UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC.,
2000 Galloping Hill Road
Kenilworth, NJ 07033;

ELI LILLY AND COMPANY,
893 Delaware Street
Indianapolis, IN 46285;

AMGEN INC.,
1 Amgen Center Drive
Thousand Oaks, CA 91320;

and

ASSOCIATION OF NATIONAL ADVERTISERS, INC.,
2020 K Street, NW
Suite 600
Washington, DC 20006;

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, SW
Washington, DC 20201;

ALEX M. AZAR II, in his official capacity as the Secretary of the United States Department of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201;

CENTERS FOR MEDICARE & MEDICAID SERVICES,
7500 Security Boulevard
Baltimore, MD 21244;

and

Case No. 1:19-cv-01738

SEEMA VERMA, in her official capacity as the Administrator of the Centers for Medicare & Medicaid Services,
7500 Security Boulevard
Baltimore, MD 21244;

Defendants.

COMPLAINT FOR RELIEF

PRELIMINARY STATEMENT

Americans deserve accurate information about the price they will pay for prescription drugs. This case involves a rule adopted by the Department of Health and Human Services (HHS) that purports to further that objective, but will instead frustrate it—by misleading patients about their out-of-pocket costs for prescription drugs in a manner that even HHS admits may "confuse[]" and "intimidate[]" patients, "discourage patients from using beneficial medications, reduce access, and potentially increase total cost of care." HHS, Centers for Medicare & Medicaid Services, *Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency*, 84 Fed. Reg. 20,732, 20,756 (May 10, 2019).

Relying on an unprecedentedly broad construction of the agency's statutory authority to enact regulations necessary for the "efficient administration" of the Medicare and Medicaid programs, the rule at issue requires virtually all direct-to-consumer pharmaceutical television advertisements to include a specific, government-scripted statement highlighting what the rule describes as the "list price" of the advertised product. That "list price" is not, as patients will likely infer from the context, a suggested sales price for the retail transactions contemplated in advertisements. Rather, the rule requires manufacturers to use the gross price at which a prescription drug is offered to wholesalers, before rebates, discounts, or any other adjustments are applied. And the mandated price figure not only ignores such wholesale price adjustments, but

also fails to account for the insurance coverage that a significant majority of Americans have for their retail purchases of prescription drugs. As a result, the "list price" that the rule requires manufacturers to convey to patients is often multiple times higher than the out-of-pocket price that a substantial majority of Americans would pay for the advertised products. Far from promoting transparency and improved decision-making, therefore, the rule would instead force pharmaceutical companies to mislead tens of millions of Americans about the price they would actually pay for important medicines that might improve their health or even save their lives. For the reasons set out below, the rule exceeds HHS's statutory authority, violates the First Amendment, and should therefore be set aside.

1. Plaintiffs in this case include three leading pharmaceutical manufacturers (Company Plaintiffs) who are working to develop and deliver innovative treatments that save lives, combat disease, and improve Americans' quality of life, as well as the Association of National Advertisers, Inc. (ANA), an industry association whose members include pharmaceutical companies that advertise prescription medications.

2. One of the most important ways in which pharmaceutical manufacturers educate the public about the availability of the treatments they develop is through direct-to-consumer (or "DTC") advertising. Such advertising alerts people who suffer from a given condition about new or existing treatment options of which they may not be aware. And even apart from awareness of a specific treatment, direct-to-consumer advertising can raise awareness about the health condition itself and prompt action, whether that be a conversation with a doctor or a positive lifestyle change. The U.S. Food & Drug Administration (FDA) has thus recognized that "DTC advertising seems to increase awareness of conditions and treatments, motivate questions for the healthcare provider, and help patients ask better questions." Kathryn J. Aikin et al., FDA, *Patient and Physician*

Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs—Summary of FDA Survey Research Results 7 (2004), https://www.fda.gov/media/112016/download.

3. In the Federal Food, Drug, and Cosmetic Act (FDCA), Congress enacted provisions to ensure that direct-to-consumer advertisements are truthful, balanced, and not misleading. For decades, HHS, acting through the FDA, has enforced those protective measures. On May 10, 2019, however, HHS published in the Federal Register a new rule, purportedly authorized by a different statute, that will have precisely the opposite effect.

4. The rule mandates that most television advertisements for pharmaceutical products include a disclosure about the "Wholesale Acquisition Cost," or "WAC," of the advertised product that HHS *concedes* may well mislead patients about their potential out-of-pocket costs for medications. (This Complaint refers to the regulation as the "Compelled WAC Disclosure Rule.")

5. As its name suggests, the "Wholesale Acquisition Cost" of a product is not a suggested retail price for patients. Instead, it is expressly defined by federal statute as the price charged to *wholesalers*, before the application of discounts, rebates, and other adjustments that substantially reduce the net payment for the prescription drug. The rule thus directs manufacturers to advertise to *consumers* the price that manufacturers charge to *wholesalers*, even though these are two entirely different concepts. And because third-party payers (like insurance plans or government health programs) generally cover the bulk of the costs of a branded drug, the overwhelming majority of patients do not pay anything remotely close to the Wholesale Acquisition Cost of an advertised drug at the pharmacy or through their provider.

6. For example, almost none of the approximately 65 million Americans on Medicaid—one of the groups toward whom HHS's statutory authority is explicitly directed—ever pays more than an $8 co-pay for prescription drugs or pharmaceutical products.

7. Nevertheless, the Compelled WAC Disclosure Rule requires pharmaceutical companies to describe WAC as the "list price" for the product in their direct-to-consumer television advertising.

8. Few patients viewing an advertisement that repeats the Compelled WAC Disclosure Rule's required statement will appreciate that the "list price" it describes may in fact be many times higher than their likely out-of-pocket cost to obtain the advertised product. The Rule is therefore likely to cause many patients to overestimate how much they would have to pay for treatment, and indeed to cause many patients to conclude—incorrectly—that it is not worth asking their doctors about the advertised product even though the treatment might save or significantly improve the quality of their lives.

9. Far from denying that the Compelled WAC Disclosure Rule will mislead patients, HHS admits that it could have that effect: "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." 84 Fed. Reg. at 20,756.

10. Even worse, HHS is actually *counting* on that misleading effect. It posits that by forcing pharmaceutical manufacturers to advertise to patients "list prices" that are many times higher than what most patients will actually pay, the Compelled WAC Disclosure Rule will "expos[e] overly costly drugs to public scrutiny." *Id.* at 20,733. And more than that, HHS believes that "[t]his could discourage patients from using beneficial medications," *id.* at 20,756, which might reduce Medicare and Medicaid expenditures on pharmaceutical products but would be directly contrary to those patients' best interests.

11. HHS acknowledges that by causing patients to forego beneficial treatments, the Compelled WAC Disclosure Rule might actually "increase the *total* cost of care," and admits that

"[w]e lack data to quantify these effects." *Id.* In other words: HHS cannot even say whether the misleading statement it is forcing manufacturers to include in their consumer advertisements will ultimately save the Medicare and Medicaid programs any money—the articulated purpose of the regulation.

12. The consumer confusion and adverse healthcare consequences that will arise from the Compelled WAC Disclosure Rule are, moreover, entirely unnecessary because there are so many legitimate ways of providing patients with *accurate* information about the potential costs they will incur for pharmaceutical products. For example, Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group representing innovative biopharmaceutical companies in the United States, has promulgated an extensive set of guidelines for direct-to-consumer television advertisements. *See* PhRMA, *Direct to Consumer Advertising Principles* (2018), https://www.phrma.org/codes-and-guidelines/direct-to-consumer-advertising-principles. In accordance with these guidelines, numerous pharmaceutical companies already voluntarily explain in their television advertisements how patients can access information that will help them determine their likely out-of-pocket costs based on the terms of their insurance, along with additional contextualized cost information. This approach provides patients with much-needed transparency about the pricing that is actually relevant to them, rather than providing them with a gross wholesale price that is typically several times higher than what a patient would actually pay.

13. To the extent additional sources of information would be helpful to patients, HHS has numerous alternatives that would be less restrictive of manufacturers' First Amendment rights (and less misleading to patients). For example, HHS can require health plans offered through government programs to provide computerized mechanisms to determine and compare the price of various treatment options. Such information is already available to Medicare Part D

beneficiaries through the Plan Finder tool at Medicare.gov, and HHS recently finalized regulations requiring that Medicare Part D plans make this patient-specific information readily accessible to providers, too, by January 2021. *See Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses*, 84 Fed. Reg. 23,832, 23,833 (May 23, 2019) (to be codified at 42 C.F.R. pts. 422, 423). When completed, those systems will allow providers to help patients understand the cost of their various treatment options and make a decision that is right for them.

14. Beyond being entirely unnecessary, bad for patients, and detrimental to health care, the Compelled WAC Disclosure Rule is also unlawful—for two basic reasons.

15. First, HHS has no statutory authority to impose the Rule. Originally, HHS indicated that it hoped the FDA—long recognized as the primary regulator of pharmaceutical advertising—would adopt a price disclosure requirement using authority delegated by Congress in the FDCA. But after commenters pointed out that the FDA has long conceded the FDCA does not authorize price disclosure mandates, HHS abandoned that course. Instead, it turned to a pair of generalized rulemaking provisions found in the Social Security Act that authorize the Secretary to adopt regulations necessary for the administration of the Medicare and Medicaid programs. Reasoning that compelling these WAC disclosures might pressure companies to reduce their WAC, and thus indirectly reduce Medicare and Medicaid spending (at least on drugs, though not necessarily on healthcare more broadly), HHS asserted that those generalized rulemaking provisions are sufficient support for this disclosure mandate. But if Congress had truly intended to give HHS authority to regulate anything and everything that indirectly affects the healthcare market—medical school tuition, the price of fatty foods, and so on—it would have said so directly. HHS's claim to have discovered such expansive power in a pair of decades-old general rulemaking

provisions of the Social Security Act is simply not credible. *See Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014) (expressing skepticism of agency claim to have "discover[ed] in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy'" (citation omitted)). And that claim is all the more dubious given that HHS turned to these generalized Medicare and Medicaid authorizations only after realizing that the statute that speaks *directly* to pharmaceutical advertising—the FDCA—does not authorize the sort of mandate that it wanted to adopt.

16. Second, even if HHS had the statutory authority that it claims, the Compelled WAC Disclosure Rule would still be unlawful because it violates the First Amendment. In general, when the government seeks to compel commercial speakers to convey the government's preferred messages, it bears a heavy evidentiary burden of showing, at a minimum, that the speech mandate will directly and materially advance a substantial government interest that could not be satisfied through other means. HHS cannot begin to make that showing here. It has no legitimate interest, much less a substantial one, in forcing pharmaceutical manufacturers to make statements in direct-to-consumer messaging that it *concedes* may mislead patients about their out-of-pocket costs for medications. HHS has admitted that it lacks any proof that compelling these statements will advance its stated goal of reducing costs for Medicare and Medicaid. And, as discussed above, it has alternatives at its disposal that would be even more effective at providing patients with accurate information about their expected costs, without distracting from and undermining protected commercial speech about the health benefits and risks of pharmaceutical products.

17. For all of these reasons, the Rule should be set aside.

PARTIES

18. Plaintiff Merck & Co., Inc. (Merck) is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. For more

than a century, Merck has been inventing medicines and vaccines for many of the world's most challenging diseases.

19. Plaintiff Eli Lilly and Company (Lilly) is a corporation organized and existing under the laws of the State of Indiana, with its principal place of business in Indiana. Founded in 1876, Lilly is a research-based company dedicated to developing innovative drugs designed to save and improve the lives of patients.

20. Plaintiff Amgen Inc. (Amgen) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in California. Amgen discovers, develops, manufactures, markets and delivers medications that treat a broad range of illnesses and improve the lives of patients. Founded in 1980, Amgen is a pioneer in the development of innovative biological human therapeutics and is one of the world's leading independent biotechnology companies.

21. Plaintiff Association of National Advertisers, Inc., (ANA) was founded in 1910 to promote and protect the well-being of the marketing community, including the promotion of robust First Amendment protections for commercial free speech. The ANA's membership includes more than 1,850 companies and organizations with 20,000 brands that engage almost 50,000 industry professionals and collectively spend or support more than $400 billion in marketing and advertising annually. The membership is comprised of more than 1,100 client-side marketers and more than 750 marketing solutions provider members, which include leading marketing data science and technology suppliers, ad agencies, law firms, consultants, and vendors.

22. Defendant United States Department of Health and Human Services (HHS) is a cabinet department of the United States government.

23. Defendant Alex M. Azar II is the Secretary of HHS and is sued solely in his official capacity.

24. Defendant Centers for Medicare & Medicaid Services (CMS) is a United States government agency within HHS. The Secretary administers the Medicare and Medicaid programs through CMS.

25. Defendant Seema Verma is the Administrator of CMS and is sued solely in her official capacity.

JURISDICTION AND VENUE

26. This action arises under the U.S. Constitution and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

27. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this case arises under federal law.

28. Company Plaintiffs have standing to bring this suit because, unless it is set aside, the Compelled WAC Disclosure Rule will force them to include a statement in their direct-to-consumer television advertisements that they believe will mislead patients. As the attached declarations explain, Company Plaintiffs are seeking judicial relief here in order to avoid being compelled to include that statement. *See* El-Dada Decl. (Merck) ¶ 16; Oleksiw Decl. (Lilly) ¶ 28; Marek Decl. (Amgen) ¶ 22.[1] Similarly, ANA's members include pharmaceutical companies that will be governed by the mandate to list the Wholesale Acquisition Cost in direct-to-consumer television advertisements. The Rule affects the interests of ANA's members, and directly implicates ANA's mission to promote strong constitutional protection for commercial free speech.

[1] These declarations, and the other declarations cited in this Complaint, are being filed as attachments hereto.

29. This Court may issue a declaratory judgment in this case pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2202.

30. Venue is proper in this Court under 28 U.S.C. § 1391(e) because the Secretary and HHS reside in this district, and a substantial part of the events giving rise to this action occurred in this district.

BACKGROUND

Direct-To-Consumer Messaging Regarding Health Conditions And Treatments

31. Today, Americans who want to learn about how to care for their health, and that of their loved ones, have more sources of information than ever before. They can and do rely on their doctors, insurance companies, government agencies, and numerous other sources to gather information about health conditions they may be experiencing and the treatments available for those conditions.

32. Company Plaintiffs, and other innovative pharmaceutical manufacturers like them, play a central role in providing that information. In the course of developing new treatments, they undertake extensive research, including rigorous clinical trials, to ensure a product's efficacy and safety, and to identify and be able to disclose potential side effects. Once a drug is approved by the FDA, they then work to educate physicians and other healthcare professionals about how the product can be used most effectively and safely to care for patients with conditions for which the drug has been approved.

33. Pharmaceutical manufacturers also use the information they gather during and after the development of new products to educate members of the public directly about health conditions and treatment options. One of the most important tools for doing this is direct-to-consumer messaging, including advertisements, about specific pharmaceutical products.

34. Members of the public health community have long recognized that direct-to-consumer advertisements are an important source of information for patients, informing them about new treatment options, raising awareness of disease, and encouraging patient discussions with healthcare providers.

35. One study by researchers at Harvard University and Massachusetts General Hospital, for example, found that 35% of respondents had discussed a medical condition with a doctor as a result of seeing a direct-to-consumer advertisement relating to a particular condition. Of those, nearly a quarter were diagnosed with a new condition following the conversation—and more than 40% of those new conditions were categorized as "high priority" conditions according to criteria developed by the Institute of Medicine. *See* Joel S. Weissman et al., *Consumers' Reports on the Health Effects of Direct-to-Consumer Drug Advertising*, Health Affairs, Feb. 26, 2003, at W3-82, W3-88, https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.W3.82.

36. Similarly, recent research by Princeton Survey Research Associates International (PSRAI) found that 60% of respondents reported that seeing an advertisement for a prescription medicine led them to take a specific action to manage their health care, such as refilling a prescription, scheduling a doctor's appointment, or taking prescription medication. *See* Princeton Survey Research Assocs. Int'l, *2017 Direct to Consumer Advertising Survey* 23 (2017), https://www.phrma.org/report/2017-direct-to-consumer-advertising-survey-results.

37. A landmark survey by the FDA shows that physicians have observed similar benefits. For example, 73% of physicians surveyed reported that consumer drug advertising helped their patients ask more thoughtful questions about their health and treatment. *See* Kathryn J. Aikin et al., FDA, *Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs—Summary of FDA Survey Research Results* 59 (2004),

https://www.fda.gov/media/112016/download. Overall, the FDA concluded that "DTC advertising seems to increase awareness of conditions and treatments, motivate questions for the healthcare provider, and help patients ask better questions." *Id*. at 7.

38. Still other studies have shown numerous additional benefits from direct-to-consumer advertisements. For example, researchers have found that such advertisements improve medical adherence (i.e., the extent to which a patient follows a prescribed course of treatment) by reminding patients of the importance of taking their medication. *See* Nilesh S. Bhutada & Brent L. Rollins, *Disease-Specific Direct-to-Consumer Advertising for Reminding Consumers to Take Medications*, 55 J. Am. Pharmacists Ass'n 434, 434 (2015) ("[D]isease specific DTC advertising can help people remember to take their prescription medication when viewed, which may lead to more positive medication-taking behavior and increased medication adherence.").

39. These benefits of direct-to-consumer advertising not only lead to better outcomes for patients, but can also produce significant cost savings for individual Americans and the healthcare industry as a whole.

40. One 2013 study found that improving responsible medication use and adherence could save $213 billion in U.S. healthcare costs every year, thereby reducing 8% of the country's total spending on healthcare. *See* Murray Aitken & Silvia Valkova, IMS Inst. for Healthcare Informatics, *Avoidable Costs in U.S. Healthcare: The $200 Billion Opportunity from Using Medicines More Responsibly* 3 (2013), http://offers.premierinc.com/rs/381-NBB-525/images/Avoidable_Costs_in%20_US_Healthcare-IHII_AvoidableCosts_2013%5B1%5D.pdf. Of this, the authors attributed $105.4 billion in savings to adherence alone. *See id.*

41. On the basis of direct-to-consumer advertising's utility in improving patient adherence, another recent study—an econometric analysis published in 2017 in the Review of

Economic Studies—found that direct-to-consumer advertising "can generate substantial social value." *See* Michael Sinkinson & Amanda Starc, *Ask Your Doctor? Direct-to-Consumer Advertising of Pharmaceuticals*, 86 Review of Economic Studies (2)836, 866 (September 2017). Looking specifically at direct-to-consumer advertising for certain anti-cholesterol medications, the authors concluded that such advertising falls "well within the [cost-benefit] bounds of what is considered an effective health intervention." *Id.* And because "the value of DTC [advertising] exceeds its cost," they reported that a reduction or elimination of direct-to-consumer advertising would "eliminat[e] large benefits to patients." *Id.* at 867, 869.

Congressional Authorization Of Direct-To-Consumer Advertising Through The Federal Food, Drug, And Cosmetic Act

42. Direct-to-consumer advertising for prescription drugs and biological products is regulated in order to ensure that patients are provided with accurate and non-misleading information about medical conditions and potential treatments. To this end, Congress long ago authorized the Secretary to regulate pharmaceutical advertising under the FDCA in order to ensure that direct-to-consumer advertisements are truthful and convey a fair balance of information about a drug's benefits and safety risks. *See* 21 U.S.C. § 321(n) (authorizing the Secretary to regulate "misbrand[ing]" of pharmaceutical products, including "advertising" that is "misleading"); *see also id.* §§ 331(n), 352(a), 352(n), 353c. The Secretary has delegated that authority, in its entirety, to the FDA, which has extensive regulations, guidance documents, and enforcement mechanisms to ensure that drug advertisements accurately describe the benefits and risks of pharmaceutical products.

43. FDA regulations, for example, require that prescription-drug advertisements: cannot be false or misleading with respect to side effects, contraindications, or effectiveness; must present a fair balance between the risks and benefits of the product; and must, depending on the

medium in which the advertisement appears, either disclose all the risks in the product's approved labeling or make "adequate provision" for disseminating the product's labeling to the audience. *See* 21 C.F.R. § 202.1(e)(5)(i)-(iii), (e)(1). Any company or person who violates these rules can be enjoined (21 U.S.C. § 332(a)) and is subject to steep criminal or civil monetary penalties (21 U.S.C. § 333(a), (g)).

44. At the same time, the FDA has also long recognized that its statutory authority does not extend to mandating disclosures about product prices. *See Reminder Labeling and Reminder Advertisements for Prescription Drugs*, 40 Fed. Reg. 58,794 (Dec. 18, 1975). To Plaintiffs' knowledge, although the FDA carefully monitors direct-to-consumer advertisements for prescription drugs to ensure that such advertisements are not misleading, the FDA has never once suggested that an advertisement is misleading because it fails to disclose that drug's list price. To the contrary, the FDA has conceded that any "decision to engage in public disclosure of prescription drug prices is not for [it] to make." *Id.* at 58,794.

45. In addition to acknowledging that it cannot, under the FDCA, *require* publication of price information, the FDA has concluded that the FDCA *prohibits* publication of price information when publication of that information would tend to mislead consumers.

46. In 2011, the FDA advised that even price disclosures that are technically "truthful" may create an "unbalanced net impression of the drug product," and thereby "create a misleading impression of risk and benefit." *Effect of Promotional Offers in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Product Perceptions*, 76 Fed. Reg. 58,011, 58,014 (Sept. 19, 2011). The FDA explained that "even if a price incentive included in an advertisement is in fact 'truthful,' the net impression of the promotional piece as a whole can be unbalanced or misleading, which may in turn violate existing regulations." *Id.*

The Pharmaceutical Pricing System

47. In the absence of any requirement—or clear permission—under the FDCA to include drug pricing information in direct-to-consumer advertisements, most direct-to-consumer advertisements do not include pricing claims about the promoted products.

48. Manufacturers' general practice of not including pricing information in the context of short television advertisements reflects, in part, the same concern about misleading patients that the FDA itself has voiced, given that the complicated system of payment, pricing, and insurance coverage in our country's multi-layered pharmaceutical distribution system leads to varying out-of-pocket costs. In most cases, manufacturers have determined that presenting an accurate, non-misleading explanation of what individual patients might pay for the product based on their individualized insurance coverage, treatment needs, and pharmacy options is simply too difficult to accomplish in the compressed time-frame of a television advertisement. As HHS has acknowledged, "it would be too complicated to . . . try to disclose every possible cost sharing outcome in a DTC television advertisement." 84 Fed. Reg. at 20,741. Instead, manufacturers have made that information available through other sources that allow for more explanation and contextualization, such as manufacturer websites (where they also post important safety information that the FDA has determined does not need to be include in the advertisement itself).

49. The need for explanation and contextualization reflects the complexity of the U.S. market for pharmaceutical products. Such products generally pass through several different entities before reaching the patients who need them. Pharmaceutical manufacturers mainly sell their products to wholesalers. Wholesalers, in turn, sell those products to healthcare providers (such as hospitals, clinics, and doctors) and to pharmacies. And healthcare providers and pharmacies ultimately dispense the products to patients and receive payment for these products from the patients and the patients' insurance plans (whether private or government-operated).

50. Each participant in this multi-layered distribution system pays a different amount for those products. Determining the price at which manufacturers will sell to wholesalers starts with the drug's Wholesale Acquisition Cost, or "WAC." Federal law defines WAC as "the manufacturer's list price" to "wholesalers or direct purchasers," "not including prompt pay or other discounts, rebates or reductions in price." 42 U.S.C. § 1395w-3a(c)(6)(B).

51. In most U.S. product markets, that wholesale price would be significantly *below* the retail price that consumers pay for the product, because of markups introduced by other participants in the distribution system. In the U.S. pharmaceutical market, however, the opposite is true: a given product's WAC is almost always *higher* than what patients pay at the pharmacy or through their provider for that same product, often several times over.

52. There are several reasons for this. One is that while WAC is the list price a manufacturer charges a wholesaler for a given pharmaceutical product, manufacturer rebates and discounts often reduce the amount owed by entities in the supply chain. *See id.* As a result of those price concessions, the net cost to payers and supply chain intermediaries may be significantly lower than WAC. *See, e.g.*, Steven M. Lieberman & Paul B. Ginsburg, Brookings Inst., *Would Price Transparency for Generic Drugs Lower Costs for Payers and Patients?* 8 (2017), https://www.brookings.edu/wp-content/uploads/2017/06/es_20170613_genericdrugpricing.pdf.

53. An even greater cause of the disconnect between patients' out-of-pocket costs and WAC, however, is the third-party payment system. For most patients and most prescriptions, private insurance or a government health program pays a significant majority of the cost of a pharmaceutical product. The patient, meanwhile, typically makes only a comparatively small out-of-pocket payment.

54. The out-of-pocket price that insured patients pay for a drug depends mainly on three factors—their deductible, co-payment, and co-insurance. A deductible is an annual amount that a patient may be required to pay for care before the insurance plan begins to provide coverage. A co-payment is a fixed dollar amount that a patient may be required to pay out-of-pocket for a given product—for example, if the plan's formulary includes three tiers of covered drugs, $15, $25, and $45. Co-insurance is a percentage of the price of care that a patient may be required to pay, and can likewise vary based on whether a drug is on a preferred tier. Of these three factors, only drug prices paid on a co-insurance basis or toward a deductible have any direct connection to WAC. Co-pays, as fixed amounts, are wholly unrelated to WAC (except to the extent that an insurer may consider WAC in deciding which co-payment tier of its formulary a particular product should be placed in). And, as explained below, even co-insurance and deductible payments often differ substantially from WAC, sometimes representing only a small fraction of a product's WAC.

55. Because of these considerations, for the vast majority of patients in the United States, the out-of-pocket cost of a pharmaceutical product is a small fraction of WAC. Indeed, the attached declaration by Dr. Craig Garthwaite, the Herman R. Smith Research Professor in Hospital and Health Service at Northwestern University's Kellogg School of Management, explains that for more than 120 million Americans whose drugs require only fixed co-payments or are covered completely by their insurer, there is no connection between out-of-pocket cost and a product's WAC. *See* Garthwaite Decl. ¶¶ 22, 25-26, 34-35.

56. As of 2017, approximately 49% of Americans had private employment-based health insurance, 7% had other forms of private health insurance, 21% were on Medicaid, 14% were on Medicare, and 9% were uninsured. Kaiser Family Found., *Health Insurance Coverage of the Total Population*, https://www.kff.org/other/state-indicator/total-population/ (last visited June

14, 2019). The distribution of coverage might vary somewhat for patients who have a particular condition or who are taking a particular medication, but these figures, based on publicly available information, provide an accurate nationwide representation of coverage.

57. Roughly half of Americans with employment-based plans—somewhere between 39% and 51% of them—pay only co-payments for covered prescription drugs. *See* Garthwaite Decl. ¶ 25. Their payment amount has no direct relationship to a drug's WAC. And even on insurance plans that require co-insurance for *some* drugs or require an insured to meet a deductible before coverage begins, many prescriptions filled over the course of a year are still paid with co-payments.

58. As for the 21% of Americans on Medicaid, none pay the WAC for pharmaceutical products, and the vast majority pay at most a small co-pay that is completely unconnected to WAC. In fact, all States other than Kentucky use fixed co-pays of $8 or less for all drugs under their Medicaid plans—if they charge a patient at all. *See* Kaiser Family Found., *Premium and Cost-Sharing Requirements for Selected Services for Medicaid Adults*, https://www.kff.org/health-reform/state-indicator/premium-and-cost-sharing-requirements-for-selected-services-for-medicaid-expansion-adults/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited June 14, 2019). Even Kentucky requires only co-payments for beneficiaries below 150% of the Federal Poverty Line, with beneficiaries above that level paying a modest co-insurance amount. Kaiser Family Found., *Cost-Sharing Requirements for Selected Medicaid Services for Section 1931 Parents*, https://www.kff.org/medicaid/state-indicator/cost-sharing-requirements-for-selected-medicaid-services-for-section-1931-parents-january/ (last visited June 14, 2019); Kaiser Family Found., *Premium and Cost-Sharing Requirements for Selected Services for Medicaid Adults*, https://www.kff.org/health-reform/state-

indicator/premium-and-cost-sharing-requirements-for-selected-services-for-medicaid-expansion-adults (last visited June 14, 2019). The percentage of Medicaid beneficiaries who pay amounts at all related to WAC—Kentuckians on Medicaid with family incomes in excess of 150% of the Federal Poverty Level—is thus exceedingly small.

59. Most of the 14% of Americans who have only Medicare coverage pay far less than WAC for their prescription drugs, too.

60. Medicare has four "Parts"—A, B, C, and D. Most drugs paid for under Medicare are covered under Part D, although Part B also includes coverage for physician-administered prescription drugs. *See* Kaiser Family Found., *10 Essential Facts About Medicare and Prescription Drug Spending* 2, https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/ (last visited June 14, 2019) (noting that, in 2016, Part D drug spending made up 15% of Medicare spending while Part B drug spending made up 4%).

61. For drugs covered under Part B, Medicare beneficiaries generally pay at most a 20% co-insurance obligation that is calculated based on the Medicare-determined price. Under the Social Security Act, these prices are generally not tied to WAC. Instead, in most instances co-insurance payments are based on a figure called the Average Sales Price (ASP), which is ordinarily lower than WAC. *See* 42 U.S.C. § 1395w-3a(b) (instructing that a drug's reimbursement is 106% times the lesser of WAC or ASP). ASP is defined as the manufacturer's sales of a drug to all U.S. purchasers in a calendar quarter, divided by the total number of units of the drug sold by the manufacturer in that same quarter. *Id.* § 1395w-3a(c). And unlike WAC, ASP is calculated using the price ultimately realized by the manufacturer—that is, WAC minus price concessions to entities in the supply chain. *Id.*

62. Coverage terms are more fractured in Part D, but there, too, beneficiaries rarely pay WAC for their drugs. For Part D drug coverage, in 2018, 45% of all Part D beneficiaries—about 19 million Americans—had plans with no deductibles. Juliette Cubanski et al., Kaiser Family Found., *Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing* tbl.4 (2018), https://www.kff.org/report-section/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing-tables/. Those patients never pay an amount close to WAC for their drugs. *See* Garthwaite Decl. ¶ 43. Instead, they would pay a fixed co-payment for their prescription, or a co-insurance amount that does not exceed 50% of WAC and is generally significantly lower (33% or less in the case of particularly expensive drugs). *See id.* ¶¶ 44-47.

63. The remainder have a maximum deductible of $415. If they ever pay WAC at all for a drug, therefore, they would do so only until they have met that deductible. *See id.* ¶ 43. Over the course of a year, therefore, a beneficiary with the maximum Part D deductible would pay out of pocket an average amount less than WAC for any monthly prescription with a WAC over $34.59. And once he has met his deductible, that beneficiary would pay only a fixed co-payment amount, or a co-insurance amount that is less than half (and generally less than a third) of WAC. *See id.* ¶¶44-47.

64. Finally, even for Americans who do not have insurance covering prescription drugs, out-of-pocket costs can be materially lower than WAC. This is because most pharmaceutical manufacturers offer programs to provide discounts or free products for need-based eligible consumers. Indeed, the manufacturers of every one of the 20 drugs with the highest direct-to-consumer advertising spending during 2016 offer assistance programs that make medication available at no cost to eligible patients, with eligibility criteria encompassing a substantial portion

of the middle class. *See id.* ¶ 52. Moreover, other assistance programs sometimes offer uninsured patients discounts ranging from 36-75% of WAC *regardless* of income. *See id.*

HHS's Attempt To Regulate Direct-To-Consumer Advertising Of Pharmaceutical Products Under The Social Security Act

65. Against this backdrop, HHS announced in May 2018 that it was considering new disclosure requirements for direct-to-consumer advertising as part of its "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs." *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, 83 Fed. Reg. 22,692 (May 16, 2018). In describing a series of actions that "HHS may undertake . . . to the extent permitted by law," HHS indicated that it would "[c]all on the FDA to evaluate the inclusion of list prices in direct-to-consumer advertising." *Id.* at 22,694-95.

66. The FDA, apparently, did not provide the response that HHS was hoping for. Having been reminded in numerous public comments (and perhaps also by the FDA itself) that the FDA has long conceded that the FDCA does not provide it authority to require drug price disclosures in direct-to-consumer advertising, HHS settled on a backup plan: It turned to CMS to promulgate the sort of industry-wide disclosure regulations that the FDCA left the FDA powerless to issue.

67. In a Notice of Proposed Rulemaking that marked this shift, HHS conceded that "Congress has not explicitly provided HHS with authority to compel the disclosure of list prices to the public." *See Medicare and Medicaid Programs: Regulation to Require Drug Pricing Transparency*, 83 Fed. Reg. 52,789, 52,791 (proposed Oct. 18, 2018). Nevertheless, it reported that "HHS has concluded that" a requirement that direct-to-consumer pharmaceutical television advertisements contain pricing information "has a clear nexus to the Social Security Act" and the Medicare and Medicaid programs that CMS administers thereunder. *Id.*

68. HHS relied on two statutory provisions that authorize it to make regulations "necessary" for the "administration of" Medicare and Medicaid. The first, Section 1102(a) of the Social Security Act, authorizes the Secretary to issue "such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions . . . under this Act." The second, Section 1871(a) of the Social Security Act, authorizes the Secretary to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under" the subchapter of the Social Security Act that establishes the Medicare program. *See* 83 Fed. Reg. at 52,790.

69. Invoking those two provisions regarding the "administration of" government health programs, HHS proposed to adopt a new requirement applicable to virtually all direct-to-consumer advertisements of pharmaceutical products airing on television in the United States. Under the proposed rule, every television advertisement for a prescription drug or biological product that is eligible for reimbursement under Medicare or Medicaid and has a WAC over $35 a month would be required to contain a statement conforming to the following HHS-prescribed script: "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." *Id.* at 52,794 (bracketed statements in original).

70. From the outset, HHS recognized that such a requirement would raise First Amendment concerns. HHS sought to allay such concerns, however, by observing that "required disclosures of factual, noncontroversial information in commercial speech may be subject to more deferential First Amendment scrutiny," pointing to the Supreme Court's decisions in *Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626 (1985), and *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) (*NIFLA*).

71. The comment period on the Notice of Proposed Rulemaking closed in December 2018. More than five months later, HHS announced that it had decided to finalize the Compelled WAC Disclosure Rule "as proposed, with minor technical modifications." 84 Fed. Reg. at 20,750.

72. In the preamble to the Rule, HHS responded to the concern expressed by several commenters that the Social Security Act does not authorize HHS to issue industry-wide regulations of direct-to-consumer pharmaceutical advertisements. The Rule is "necessary" to the efficient "administration" of the Medicare and Medicaid programs, HHS argued, because it is intended to "help improve the efficiency of [those] programs by reducing wasteful and abusive increases in drug and biological product list prices." *Id.* at 20,733, 20,736. HHS hoped it would do so in two ways. "First," HHS asserted, "it will provide manufacturers with an incentive to reduce their list prices by exposing overly costly drugs to public scrutiny." *Id.* at 20,733. And "[s]econd," HHS said "it will provide some consumers with more information to better position them as active and well-informed participants in their health care decision-making." *Id.* But while HHS "believe[d] that this rule may provide a moderating force to counteract prescription drug or biological product price increases" by "improving awareness and allowing the general public to signal in some cases that prescription drug or biological product prices have risen beyond their willingness to pay," it conceded that "[w]e lack data to quantify these effects." *Id.* at 20,756.

73. HHS also responded to the numerous commenters who had argued that the Rule would violate the First Amendment. It insisted that the Rule should be analyzed under and satisfies the standards established by the Supreme Court in *Zauderer* and *NIFLA*. The statement that the Compelled WAC Disclosure Rule requires pharmaceutical advertisements to include, HHS maintained, "is undeniably a truthful statement of objective fact." *Id.* at 20,744. Requiring such

"disclosures of factual and uncontroversial information," HHS argued, does not violate the First Amendment. *Id.*

74. At the same time, HHS acknowledged that the supposedly "truthful statement of objective fact" required by the Rule might leave viewers with a decidedly *un*truthful impression. Numerous organizations had filed comments warning that the proposed mandate would—in the words of the National Alliance on Mental Illness—"give viewers the misleading impression that they will be required to pay the full price to obtain a medication, rather than a co-pay or coinsurance required by their health plan." And ultimately, HHS acknowledged that this was a valid concern, recognizing that after seeing the required disclosure in an advertisement, "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." *Id.* at 20,756 (emphasis added). And here too, HHS acknowledged, "[w]e lack data to quantify these effects." *Id.*

GROUNDS FOR SETTING ASIDE THE COMPELLED WAC DISCLOSURE RULE

75. HHS acknowledges that it lacks express authority to adopt the Compelled WAC Disclosure Rule, acknowledges that the Rule may mislead patients, acknowledges that by doing so the Rule may actually *increase* the total cost of care in the Medicare and Medicaid programs, and acknowledges that it lacks the data necessary to evaluate those effects.

76. Despite all of those admissions, HHS pressed forward with the Compelled WAC Disclosure Rule. But the Rule is unlawful on multiple grounds.

The Social Security Act Does Not Give HHS Authority To Require Price Disclosures In Direct-To-Consumer Television Advertisements Of Pharmaceutical Products

77. HHS had no statutory authority to promulgate the Compelled WAC Disclosure Rule.

78. The D.C. Circuit has held that a regulator, like HHS, "cannot rely on its general authority to make rules necessary to carry out its functions when a specific statutory directive defines the relevant functions of [the regulator] in a particular area." *Nat'l Mining Ass'n v. Dep't of Interior*, 105 F.3d 691, 694 (D.C. Cir. 1997); *see also Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005) (regulators cannot use a "general authority to expand the specific but more limited" authority conferred by specific statutory provisions). And general statutory authority must be interpreted particularly narrowly when the assertion of power encroaches on First Amendment interests. *See Mot. Picture Ass'n of Am., Inc. v. FCC*, 309 F.3d 796, 805 (D.C. Cir. 2002) (general statutory authority must be interpreted narrowly where First Amendment interests are implicated).

79. As discussed above, however, that is precisely what HHS is attempting to do here. When it originally proposed imposing drug-price disclosure obligations in direct-to-consumer advertising, HHS indicated that it intended those regulations to be issued by the FDA, using the express authority conferred on the Secretary under the FDCA to regulate pharmaceutical advertising. It was only after commenters pointed out that the FDCA does not authorize regulations mandating *price* disclosures that HHS switched gears and purported to discover authority to issue such regulations in general provisions authorizing the issuance of regulations for the efficient administration of the Medicare and Medicaid programs.

80. Making the attempt to sidestep the limitations of the statute that actually governs this specific area all the more concerning, the breadth of regulatory authority HHS is claiming

under the general rulemaking provisions of the Social Security Act is virtually limitless. HHS reasons that anything that affects the costs incurred in the Medicare and Medicaid programs is fair game for regulation. *See* 84 Fed. Reg. at 20,736. If that assertion were true, HHS could use Sections 1102(a) and 1871(a) of the Social Security Act to regulate almost anything—executive compensation at hospitals, medical school tuition rates, even the price of tobacco products or fatty foods—so long as HHS first determines that doing so might indirectly benefit the Medicare and Medicaid programs.

81. It is unthinkable that Congress would have hidden such an immense grant of power in vague, general provisions of the Social Security Act. *See Util. Air Regulatory Grp.*, 573 U.S. at 324 (expressing skepticism of agency claim to have "discover[ed] in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy'" (citation omitted)); *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes."); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159-60 (2000). When Congress intends to give an administrative agency authority to regulate an entire sector of the economy, it speaks clearly on the subject. *See Util. Air Regulatory Grp.*, 573 U.S. at 324.

82. Moreover, if Congress *had* intended to delegate such expansive authority to HHS in Sections 1102(a) and 1871(a), to avoid serious constitutional concerns it would have needed to provide more guidance for the exercise of that authority than simply directing HHS not to adopt regulations that are "inconsistent" with other portions of the Social Security Act.

The Compelled WAC Disclosure Rule Violates The First Amendment By Requiring Manufacturers To Deliver Misleading, And Potentially Harmful, Messages To Patients

83. The Compelled WAC Disclosure Rule is also invalid because it violates the First Amendment.

84. In general, the government can no more compel people to speak than it can bar them from speaking, *see Wooley v. Maynard*, 430 U.S. 705, 715-16 (1977), and the government bears a heavy burden to justify laws compelling speech, even in the commercial arena.

85. The Rule is subject to at least intermediate scrutiny because it constitutes, on its face, a content-based regulation of commercial speech. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980). To satisfy intermediate scrutiny, the government bears the burden of showing that the regulation in question directly and materially advances a substantial government interest that could not be served just as well by means that do not regulate speech to the same degree.

86. HHS cannot carry that burden, for several reasons.

87. First, HHS has not shown that the Compelled WAC Disclosure Rule directly and materially advances a substantial government interest.

88. HHS asserts that one purpose of the Compelled WAC Disclosure Rule is to "improve the CMS customer experience by providing transparency into drug prices." 84 Fed. Reg. at 20,754. As discussed above, however, the Rule is likely to have exactly the opposite effect because of its reference to a "list price" that is many times higher than the price most "CMS customers" who see the direct-to-consumer advertisement would pay for the product.

89. Even HHS concedes that, because of the statement's formulation, "[c]onsumers 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." *Id.* at 20,756.

90. Indeed, that result is extremely likely. In finalizing the Compelled WAC Disclosure Rule, HHS pointed to a 2019 study regarding consumer responses to advertisements that contain information about a product's WAC. *See id.* at 20,734 (citing Jace B. Garrett et al., *Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising*, 179 JAMA Internal Med. 435, 437 (2019) (JAMA 2019 Study)). In that study, participants who viewed advertisements for a hypothetical diabetes drug with a "price" of $15,500 for a 30-day supply were asked what they expected they would have to pay out-of-pocket for the drug. *See* JAMA 2019 Study at 436. Responses varied widely, but on average respondents expected they would have to pay $2,787.08 for the drug. *Id.* at 437 tbl.2. Moreover, even when they were told that "eligible patients may be able to get Mayzerium for as little as $0 per month," respondents still estimated (on average) that their out-of-pocket cost would be $1,355.39. *Id.*

91. As the above discussion of patients' out-of-pocket costs indicates, those estimates are wildly inaccurate for the majority of Medicaid and Medicare beneficiaries. For approximately 65 million Americans on Medicaid, for example, the *maximum* out-of-pocket cost for the drug would be just $8. Garthwaite Decl. ¶ 35. And for Medicare Part D beneficiaries who have already made significant out-of-pocket expenditures on prescription drugs over the course of the year (as many Medicare beneficiaries with diabetes would have), the out-of-pocket cost would be at most $775. *See id.* ¶¶ 49-50. For all of those "CMS customers," the impression conveyed by the advertisement would be highly misleading.

92. HHS also hopes that the Compelled WAC Disclosure Rule will "reduc[e] wasteful and abusive increases in drug and biological product list prices" by "provid[ing] manufacturers

with an incentive to reduce their list prices by exposing overly costly drugs to public scrutiny," 84 Fed. Reg. at 20,733, and "allowing the general public to signal in some cases that prescription drug or biological product prices have risen beyond their willingness to pay," *id.* at 20,756.

93. Here, the key to evaluating the Rule's "effectiveness" is the misleading impression it will convey about patients' out-of-pocket costs.

94. As discussed above, most Americans in most transactions pay far less than WAC for their prescriptions. Indeed, for more than 120 million Americans whose out-of-pocket drug costs depend entirely on co-payments, WAC is irrelevant to the calculation of the price they would pay for an advertised drug. And even Americans who do not have insurance that covers prescription drugs might still pay significantly less than WAC, depending on the availability of cost assistance and discount programs available for the drug in question—a fact the mandated statement impliedly denies by suggesting that "your cost may be different" only "if you have health insurance that covers drugs."

95. Nevertheless, HHS transparently expects that it will be easier to inflame public opinion about the affordability of pharmaceutical products if people believe those products would cost them many times more than they actually would. And because "consumers . . . may be deterred from contacting their physicians about drugs or medical conditions" if they have been "intimidated and confused by high list prices," HHS evidently hopes that either utilization rates will fall or manufacturers will reduce the WAC for their products to avoid losing consumers to such confusion. 84 Fed. Reg. at 20,756.

96. HHS has no *legitimate* interest, much less a *substantial* interest, in misleading patients in this way, even if it could show that the deception would cause Medicare and Medicaid beneficiaries to forego treatment or pressure manufacturers to reduce WAC. *See, e.g.*, *Video*

Software Dealers Ass'n v. Schwarzenegger, 556 F.3d 950, 965-67 (9th Cir. 2009) (explaining that a State has no legitimate reason to force retailers to affix misleading labels on their products). Indeed, as the FDA has previously recognized, the FDCA affirmatively prohibits the inclusion of price information in pharmaceutical advertisements in a way that is likely to create an inaccurate "net impression." *Effect of Promotional Offers in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Product Perceptions*, 76 Fed. Reg. 58,011, 58,014 (Sept. 19, 2011).

97. Moreover, even if HHS could possibly have a legitimate substantial interest in reducing programmatic costs by misleading patients, HHS cannot show that the Compelled WAC Disclosure Rule will materially and directly advance that cost-reduction interest. HHS's burden in this respect is substantial: It must show, with actual evidence, "that the measure . . . would 'in fact alleviate' the harms it recited 'to a material degree.'" *Nat'l Ass'n of Mfrs. v. SEC.*, 800 F.3d 518, 526-27 (D.C. Cir. 2015) (citation omitted); *see also Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 26 (D.C. Cir. 2014) (en banc) (requiring "evidence of a measure's effectiveness"). And HHS has, remarkably, *conceded* that it cannot do so.

98. Specifically, HHS conceded in the Rule that "[w]hile we expect this rule to put downward pressure on the list prices of drugs, *we cannot quantify the level of this impact because there is not data or examples that we can use.*" 84 Fed. Reg. at 20,754 (emphasis added). Moreover, HHS acknowledged that even if "the list price would go down, it would not necessarily affect" actual net payment amounts for those drugs; instead, it might simply cause manufacturers to eliminate rebates, discounts, and other existing price concessions, with the net cost to the Medicare and Medicaid programs remaining unchanged. *Id.* at 20,757.

99. Beyond HHS's acknowledgment that it lacks evidence about the Rule's likely effects on drug prices, HHS has also conceded that it lacks evidence that the Rule would reduce

spending in the Medicare and Medicaid programs *even if* it were to reduce drug prices. That is because one likely effect of the Rule is to "discourage patients from using beneficial medications [and] reduce access," since patients, "intimidated and confused by high list prices, may be deterred from contacting their physicians about drugs or medical conditions." *Id.* at 20,756. The Compelled WAC Disclosure Rule will thus undermine and diminish the value of direct-to-consumer television advertisements for informing patients about available treatments and encouraging them to speak with their doctors, and instead affirmatively discourage patients from seeking out information from their doctors that could help them better care for their health.

100. Those effects are not just bad for patients and the quality of health care. They could also, as HHS admits, "potentially *increase* total cost of care" for the Medicare and Medicaid programs. *Id.* (emphasis added). And HHS again acknowledges that "[w]e lack data to quantify these effects." *Id.*

101. Second, HHS also has not shown that it could not advance its asserted interests in improving drug price transparency and reducing programmatic expenditures by alternative means that would be less restrictive of speech.

102. HHS acknowledges that CMS could make information about out-of-pocket costs available to patients on an individualized basis through multiple alternative channels, including by paying providers and pharmacists to counsel patients about their specific cost of treatment. That information—because it would be specific to individual patients—would be far more accurate than a blanket required disclosure of WAC, which (as discussed above) patients enrolled in government health programs rarely ever pay. And it would not require manufacturers to convert direct-to-consumer advertisements that are intended to focus on the health benefits and risks of their

products into discourses that instead focus on the complexities of the American pharmaceutical pricing system, distracting from and undermining the manufacturers' intended message.

103. In an attempt to evade the requirements of intermediate scrutiny, HHS argued in the preamble that the Rule's compelled speech requirement should be entitled to more deferential First Amendment review under the standard articulated in *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985). *See* 83 Fed. Reg. at 20,744.

104. That is incorrect. In *Zauderer*, the Court set forth a standard applicable in limited circumstances, where the government requires disclosure of "purely factual and uncontroversial information about the terms under which [products] will be available." 471 U.S. at 651. Requirements of that narrow sort, the Court held, are permissible so long as they are not "unjustified" or "unduly burdensome." *Id.*; *see also NIFLA*, 138 S. Ct. at 2372 (discussing *Zauderer* standard). For multiple reasons, however, the statement mandated by the Compelled WAC Disclosure Rule does not come within *Zauderer*'s scope.

105. *First*, because WAC is not the price at which drugs are offered to individual patients (and, indeed, bears no relation to the price paid by individuals in most transactions), the required statement does not refer to the "terms under which . . . [products] will be available" to the viewers of the advertisement. *Zauderer*, 471 U.S. at 650.

106. *Second*, the required statement is not "purely factual and uncontroversial." *Id.* at 651. The D.C. Circuit has recognized that compelled statements qualify as "purely factual and uncontroversial" within the meaning of *Zauderer* only where they are not "one-sided or incomplete," *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d at 27, and are not misleading, "inflammatory," or "subject to misinterpretation by consumers," *RJ Reynolds Tobacco Co. v. FDA*,

696 F.3d 1205, 1216 (D.C. Cir. 2012), *overruled on other grounds by Am. Meat Inst.*, 760 F.3d at 22.

107. Here, as set out above, it is clear that the compelled statement is "subject to misinterpretation by consumers." *RJ Reynolds Tobacco*, 696 F.3d at 1216-17. Dr. Ravi Dhar, the George Rogers Clark Professor of Management and Marketing at the Yale School of Management, has evaluated the Compelled WAC Disclosure Rule and concluded that the Rule is likely to mislead consumers into overestimating their actual out-of-pocket costs for many drugs. Dhar Decl. ¶¶ 14-34 (June 14, 2019). As Dr. Dhar explains, the Rule refers to WAC as the "list price" for the drug in a context—a direct-to-consumer television advertisement—where that term will naturally be understood to mean "suggested retail price," even though the truth is that the figure represents the gross price to *wholesalers* and vastly exceeds the out-of-pocket price paid by most patients. *Id*. ¶ 30. The Federal Trade Commission has promulgated guidance indicating that when companies advertise a 'list price' to consumers that "is significantly in excess of the highest price at which substantial sales in the trade area are made, there is a *clear and serious danger* of the consumer being misled." 16 C.F.R. § 233.3(d) (emphasis added). And the D.C. Circuit, too, has recognized that consumer advertisements suggesting that a given "list price" is a price charged to consumers are "deceptive" where the "list price" is not an accurate representation of the price actually paid by consumers. *Giant Food Inc. v. FTC*, 322 F.2d 977, 982 (D.C. Cir. 1963).[2]

108. Indeed, HHS has *admitted* that viewers of advertisements that contain the statement required by the Compelled WAC Disclosure Rule "might believe they are being asked to pay the

[2] Because WAC is a list price to wholesalers, there is nothing inherently deceptive about the fact that it diverges from the price paid by patients. But requiring manufacturers and advertisers to characterize WAC simply as a "list price" in short television advertisements that are specifically directed at consumers creates the serious risk of deception.

list price rather than a co-pay or co-insurance"—and it is precisely that misinterpretation that HHS hopes will cause "the general public to signal in some cases that prescription drug or biological product prices have risen beyond their willingness to pay." 84 Fed. Reg. 20,756. *Zauderer* review is not available for compelled speech mandates that mislead the public in that way. *See also Sorrell*, 564 U.S. at 567 (government cannot seek to "tilt the public debate in a preferred direction" by "hamstring[ing] the opposition").

109. In any event, the Compelled WAC Disclosure Rule would fail even under *Zauderer*'s more deferential standard. The Supreme Court's decision in *NIFLA* makes clear that even when the government adopts a truthful, non-misleading disclosure mandate, it still must show that the mandate is not "unjustified or unduly burdensome." 138 S. Ct. at 2372 (citation omitted). And for the reasons already discussed, HHS cannot satisfy either of those requirements. The Rule is unjustified because HHS has not shown and cannot show that requiring disclosure of WAC will in fact reduce overall costs to the Medicare and Medicaid programs, and the Rule is "unduly burdensome" because its ostensible objective of informing Medicare and Medicaid beneficiaries of their out-of-pocket expenses could be accomplished far more effectively, and without the need to undermine protected commercial speech, through government-sponsored individual counseling and disclosures by Medicare Part D plans.

COUNT I

VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT

110. Plaintiffs reassert and incorporate by reference each of the above paragraphs as if set forth in full herein.

111. The Compelled WAC Disclosure Rule violates the Administrative Procedure Act in three ways: (1) it exceeds the HHS's statutory authority, *see* 5 U.S.C. § 706(2)(C); (2) it is

arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, *id.* § 706(2)(A); and (3) it is contrary to the First Amendment of the U.S. Constitution, *id*. § 706(2)(B).

112. First, the statutory provisions that HHS invokes—Sections 1102(a) and 1871(a) of the Social Security Act—do not give HHS authority to regulate direct-to-consumer television advertising of pharmaceutical products in the manner set forth in the Rule.

113. Second, HHS does not cite any evidence that the Compelled WAC Disclosure Rule will increase the efficiency of the Medicare and Medicaid programs—and, indeed, *concedes* that it lacks such evidence.

114. Third, HHS cannot carry its burden to demonstrate that the Rule comports with the Free Speech Clause of the First Amendment of the United States Constitution.

PRAYER FOR RELIEF

Plaintiffs thus seek a judgment from this Court:

1. Declaring the Compelled WAC Disclosure Rule invalid under the First Amendment and the Administrative Procedure Act;
2. Vacating the Compelled WAC Disclosure Rule;
3. Granting Plaintiffs attorneys' fees and costs; and
4. Awarding any other relief the Court deems just and proper.

Dated: June 14, 2019

Respectfully submitted,

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