drugs, your cost may be different." I understand that the Rule defines the price that must be included in the advertisement as the Wholesale Acquisition Cost ("WAC") or list price "for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate." 84 Fed. Reg. 20,758 (May 10, 2019). I also understand that 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. *Id.* I understand that the Rule does not apply to drugs that have a list price of less than $35 per month for a 30-day supply or typical course of treatment. *Id.*

8. I understand that the Rule states 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

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[1] *See* https://www.fda.gov/about-fda/center-drug-evaluation-and-research/office-prescription-drug-promotion-opdp (last visited June 13, 2019).

Amgen's products were to appear on such a list, Amgen would suffer reputational harm and economic injury. I also understand that the Rule's 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. On this basis, Amgen would face a credible threat of civil litigation if it did not comply with the Rule.

9. I understand that, absent a stay pending review, the Rule will take effect on July 9, 2019.

10. Amgen does not believe that the Rule's requirement will improve price transparency or decision making, because the information the rule requires will not help patients understand what they will pay for the medication in question. Instead, Amgen believes that the Rule is likely to confuse and mislead many viewers about price, causing them to overestimate how much they will actually need to pay. The Rule also could dissuade patients from consulting with their healthcare providers about medical conditions and possible treatments, or even from seeking treatment at all. Amgen thus would not voluntarily include the required information in its DTC television advertisements. The Rule will force Amgen to do so against its wishes.

The Rule will not promote transparency for patients about the price they will pay.

11. Most viewers of a television advertisement covered by the Rule will not be able to use list price to calculate what their out-of-pocket price will be. One significant reason is the way that pharmaceutical and biological products are sold and distributed. List price, as defined by the Rule, is the price "to wholesalers or direct purchasers," and does not include "prompt pay or other discounts, rebates or reductions in price," all of which can affect the price ultimately paid by the patient. 84 Fed. Reg. 20,758 (May 10, 2019). Reference to the list price alone does not account for any of these additional factors.

12. Another reason reference to list price is likely to be confusing or misleading is that it fails to account for the effect on out-of-pocket price of a patient's insurance, if any. To be

sure, the Rule requires inclusion of a "caveat" statement that, "[i]f you have health insurance that covers drugs, your cost may be different." 84 Fed. Reg. 20,758 (May 10, 2019). But although the caveat alerts patients with insurance that they may pay a different amount than list price, it provides no information about the extent of that possible difference or the various factors that may affect it, whether across insurance programs or even as to the same patient on the same plan. Nor could it, given that insurance coverages differ so widely among individuals. For example, there are differences not only among plans (e.g., co-payments, co-insurance and deductibles (and whether they apply individually or to the patient's family)), and available coverage. Coverages can even differ as to the same patient, depending for example on whether the patient seeks coverage before or after any annual or lifetime insurance-mandated out-of-pocket maximum cost is reached. Even with the caveat, therefore, Amgen believes that the statement required by the Rule will result in patients being confused or misled about price and thus will not increase transparency or improve decision making.

13. The caveat also creates the impression that patients who do not have insurance will pay the full list price. This may not always be the case, and could cause such patients to overestimate their out-of-pocket price.

14. This confusion around price will be exacerbated by the lack of clarity in the Rule about what the disclosed price is based on and how it is calculated. The Rule requires that an advertisement display a single list price for a typical 30-day regimen or a typical course of treatment, but provides no guidance concerning what CMS considers to be a "typical course of treatment" or how to determine whether a "typical 30-day regimen" or a "typical course of treatment" is more appropriate. *See* 84 Fed. Reg. 20,758 (May 10, 2019).

15. In some circumstances, there is no typical 30-day regimen or course of treatment applicable to a majority of patients. Rather, any given patient's prescription may depend on a number of factors, including the state of their disease, their symptoms, individual risk factors, weight, age, whether a titration period is necessary, how they responded to underlying treatment (if the drug is supportive care) and so on. In each case, the "list price" associated with a 30-day

regimen or a "typical course of treatment" may be different, and a "typical course of treatment" can change over time, especially in cases of diseases that are not chronic in nature and may call for highly varied courses of treatment given individualistic patient presentations (e.g., in oncology).

16. To take a specific example, Amgen's product Neulasta® is approved for patients with non-myeloid malignancies receiving strong chemotherapy.[2] Neulasta® is administered as a single dose per chemotherapy cycle. Dosing time is 24 hours after administration of chemotherapy and not within 14 days of the next chemotherapy dose. But the number of chemotherapy cycles a patient receives can depend on various factors, including the type of cancer being treated, the chemotherapy regimen being used, the number of chemotherapy cycles prescribed, prior or current experience with chemotherapy, and the patient's overall health. Given these variables, which may differ from patient to patient, or even as to a particular patient over the course of her individual treatment, the concept of a typical course of treatment, or even a typical 30-day supply, does not fit the product. The Rule provides no guidance about how to proceed.

17. But even if the Rule did give guidance about what list price to include, doing so still would be confusing, as most viewers of television advertisements covered by the Rule will likely not have access to all the information necessary to understand how the price set forth in the advertisement relates to what their particular treatment course may be (let alone the various factors related to rebates, discounts and insurance, such as those noted above).

18. Because the Rule will cause viewers to be confused or to overestimate their out-of-pocket price, the Rule may discourage such individuals from taking the initiative to discuss the advertised drugs or biological products with their healthcare providers, or otherwise encourage them to "opt out" of taking or pursuing an advertised medication.

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[2] Neulasta® US Prescribing Information at 2 (available online at https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/neulasta/neulasta_pi_hcp_english.ashx) last visited June 13, 2019.

19. Far from improving decision making, this may lead to less-informed healthcare choices and/or worse health outcomes for patients. Consider two examples. Amgen's medication Prolia® is approved in the United States for, *inter alia*, "treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture."[3] In postmenopausal women with osteoporosis, Prolia® "reduces the incidences of vertebral, nonvertebral and hip fractures."[4] Amgen's product Repatha®, in turn, "is approved in the United States to reduce the risk of myocardial infraction, stroke and coronary revascularization."[5] Osteoporosis, myocardial infraction, stroke and coronary revascularization are often silent diseases. Patients may not realize they have these conditions until they are faced with a life changing bad outcome or medical decision point. Or, even if they are aware of certain health risks, they may not be aware of the availability of treatments for the condition, and therefore may not be incentivized to begin a discussion with their healthcare provider. A patient who is deterred from asking her healthcare provider about Prolia® or Repatha® may be deprived of the opportunity for early intervention (including positive lifestyle changes) and the risk-reducing benefits those medications can offer. An individual who foregoes preventative or risk-reducing medication may be more likely to suffer the very outcomes the medication is intended to prevent or reduce, thus incurring additional medical cost and intervention. Not only would that result in worse health outcomes, but potentially higher costs for the patient and third-party payers as well.

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3 *See* Prolia® US Prescribing Information at 3 (available online at https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/prolia/prolia_pi.ashx) (last visited June 13, 2019).

4 *Id.* (citing 14.1).

5 Repatha® US Prescribing Information at 2 (available online at https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/repatha/repatha_pi_hcp_english.pdf), last visited June 13, 2019.

Given individual price variability among patients, Amgen would not voluntarily include list price information in its DTC television advertising.

20. Even with the "caveat" language required by the Rule, it would be impossible for a television advertisement to account for all of the points that can affect out-of-pocket price in an advertisement designed to fit into a short time slot, let alone to acknowledge the many contingencies that can affect a patient's out-of-pocket price (including those related to the patient's health and insurance coverage). Indeed, in the context of a short television spot, any attempt to present that sort of discussion would be confusing and, what's more, essentially take over the advertisement altogether, significantly detracting from the intended message about the benefits and risks associated with a particular product.

21. Including the statement required by the Rule also will make DTC television advertisements more expensive to Amgen, which already has incurred costs (both internal and external) related to attempting to understand and comply with the Rule. Although Amgen still would be required to pay for 100% of the advertisement time it purchases, it will be required to devote a not insubstantial share of every such advertisement to conveying the Centers for Medicare & Medicaid Services's ("CMS") required message. In other words, as a result of the Rule, CMS would effectively coopt, to convey its own message, a portion of every covered DTC advertisement paid for by Amgen.

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22. Amgen believes patients deserve clear and relevant information about the price they can expect to pay for their medications—and we have already taken steps in our television advertisements and related product websites to enhance price transparency—but we do not believe the Rule furthers this goal. To the contrary, Amgen believes the Rule would harm patients by confusing and misleading them about price and, in turn, could impede patient-provider dialogue about important healthcare issues and treatments. For this and all the other reasons set forth in this declaration, Amgen would not voluntarily include in its DTC television advertising the information required by the Rule.

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

David Marek

Executed on June 13, 2019