ORAL ARGUMENT SCHEDULED FOR JANUARY 13, 2020

No. 19-5222

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX M. AZAR II, in his official capacity as the Secretary of the United States Department of Health and Human Services, CENTERS FOR MEDICARE & MEDICAID SERVICES, and SEEMA VERMA, in her official capacity as the Administrator of the Centers for Medicare & Medicaid Services,
Defendants-Appellants.

On Appeal from the
U.S. District Court for the District of Columbia
(No. 1:19-cv-01738-APM)

AMICUS CURIAE BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION SUPPORTING PLAINTIFFS-APPELLEES AND AFFIRMANCE

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Under D.C. Circuit Rule 28(a)(1), the undersigned counsel of record certifies:

A. Parties and *Amici*

Except for Allied Educational Foundation and the Chamber of Commerce of the United States of America, all parties and *amici* are listed in certificates in the Defendants-Appellants' and Plaintiffs-Appellees' briefs.

B. Ruling Under Review

The ruling under review is the July 8, 2019 opinion and order of the U.S. District Court for the District of Columbia in *Merck & Co. v. U.S. Dep't of Health & Human Servs.*, 385 F. Supp. 3d 81 (D.D.C. 2019) (Mehta, J.).

C. Related Cases

This case has not been before this Court or any other court, save the district court which issued the judgment under review. Counsel is unaware of any related case under D.C. Circuit Rule 28(a)(1)(C).

/s/ Cory L. Andrews
Cory L. Andrews

CORPORATE DISCLOSURE STATEMENTS

Under Federal Rules of Appellate Procedure 26.1 and 29(4)(a) and Circuit Rules 29(b) and 26.1(a), Washington Legal Foundation (WLF) and Allied Educational Foundation (AEF) each disclose that they are nonprofit, charitable corporations organized under § 501(c)(3) of the Internal Revenue Code. They have no parent company, issue no stock, and no publicly held company owns a 10% or greater interest in either of them.

Under Circuit Rule 26.1(b), WLF discloses that it is a public-interest law firm and policy center whose mission is to defend and promote free enterprise, individual rights, limited government, and the rule of law. AEF discloses that it is a nonprofit charitable and educational foundation based in Tenafly, New Jersey and dedicated to promoting education in diverse areas of study, such as law and public policy.

/s/ Cory L. Andrews
Cory L. Andrews

STATEMENT ON CONSENT TO FILE, AUTHORSHIP, MONETARY CONTRIBUTIONS, AND SEPARATE BRIEFING

Under Federal Rule of Appellate Procedure 29(a)(2) and Circuit Rule 29(b), *amici curiae* Washington Legal Foundation and Allied Educational Foundation file this brief with the consent of all parties.

Under Federal Rule of Appellate Procedure 29(a)(4)(E), *amici* state that no party's counsel authored any part of this brief. No one, apart from *amici* and their counsel, contributed money intended to fund the brief's preparation or submission.

Under Circuit Rule 29(d), *amici* state that a separate brief is necessary to provide *amici*'s unique free-market perspective and to underscore the need for the Court to interpret the relevant statutory provisions in a way that avoids placing their constitutionality in doubt.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES:

Page(s)

Page(s)

STATUTES:

OTHER SOURCES:

Page(s)

GLOSSARY

AEF	Allied Educational Foundation
CMS	Centers for Medicare & Medicaid Services
DTC	Direct-to-Consumer
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
HHS	U.S. Department of Health and Human Services
WLF	Washington Legal Foundation

INTERESTS OF *AMICI CURIAE*

Founded in 1977, Washington Legal Foundation (WLF) is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes and defends free enterprise, individual rights, limited government, and the rule of law. WLF often appears as an *amicus curiae* in important statutory-interpretation cases, to urge the judiciary to prevent executive agencies from rewriting federal law. *See, e.g.*, *King v. Burwell*, 135 S. Ct. 2480 (2015); *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302 (2014); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

The Allied Educational Foundation (AEF) is a nonprofit charitable and educational foundation based in Tenafly, New Jersey. Founded in 1964, AEF promotes education in diverse areas of study, including law and public policy, and often appears as an *amicus curiae* in this and other federal courts.

The administration's goal of reducing health care costs, including lowering the cost of prescription drugs, is a laudable one. But executive agencies do not wield the statutes they want; they must implement the statutes Congress gives them. By relying on its purported authority

under the Social Security Act to require prescription-drug makers to display a drug's "list price" in direct-to-consumer (DTC) television ads, the Department of Health and Human Services (HHS) has improperly expanded that statute's reach far beyond anything its text can sustain. In doing so, HHS has crossed the line from implementing policy into making policy. *Amici* urge the Court to affirm the district court's well-reasoned decision, which vindicates Congress's exclusive prerogative to write the law.

INTRODUCTION

Congress has a formidable job. Crafting federal statutory law is hard enough, but crafting statutes that delegate authority—*limited* authority—to executive agencies implementing those statutes is harder still. And the executive branch, feeling unduly constrained by the limits Congress places on its authority, often seeks to push those limits beyond the boundaries fixed by Congress. In fact, executive agencies often do what they regard as expedient, backing down only when the courts decide they have overreached.

Further complicating Congress's job, *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.* allows agencies to formulate

"policy and [make] rules to fill any gap left, implicitly or explicitly, by Congress." 467 U.S. 837, 843 (1984) (citation and internal quotations omitted). So when Congress expressly authorizes such gap-filling by agencies, or when a reviewing court finds the statutory language ambiguous on that question, courts will generally defer to an agency's reasonable interpretation of statutory language. *Id.* Congress legislates with knowledge of these basic rules.

Yet no meaningful system of checks and balances can exist if the executive branch can vest itself with powers beyond those Congress has provided it. Even under *Chevron*, an "administrative agency's power to regulate ... must always be grounded in a valid grant of authority from Congress." *Brown & Williamson*, 529 U.S. at 161. If Congress's intent is clear, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43. That is why the most powerful constraint Congress has on executive power is the plain language of the statutes it writes.

The Social Security Act authorizes the Secretary of HHS to promulgate regulations for the "efficient administration" of the

Medicare and Medicaid programs. 42 U.S.C. § 1302(a). Congress authorized the Secretary to adopt rules "necessary to carry out the administration of the insurance programs." *Id.* § 1395hh(a)(1). Relying on these meager grants of administrative authority, HHS claims (for the first time in its 71-year history) the power to require prescription-drug makers—who receive *no* payments from Medicare or Medicaid—to display in their DTC-television ads the wholesale acquisition cost (WAC) of a 30-day supply of the advertised drug.

As the district court rightly found, the Social Security Act supplies no plausible basis for that power. Nothing in *that* statute authorizes HHS to regulate the private health care industry writ large, much less to police the content of prescription-drug makers' DTC advertising to the public. Among other defects, adopting HHS's position on appeal would assume that Congress delegated vast lawmaking authority without a sufficiently "intelligible principle" to guide the exercise of that authority. This Court should construe the statute to avoid that constitutional problem.

Lacking any affirmative statutory authorization for the DTC Rule, HHS contends (as it did below) that it may take virtually any action

"reasonably related" to "administering" the Medicare and Medicaid programs—so long as Congress has not *prohibited* it from doing so. But that view of Congress's delegation of agency power "has it backwards as a matter of basic separation of powers and administrative law." *Bais Yaakov of Spring Valley v. FCC*, 852 F.3d 1078, 1082 (D.C. Cir. 2017) (Kavanaugh, J.). A grant of authority can never be inferred from the lack of an express prohibition against an agency's newfound statutory construction.

Nor is that all. By compelling drug makers to speak when they would prefer to remain silent, the DTC Rule flouts the First Amendment. While the First Amendment does not bar HHS from requiring drug makers to disclose "purely factual and uncontroversial information" about the drug being advertised, the DTC Rule's mandatory disclosure of a drug's "list price" is highly misleading and therefore controversial. Obliged to point to record evidence that proves the DTC Rule will not confuse or mislead consumers, HHS offers only speculation. The First Amendment requires much more.

ARGUMENT

I. THE DECISION BELOW VINDICATES CONGRESS'S CONSTITUTIONAL PREROGATIVE TO WRITE THE LAW.

The judiciary stands as a bulwark against the tendency of federal agencies to expand their authority beyond the statutory lines Congress has drawn. Above all, courts must "take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." *Brown & Williamson*, 529 U.S. at 161 (internal quotation marks and citations omitted). As Justice Breyer has observed, "the public now relies more heavily on courts to ensure the fairness and rationality of agency decisions." Stephen Breyer, *The Executive Branch, Administrative Action, and Comparative Expertise*, 32 Cardozo Law Rev. 2189, 2195 (2011). The district court dutifully performed that function here.

Congress knows that courts often defer to executive-branch interpretations of technical and complex statutory terms, and agencies often attempt to give every term the current administration's preferred meaning. At step one of *Chevron*, courts must use "traditional tools of statutory construction" to decide whether Congress has "directly spoken to the precise question at issue." 467 U.S. at 842, 843 n.9. The most

"fundamental canon of statutory construction" is that "the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Brown & Williamson*, 529 U.S. at 133 (citation and internal quotations omitted).

The Social Security Act is the only statutory justification HHS offers for the DTC Rule. As the district court rightly found, Congress's authorization for HHS to "administer" the Medicare and Medicaid programs merely confers the power to "control the operation" of those programs over which it "has executive authority." Op. at 12-13. Nothing in the Social Security Act authorizes HHS, even "in the name of attempting to reduce the costs," to "regulate the health care market itself" or the promotional speech of market actors. *Id*. at 15. Simply put, HHS's general rulemaking power cannot give the Secretary "*carte blanche* authority to promulgate any rules, on any matter." *In re Permanent Surface Mining Regulation Litig.*, 653 F.2d 514, 523 (D.C. Cir. 1981) (en banc).

When Congress intends to grant HHS authority over the televised marketing of prescription drugs, it knows how to do so. Look no further than the Food, Drug, and Cosmetic Act (FDCA), which gives the

Secretary well-defined yet limited power to ensure the veracity of pharmaceutical DTC-television advertising and to prescribe minimum content for all pharmaceutical DTC-television ads. *See* 21 U.S.C. §§ 321(n), 352(n). Yet the Food and Drug Administration (FDA), which implements the FDCA, has long conceded that it lacks the statutory authority to require price disclosures. Any "decision to engage in public disclosure of prescription drug prices is not for the Food and Drug Administration to make." FDA, *Reminder Labeling and Reminder Advertisements for Prescription Drugs*, 40 Fed. Reg. 58,794, 58,794 (Dec. 18, 1975).

HHS rightly disclaims the FDCA as a statutory justification for the DTC Rule. But the Social Security Act is even further afield from the FDCA as a plausible basis for the Rule. For while the authority Congress delegates in the FDCA is specific and policy-based, the power it grants in the Social Security Act is both generic and administrative. If the canons of statutory construction teach anything, it's that a "specific statute will not be controlled or nullified by a general one, regardless of the priority of the enactment." *Morton v. Mancari*, 417 U.S. 535, 551 (1974).

By disregarding Congress's clear intent—manifest in its use of words with plain meanings—HHS seeks to appropriate Congress's legislative power and distort the Constitution's framework. But Congress must be able to legislate secure in the knowledge that the words it uses in statutes will receive their ordinary meaning, and that the executive branch won't be allowed to twist those words in an attempt to extract from "a long-extant statute an unheralded power to regulate 'a significant portion of the American economy.'" *Util. Air Regulatory Grp.*, 573 U.S. at 324 (quoting *Brown & Williamson*, 529 U.S. at 159).

What's more, if HHS's reading of the Social Security Act were to prevail on appeal, "it would completely eviscerate the power of Congress to determine the scope of the statutes it passes." *Mobile Commc'ns Corp. of Am. v. FCC*, 77 F.3d 1399, 1413 (D.C. Cir. 1996). Reversing the decision below would not only relieve Congress of political accountability for policymaking but also raise serious constitutional doubts about whether the Act delegates powers sufficiently "definite and precise to enable Congress, the courts, and the public to ascertain"

whether Congress's guidance has been followed. *Yakus v. United States*, 321 U.S. 414, 426 (1944).

If the Court were to construe the Social Security Act as giving the Secretary the power to do anything reasonably calculated to reduce healthcare costs, then the Act would lack any "intelligible principle" to guide the exercise of that power. It would allow HHS, relying solely on its general administrative authority over the Medicare and Medicaid programs, to regulate private industry, to impose direct price controls on drug makers, and even to set the fees that hospitals and physicians may charge their patients. Such unrestricted delegation "undermines the separation of powers, not only by expanding the power of executive agencies," but also by "unraveling the institutional interests of Congress." Neomi Rao, *Administrative Collusion: How Delegation Diminishes the Collective Congress*, 90 N.Y.U. L. Rev. 1463, 1465 (2015).

This Court should affirm the district court and vindicate Congress's core function, which requires the ability to draft laws that confer authority, but not *unbridled* authority, on federal agencies.

II. THE LACK OF AN EXPRESS STATUTORY PROHIBITION AGAINST THE DTC RULE CANNOT JUSTIFY THE DTC RULE.

HHS has already conceded that Congress never "explicitly provided [it] with authority to compel the disclosure of list prices to the public." Centers for Medicare and Medicaid Services (CMS), *Regulation to Require Drug Pricing Transparency*, 83 Fed. Reg. 52,789, 52,791 (Oct. 18, 2018). Lacking any express authority, HHS claims that whatever Congress does not prohibit, it permits. HHS advanced that very rationale in its final Rule: "Viewing the Medicare and Medicaid schemes as a whole, nothing prohibits the requirements we are finalizing in this rule." CMS, *Regulation to Require Drug-Pricing Transparency*, 84 Fed. Reg. 20,732, 20,736 (May 10, 2019).

On appeal, however, the government now strangely insists that, "[c]ontrary to the district court's suggestion," HHS is *not* "appropriat[ing] the power to regulate simply because Congress has not taken that power away." (Appellants' Br. 35) Yet on the same page of its brief as that blanket denial, HHS contends:

- "Without identifying any specific provision or structural feature of the Medicare or Medicaid statutes that place DTC drug advertising off limits, the district court had no basis to rule that HHS acted in excess of its statutory authority." (*Id.*)

- "The district court did not identify a single structural feature of the Medicare and Medicaid statutes that prohibits the DTC rule, or that reflects a congressional decision to preclude HHS from regulating prescription drug price advertising under those programs." (*Id.*)

- "Congress has explicitly granted the power to regulate. While Congress was free to qualify that grant in other provisions of the Medicare and Medicare statutes, it has not done so." (*Id.*)

The above statements (and others like them) appear under an argument heading in the government's brief titled: "**Nothing in the Medicare or Medicaid statutes prohibits the DTC rule.**" (*Id.* at 32) Simply put, HHS's own arguments keep getting in the way of its denial.

Whatever else it may argue, HHS has consistently claimed that the lack of an express prohibition is itself a statutory justification for the DTC Rule. (*Id.* at 32-36) But that is not the law. "Deciding what competing values will or will not be sacrificed to the achievement of a particular directive is the very essence of legislative choice." *Rodriguez v. United States*, 480 U.S. 522, 526 (1987). That is why it "frustrates rather than effectuates legislative intent" simply to assume that "*whatever* furthers the statute's primary objective must be the law." *Id.*

Indeed, HHS's argument ignores the realities of the legislative process and what reasonably may be expected of Congress when

drafting a law that delegates limited authority to an executive-branch agency. The notion that it was somehow incumbent on Congress not only to specify the power it intended to grant HHS but also to go further and specify every power it *did not* intend to grant the agency, is deeply misguided. Congress cannot possibly anticipate—and then negate with exhaustive statutory language—every conceivable, far-fetched construction an agency may one day seek to impose on Congress's statutory directives. This case proves the point.

"Were courts to presume a delegation of power absent an express withholding of such power," this Court has explained, "agencies would enjoy virtually limitless hegemony, a result plainly out of keeping with *Chevron* and quite likely with the Constitution as well." *Ry. Labor Execs. Ass'n v. Nat'l Mediation Bd.*, 29 F.3d 655, 671 (D.C. Cir. 1994) (en banc) (citations omitted).

In an unbroken line of decisions, the Court has steadfastly rejected HHS's Congress-didn't-say-we-couldn't justification for *ultra vires* agency action. *See, e.g.*, *Aid Ass'n for Lutherans v. USPS*, 321 F.3d 1166, 1174 (D.C. Cir. 2003) (rejecting as "entirely untenable under well-established case law" the argument "that the disputed regulations are

permissible because the statute does not expressly foreclose the construction advanced by the agency"); *ExxonMobil Gas Mktg. Co. v. FERC*, 297 F.3d 1071, 1088 (D.C. Cir. 2002) ("We have repeatedly admonished federal agencies that jurisdiction may not be *presumed* based solely on the fact that there is not an express withholding of jurisdiction."); *Nat'l Mining Ass'n v. U.S. Dep't of Interior*, 105 F.3d 691, 695 (D.C. Cir. 1997) (rejecting the "extreme position" that "because Congress did not specifically preclude" an agency action, the court "should defer to [the agency's] interpretation of the statute"); *Am. Petroleum Inst. v. EPA*, 52 F.3d 1113, 1120 (D.C. Cir. 1995) ("[W]e will not presume a delegation of power based solely on the fact that there is not an express withholding of that power."); *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1060 (D.C. Cir. 1995) ("We refuse ... to presume a delegation of power merely because Congress has not expressly withheld such power.").

Put another way, when Congress wants to delegate authority, but not *unlimited* authority, to an agency, it "need not lace the United States Code with the phrase, 'You shall not pass!'" *Oregon Rest. & Lodging v. Solis*, 948 F. Supp. 2d 1217, 1225-26 (D. Or. 2013). *Chevron*

deference does not work that way. If anything, such "statutory silence, when viewed in context, is best interpreted as *limiting* agency discretion." *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 223 (2009) (emphasis added).

HHS is not a legislative body; it must abide by the words of the Social Security Act that Congress wrote into law. The decision below secures this basic principle. Conversely, a decision in the government's favor would make it nearly impossible for Congress to write legislation that constrains an executive agency's power and discretion, eroding the separation of powers.

III. THE DTC RULE'S COMPULSION OF SPEECH BY DRUG MANUFACTURERS VIOLATES THE FIRST AMENDMENT.

This Court may affirm on any ground properly raised below, even if the district court did not rely on it. *Tymshare Inc. v. Covell*, 727 F.2d 1145, 1150 (D.C. Cir. 1984). As they did below, the plaintiffs contend here that the DTC Rule violates the First Amendment. The First Amendment's guarantee of "freedom of speech" encompasses "the decision of what to say and what *not* to say." *Riley v. Nat'l Fed'n of the Blind of N. Carolina, Inc.*, 487 U.S. 781, 797 (1988). By compelling drug

makers "to speak a particular message" they would not otherwise recite, the DTC Rule "alters the content of [their] speech." *Id.* at 795.

As this Court has explained, *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985), and *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980), both apply the same intermediate scrutiny to commercial-speech regulations. *Zauderer* simply applies that scrutiny to one kind of regulation: government-mandated disclaimers on advertising. *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 26-27 (D.C. Cir. 2014) (en banc). In such cases, "the means-end fit is self-evidently satisfied when the government acts only through a reasonably crafted mandate to disclose 'purely factual and uncontroversial information' about attributes of the product or service being offered." *Id.* at 26. *Zauderer* is thus best understood as "an *application* of *Central Hudson*, where several of *Central Hudson*'s elements have already been established." *Id.* at 27 (citation and quotation marks omitted).

But requiring drug manufacturers to disclose a drug's "list price" is *not* uncontroversial; it is highly misleading. As HHS readily concedes, a drug's list price bears no relation to the consumer's out-of-pocket cost

for that drug. Most patients do not understand the complex system of preferred and non-preferred pricing tiers, deductibles, co-payments, and co-insurance. *See* 84 Fed. Reg. at 20,734. For example, a Medicare beneficiary's out-of-pocket costs will vary dramatically depending on the stage of the Part D benefit she is in and on whether she is eligible for "extra help" from the Low-Income Subsidy. Beyond those factors, actual cost turns on whether the consumer's supplemental insurance plan includes any co-pay and deductible amounts. And in many cases, the consumer's co-pay is a fixed dollar amount that bears no relation to the list price. A drug's final cost also depends on the consumer's eligibility to participate in third-party co-pay and assistance programs.

In short, disclosing a drug's list price in a DTC ad will *not* inform a potential consumer of his or her out-of-pocket cost for the advertised drug. That is why the FDA has cautioned drug makers that comparing competitors' list prices in ads can be misleading. FDA has objected, for example, to cost-effectiveness claims based on list-price comparisons because "even if a price incentive included in an advertisement is in fact 'truthful,' the net impression of the promotional piece as a whole can be unbalanced or misleading." FDA, Notice, *Effect of Promotional Offers in*

Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Product Perceptions, 76 Fed. Reg. 58,011, 58,014 (Sept. 19, 2011).

Nor has HHS offered any empirical evidence that predicts how the average consumer is likely to behave once aware of a drug's list price. A consumer who views a television ad and compares the list prices of two competing drugs may explore only the drug with the lowest list price, even though the co-pay for that drug may be the same or even higher than its competitor. Another consumer may behave counterintuitively. For example, "[i]f a consumer has a choice of five drugs and one is more expensive, the consumer may think the more expensive drug is the better drug. That's often how people make decisions." Wendy W. Blackburn, quoted in Robert Pear, *Requiring Prices in Drug Ads: Would It Do Any Good? Is It Even Legal?*, N.Y. Times, May 19, 2018, at A16.

Even worse, the list price may be so steep that it deters a viewer from even consulting a doctor to obtain a prescription for the drug. That person could get much sicker as a result, and end up costing the system *more* than if he'd never considered the list price. Gaming out such

scenarios is inherently unreliable, but the likelihood for confusion abounds.

In the past, when HHS has sought to understand how consumers would likely respond to information in a DTC ad, it has used the FDA's research arm to do so. The FDA's Office of Prescription Drug Promotion routinely studies the effects of DTC advertising, including conducting "telephone surveys of DTC-related patient and physician attitudes and behaviors." *See* FDA, Office of Prescription Drug Promotion (OPDP) Research (May 21, 2019), <https://tinyurl.com/vcs4t3b>.

FDA has, for example, surveyed 5,850 people to learn whether pharmaceutical sales promotions—free trial offers, discounts, money-back guarantees, and rebates—meaningfully reduce out-of-pocket costs. *See* 76 Fed. Reg. at 58,013. It has studied the behavior of 1,350 consumers to understand the effect, if any, that coupons and rebates in DTC-print ads have on a consumer's overall cost-benefit calculus. *See* FDA, Notice, *Experimental Study of the Impact of Coupons Embedded in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Perceptions of Product Risks and Benefits*, 73 Fed. Reg. 76,034 (Dec. 15, 2008).

Yet HHS undertook no such research here. While HHS claims it is "reasonable for CMS to assume that Medicare and Medicaid beneficiaries are familiar with deductibles and co-insurance" (Appellants' Br. 27), an assumption is not evidence. HHS hasn't even sought to learn whether consumers viewing DTC ads displaying the WAC of a 30-day supply of the advertised drug would respond as the agency predicts they would. HHS's lack of research only underscores how little the agency has done to meet its evidentiary burden to justify intruding on First Amendment rights.

"If the disclaimer creates confusion, rather than eliminating it, the only possible constitutional justification for [the] speech regulation is defeated." *Borgner v. Fla. Bd. of Dentistry*, 537 U.S. 1080, 1080 (2002) (Thomas and Ginsburg, JJ., dissenting from denial of certiorari). Here, the value to the viewing public of the DTC Rule's highly misleading compelled speech is zero.

At all events, the government never has a legitimate reason to force a company to deliver misleading information about its products. *See Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 967 (9th Cir. 2009), *aff'd sub nom. Brown v. Entm't Merchants Ass'n*, 564

U.S. 786 (2011); *see also R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1216 (D.C. Cir. 2012) (a compelled disclosure fails First Amendment scrutiny if it "could be misinterpreted by consumers"), *overruled on other grounds by Am. Meat Inst.*, 760 F.3d 18.

The DTC Rule's compelled-speech mandate thus constitutes a significant constitutional and commercial harm. It would be ironic indeed if the government could transform *Zauderer*, a First Amendment case concerned with correcting false or misleading speech, into a justification for foisting false or misleading speech onto the public. But that is precisely what HHS asks this Court to let it do.

If HHS is concerned about deceptive marketing, it can address that concern through enforcement actions against manufacturers that make misleading claims. But that concern does not justify a Rule compelling speech more likely to mislead than to inform consumers about the costs they can expect to pay for their prescription drugs.

As the district court's decision makes clear, by rejecting HHS's construction of the scope of the agency's authority under the Social Security Act, courts can avoid reaching the DTC Rule's glaring First Amendment problem. But if this Court were to agree with that

construction, it should confront the First Amendment question in the first instance. The free-speech implications of the Rule are too troubling, and the First Amendment's protections too vital, to postpone reaching the issue any longer.

CONCLUSION

The judgment of the district court should be affirmed.

November 19, 2019 Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify:

(i) That this brief complies with the page limit set forth in Circuit Rule 29-2(c)(2). It contains 4,066 words.

(ii) That this brief complies with the format, typeface, and type-style requirements of Fed. R. App. P. 32(a)(4)-(6) because it has been prepared using Microsoft Office Word 2016 and is set in 14-point Century Schoolbook font.

November 19, 2019

/s/ Cory L. Andrews

CERTIFICATE OF SERVICE

I certify that on November 19, 2019, I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. All participants in the case are CM/ECF users so service will be accomplished by the appellate CM/ECF system.

/s/ Cory L. Andrews