ORAL ARGUMENT NOT YET SCHEDULED
No. 19-5222

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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

Plaintiffs-Appellees,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX MICHAEL AZAR, II, IN HIS OFFICIAL CAPACITY AS THE SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CENTERS FOR MEDICARE AND MEDICAID SERVICES; SEEMA VERMA, IN HER OFFICIAL CAPACITY AS THE ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Columbia

BRIEF FOR PLAINTIFFS-APPELLEES

Robert Corn-Revere
Ronald G. London
DAVIS WRIGHT TREMAINE LLP
1919 Pennsylvania Avenue, NW
Suite 800
Washington, DC 20006
(202) 973-4200
bobcornrevere@dwt.com

Counsel for Appellee Association of National Advertisers, Inc.

Richard P. Bress
Daniel Meron
Michael E. Bern
Caroline A. Flynn
Gregory B. in den Berken
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004
(202) 637-2200
richard.bress@lw.com

Counsel for Appellees Merck & Co., Inc., Eli Lilly and Company, and Amgen Inc.

(additional counsel on inside cover)

Annie M. Wilson
LATHAM & WATKINS LLP
330 North Wabash Avenue
Suite 2800
Chicago, IL 60611
(312) 876-7700

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), the undersigned counsel certifies the following:

A. Parties And Amici

Except for the following, all parties, intervenors, and amici appearing before the district court and in this Court are listed in the Brief for Appellants. As of the date of this filing, the following amici have filed amicus briefs or motions for leave to participate as amici before this Court in support of Appellees: Washington Legal Foundation; Goldwater Institute; National Association of Broadcasters; NCTA - The Internet & Television Association; and Cato Institute. In addition, AARP Foundation and AARP filed an amicus brief in support of Appellants.

B. Rulings Under Review

Reference to the ruling under review appears in the Brief for Appellants.

C. Related Cases

This case has not previously come before this Court or any other court. There are no related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

/s/ Robert Corn-Revere
Robert Corn-Revere
DAVIS WRIGHT TREMAINE LLP
1919 Pennsylvania Avenue, NW
Suite 800
Washington, DC 20006
(202) 973-4200
bobcornrevere@dwt.com

Counsel for Appellee Association of National Advertisers, Inc.

/s/ Richard P. Bress
Richard P. Bress
LATHAM & WATKINS LLP
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004
(202) 637-2200
richard.bress@lw.com

Counsel for Appellees Merck & Co., Inc., Eli Lilly and Company, and Amgen Inc.

APPELLEES' CORPORATE DISCLOSURE STATEMENT

As required by Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Appellees submit the following corporate disclosure statement:

1. Appellees are three leading pharmaceutical manufacturers—Merck & Co., Inc., Eli Lilly and Company, and Amgen Inc.—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., an industry association whose members include pharmaceutical companies that advertise prescription medications.

2. 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. Merck has no parent corporation and no publicly held company has a 10% or greater ownership interest in Merck.

3. 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 pharmaceutical company that develops and manufactures life-saving and life-enhancing pharmaceutical products. Lilly has no parent corporation and no publicly held company has a 10% or greater ownership interest in Lilly.

4. 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. Amgen has no parent corporation and no publicly held company has a 10% or greater ownership interest in Amgen.

5. The 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. Merck, Lilly, and Amgen are ANA members, as are other pharmaceutical companies affected by the challenged rule. The ANA has no parent

corporation and no publicly held company has a 10% or greater ownership interest in the ANA.

/s/ Robert Corn-Revere
Robert Corn-Revere
DAVIS WRIGHT TREMAINE LLP
1919 Pennsylvania Avenue, NW
Suite 800
Washington, DC 20006
(202) 973-4200
bobcornrevere@dwt.com

Counsel for Appellee Association of National Advertisers, Inc.

/s/ Richard P. Bress
Richard P. Bress
LATHAM & WATKINS LLP
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004
(202) 637-2200
richard.bress@lw.com

Counsel for Appellees Merck & Co., Inc., Eli Lilly and Company, and Amgen Inc.

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GLOSSARY

CMS	Centers for Medicare and Medicaid Services
DTC	Direct-to-Consumer
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
Goldwater Comment	Goldwater Institute, Comment Letter on Proposed Rule for Medicare and Medicaid Programs: Drug Pricing Transparency (Dec. 17, 2018), https://www.regulations.gov/document?D=CMS-2018-0123-0113
HHS	U.S. Department of Health and Human Services
HUD	U.S. Department of Housing and Urban Development
KFF	Kaiser Family Foundation
KFF Benefits Survey	KFF, *Employer Health Benefits: 2018 Annual Survey* (2018), http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018
Lilly Comment	Eli Lilly & Co., Comment Letter on Proposed Rule for Medicare and Medicaid Programs: Drug Pricing Transparency (Dec. 17, 2018), https://www.regulations.gov/document?D=CMS-2018-0123-0142
PhRMA	Pharmaceutical Research and Manufacturers of America
SSA	Social Security Act
WAC	Wholesale Acquisition Cost

INTRODUCTION

This is a case of "agency action in search of a statutory home." Op. 25. As part of a much-touted initiative to "lower drug prices and reduce out-of-pocket costs" for American consumers, the Department of Health and Human Services ("HHS") announced its intention to have the Food and Drug Administration ("FDA") issue a rule requiring pharmaceutical manufacturers to include the "list price" of their products in direct-to-consumer television advertising. HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 83 Fed. Reg. 22,692, 22,695 (May 16, 2018). But the plan hit a snag: FDA has long recognized that the statute authorizing it to regulate *some* aspects of pharmaceutical advertising—the Federal Food, Drug, and Cosmetic Act ("FDCA")—does not authorize it to compel pharmaceutical manufacturers to disclose a drug's *price*. So HHS turned instead to the Social Security Act and its provisions enabling HHS to issue rules necessary to the "administration" of the Medicare and Medicaid programs. HHS claimed that its compelled-disclosure rule was necessary to those programs' administration because displaying a drug's "list price" in television advertising might indirectly lead to lower list prices, which might decrease program spending on prescription drugs, and might reduce the programs' overall healthcare expenditures.

That capacious assertion of HHS's authority as administrator of the federal health-insurance programs is unprecedented—and manifestly contrary to the

statutory text and other indicia of congressional intent. This rule goes well beyond interstitial rulemaking implementing facets of Medicare and Medicaid. Instead, it directly regulates private actors' marketing of their products to the American public, in the hope of reducing prices economy-wide. But if Congress wished to give HHS the authority to regulate *anything* that might conceivably affect healthcare prices in the United States, it would not have buried that breathtaking power in generalized provisions giving HHS the authority to operate public programs. This is agency overreach, plain and simple.

Beyond HHS's lack of statutory authority lies an equally serious constitutional problem. Far from offering "transparency" into drug pricing, the government-scripted statement that this rule demands is highly misleading. A drug's "list price" is not, as viewers will likely infer from a consumer-focused advertisement, an actual or even suggested retail price. It is instead defined as the "Wholesale Acquisition Cost" (or "WAC"), a gross price at which a drug is offered to *wholesalers*—before rebates, discounts, or any other adjustments are applied, and without accounting for the insurance coverage that a great majority of Americans have. Even HHS admits (at 9) that "individuals covered by insurance will rarely pay a drug's list price." But upon seeing that price in a television ad, patients will wrongly believe their cost for the medication to be many times higher than they would actually pay. HHS has thus acknowledged that its compelled disclosure may

"confuse[]" and "intimidate[]" patients, "deter[]" them from "using beneficial medications," and even "potentially *increase* total cost of care." Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency, 84 Fed. Reg. 20,732, 20,756 (May 10, 2019) (emphasis added). Given this frank admission that the compelled disclosure may actually *mislead* consumers and *undermine* the government's cost-saving goals, it cannot survive First Amendment scrutiny.

Plaintiffs—a group of leading biopharmaceutical companies and a trade association that counts Plaintiffs and other companies among its members—initiated this suit to set aside the rule on the grounds that it exceeds HHS's statutory authority and violates the First Amendment. The district court agreed that HHS had overstepped its statutory bounds: the court concluded that HHS's asserted "ability to regulate the health care marketplace" in the name of lowering program costs represented a significant "expansion of regulatory authority" that "Congress surely did not envision." Op. 26. This Court should conclude likewise. In the alternative, it should consider the constitutional claim that was fully briefed but not addressed below, and hold that the rule compels misleading speech and lacks anything approaching sufficient justification. On either basis, the judgment should be affirmed.

STATEMENT OF THE ISSUES

1. Whether the district court correctly concluded that HHS lacks statutory authority to compel pharmaceutical manufacturers to disclose price information in their direct-to-consumer television advertisements.

2. In the alternative, whether (a) the judgment should be affirmed because HHS's rule violates the First Amendment or, at minimum, (b) the rule's effective date should be stayed under 5 U.S.C. § 705 because Plaintiffs will likely prevail on their First Amendment claim.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutory and regulatory provisions are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. Direct-To-Consumer Advertisements

Inventing and developing a new prescription drug is an extraordinary undertaking. Pharmaceutical manufacturers spend many years and billions of dollars to develop a product and bring it to market. And that time and expense is continually rising, due to high failure rates, increasingly complex research demands, and expanding regulatory compliance costs. But the effort is undeniably worth it. Thanks to recent pharmaceutical breakthroughs, many diseases that were once regarded as deadly are now treatable and even curable, and patients suffering from previously debilitating conditions can now live immensely more fulfilling lives.

Innovative medicines also reduce overall healthcare costs by reducing the need for costly emergency-room visits, surgeries, and long-term care.

Once a new drug is approved, pharmaceutical manufacturers devote extensive resources to educating healthcare providers about how the medicine can be used most effectively and safely to treat patients. Manufacturers also communicate directly to the public. One facet of this outreach is direct-to-consumer ("DTC") advertising, including television commercials. These advertisements play an important role in empowering patients to manage their health. As HHS acknowledges, research shows that DTC advertising can "increase disease awareness," "facilitate more informed [patient-doctor] discussions," and "provide a source of patient education." 84 Fed. Reg. at 20,734, 20,738.

In the FDCA, Congress authorized HHS to regulate DTC advertisements to ensure that the information provided is accurate and non-misleading. 21 U.S.C. § 321(n); *see also id.* §§ 331(n), 352(a), 352(n), 353c. The Secretary has delegated that authority to FDA, which has promulgated detailed implementing regulations: advertisements must not be false or misleading with respect to side effects, contraindications, or effectiveness; they must present a fair balance between the risks and benefits of the product; and, depending on the medium in which the advertisement appears, they must either disclose all the risks in the product's

labeling or make "adequate provision" for disseminating that information to the audience. 21 C.F.R. § 202.1(e).

FDA has long recognized, however, that it has no statutory authority to require manufacturers to disclose *a product's price* in such advertisements. In 1975, FDA explained that any "decision to engage in public disclosure of prescription drug prices is not for the Food and Drug Administration to make." Reminder Labeling and Reminder Advertisements for Prescription Drugs, 40 Fed. Reg. 58,794, 58,794 (Dec. 18, 1975). To Plaintiffs' knowledge, FDA has never altered that position.

B. The Pharmaceutical Pricing System[1]

The payment and pricing structure for pharmaceutical products is complex and highly variable, in part because these products generally pass through several

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[1] HHS has not yet compiled the administrative record for the rule challenged here. In its absence, to provide this Court with basic background information relevant to Plaintiffs' First Amendment claim, Plaintiffs have cited (in addition to rule comments) government websites and other sources the government considers authoritative containing undisputed facts about how out-of-pocket costs for medications are determined under Medicare and Medicaid and private health plans. *See* 42 C.F.R. § 100.2 (deeming the Kaiser Family Foundation ("KFF") an "authoritative source"). That background is not relevant to Plaintiffs' statutory argument, however. *See* Op. 8. And because the First Amendment squarely places the burden of proof on *the government* to justify its compelled-disclosure requirement, *see infra* pages 42-43, 50, 52, 54-55, consideration of the sources proffered by Plaintiffs is also not essential to the disposition of the constitutional claim.

In the district court, Plaintiffs also submitted expert declarations providing a detailed description of the pharmaceutical pricing system and reinforcing

intermediaries before reaching patients. Pharmaceutical manufacturers mainly sell to wholesalers, who, in turn, sell to healthcare providers (such as hospitals, clinics, and doctors) and to pharmacies.[2] Healthcare providers and pharmacies ultimately dispense the medications to patients and receive payment from patients and their insurance plans.

Federal law defines a drug's "Wholesale Acquisition Cost" as "the manufacturer's list price" to "wholesalers or direct purchasers," "not including" the "prompt pay or other discounts, rebates or reductions in price" provided by manufacturers. 42 U.S.C. § 1395w-3a(c)(6)(B). WAC is thus not the prescribed or suggested retail price of a drug. And it is almost always *higher*—and often a great

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commenters' assertions that the compelled disclosure is likely to mislead consumers. *See* ECF Nos. 1-1, 1-2. Plaintiffs Merck, Lilly, and Amgen additionally provided declarations attesting to the irreparable harms they would suffer should the rule go into effect. *See* ECF Nos. 1-3, 1-4, 1-5. Although Plaintiffs believe this Court could also properly consider these materials in ruling on the merits of the First Amendment claim, Plaintiffs do not believe that is necessary and thus are not asking this Court to do so. But if this Court should address Plaintiffs' alternative request for a stay pending final review of that claim, *see infra* page 55, the Court unquestionably can and should consider the declarations for that purpose. *See League of Women Voters of the U.S. v. Newby*, 838 F.3d 1, 8-9, 14 (D.C. Cir. 2016) (relying on declarations to grant interim injunctive relief).

[2] *See, e.g.*, Goldwater Institute, Comment Letter on Proposed Rule for Medicare and Medicaid Programs: Drug Pricing Transparency 2 (Dec. 17, 2018), https://www.regulations.gov/document?D=CMS-2018-0123-0113 ("Goldwater Comment").

deal higher—than what patients would actually pay, including virtually all Medicare and Medicaid beneficiaries.

A patient's out-of-pocket cost for any given drug depends primarily on the terms of her insurance plan. Many patients are responsible only for a fixed "copayment"; for example, if a plan includes three tiers of covered drugs, the copay by tier might be $15, $25, and $45.[3] Alternatively, a patient may be responsible to pay a percentage of the drug's total cost as "co-insurance" (which, again, may vary for different classes of drugs). And some patients have a "deductible," which is an amount they first have to pay during a year before their insurer takes responsibility. If a patient's deductible requirement applies to prescriptions, her out-of-pocket cost for the same medicine may therefore vary over the course of the year.

For more than 120 million Americans whose plans require solely fixed co-payments or no payments—virtually all of the 65 million Americans on Medicaid, and roughly half of Americans with private insurance—there is *no connection at all* between a product's WAC and out-of-pocket cost.[4] And even those with co-

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[3] KFF, *Employer Health Benefits: 2018 Annual Survey* 153-56 (2018), http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018 ("KFF Benefits Survey").

[4] Eli Lilly & Co., Comment Letter on Proposed Rule for Medicare and Medicaid Programs: Drug Pricing Transparency 3 (Dec. 17, 2018), https://www.regulations.gov/document?D=CMS-2018-0123-0142 ("Lilly Comment") (virtually all Medicaid beneficiaries pay "low fixed copays or no copays

insurance obligations often pay only a small fraction of WAC. For example, under Medicare Part B, which covers physician-administered drugs, the maximum co-insurance amount is 20%—and roughly 80% of Part B patients have supplemental coverage that covers all or most of that cost-sharing.[5]

Even under Medicare Part D, the vast majority of patients pay small, fixed co-payments, rather than co-insurance, for preferred-brand drugs.[6] The maximum co-insurance level for even non-preferred drugs is 50%, and many drugs have a maximum co-insurance of only 25% or 33% of a drug's negotiated price.[7] In addition, 13 million Part D patients qualify for additional financial assistance that generally reduces their cost-sharing to a copay of $3-9.[8]

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at all"); KFF Benefits Survey 153, 158 (92% of individuals with employer-sponsored plans pay something for prescription medications, but half to two-thirds of their plans employ fixed co-payments rather than coinsurance).

[5] Lilly Comment 3-4.

[6] Medical Information Working Group, Comment Letter on Proposed Rule for Medicare and Medicaid Programs: Drug Pricing Transparency 3 (Oct. 18, 2018), https://www.regulations.gov/document?D=CMS-2018-0123-0127 ("[I]n 2018, 77% of enrollees in Medicare prescription drug plans, and 99% of enrollees in Medicare Advantage plans, paid a copayment for preferred brand drugs.").

[7] KFF, *10 Things to Know About Medicare Part D Coverage and Costs in 2019* (June 4, 2019), https://www.kff.org/report-section/10-things-to-know-about-medicare-part-d-coverage-and-costs-in-2019-tables/; 42 C.F.R. § 423.104(d).

[8] Lilly Comment 3.

Even for patients with deductible obligations, a drug's WAC is often not relevant. Deductibles do not generally apply to prescription drug purchases: only about 10% of Americans with employer-sponsored insurance have deductibles for prescriptions,[9] and none of the 65 million Americans on Medicaid do.[10] Forty percent of the 43 million Americans on Medicare Part D last year also had no deductible, and for the remainder the maximum deductible was only $405 (an amount that would be satisfied over the course of a year by a monthly prescription under $35).[11]

Even those Americans who lack health insurance often pay costs far below WAC. Pharmaceutical manufacturers offer financial assistance programs that provide products to low-income consumers at greatly reduced or no cost.[12] And other programs—such as the federal 340B Discount Drug Pricing Program, which

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[9] KFF Benefits Survey 104, 121 (showing that 85% of individuals with employer-sponsored insurance have an annual deductible, but that for 83%-95% of those individuals the deductible does not apply to prescription drugs).

[10] KFF, *Medicaid Benefits: Prescription Drugs (Timeframe: 2018)*, https://www.kff.org/medicaid/state-indicator/prescription-drugs (last visited Nov. 11, 2019).

[11] KFF, *Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing* (May 17, 2018), https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing.

[12] *See, e.g.*, Lilly Comment 4; Sanofi, *Comment Letter on Proposed Rule for Medicare and Medicaid Programs: Drug Pricing Transparency* 2-3 (Dec. 17, 2018), https://www.regulations.gov/document?D=CMS-2018-0123-0110.

applies to outpatient drugs for patients of certain clinics—further reduce costs for uninsured patients.[13]

Thus, for the overwhelming majority of prescription medications, the patient's out-of-pocket cost is well below WAC—and often has *no* relationship to WAC whatsoever. Moreover, that cost is highly individualized: the dollar amount varies widely depending on the patient's insurance plan, the plan's level of coverage for the particular drug, and (for those with applicable deductibles) the patient's other health expenses. For these reasons, displaying a drug's WAC in consumer advertisements tells most consumers little or nothing about what they will actually pay for the drug—let alone whether that cost will be higher or lower than available alternatives.

C. The Challenged WAC Disclosure Rule

In May 2018, HHS released a policy statement titled "HHS Blueprint To Lower Drug Prices and Reduce Out-of-Pocket Costs." 83 Fed. Reg. 22,692. In describing a series of actions that "HHS may undertake . . . in response to President Trump's call to action," HHS stated that it would "[c]all on the FDA to evaluate the inclusion of list prices in direct-to-consumer advertising." *Id.* at 22,694, 22,695.

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[13] Goldwater Comment 4.

In response, commentators pointed to FDA's longstanding position that it has no authority under the FDCA to require price disclosures.[14] So, in its notice of proposed rulemaking, HHS settled on a backup plan: A different subagency within HHS—the Centers for Medicare & Medicaid Services ("CMS")—would instead issue the regulation under the Social Security Act ("SSA").

HHS acknowledged that "Congress has not explicitly provided HHS with authority to compel the disclosure of list prices to the public." Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency, 83 Fed. Reg. 52,789, 52,791 (Oct. 18, 2018). But HHS asserted that two provisions of the SSA nonetheless provided sufficient authority. The first, 42 U.S.C. § 1302(a), allows the Secretary to issue "such rules and regulations, not inconsistent with [the SSA], as may be necessary to the efficient administration of [his] functions . . . under" the Medicare and Medicaid statutes. The second, 42 U.S.C. § 1395hh(a)(i), more narrowly authorizes the Secretary to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under" the Medicare subchapter.

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[14] *See, e.g.*, Pharmaceutical Research & Manufacturers of America ("PhRMA"), Comment Letter on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs 120 (July 16, 2018), https://www.regulations.gov/document?D=CMS-2018-0075-2808.

Invoking those general provisions regarding the "administration" of Medicare and Medicaid, HHS proposed to adopt a requirement applicable to *all* direct-to-consumer television advertisements, with minor exceptions. Under the proposal, every advertisement for a prescription drug or biological product that is eligible for reimbursement under Medicare or Medicaid and has a WAC of over $35 a month would be required to contain the following statement:

> The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.

83 Fed. Reg. at 52,794 (brackets in original). Manufacturers would be required to use a product's WAC as the "list price." *Id.*

Observing that "Congress has explicitly directed HHS to operate Medicare and Medicaid programs efficiently," HHS asserted that regulations promoting "efficient markets[] for drugs funded through those programs fall[] within the scope of that mandate." *Id.* at 52,791. HHS suggested that compelling manufacturers to disclose price information in their advertisements might lower the programs' costs in two ways. First, it contended that the disclosure would "provide some consumers with more information to better position them as active and well-informed participants in their health care decision-making," thereby decreasing overutilization of prescription drugs. *Id.* at 52,792-93. Second, it hypothesized that, by "exposing overly costly drugs to public scrutiny," the compelled disclosure may "provide

manufacturers with an incentive to reduce their list prices" and compete based on price. *Id.*

HHS acknowledged, however, that the proposed rule might not achieve its stated cost-saving goal. HHS conceded it "lack[ed] data" regarding the extent to which the compelled disclosure would provide transparency into the out-of-pocket costs of prescription drugs, and also the extent to which the rule would lead to more effective utilization; it asked commenters to provide insight. *Id.* at 52,798; *see also id.* at 52,793. HHS also conceded the rule might actually *frustrate* its cost-saving objective, admitting:

> 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 52,797-98. HHS acknowledged it also "lack[ed] data to quantify these effects," and asked commenters to provide "estimates" of those "impacts." *Id.* at 52,798.

HHS did not receive the supportive evidence it hoped for. Instead, numerous medical-professional and patient organizations—including the American Heart Association, the American College of Obstetricians and Gynecologists, the Cancer Support Community, and the American Academy of Neurology—expressed serious concern that displaying a drug's WAC in television advertisements would be

"misleading,"[15] "cause distress,"[16] and cause patients to "forgo care out of fear of being responsible for paying" WAC.[17] As the National Alliance on Mental Illness put it, the required statement is likely to "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," thereby "deter[ing] people from seeking needed care."[18] Even private insurers warned that the rule "may lead to consumer confusion" and "increase costs."[19]

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[15] Cancer Support Cmty., Comment Letter on Proposed Rule for Medicare and Medicaid Programs: Drug Pricing Transparency 2 (Nov. 17, 2018), https://www.regulations.gov/document?D=CMS-2018-0123-0038.

[16] *Id.*

[17] Am. Acad. of Neurology, Comment Letter on Proposed Rule for Medicare and Medicaid Programs: Drug Pricing Transparency (Dec. 5, 2018), https://www.regulations.gov/document?D=CMS-2018-0123-0056.

[18] Nat'l All. on Mental Illness, Comment Letter on Proposed Rule for Medicare and Medicaid Programs: Drug Pricing Transparency 1-2 (Dec. 17, 2018), https://www.regulations.gov/document?D=CMS-2018-0123-0112; *see also* Am. Heart Ass'n, Comment Letter on Proposed Rule for Medicare and Medicaid Programs: Drug Pricing Transparency 1 (Dec. 17, 2018), https://www.regulations.gov/document?D=CMS-2018-0123-0132 (disclosure could "result in patients foregoing beneficial treatment due to concern about high costs").

[19] UnitedHealth Group, Comment Letter on Proposed Rule for Medicare and Medicaid Programs: Drug Pricing Transparency 2 (Dec. 17, 2018), https://www.regulations.gov/document?D=CMS-2018-0123-0090. The pharmaceutical industry raised the same concerns. *See, e.g.*, PhRMA, Comment Letter on Proposed Rule for Medicare and Medicaid Programs: Drug Pricing Transparency 3-7 (Dec. 17, 2018), https://www.regulations.gov/document?D=CMS-2018-0123-0126 ("PhRMA Comment").

Despite these warnings, HHS finalized the rule (hereinafter "the WAC Disclosure Rule") with no material changes. 84 Fed. Reg. 20,732. While still maintaining that it "expect[ed]" the Rule "to put downward pressure on the list prices of drugs," HHS conceded that it could not "quantify the level of this impact." *Id.* at 20,754. And HHS again acknowledged that the Rule might frustrate its stated cost-saving objective by discouraging patients from using beneficial medications and thereby "increas[ing] total cost of care," noting that it still "lack[ed] data" to know whether that was so. *Id.* at 20,756. HHS nonetheless dismissed commenters' First Amendment concerns, maintaining that an advertised drug's WAC is an "objective fact" that the government may compel manufacturers to disclose to consumers. *Id.* at 20,744.

HHS set the Rule to take effect on July 9, 2019. *Id.* at 20,732.

D. Proceedings Below

Plaintiffs brought this challenge alleging that the WAC Disclosure Rule exceeds HHS's statutory authority; that the Rule is arbitrary and capricious; and that it violates the First Amendment. *See* 5 U.S.C. § 706(2)(A), (B), (C). Plaintiffs asked the district court to stay the Rule's effective date "to preserve status or rights pending conclusion of the review proceedings," *id.* § 705, based on their statutory and constitutional claims.

The district court converted Plaintiffs' stay request into a motion for judgment on the merits and vacated the Rule. Op. 8, 26-27. Rejecting HHS's argument that a more expansive standard should apply when determining the scope of HHS's statutory authority, the court held that the usual framework of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), governed and that the Rule failed at *Chevron* Step One. Op. 8-12.

The court first concluded that the text of 42 U.S.C. §§ 1302(a) and 1395hh(a)(1) "simply does not support the notion" that "Congress intended for the Secretary to possess the far-reaching power to regulate the marketing of prescription drugs." Op. 12-14. The provisions' use of the word "administration," the court explained, "conveys the types of actions that are directed toward controlling the operation of something over which a person has executive authority"; the WAC Disclosure Rule, in contrast, "'regulates primary conduct several steps removed from the heartland of HHS's authority,'" extending HHS's reach to "regulat[ion] [of] the health care market itself." Op. 13, 15, 19 (citation omitted).

The district court also found several contextual factors significant in determining that Congress had not implicitly delegated such authority to HHS. The court noted that Congress had "deliberately and precisely legislated in the area of drug marketing under the FDCA," demonstrating that "Congress knows how to speak on that subject when it wants to." Op. 23. It was also "not lost" on the court

that HHS had never previously used the SSA to "directly regulate the market for pharmaceuticals"; the agency's newfound understanding of its general rulemaking authorities thus "represent[ed] a significant shift in HHS's ability to regulate the health care marketplace." Op. 24-26. The court recognized, moreover, that HHS's interpretation would "swing the doors wide open to any regulation, rule, or policy that might reasonably result in cost savings to the Medicare and Medicaid programs, unless expressly prohibited." Op. 26. But "Congress surely did not envision such an expansion of regulatory authority when it granted HHS the power to issue regulations necessary to carry out the 'efficient administration' of the Medicare and Medicaid programs." Op. 26.

Having determined that HHS exceeded its statutory authority, the district court had no need to reach Plaintiffs' constitutional claim. Op. 2.

The government appealed.

SUMMARY OF ARGUMENT

1. The district court correctly concluded, under *Chevron* Step One, that HHS lacks the statutory authority to issue the WAC Disclosure Rule. HHS is asserting that its general authority to enact rules administering the *federal health-insurance programs* has, unnoticed for decades, empowered the agency to enact any rule that *might reduce healthcare costs economy-wide*—even rules regulating the primary conduct of private actors in the healthcare marketplace. HHS's

breathtakingly expansive understanding of the power conferred by 42 U.S.C. §§ 1302(a) and 1395hh(a)(1) cannot be squared with the plain meaning of the provisions' text, which encompasses only those measures appropriate to managing the programs themselves. Other indicia of congressional intent likewise rebuke HHS's interpretation. When Congress has intended to give HHS the authority to regulate the content of private parties' advertising, including pharmaceutical advertising, it has spoken clearly and imposed well-defined limits—and Congress did neither here. HHS's newfound understanding of its general rulemaking provisions also runs afoul of the presumption, grounded in common sense and constitutional principle, that Congress does not through subtle implication grant an agency powers to issue regulations of major political and economic import.

Nor can HHS sidestep the proper *Chevron* inquiry by arguing that an entirely different and more deferential test governs because the agency is acting pursuant to generalized rulemaking authorities. The pre-*Chevron* analysis in *Mourning Family Publications Service, Inc.*, 411 U.S. 356, 369 (1973), at most represents an early articulation of the appropriate inquiry respecting the statute in that case under *Chevron* Step Two, not a standalone rule of decision that displaces the ordinary tools of statutory construction across an entire class of statutes.

2. Alternatively, this Court should affirm on the other claim fully briefed below: that the WAC Disclosure Rule violates the First Amendment.

Under *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), if the government wishes to force private parties to express its preferred message in their commercial advertising, it must *affirmatively prove* that the requirement directly and materially advances a substantial government interest and is narrowly tailored to achieve that interest. HHS offered no such proof here. The Rule is supposedly designed to lower Medicare and Medicaid spending by providing transparency into consumers' drug costs and putting public pressure on manufacturers to lower their prices. But HHS adduced no evidence in the course of its rulemaking that the Rule will in fact lower program costs. HHS expressly conceded that it lacked such evidence, and repeatedly acknowledged that highlighting the WAC of medications in consumer advertisements may instead mislead patients about their likely out-of-pocket costs, discourage them from seeking necessary treatment, and thereby *increase* overall healthcare spending. HHS also never explained why it rejected readily available alternative measures—such as providing consumers (accurate) pricing information itself—that would obviate the need to compel involuntary speech.

Contrary to HHS's view, moreover, the Rule cannot not be upheld under the more deferential standard of *Zauderer v. Office of Disciplinary Counsel of the Supreme Court*, 471 U.S. 626 (1985). To begin with, the Rule is not eligible for review under *Zauderer*—most notably because the speech compelled by the Rule is

not "purely factual and uncontroversial," *id.* at 651, given its conceded potential to confuse and mislead consumers. And the Rule would fail under *Zauderer* in any event due to the utter lack of evidence that it will advance its stated purpose, and because the government cannot compel speech that tends to mislead consumers under any level of First Amendment scrutiny.

3. At a minimum, the Court should continue to stay the Rule's effective date under 5 U.S.C. § 705. Plaintiffs are highly likely to prevail on their constitutional claim, and a stay would be necessary to prevent irreparable harm to their First Amendment rights until this issue can be fully decided.

ARGUMENT

I. HHS LACKS STATUTORY AUTHORITY TO PROMULGATE THE WAC DISCLOSURE RULE

A. The Rule Fails At *Chevron* Step One

"[A]n agency literally has no power to act . . . unless and until Congress confers power upon it." *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986). As HHS has acknowledged, nothing in the SSA—or any other statute—expressly grants HHS the authority to require drug manufacturers to disclose prices in their advertisements. 83 Fed. Reg. at 52,791; 84 Fed. Reg. at 20,736; *see also* 40 Fed. Reg. at 58,794. The agency instead argues that Congress implicitly conferred this authority through two provisions giving HHS the ability to enact rules implementing the Medicare and Medicaid programs.

HHS's claim of authority must be reviewed under the familiar framework of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). At *Chevron* Step One, courts "apply[] the ordinary tools of statutory construction" to determine if Congress's intent on "the precise question at issue" is clear. *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013) (citation omitted). Those tools include examining the statute's text, "the broader statutory framework," and "the nature and scope of the authority being claimed" by the agency. *Loving v. IRS*, 742 F.3d 1013, 1016, 1020, 1021 (D.C. Cir. 2014). Here, application of those tools confirms that Congress did not implicitly delegate to HHS the authority to require price disclosures in DTC advertisements.

1. *The text.* "Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose." *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 252 (2004) (citation omitted). Here, the SSA permits HHS to enact regulations "necessary to the efficient administration of the functions" with which the Secretary "is charged" under the Medicare and Medicaid statutes (Section 1302(a)), and regulations "necessary to carry out the administration" of the Medicare program (Section 1395hh(a)(1)).

The ordinary meaning of those phrases does not permit the agency's expansive interpretation. As the district court explained, the word "administration"

"means '[t]he process or activity of running a business, organization, etc.,' or '[t]he management or performance of the executive duties of a government, institution, or business; collectively, all the actions that are involved in managing the work of an organization.'" Op. 13 (alteration in original) (footnote omitted) (quoting *Oxford Dictionary of English*, https://www.lexico.com/en/definition/administration, and *Black's Law Dictionary* (11th ed. 2019)). Here, the specified *object* of HHS's administration—the underlying "work" at which the agency's "actions" are directed—is its implementation of "the [Medicare] insurance programs" (Section 1395hh(a)(1)), and its "charged" "functions" under the Medicare and Medicaid statutes (Section 1302(a)). "Thus, the basic power that Congress gave to the Secretary was to establish rules and regulations for 'running' or 'managing' the federal public health insurance programs through CMS." Op. 13.

To be sure, those provisions give HHS flexibility—in its capacity as insurer—to decide what rules are appropriate for operating those programs. For instance, so long as it operates within the constraints imposed by other relevant statutory provisions, HHS can require certain agreements related to Medicare and Medicaid to be in writing, *see Cottage Health Sys. v. Sebelius*, 631 F. Supp. 2d 80, 91-93 (D.D.C. 2009); define the coverage of particular products and services, *see Goodman v. Sullivan*, 891 F.2d 449, 450 (2d Cir. 1989) (per curiam); and set methodology for determining reimbursement amounts, *see Whitecliff, Inc. v.*

Shalala, 20 F.3d 488, 491 (D.C. Cir. 1994). Such are the typical functions of administrating an insurance program, and HHS may issue reasonable regulations to that end.

But "HHS seeks to do more than that here." Op. 13. HHS is reaching out to the commercial marketplace to directly regulate consumer advertisements in an effort to achieve economy-wide effects on drug prices. The agency's theory is that regulating television advertisements is permissible because it might indirectly save its programs money down the line. But it is preposterous to maintain that an agency "runs" an insurance program by regulating how third parties interact with one another in the hope that the regulation might have the indirect effect of saving program funds. Nor would anyone plausibly say that HHS's responsibility to "disburs[e] hundreds of billions of dollars for prescription drugs," HHS Br. 28, carries with it the power to enact any measure that might indirectly reduce those drugs' cost—such as rules regulating the cost of ingredients and shipping, or employee compensation. That is simply not the "management" of the government's "work."

To bridge that gap, HHS emphasizes Section 1302(a)'s use of the word "efficient," noting that the word can describe actions that produce a minimum of expense. *Id.* at 25. But "efficient" modifies "*administration of the functions with which [the agency] is charged*." 42 U.S.C. § 1302(a) (emphasis added). In other

words, Section 1302(a) merely instructs HHS to take reasonable steps to perform its *charged functions* efficiently. It twists the text to suggest that this phrasing bestows upon HHS the a roving authority to regulate any aspect of the healthcare sector in order to hold down its own costs.

Perhaps recognizing that the most natural reading of Sections 1302(a) and 1395hh(a)(1) lends the agency little support, HHS invokes a handful of *other* Medicare and Medicaid provisions to bolster its case. HHS argues that these specific provisions reflect, variously, "the importance of administering [Medicare and Medicaid] in a manner that minimizes unnecessary expenditures"; a congressional "commitment to informing beneficiaries about their benefits"; and a "focus on cost reduction [with respect to] prescription drugs." HHS Br. 25-27.

But of course, HHS is not claiming (and has never claimed) that the WAC Disclosure Rule implements *any* of those other provisions. For good reason: none is on point. None of the anti-waste provisions that HHS cites on page 26 of its brief (42 U.S.C. §§ 1396a(a)(30)(A), 1395u(b)(8), 1395w-104(c)(3), 1395ddd) regulates drug manufacturers. The statutory provisions HHS cites on page 27 (42 U.S.C. §§ 1395b-3, 1395b-7, 1395w-104(a), 1395w-21(h)-(j)[20]) concern public outreach and disclosures *about Medicare programs and benefits*; again, they do not impose

[20] HHS also cites 42 U.S.C. § 1396d(u)(2), but it is unclear why.

any obligations on pharmaceutical manufacturers. And the provisions HHS cites that do concern manufacturers (at 6-7, 26-27, 30) are even less helpful to the agency—because those provisions do not give it any kind of freestanding power to regulate manufacturers outright. *See* 42 U.S.C. §§ 256b(a)(1), 1395w-3a(f), 1395w-114a(a), 1395w-153, 1396r-8(a), (b)(3). In each instance, Congress granted HHS the authority to "enter into an agreement," *e.g.*, *id.* § 256b(a)(1), with drug manufacturers requiring the latter to undertake specific obligations as a condition of obtaining program coverage. But HHS did not impose the WAC Disclosure Rule as a condition of Medicare or Medicaid coverage for a drug, and the agency has never claimed that it has the power to do that.[21] Nor is HHS regulating manufacturers' interactions *with the agency* in any way. Instead, HHS is regulating *how manufacturers market their products to the general public*, in order to "improve market efficiency" writ large. 84 Fed. Reg. at 20,735.

For this reason, HHS's insistence that the district court misunderstood the extent to which drug manufacturers act as "direct participants" in the Medicare and Medicaid programs is a red herring. Plaintiffs do not deny that they participate in those programs in limited respects—they execute rebate and discount agreements,

[21] Instead, if a manufacturer fails to comply with the WAC Disclosure Rule, its product will appear on a "public list" of drugs "advertised in violation of [the Rule]." 42 C.F.R. § 403.1204(a).

provide congressionally-mandated information to HHS, and so on. But the WAC Disclosure Rule does not regulate Plaintiffs in *any* of those capacities. Instead, it regulates them as actors in a commercial marketplace in which, for some transactions, HHS happens to be an indirect payer. HHS's unbounded conception of its regulatory jurisdiction—that once private actors come into contact with a government program in any limited respect, then the agency may exercise control over *any* aspect of their operations—is worlds away from the "administration" of a government program.

2. *The structure.* It is also a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citation omitted). In addition, "the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand." *Id.* Here, other parts of the SSA and the FDCA only strengthen the conviction that Congress did not implicitly delegate to HHS the authority to regulate pharmaceutical marketing through the SSA's general rulemaking provisions.

First, if Sections 1302(a) and 1395hh(a)(1) truly gave HHS the power to enact any regulation that "has the potential to reduce [the] [financial] burden" on Medicare and Medicaid, HHS Br. 22, those provisions would render many of the agency's

other SSA prerogatives wholly unnecessary. Take, for instance, 42 U.S.C. § 1396r-8(b)(3)(A), which gives HHS the ability to require pharmaceutical manufacturers to disclose the WAC of certain drugs to *the agency*, to enable HHS to set reimbursement amounts for Medicare Part B. If HHS has long had the authority to require manufacturers to disclose the WAC of any or all of their products to the general public, Congress would not have needed to amend the SSA in 1990 to give HHS that much more limited authority. *See* Pub. L. No. 101-508, § 4401(a)(3), 104 Stat. 1388, 1388-145 (1990). HHS—"by virtue of its heretofore undiscovered carte blanche grant of authority" in Sections 1302(a) and 1395hh(a)(i)—"would already have had free rein" to take that action. *Loving*, 742 F.3d at 1020.

Second, when Congress has granted HHS the authority to regulate private speech—including pharmaceutical advertising—the legislature has made that grant explicit and prescribed its bounds.

Start with the SSA. In 1997, Congress amended the statute to give HHS the express authority to regulate the distribution of marketing materials prepared by Medicare Advantage organizations to sell their Medicare plans to beneficiaries. Pub. L. No. 105-33, § 4001, 111 Stat. 251, 285 (1997) (current version at 42 U.S.C. § 1395w-21(h)). And Congress limited that authority with equally explicit standards: rather than giving HHS discretion to decide what such marketing

materials should contain, HHS may disapprove a material only if it is "materially inaccurate or misleading" or makes "a material misrepresentation." *Id.*

Then consider the FDCA. When the 1962 Congress granted HHS the authority to regulate prescription drug marketing, including DTC advertising, that delegation was express. *See* Pub. L. No. 87-781, § 131, 76 Stat. 780, 791-92 (1962) (current version at 21 U.S.C. § 352(n)). And the delegation was again subject to explicit limits: the statute detailed *exactly* what kind of safety and efficacy information HHS could require manufacturers to include. *Id.*; *see supra* pages 5-6.

Congress spoke just as clearly (and carefully) in 2007 when it authorized the FDA to prereview television advertisements for prescription drugs. *See* Pub. L. No. 110-85, § 901(d)(2), 121 Stat. 823, 939 (2007) (current version at 21 U.S.C. § 353c). Congress authorized the agency only to make *recommendations* about changes "necessary to protect the consumer good and well-being." 21 U.S.C. § 353c(b)(1)(A). And Congress prohibited the Secretary from "requir[ing] changes" unless the ad failed to disclose a serious health risk. *Id.* § 353c(c).

HHS insists that the FDCA's circumscribed provisions have no bearing here, because the FDCA and the SSA serve different purposes. HHS Br. 37-38. But as the district court explained, HHS's focus on statutory purpose "misses the larger point." Op. 23. The FDCA provisions authorizing limited regulation of certain aspects of drug marketing "demonstrate[] that Congress knows how to speak on that

subject when it wants to," and caution strongly against inferring additional regulatory authority in this area from congressional silence. *Id.*; *see also Federal Maritime Comm'n v. Seatrain Lines, Inc.*, 411 U.S. 726, 742, 744 (1973) (rejecting agency's interpretation because "an examination of contemporaneous and related statutes makes clear that when Congress intended to [address the subject matter], it did so in unambiguous language").

Such caution against inferring authority from silence is particularly warranted here, where the agency is claiming implicit authority to regulate private speech. Giving an agency the power to control advertising content is an inherently fraught endeavor, and courts should expect Congress to speak clearly if it wanted HHS to wade into those depths. *Cf. Motion Picture Ass'n of Am., Inc. v. FCC*, 309 F.3d 796, 805 (D.C. Cir. 2002) ("*MPAA*") (declining to interpret Communications Act provision to implicitly empower the FCC to regulate programming content "because such regulations invariably raise First Amendment issues").

3. *The nature and scope of the claimed authority.* The astonishing breadth of the authority HHS claims to have discovered in Sections 1302(a) and 1395hh(a)(1) also strongly indicates that its reading cannot be correct. *See Loving*, 742 F.3d at 289. "When an agency claims to discover in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy,' [courts] typically greet its announcement with a measure of skepticism." *Utility Air*

Regulatory Grp. v. EPA, 573 U.S. 302, 324 (2014) (citation omitted). That skepticism is amply warranted here. HHS contends that its prerogative to carry out the federal health-insurance programs allows it to regulate the primary conduct of actors in the *healthcare market generally*—a $3.5 trillion sector of the U.S. economy. HHS's unbridled conception of its authority to lower healthcare costs would seemingly empower it to prohibit DTC advertising altogether, or even to set drug list prices outright. And those are just what it could do with prescription drugs—in HHS's view, it presumably could also regulate executive compensation for hospital systems, set a mandatory limit on medical school tuition, or even place nationwide limits on medical malpractice liability.

Courts "must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency." *Brown & Williamson*, 529 U.S. at 133. It is unthinkable that Congress would have delegated authority of the magnitude HHS claims without clearly saying so. *See King v. Burwell*, 135 S. Ct. 2480, 2489 ("[H]ad Congress wished to assign [a] question [of deep 'economic and political significance'] to an agency, it surely would have done so expressly."). Congress does not "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." *Whitman v. American Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001).

HHS counters that *this particular rule* is no big deal. *See* HHS Br. 40, 41. Plaintiffs strenuously disagree: the WAC Disclosure Rule directly interferes with their speech to consumers in a manner that violates Plaintiffs' constitutional rights and will harm patients. *See infra* Part II. But regardless, in the "elephants in mouseholes" analogy, the elephant is not the rule—it is the rulemaking authority the agency claims to have discovered. "It is the agency's incursion into a brand-new regulatory environment, *and the rationale for it*, that make the Rule so consequential." Op. 26 (emphasis added). Given that healthcare costs amount to roughly 18% of the economy, elephants do not get much larger.

Judicial skepticism, moreover, is at its peak when the supposed elephant has gone unnoticed for decades. *See Utility Air*, 573 U.S. at 324; *Loving*, 742 F.3d at 1021. If Sections 1302(a) and 1395hh(a)(1) gave HHS the authority to enact any measure that might indirectly reduce Medicare and Medicaid costs, then one would expect HHS to have used that formidable power before now. But throughout its rulemaking and this litigation, HHS has been unable to point to any such precedent. That too is a significant problem for the agency: "just as established practice may shed light on the extent of power conveyed by general statutory language, so the want of assertion of power by those who presumably would be alert to exercise it, is

equally significant in determining whether such power was actually conferred." *Bankamerica Corp. v. United States*, 462 U.S. 122, 131 (1983) (citation omitted).

Moreover, HHS still cannot articulate a meaningful limiting principle on its newfound authority. It suggests that Sections 1302(a) and 1395hh(a)(1) "*may* not support regulatory initiatives of vast 'economic and political significance.'" HHS Br. 42 (emphasis added) (quoting *Brown & Williamson*, 529 U.S. at 160). That hedged phrasing is hardly comforting, as HHS offers no clues about what qualifies as too much "economic and political significance" by its measure (and HHS apparently believes that directly regulating how the pharmaceutical industry communicates with patients nationwide does not qualify, *but see supra* page 32.) The only other limit HHS offers—aside from the truism that its regulations may not contravene another statute—is the APA's prohibition against "arbitrary and capricious" rulemaking. HHS Br. 42. But that is a procedural standard about reasoned decisionmaking, not a substantive limit on the scope of HHS's authority.

HHS also tells this Court not to worry about one potential application of its expansive power—setting prices outright—because Congress has elsewhere prohibited HHS from directly "control[ling]" the price of prescription drugs. HHS Br. 43. But if HHS's general rulemaking authority were as broad as it now contends, the statutory provisions it cites would not foreclose this possibility. The first, 42 U.S.C. § 1395, applies only to Medicare, and prohibits the federal government from

"exercis[ing] any supervision or control over *the practice of medicine*" (emphasis added)—language that does not address drug pricing. The second, 42 U.S.C. § 1395w-111(i)(1), does prohibit HHS from interfering with pricing decisions—but it only applies to drugs covered by Medicare Part D. More fundamentally, HHS's argument suggests that it believes it *could* take the "extraordinary step[]" of directly setting drug prices had Congress not specifically anticipated and prohibited it. HHS Br. 43. That should be alarming.

4. *Constitutional avoidance.* Finally, even if it were a close call, the canon of constitutional avoidance would weigh heavily against HHS's interpretation. *See Chamber of Commerce of the U.S. v. FEC*, 69 F.3d 600, 605 (D.C. Cir. 1995) ("We are obliged to construe the statute to avoid constitutional difficulties if such a construction is not plainly contrary to the intent of Congress.").

Interpreting Sections 1302(a) and 1395hh(a)(1) to give HHS the power to regulate everything that might conceivably affect nationwide healthcare costs would present serious constitutional difficulties under the nondelegation doctrine. *See Gundy v. United States*, 139 S. Ct. 2116, 2121 (2019) (plurality opinion) (nondelegation doctrine "bars Congress from transferring its legislative power to another branch of Government"). If Congress truly intended to convey to the executive branch the power to regulate the entire healthcare sector, it would have needed to establish guidelines for the power's exercise, so that courts could

"ascertain whether the will of Congress has been obeyed." *United States v. E.I. DuPont de Nemours & Co.*, 432 F.3d 161, 167 (3d Cir. 2005) (en banc) (citation omitted). Absent such guidelines, it is safest to assume that Congress did not believe it was delegating the sort of expansive authority that would make them constitutionally necessary.[22]

B. HHS's General Rulemaking Provisions Do Not Give The Agency Carte Blanche To Take Any Action That Is "Reasonably Related" To Statutory Purposes

Although HHS pays lip service to the *Chevron* framework, the agency's core argument is that a different standard "control[s]" this Court's inquiry. HHS Br. 19-20. HHS continues to rely on the pre-*Chevron* decision in *Mourning v. Family Publications Service, Inc.*, 411 U.S. 356 (1973), to argue that any regulation HHS enacts pursuant to Sections 1302(a) and 1395hh(a)(1) must be "'sustained so long as it is "reasonably related to the purposes of the enabling legislation."'" HHS Br. 20 (quoting *Mourning*, 411 U.S. at 369 (quoting *Thorpe v. Housing Auth. of City of Durham*, 393 U.S. 268, 280-81 (1969))).

[22] For many of these same reasons, even if the Court were to conclude that Sections 1302(a) and 1395hh(a)(1) did not unambiguously foreclose HHS's interpretation, that interpretation should fail at *Chevron* Step Two. *See Utility Air*, 573 U.S. at 321-24 (finding agency action unreasonable at Step Two because it "would bring about an enormous and transformative expansion in [the agency's] regulatory authority without clear congressional authorization").

The district court properly rejected this attempt to sidestep the dispositive inquiry into congressional intent discussed above. Op. 9-10. The notion that there is a universally applicable "reasonable relationship" standard for evaluating *any* rule that *any* agency may enact pursuant to *any* broad rulemaking authority cannot be correct; as with any other question of statutory interpretation, the text of the provision and its statutory context matter. *See Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 92 (2002) ("Our previous decisions, *Mourning* included, do not authorize agencies to contravene Congress' will . . . ."); Harry T. Edwards & Linda A. Elliott, *Federal Standards of Review* 223 (3d ed. 2018) (explaining that "*Mourning* has only limited precedential value in the *Chevron* regime"). Thus, *Mourning* is best understood as an early articulation of the inquiry that today would have been applied in that case under *Chevron* Step Two, not a universal standalone rule of decision at Step One. *See Chamber of Commerce of the U.S. v. NLRB*, 721 F.3d 152, 158 (4th Cir. 2013); *International Swaps & Derivatives Ass'n v. U.S. Commodity Futures Trading Comm'n*, 887 F. Supp. 2d 259, 271 (D.D.C. 2012); *cf. AFL-CIO v. Chao*, 409 F.3d 377, 384 (D.C. Cir. 2005) (considering *Mourning* at Step Two).

Consistent with that understanding, this Court has long made clear that a general rulemaking provision does not "provide the [agency] with *carte blanche* authority to promulgate any rules, on any matter relating to [the statute], in any

manner that the [agency] wishes." *Citizens to Save Spencer Cty. v. U.S. EPA*, 600 F.2d 844, 873 (D.C. Cir. 1979); *see also Colorado River Indian Tribes v. Nat'l Indian Gaming Comm'n*, 466 F.3d 134, 139 (D.C. Cir. 2006) ("An agency's general rulemaking authority does not mean that the specific rule the agency promulgates is a valid exercise of that authority.").

Colorado River is an illustrative case. The statute (the Indian Gaming Regulatory Act) gave the agency (the National Indian Gaming Commission) express authority to set rules governing aspects of "Class II" gaming, but said nothing about the Commission's ability to set rules for "Class III" gaming (which was to be carried out under a tribal-state compact). 466 F.3d at 137-38. The Commission nonetheless argued, invoking *Mourning*, that it could regulate Class III gaming pursuant to its authority to "'promulgate such regulations and guidelines as it deems proper to implement the [Act's] provisions,'" because its regulations furthered the statutory purpose of "integrity in Indian gaming." *Id.* at 139 (citation omitted). This Court disagreed. It explained that agencies are "bound, not only by the ultimate purposes Congress has selected, but by *the means it has deemed appropriate*, and *prescribed*, for the pursuit of those purposes"—and in the Act, Congress had not prescribed any

such means for regulating Class III gaming. *Id.* at 139-40 (emphasis added).[23] The same holds true here: nothing in the SSA remotely suggests that Congress intended for HHS to require price disclosures in DTC advertising.

HHS's theory also runs headlong into this Court's oft-repeated "refus[al]" to "presume a delegation of power merely because Congress has not expressly withheld such power." *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1060 (D.C. Cir. 1995); *see also, e.g.*, *American Petroleum Inst. v. EPA*, 52 F.3d 1113, 1120 (D.C. Cir. 1995) (rejecting the suggestion that "*Chevron* step two is implicated any time a statute does not expressly *negate* the existence of a claimed administrative power" (citation omitted)). Indeed, this Court has rebuked agencies for taking this "entirely untenable position." *MPAA*, 309 F.3d at 805; *see also Aid Ass'n for Lutherans v. USPS*, 321 F.3d 1166, 1174-75 (D.C. Cir. 2003). HHS claims that none of those cases "involve[] statutes like sections 1302 and 1395hh," HHS Br. 36, but that is just wrong: in *MPAA*, the court discussed the Federal Communications Commission's general rulemaking authorities (phrased similarly to HHS's here), and *rejected* the

[23] HHS tries to argue that *Colorado River* turned on the fact that Congress had "explicitly" left Class III gaming to tribes and states. HHS Br. 34. But the court rejected the Commission's *Mourning* argument due to the absence of any "statutory basis empowering the Commission" to regulate, not based on the Act's reference to other regulators. 466 F.3d at 140. And to the extent *Colorado River* relied on clear contextual clues, equally probative indicators are present here, *see supra* pages 25-35.

agency's attempt to ground its rules in those provisions. *See* 309 F.3d at 802-03, 806-07.

Finally, a closer examination of the cases on which HHS relies—*Mourning*, *Thorpe*, and *Doe, 1 v. FCC*, 920 F.3d 866 (D.C. Cir. 2019)—demonstrates that they cannot carry the agency as far as it needs to go.

Thorpe involved a rule issued by the Department of Housing and Urban Development ("HUD") pursuant to its authority to carry out the U.S. Housing Act of 1936. 393 U.S. at 274-75. The rule required local housing authorities receiving federal funding to give tenants notice and an opportunity to be heard prior to eviction, *id.* at 272; the Court held that this funding condition was "reasonably related to" the statutory goal of "provid[ing] 'a decent home and a suitable living environment for every American family' that lacks the financial means of providing such a home without government aid." *Id.* at 280-81 (footnote omitted). But unlike here, Congress had specifically required HUD to exercise its rulemaking authority in pursuit of that express statutory policy. *See id.* at 281 n.37. There was thus no serious question about whether Congress had delegated to HUD the authority to impose conditions on evictions from federally funded housing to further that statutory purpose.

Mourning, which involved the Federal Reserve Board's enforcement of the Truth in Lending Act, is ever further afield. A provision of the Act established

disclosure requirements for transactions involving a "finance charge." The Board issued a rule requiring disclosures in additional circumstances—in order to prevent creditors from evading the requirement by re-characterizing their transactions—and the Supreme Court upheld it. *Mourning*, 411 U.S. at 361, 365-66. Crucially, however, the relevant statutory provision not only authorized the Board to prescribe regulations "necessary or proper to effectuate the purposes of (the Act)," but also to "*prevent circumvention or evasion thereof*." *Id.* at 361-62 (quoting 15 U.S.C. § 1604) (emphasis added). So, again, the agency's rule was much more closely tethered to an explicit statutory authority, which charged the agency with achieving a specified objective.

Doe, in turn, involved the Federal Election Commission's decision to release internal agency documents about an investigation it had undertaken. 920 F.3d at 868. The Federal Election Campaign Act directs the Commission to release certain final documents related to its investigations, *see id.* at 869-70, and this Court held that the Commission had acted reasonably in adopting a policy of releasing additional documents, because doing so would "deter[] future violations and promot[e] Commission accountability." *Id.* at 870-71 (citation omitted). The Commission's action thus lay in the core of the agency's authority—its internal operations—and was also tied to other statutory requirements.

Here, the HHS Rule does not impose a funding condition to further an express program purpose, implement a more specific statutory authorization, or relate to the agency's internal procedures. It instead "regulates primary conduct several steps removed from the heartland of HHS's authority under the Social Security Act." Op. 19 (citation omitted). HHS has pointed to no case that is remotely analogous.

Finally, acceptance of the government's position would have ramifications well beyond this agency, this statute, and this rule. Numerous federal agencies have general rulemaking provisions enabling them to implement whole swaths of the U.S. Code.[24] Endorsing HHS's argument here would invite those agencies to enact *any* regulation they choose so long as it has some connection to an underlying statutory purpose and Congress had not already explicitly foreclosed it. This Court should not throw open that door.

II. THE WAC DISCLOSURE RULE VIOLATES THE FIRST AMENDMENT

The result below can also be affirmed on the readily available alternative ground that the Rule violates the First Amendment. This Court may "affirm a judgment on any basis adequately preserved in the record." *United States ex rel.*

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[24] *See, e.g.*, 47 U.S.C. § 303(r) (authorizing the Federal Communications Commission to issue rules "as may be necessary to carry out" the Communications Act of 1934); 42 U.S.C. § 405(a) (authorizing the Social Security Commissioner to issue rules "which are necessary or appropriate to carry out" the Social Security program); 39 U.S.C. § 401(2) (granting the Postal Service the "general power[]" to adopt rules "as may be necessary in the execution of its functions under this title").

Heath v. AT&T, Inc., 791 F.3d 112, 123 (D.C. Cir. 2015). That condition is fully satisfied here. The constitutional issue was fully briefed below, and as the government necessarily conceded in consenting to the district court's conversion of Plaintiffs' motion for a stay into a judgment on the merits, *see* ECF No. 24, the issue is ripe for a final determination.

At a minimum, should this Court find that HHS has the requisite statutory authority, Plaintiffs respectfully request that the Court enter a stay delaying the Rule's effective date, given the high likelihood that Plaintiffs will prevail on this constitutional claim.

A. The WAC Disclosure Rule Cannot Satisfy Any Level Of First Amendment Scrutiny

1. The Rule Fails Under *Central Hudson*

The First Amendment protects both "the right to speak freely and the right to refrain from speaking at all." *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). Even in the context of commercial advertising, the government generally must satisfy intermediate scrutiny if it wishes to force private parties to express its preferred message. *See Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 566 (1980). The government must "affirmatively prove that (1) its asserted interest is substantial, (2) the restriction directly and materially advances that interest, and (3) the restriction is narrowly tailored." *RJ Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1212 (D.C. Cir. 2012), *overruled on other grounds by*

American Meat Inst. v. U.S. Dep't of Agric., 760 F.3d 18 (D.C. Cir. 2014) (en banc) ("*AMI*"). Here, even assuming the first requirement is met, HHS has not proven the second and third.

The government has not proven that the Rule will directly and materially advance its interest. To show that a regulation will directly advance a substantial interest, the government "may not rest on . . . speculation or conjecture," but must "demonstrat[e] that the measure it adopted would 'in fact alleviate' the harms it recited 'to a material degree.'" *National Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 527 (D.C. Cir 2015) ("*NAM II*") (quoting *Edenfield v. Fane*, 507 U.S. 761, 771 (1993)). HHS manifestly has not done that here.

As discussed above, the stated purpose of the WAC Disclosure Rule is to lower Medicare and Medicaid spending. 84 Fed. Reg. at 20,732, 20,744. HHS "believe[d]" the mandated disclosure might accomplish that objective in two ways: (1) it might "provid[e] transparency into drug prices" by giving beneficiaries "an anchor price" to use "when making decisions about therapeutic options," thereby decreasing the risk of overutilization of advertised drugs; or (2) it might "allow[] the general public to signal in some cases that [drug] prices have risen beyond their willingness to pay," and thereby cause manufacturers to lower their prices. *Id.* at 20,733-34, 20,735, 20,754, 20,756; *see also* D.D.C. Opp. Br. 30-31 (ECF No. 20) (government asserting that the Rule was meant to address the harm of "prescription

drug spending" by "increas[ing] transparency" and "exposing overly costly drugs to public scrutiny"). But HHS presented no evidence that the Rule will have any of those effects. And there is good reason to believe that the Rule will instead *mislead* patients about their out-of-pocket costs for medications and lead to an *increase* in overall program spending.

First, far from providing "transparency" into drug prices, the requirement that manufacturers include a drug's WAC as its "list price" in DTC advertisements will mislead patients into thinking that their costs will be far higher than they actually are.[25] As the Federal Trade Commission has found, "[m]any members of the purchasing public believe that a manufacturer's list price . . . is the price at which an article is generally sold." 16 C.F.R. § 233.3(a). The Commission has accordingly concluded 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." *Id.* § 233.3(d). This Court's precedent likewise recognizes that consumer

[25] To be clear, Plaintiffs support the goal of providing patients with meaningful, non-misleading information about the costs of prescription medications. This is why Plaintiffs use their DTC advertisements to direct viewers to sources—including company websites—that provide patients with substantial information to help them determine their actual out-of-pocket costs for the advertised drug. *See* PhRMA Comment 1-2. But the compelled disclosure of WAC in brief DTC television ads will not achieve that goal: Rather than educating patients about their likely costs, it will confuse and mislead them, and potentially endanger their health.

advertisements suggesting that consumers ordinarily are charged a particular "list price" are "deceptive" where that "list price" is not an accurate representation of what consumers actually pay. *Giant Food Inc. v. FTC*, 322 F.2d 977, 981-82 (D.C. Cir. 1963); *see also Spirit Airlines, Inc. v. U.S. DOT*, 687 F.3d 403, 413 (D.C. Cir. 2012) (finding it "common sense" that it could be "deceitful and misleading when the most prominent price listed [in an airline DTC advertisement] is anything other than the total, final price").

That is the problem here. A drug's WAC is a gross list price to *wholesalers*. It is not a suggested retail price, and as HHS admits it is "rarely" the amount paid by patients with any form of coverage. HHS Br. 9. WAC vastly exceeds the out-of-pocket cost for the overwhelming majority of consumers—including patients on Medicaid and those on Medicare who have met a small deductible. And WAC bears absolutely *no* relationship to the price paid by about half of all consumers—including all of the 65 million Americans on Medicaid, about 13 million of the 43 million Americans on Medicare Part D, and roughly half of Americans with private insurance. By nonetheless telling consumers that WAC is the "list price," HHS's compelled disclosure creates "a clear and serious danger of the consumer being misled." 16 C.F.R. § 233.3(d).

That problem should be fatal under any level of First Amendment scrutiny, as at minimum the government cannot force companies to speak in a way that will

mislead the public. *See Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 967 (9th Cir. 2009) (a state "has no legitimate reason to force retailers to affix false information on their products"), *aff'd sub nom. Brown v. Entertainment Merchants Ass'n*, 564 U.S. 786 (2011); *NAM II*, 800 F.3d at 539 (Srinivasan, J., dissenting) (explaining that just as a company's own "misleading disclosure" would lack First Amendment protection, the government cannot compel such disclosures).

Even though it has acknowledged that a patient will "rarely" pay WAC, HHS Br. 9, and admitted that disclosure of WAC in DTC advertisements may "intimidate[] and confuse[]" consumers, 84 Fed. Reg. at 20,756, HHS has nonetheless maintained that such disclosure will enable consumers "to approximate their [out-of-pocket] costs," *id.* at 20,741. But HHS has adduced no evidence to support that assertion, and it is certainly wrong for tens of millions of patients. The drug-pricing system is incredibly complex and highly individualized; the government itself concedes that "[t]here is no simple figure that would perfectly educate consumers about the byzantine world of drug pricing." D.D.C. Opp. Br. 35. Holding out a drug's WAC as an "anchor price" in a fleeting television advertisement therefore will do far more to misdirect many patients than enable them to calculate what they might actually pay.

Indeed, the only evidence HHS even invoked to support the premise that knowing a drug's WAC will enable consumers to better determine their out-of-

pocket price was a three-page article published just prior to HHS's promulgation of the final Rule. *See, e.g.*, 84 Fed. Reg. 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 (2019) (ECF No. 23-1)). But it is facially obvious that the "JAMA Study" provides HHS no support. In what the article's authors termed a "behavioral experiment" to assess whether WAC disclosure would be "effective in reducing consumer interest in high-priced drugs," ECF No. 23-1 at 2, 4, consumers viewed printed advertisements for an imaginary diabetes drug and were asked what they believed they would pay for the drug out-of-pocket. When respondents were shown an ad listing a WAC of $15,500 as the drug's "price," *id.* at 3, on average they expected to pay $2,787.08 for the drug, *id.* at 4 (Table 2). When respondents were told that "***eligible patients may be able to get Mayzerium for as little as $0 a month***," *id.* at 9, they still estimated that their out-of-pocket cost to be an average of $1,355.39, *id.* at 4 (Table 2). When respondents were not shown the WAC, they predicted their cost would be $78. *Id.*

In the preamble to the final Rule, HHS repeatedly asserted that the JAMA respondents' estimates of their costs after they saw the drug's WAC were "more accurate[]" than the estimates they made when they were not shown the WAC. 84 Fed. Reg. at 20,735, 20,741; *see also id.* at 20,734. But HHS had absolutely no basis for that assertion. The JAMA study did not purport to measure the effect of WAC

disclosure on the accuracy of respondents' estimates of their out-of-pocket cost. Nor could its results be used for that purpose, because the JAMA Study does not report the out-of-pocket cost for any given respondent (which makes sense, as Mayzerium is fictional, and the terms of respondents' insurance coverages were unknown). The JAMA study is therefore of no help to HHS.

HHS also speculated that the Rule's potential to mislead might be "mitigated" by the included caveat that "[i]f you have health insurance that covers drugs, your cost may be different." *See id.* at 20,755. But as phrased, that caveat is disingenuous in its own right. First, it strongly indicates that those *without* insurance will inevitably pay the list price—something that is inaccurate for many uninsured patients. *See supra* pages 10-11. In addition, it is highly misleading to say that for those *with* insurance "your cost *may* be different," 84 Fed. Reg. at 20,741 (emphasis added), when in reality the cost for those with insurance will *almost always* be different, and usually *far lower*, than WAC.

Moreover, as with HHS's other predictions, this one lacks evidentiary support. Once again, the agency's sole basis for concluding that the caveat would "mitigate" confusion was the JAMA Study. *See id.* at 20,741-42, 20,747, 20,757. But the JAMA respondents saw a printed advertisement stating that "***eligible patients may be able to get Mayzerium for <u>as little as $0 per month</u>***." Being told in boldface and

underlined text that you might pay *nothing* for a drug notwithstanding its high price is worlds away from being told your costs "may be different."

HHS was also unable to produce any evidence that forcing manufacturers to display a drug's WAC will have the effect of lowering drug prices overall. The agency hoped that the compelled disclosure would pressure manufacturers to reduce their prices by "exposing overly costly drugs to public scrutiny." 84 Fed. Reg. at 20,733. But HHS recognized that the Rule may instead simply cause manufacturers to cut back on their television advertisements, or else induce manufacturers to lower the WAC while simultaneously eliminating discounts, rebates, and other price concessions—leaving the net costs to payers and consumers largely the same. *Id.* at 20,756-57. And HHS all but admitted that its prediction that the Rule would lower drug prices was nothing more than a hypothesis, explaining, "[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*." *Id.* at 20,754 (emphasis added).

Finally, HHS offered no evidence that the WAC Disclosure Rule would produce overall cost savings *even if* the disclosure indirectly lowered drug prices. When it first proposed the Rule, HHS recognized that "consumers, intimidated and confused by high list prices, may be deterred from contacting their physicians about drugs or medical conditions," and that the Rule could therefore "discourage patients

from using beneficial medications, reduce access, and *potentially increase total cost of care*." 83 Fed. Reg. at 52,797-98 (emphasis added). HHS hoped that commenters would dispel those concerns, *see id.* at 52,798, but they did not—and it was forced to admit in the final Rule that it still "lack[ed] data to quantify these effects." 84 Fed. Reg. at 20,756.

The government cannot satisfy its burden in the face of such vast "evidentiary gaps." *NAM II*, 800 F.3d at 525. Where, as here, there is substantial "doubt [about] whether the [regulation] either alleviates or aggravates the stated problem," and the government has been "unable to quantify any benefits of the forced disclosure regime," the government cannot compel speech. *Id*. at 526.

HHS has not shown that less burdensome means are insufficient. *Central Hudson* also requires the government to "present[] . . . evidence that less restrictive means would fail" to accomplish its interests. *National Ass'n of Mfrs. v. SEC*, 748 F.3d 359, 372 (D.C. Cir. 2014), *overruled on other grounds by AMI*, 760 F.3d 18. HHS has not carried that burden either.

HHS has plenty of alternatives short of "burdening a speaker with unwanted speech." *National Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2376 (2018) ("*NIFLA*") (citation omitted). Most obviously, HHS could directly provide drug-pricing information to Medicare and Medicaid beneficiaries itself—for instance, through a website tool that beneficiaries could use to determine what a

particular drug will cost based on their particular coverage. *See id.* (explaining, in finding that a compelled-speech requirement failed intermediate scrutiny, that the government could have conducted its own "public-information campaign").

HHS had other options as well. For instance, around the time HHS promulgated this Rule, it finalized another regulation requiring Medicare Part D plans to make patient-specific information about the cost of treatment options readily accessible to providers so that they could better educate their patients. *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). In addition, HHS could reimburse Medicare and Medicaid providers for including counseling about treatment costs in their patient discussions—a suggestion that commenters specifically raised as a better alternative to the WAC Disclosure Rule (which might cause patients to never ask their doctor about a treatment in the first place). 84 Fed. Reg. at 20,751. HHS acknowledged that "CMS could create a new payment code, in a budget neutral manner," for such cost counseling; HHS even recognized that such a measure could be effective. *See id.* HHS nonetheless rejected the alternative, stating only that it would "consider" such a measure in "future rulemaking." *Id.* But the First Amendment does not allow the state to compel speech first and try other alternatives

later. *See Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 373 (2002) ("[R]egulating speech must be a last—not first—resort.").

2. The Rule Would Fail Even Under *Zauderer*

Perhaps recognizing that the WAC Disclosure Rule flunks *Central Hudson*, HHS has primarily defended the Rule by arguing that it should be subject to the more lenient standard articulated in *Zauderer v. Office of Disciplinary Counsel of the Supreme Court*. *See* 471 U.S. 626, 653 (1985) (finding a commercial disclosure requirement permissible where it was "reasonably related to the State's interest" in preventing deception of consumers); *see also* 84 Fed. Reg. at 20,743-44; D.D.C. Opp. Br. 24-32.

But *Zauderer*'s less exacting standard applies only in limited circumstances where the government requires disclosure of "purely factual and uncontroversial information about the terms under which [the speaker's product] will be available." 471 U.S. at 651. And even under *Zauderer*, courts will not uphold regulations that are "unjustified" or "unduly burdensome." *Id.*; *see also NIFLA*, 138 S. Ct. at 2372. Here, HHS cannot carry its burden of showing that *Zauderer* applies, nor that the Rule complies with its requirements. *See NIFLA*, 138 S. Ct. at 2377; *AMI*, 760 F.3d at 26.

Zauderer does not apply. The compelled disclosure meets neither of the requirements for *Zauderer* review. First, it is not about "the terms under which . . .

[the product] will be available." *NIFLA*, 138 S. Ct. at 2372 (omission in original) (citation omitted). A drug's WAC is not, and does not even approximate, the amount at which the product would be made "available" to the vast majority of consumers viewing the advertisement. *See supra* pages 7-11, 45.

Second, and more fundamentally, HHS cannot remotely establish that the required disclosure is "purely factual and uncontroversial." *Zauderer*, 471 U.S. at 651. To qualify, government-compelled statements must be neither "one-sided [n]or incomplete," *AMI*, 760 F.3d at 27; they also cannot be "inflammatory," "subject to misinterpretation by consumers," *RJ Reynolds*, 696 F.3d at 1216-17, or "misleading," *NAM II*, 800 F.3d at 539 (Srinivasan, J., dissenting).

The statement compelled by the Rule is, for all the reasons discussed above, subject to misinterpretation by consumers, incomplete, and misleading. Indeed, this Court does not have to take Plaintiffs' word for it: a chorus of patient and medical groups and others explicitly warned HHS that advertising a drug's WAC on television—even with the caveat language—would "give viewers the misleading impression that they will be required to pay the full price to obtain a medication" and even cause patients to "forgo care out of fear of being responsible for paying" that price. *See supra* nn.15–19. Even *the agency* has conceded as much: HHS admitted in both the notice of proposed rulemaking and the final Rule that upon seeing the compelled statement, "[c]onsumers might believe they are being asked to

pay the list price rather than a co-pay or co-insurance." 83 Fed. Reg. at 52,797; 84 Fed. Reg. at 20,756. The most the government can say to defend the Rule is that for "'some consumers'" WAC can be a "relevant benchmark" in calculating out-of-pocket price. D.D.C. Opp. Br. 14, 35 (citation omitted). But the proposition that the compelled disclosure won't mislead *all* patients falls well short of the constitutional bar. *Cf. Giant*, 322 F.2d at 982 (upholding finding that advertising was false and deceptive even though it might not deceive "*all* potential buyers" (emphasis added)).

The Rule flunks Zauderer. Even if *Zauderer* applied, the Rule would not satisfy that standard because the compelled disclosure is both "unduly burdensome" and "unjustified." *NIFLA*, 138 S. Ct. at 2377. As discussed, the Rule's interference with Plaintiffs' speech rights is wholly unnecessary, because the government's objectives could readily be accomplished through other means. *See supra* pages 50-51. And the Rule lacks justification, because HHS has not presented a shred of evidence establishing that disclosure of a drug's WAC in consumer advertisements will reduce overall program spending. *See supra* pages 44-50. That is a problem for the government even under *Zauderer*: as this Court emphasized in applying that standard in *NAM II*, the government cannot rest on "speculation or conjecture," and must still prove that its proposed disclosure will alleviate consumer harm "'to a material degree.'" 800 F.3d at 527 (citation omitted).

Indeed, this case is a dead-ringer for *NAM II*: here, as in *NAM II*, there is substantial doubt about whether the "rule either alleviates or aggravates" the problem it is designed to solve; the evidence (at a minimum) goes "both ways"; and the government has *admitted* that it cannot "quantify any benefits of the forced disclosure regime." *Id.* at 525-26. It is thus similarly impossible to conclude here that HHS has "proven [the Rule's effectiveness] to the degree required under the First Amendment to compel speech." *Id.* at 527. The Rule cannot survive.

B. At A Minimum, The Rule Should Be Stayed

If the Court chooses not to reach the merits of Plaintiffs' First Amendment claim, it should nonetheless stay the Rule's effective date until this issue can be fully adjudicated. *See* 5 U.S.C. § 705.

A stay is warranted under the APA so long as the traditional criteria for interim injunctive relief are satisfied. *See Nken v. Holder*, 556 U.S. 418, 426 (2009). The court must weigh "four factors, taken together": (1) "likely success on the merits," (2) "likely irreparable harm in the absence of preliminary relief," (3) "a balance of the equities" that takes into account any harm to the opposing party, and (4) the extent to which interim relief would be in "accord with the public interest." *Pursuing America's Greatness v. FEC*, 831 F.3d 500, 505 (D.C. Cir. 2016).

Plaintiffs' claim amply satisfies these factors. "The loss of First Amendment 'freedoms, "for even minimal periods of time, unquestionably constitutes irreparable

injury."'" *Id.* at 511 (citations omitted). And there can be no government or public interest in the "enforcement of an unconstitutional law." *Gordon v. Holder*, 721 F.3d 638, 653 (D.C. Cir. 2013).

A stay is therefore warranted so long as this Court concludes that Plaintiffs have alleged a "threatened constitutional deprivation." *Id.* (citation omitted). For all the reasons above, the WAC Disclosure Rule violates Plaintiffs' First Amendment rights by compelling them to engage in speech that is likely to be misinterpreted, cause widespread public confusion, and reduce patients' willingness to seek medical treatment—all without materially advancing the Rule's stated interests in containing program costs. Given the very high likelihood that Plaintiffs will prevail on this claim, this Court should maintain the status quo until this important constitutional question receives a full airing.

CONCLUSION

The judgment of the district court should be affirmed.

Date: November 12, 2019

Respectfully submitted,

/s/ Robert Corn-Revere
Robert Corn-Revere
Ronald G. London
DAVIS WRIGHT TREMAINE LLP
1919 Pennsylvania Avenue, NW
Suite 800
Washington, DC 20006
(202) 973-4200
bobcornrevere@dwt.com

Counsel for Appellee Association of National Advertisers, Inc.

/s/ Richard P. Bress
Richard P. Bress
Daniel Meron
Michael E. Bern
Caroline A. Flynn
Gregory B. in den Berken
LATHAM & WATKINS LLP
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004
(202) 637-2200
richard.bress@lw.com

Annie M. Wilson
LATHAM & WATKINS LLP
330 North Wabash Avenue
Suite 2800
Chicago, IL 60611
(312) 876-7700

Counsel for Appellees Merck & Co., Inc., Eli Lilly and Company, and Amgen Inc.

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/s/ Richard P. Bress
Richard P. Bress

CERTIFICATE OF SERVICE

I certify that on November 12, 2019, I filed the foregoing Brief for Plaintiffs-Appellees with the Clerk of the United States Court of Appeals for the D.C. Circuit via the CM/ECF system, which will notify all participants in the case who are registered CM/ECF users.

/s/ Richard P. Bress
Richard P. Bress

ADDENDUM

Pursuant to Federal Rule of Appellate Procedure 28(f)

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42 U.S.C. § 1302(a)

§ 1302. Rules and regulations; impact analyses of Medicare and Medicaid rules and regulations on small rural hospitals

(a) The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services, respectively, shall make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which each is charged under this chapter.

42 U.S.C. § 1395hh(a)(1)

§ 1395hh. Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

42 C.F.R. §§ 403.1200-403.1204

§ 403.1200 Scope.

(a) *Covered pharmaceuticals.* Except as specified in paragraph (b) of this section, this subpart applies to advertisements for a prescription drug or biological product distributed in the United States for which payment is available, directly or indirectly, under titles XVIII or XIX of the Social Security Act.

(b) *Excepted pharmaceuticals.* An advertisement for any prescription drug or biological product that has a list price, as defined in § 403.1201, less than $35 per month for a 30-day supply or typical course of treatment shall be exempt from the requirements of this subpart.

§ 403.1201 Definitions.

For the purposes of this subpart, the following definitions apply:

(a) *Biological product.* Biological product means any biological product, as that term is defined in Public Health Service Act ("PHS Act") section 351(i), that is licensed by the Food and Drug Administration pursuant to section 351 and is subject to the requirements of Federal Food, Drug, and Cosmetic Act (FDCA) section 503(b)(1).

(b) *Prescription drug.* Prescription drug means any drug, as defined in the FDCA section 201(g), that has been approved by the Food and Drug Administration pursuant to FDCA section 505 and is subject to the requirements of FDCA section 503(b)(1).

(c) *List price.* List price means the wholesale acquisition cost, as defined in paragraph (d) of this section.

(d) *Wholesale acquisition cost.* Wholesale acquisition cost means, with respect to a prescription drug or biological product, the 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, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data.

§ 403.1202 Pricing information.

Any advertisement for any prescription drug or biological product on television (including broadcast, cable, streaming, or satellite) must contain a textual statement indicating the current list price for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast, as follows: "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." Where the price is related to the typical course of treatment and that typical course of treatment varies depending on the indication for which a prescription drug or biological product is prescribed, the list price to be used is the one for the typical course of treatment associated with the primary indication addressed in the advertisement.

§ 403.1203 Specific presentation requirements.

The textual statement described in §403.1202 shall be presented at the end of an advertisement in a legible manner, meaning that it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.

§ 403.1204 Compliance.

(a) *Identification of non-compliant products.* The Secretary will maintain a public list that will include the prescription drugs and biological products identified by the Secretary to be advertised in violation of this subpart.

(b) *State or local requirements.* No State or political subdivision of any State may establish or continue in effect any requirement concerning the disclosure in a television advertisement of the pricing of a prescription drug or biological product which is different from, or in addition to, any requirement imposed by this subpart.