ORAL ARGUMENT SCHEDULED FOR MONDAY, JANUARY 13, 2020

No. 19-5222

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

MERCK & CO., INC., et al.,

Plaintiffs-Appellees,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Columbia, Case No. 19-cv-01738

BRIEF OF CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

Daryl L. Joseffer
Jonathan Urick
U.S. CHAMBER LITIGATION CENTER
1615 H Street, NW
Washington, DC 20062
Telephone: (202) 463-5337
Email: djoseffer@uschamber.com

Jeffrey S. Bucholtz
Joel McElvain
I. Cason Hewgley IV
KING & SPALDING, LLP
1700 Pennsylvania Ave., NW
Washington, D.C. 20006
Telephone: (202) 737-0500
Email: jbucholtz@kslaw.com
Email: jmcelvain@kslaw.com
Email: chewgley@kslaw.com

Counsel for Amicus Curiae

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Parties and Amici Curiae. All parties, intervenors, and *amici curiae* appearing before this Court are listed in the Brief of Appellees, except for the Chamber of Commerce of the United States of America, which is *amicus curiae* in support of Appellees.

Rulings Under Review. An accurate reference to the rulings at issue appears in the Brief of Appellants.

Related Cases. As stated in the Brief of Appellees, this case has not previously come before this Court or any other, and there are no related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

Dated: November 19, 2019

CERTIFICATE PURSUANT TO CIRCUIT RULE 29(d)

In accordance with Circuit Rule 29(d), undersigned counsel for the Chamber of Commerce of the United States of America (the "Chamber") represent that the other *amici curiae* supporting Appellees of which we are aware are the Washington Legal Foundation, the Goldwater Institute, the National Association of Broadcasters, NCTA – The Internet & Television Association, and the Cato Institute.

Uniquely among the *amici* supporting Appellees, the Chamber represents the interests of businesses across every sector of the nation's economy that are regulated by the entire spectrum of regulatory agencies. The Chamber is the world's largest business federation, representing 300,000 direct members and indirectly representing the interests of more than three million businesses and organizations. Because many agencies operate under generalized grants of rulemaking authority similar to those relied on by CMS here, the importance of this case extends far beyond the CMS rule at issue. By virtue of the Chamber's economy-wide member base—including both sellers and purchasers of prescription drugs—the Chamber believes it has a unique perspective that will aid the Court.

CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America is a not-for-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent company, and no publicly held company has 10% or greater ownership in the Chamber.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Other Authorities

GLOSSARY

CMS	Centers for Medicare and Medicaid Services
FDA	Food and Drug Administration
FICA	Federal Insurance Contributions Act
HHS	Department of Health and Human Services
IRS	Internal Revenue Service
The Secretary	Secretary of Health and Human Services
SNAP	Supplemental Nutritional Assistance Program
TSA	Transportation Security Administration
WAC	Wholesale Acquisition Cost

STATEMENT OF IDENTIFICATION OF AMICUS CURIAE, ITS INTEREST IN THIS CASE, AND ITS AUTHORITY TO FILE

The Chamber is the world's largest business federation. For more than 100 years, it has represented American businesses of every size, in every sector of the economy, and from every region of this country. The Chamber represents 300,000 direct members and indirectly represents the interests of 3 million businesses and trade and professional organizations. An important function of the Chamber is to represent the interests of its members before Congress, the Executive Branch, and the courts. For this reason, the Chamber often files *amicus curiae* briefs in cases that involve issues of significant importance to the business community.

This is such a case because, if CMS's view of its regulatory power were accepted, it is difficult to see where it would end. CMS would leverage its authority to promulgate regulations for the efficient administration of the Medicare and Medicaid programs into a blank check to regulate health care writ large. And because many other administrative agencies have similar rulemaking authority, CMS's approach would have startling implications across the economy.

Counsel for all parties to this appeal have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no one other than *amicus*, its members, or its counsel contributed money that was intended to fund the preparation or submission of this brief.

SUMMARY OF THE ARGUMENT

In requiring pharmaceutical manufacturers to state the wholesale acquisition cost (or "WAC") for drugs in TV ads, CMS was candid about what it hoped to accomplish: driving down drug prices. The problem is that Congress has given CMS no authority to regulate either drug prices or TV ads. CMS, after all, does not "administer" the national health care market.

But CMS was determined to "do something" about drug prices. So it invoked the authority Congress *has* given it: to promulgate regulations for the efficient administration of the Medicare and Medicaid programs. The simple reality, however, is that as a matter of plain English TV ads for drugs have nothing to do with the efficiency of CMS's administration of those programs.

CMS nonetheless argues that requiring TV ads to state drugs' WAC will lead manufacturers to reduce their drugs' WAC and, as a result, will reduce Medicare and Medicaid expenditures. That prediction is highly questionable on its own terms. But more fundamentally, promoting "efficient markets[] for drugs funded through those programs"—CMS's goal, in its own words, *see* Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency, 83 Fed. Reg. 52,789, 52,791 (Oct. 18, 2018)—is not at all the same thing as administering those programs themselves. Regulating the primary conduct of pharmaceutical manufacturers in their communications with patients simply cannot be reimagined as administering federal health care programs. As the District Court explained, nothing in the statute authorizes the agency, "in the name of attempting to reduce the costs [of federal health expenditures], to regulate the health care market itself or market actors that are not direct participants in" Medicare or Medicaid. Op. 15.

In fact, CMS's brief gives away the game. Its opening line is: "The nation is experiencing a crisis of prescription drug costs." CMS Br. 1. Doing something to reduce drug prices is therefore necessary, in CMS's view. But Congress did not give CMS authority to take any action it

might find to be "necessary" in the abstract or even to take any action that might in some sense be said to "relate to" the "purposes" of the Social Security Act. *See* CMS Br. 2. Whatever one might think of the "necessity" *vel non* of disclosing WAC in TV ads, this rule is authorized by statute only if disclosing WAC in TV ads is "necessary to the efficient administration of the functions with which" Congress charged the Secretary, 42 U.S.C. § 1302(a), or "necessary to carry out the administration of the [Medicare] insurance programs," *id.* § 1395hh(a)(1). As the District Court explained, it is not. Op. 12-13.

Because agencies have no power other than what Congress has delegated, the above plain-text analysis should end this case. If any doubt remained, however, the "major questions" doctrine and the canon of constitutional avoidance would resolve it. For CMS to move from running Medicare and Medicaid to regulating the health care market writ large would be a quantum leap, with enormous ramifications for our country.

If CMS's theory were accepted, it is difficult to see where CMS's authority would end. Banning smoking and sweets or mandating exercise, for example, would certainly reduce health care costs in general,

resulting in savings for Medicare and Medicaid. And because many other administrative agencies operate under similarly generalized grants of rulemaking authority, accepting CMS's interpretation would invite other agencies to roam into new areas and assert new powers that Congress did not intend. *See infra* at 22-24.

It defies belief to suggest that Congress would have simply punted such a monumental question to CMS, leaving it to CMS to decide in its own discretion whether to regulate the overall health care market with no guidance from Congress—if Congress even could do so consistent with the constitutional rule against unbounded delegations of legislative power. As a matter of common sense, there is an obvious reason why it did not cross CMS's mind for decades that it might be able to assert the power it asserted here: CMS does not have such a power.

In short, this is a case of blatant executive overreach. The Court should affirm the District Court's judgment.

ARGUMENT

CMS, an agency charged with administering federal health insurance programs, has asserted the authority to regulate the content of TV ads. It's as illegal as it is strange.

The rule at issue requires ads to communicate the wholesale acquisition cost, or WAC, for a 30-day supply of drugs costing more than $35 per month. *See* Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency, 84 Fed. Reg. 20,732 (May 10, 2019) (the "WAC Disclosure Rule"). The agency's statutory authority for this rulemaking is, ostensibly, Sections 1102(a) and 1871(a)(1) of the Social Security Act, 42 U.S.C. §§ 1302(a), 1395hh(a)(1), which empower the Secretary of Health and Human Services to issue such regulations "as may be necessary to the efficient administration of [his] functions" under the Act, and "as may be necessary to carry out the administration" of the Medicare "insurance programs." The WAC Disclosure Rule, so the argument goes, will lower drug costs, thereby "improv[ing] market efficiency," 84 Fed. Reg. at 20,735, with the collateral result being savings in federal expenditures under the Medicare and Medicaid programs.

The Social Security Act cannot plausibly be read to countenance such a novel expansion of the agency's regulatory authority. When "determining whether the agency's interpretation is permissible or instead is foreclosed by the statute, we must employ all the tools of statutory interpretation, including 'text, structure, purpose, and

legislative history.'" *Loving v. IRS*, 742 F.3d 1013, 1016 (D.C. Cir. 2014) (quoting *Pharmaceutical Research & Manufacturers of America v. Thompson*, 251 F.3d 219, 224 (D.C. Cir. 2001)). "No matter how it is framed, the question a court faces when confronted with an agency's interpretation of a statute it administers is always, simply, *whether the agency has stayed within the bounds of its statutory authority*." *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013).

In light of these standards, the WAC Disclosure Rule is unlawful. Administrative agencies like CMS cannot issue rules without the statutory authority to do so, and the general grant of authority to the agency to "administer" federal health care programs cannot plausibly be read to give CMS the power to regulate private transactions in the health care market simply because the agency believes that doing so would improve the functioning of that market.

I. CMS unambiguously lacks the authority of "administration" over the private health care market.

As CMS concedes in the preamble to the WAC Disclosure Rule, "Congress has not explicitly provided HHS with authority to compel the disclosure of list prices to the public." 83 Fed. Reg. at 52,791. This poses a problem for the agency, because it "literally has no power to act . . .

unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986); *accord City of Arlington*, 569 U.S. at 291.

Unable to find an on-point grant of authority, CMS seized instead on two provisions in which Congress gave it the authority to issue regulations needed to administer the Medicare and Medicaid programs. *See* 42 U.S.C. §§ 1302(a) (authorizing rules "necessary to the efficient administration of the functions with which" the Secretary is charged under the Social Security Act), 1395hh(a)(1) (authorizing rules "necessary to carry out the administration of the insurance programs under [Medicare]"). In the agency's view, because the statute does not say that CMS cannot regulate TV ads for drugs, CMS may do so. But agency authority requires affirmative authorization—not a double negative.

The Social Security Act cannot plausibly be read to grant CMS this power. The Act does not give CMS the power of "administration" over the health care market in general; instead, the agency has the power to administer the federal health insurance programs that are under its purview. In this context, "administration" means "the management of

any office, business, or organization," Random House Unabridged Dictionary (2019), or "the management or performance of the executive duties of a government, institution, or business," Black's Law Dictionary (11th ed. 2019). As the District Court put it, "[t]he word thus conveys the types of actions that are directed toward controlling the operation of something over which a person has executive authority." Op. 13.

CMS may use Sections 1302 and 1395 to impose rules that it needs to perform its own duties in running Medicare and Medicaid. For example, reimbursement to health care providers may turn on the average sales price of a drug. To administer the program, CMS thus needs to know what that average sales price is. And so the agency may use its general rulemaking authority to prescribe standards for the reporting of that information. *See, e.g.*, 42 U.S.C. § 1395w-3a(f) (requiring such reporting).

But CMS has not contended, and could not contend, that it issued the WAC Disclosure Rule to assist it in the performance of its own duties under the Medicare or Medicaid programs. CMS asserts instead that the rule will "enable consumers to make good health care choices," 84 Fed. Reg. at 20,735, which will "improve market efficiency," *id.*, and hence

"improve the efficiency of the Medicare and Medicaid programs," *id.* Congress, however, has not given CMS authority to regulate consumers' health care choices or to try to improve the efficiency of the health care market as a general matter. Section 1302 or Section 1395, by their plain text, give CMS much more limited authority. That CMS runs Medicare and Medicaid does not mean that CMS has the power to run the national health care market as a whole.

Nor does any other provision of the Social Security Act give CMS the power to regulate prices in the private health care market, let alone to do so by compelling speech by certain participants in that market. To the contrary, when the Act addresses the relationship between the agency and the private market, it takes care to clarify that CMS's powers do not extend so far as to allow it to regulate primary conduct. *See* 42 U.S.C. §§ 1395 ("Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the

administration or operation of any such institution, agency, or person."); § 1395w-111(i)(1) ("the Secretary—(1) may not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs."). CMS should not be permitted to use Sections 1302 and 1395 to create a power for itself that Congress has carefully withheld. *See Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 86, 90 (2002) (agency may not invoke its authority to "carry out" a statute to "alter" its powers "in a fundamental way").

Nor may CMS grant itself that authority simply by positing that regulating TV ads for drugs might lead to lower list prices or lower drug utilization and, in turn, to lower Medicare and Medicaid expenditures. "[A]lthough agency determinations within the scope of delegated authority are entitled to deference, it is fundamental that an agency may not bootstrap itself into an area in which it has no jurisdiction." *Smith v. Berryhill*, 139 S. Ct. 1765, 1778 (2019) (internal quotation omitted). CMS has "executive authority," Op. 13, over the Medicare and Medicaid programs themselves, not over price setting in the private market. The

truism that everything is related to everything else is not a license to bootstrap authority to make rules needed to run Medicare and Medicaid—such as claims-processing rules or rules governing reimbursement methodologies—into executive authority to run the health care market writ large.

II. Fundamental interpretive principles confirm that the Social Security Act cannot be read to authorize this Rule.

If there were any doubt about the plain meaning of the Act, the "major questions" doctrine would resolve it. When regulating under general rulemaking authority, which this Court has referred to as an administrative "necessary and proper clause," agency action "must be 'reasonably ancillary' to other express provisions. . . . The reason for th[is] limitation[] is plain: Were an agency afforded *carte blanche* under such a broad provision . . . it would be able to expand greatly its regulatory reach." *Motion Picture Ass'n of Am., Inc. v. FCC*, 309 F.3d 796, 806 (D.C. Cir. 2002) (internal quotation marks omitted).

CMS's assertion of regulatory authority over TV drug advertising is a claim to a new substantive power that is completely different from, and cannot be considered ancillary to, its authority to administer Medicare and Medicaid. Although the government now (for the first time

on appeal) claims *Chevron* deference for its new reading of Sections 1302 and 1395, *Chevron*'s central premise is that a statutory ambiguity or silence indicates that Congress intended to delegate to the agency the power to fill in the statutory gaps. *See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.* 467 U.S. 837, 844 (1984). But major questions of law and policy are not "gaps," so when it comes to such major questions, "there may be reason to hesitate before concluding that Congress has intended such an implicit delegation." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000). Then-Judge Kavanaugh explained the idea as follows:

> This major rules doctrine (usually called the major questions doctrine) is grounded in two overlapping and reinforcing presumptions: (i) a separation of powers-based presumption against the delegation of major lawmaking authority from Congress to the Executive Branch, and (ii) a presumption that Congress intends to make major policy decisions itself, not leave those decisions to agencies.

United States Telecom Ass'n v. FCC, 855 F.3d 381, 419 (D.C. Cir. 2017) (Kavanaugh, J., dissenting from denial of reh'g en banc) (citation omitted).

In these sorts of cases, courts apply the default rule that Congress does not "delegate a decision of such economic and political significance

to an agency" in a "cryptic . . . fashion." *Brown & Williamson*, 529 U.S. at 160. CMS's claim of authority to issue the WAC Disclosure Rule raises a question "of such economic and political significance" that it implicates the major questions doctrine. As CMS now reads its governing statutes, it may regulate any form of primary conduct of private actors in the health care industry, so long as the agency believes the regulation will lead to savings in federal health care expenditures.

If Congress had intended to grant such a fundamental power to the agency, "it surely would have done so expressly." *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015). So even if the Court considers the statute ambiguous on the question at issue (which it is not), no deference is warranted. *Id.* at 2490. And even if the scope of CMS's administrative powers might be fuzzy at the margins, the regulation of TV drug ads still unambiguously falls far beyond those bounds. *See United States v. Home Concrete & Supply, LLC*, 566 U.S. 478, 494 n.1 (2012) (Scalia, J., concurring) ("Whether a particular statute is ambiguous makes no difference . . . if the agency interpretation is clearly beyond the scope of any conceivable ambiguity."). No provision in the Social Security Act expressly gives CMS anything remotely resembling this power. What is

more, far from clearly demonstrating Congress's intent to grant CMS the power to regulate the national health care market itself, the statute provides multiple reasons to conclude the contrary.

A. CMS's claim to find an unheralded power in a long-extant statute should be treated with skepticism.

Courts are properly "skeptic[al]" when "an agency claims to discover in a long-extant statute an unheralded power" to issue major regulations like the WAC Disclosure Rule. *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014). As the Supreme Court has explained, "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); *cf. Printz v. United States*, 521 U.S. 898, 905 (1997) (reasoning that if an asserted government power would be "highly attractive" but nevertheless went long unused, "we would have reason to believe that the power was thought not to exist").

This Court has repeatedly rejected novel interpretations of old statutes when the interpretation seeks to expand an agency's authority.

See, e.g., District of Columbia v. Department of Labor, 819 F.3d 444, 446 (D.C. Cir. 2016) (rejecting Department of Labor's interpretation of Davis-Bacon Act, which regulates public works, to apply to construction of privately funded, owned, and operated buildings); *Loving*, 742 F.3d at 1021 (rejecting IRS's interpretation of a tax statute to authorize new regulation of hundreds of thousands of tax-return preparers); *Financial Planning Ass'n v. SEC*, 482 F.3d 481, 490 (D.C. Cir. 2007) ("an additional weakness" in SEC's interpretation was that it "flouts six decades of consistent SEC understanding of its authority under" the statute).

The novelty of CMS's reimagining of the scope of its rulemaking authority is unmistakable. Drug manufacturers are involved in Medicare and Medicaid in certain limited ways, such as by entering into agreements to provide rebates to certain parties as a condition for Medicaid coverage of some drugs. *See* 42 U.S.C. § 256b(a)(1). Apart from these discrete contacts, drug manufacturers are only indirectly connected to Medicare and Medicaid, given that those programs operate by reimbursing private parties who separately contract for drug coverage. The WAC Disclosure Rule, however, purports to impose a free-standing regulatory obligation on drug manufacturers.

Here, as in *Brown & Williamson*, the novelty of the agency's attempt "to regulate an industry consisting of a significant portion of the American economy," when it had never done so before, would be reason for pause even if the words of Sections 1302 or 1395, read in isolation from common sense, could be made to extend that far. CMS claims the authority to regulate any conduct that could plausibly affect health care expenses—merely because *some* health care expenses are paid for by programs that CMS administers. Given that health care accounts for a large portion of our economy, it's hard to imagine what this authority would not touch.

As Appellees explain, it defies common sense to suggest that Congress intended to delegate such broad authority so inconspicuously and with so little guidance. *See* Appellees' Br. 31-32. Indeed, the offense is to separation-of-powers principles as well as common sense: CMS's theory depends on the notion that Congress left it to the agency to regulate the health care market writ large however the agency sees fit. But a congressional punt of such an important question, with no guidance, would raise serious constitutional concerns under the nondelegation doctrine. *See Gundy v. United States*, 139 S. Ct. 2116,

2121 (2019) (plurality op.) (nondelegation doctrine "bars Congress from transferring its legislative power to another branch of Government"); *id.* at 2133 (Gorsuch, J., dissenting) (explaining invalidity of a statute that leaves an agency with "unbounded policy choices"). After all, the Supreme Court unanimously held that a statute enabling the executive to author a code of competition for the poultry industry was unconstitutional. *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 537-42 (1935). The stakes here, where CMS has claimed virtually unbounded control over one of the largest sectors of the American economy, are far higher.

The better course is to construe the statutes "to avoid, rather than to create, constitutional problems," *Allegheny Def. Project v. FERC*, 932 F.3d 940, 953 (D.C. Cir. 2019), by declining to endorse CMS's attempt to assume unbounded regulatory authority.

B. This Court should reject CMS's claim that it may regulate in any way that it chooses unless Congress has foreclosed it from acting.

In issuing the WAC Disclosure Rule, CMS demonstrated a fundamental misunderstanding of the scope of its delegated authority. Rather than attempting to locate a statutory basis that would

affirmatively authorize its rule, CMS reasoned that it could take any action that it believed would reduce health care expenditures so long as Congress has not *revoked* that authority. Sections 1302 and 1395, CMS asserted, "do not impose a limit on the means" the agency may use to "promote" the "responsible use of federal funds," 84 Fed. Reg. at 20,736, in the absence of any specific provision in the Social Security Act foreclosing the rule.

This gets the issue precisely backwards. The well-settled default rule is that "an agency literally has no power to act . . . unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n*, 476 U.S. at 374. And, in determining whether Congress has conferred such a power, a court must consider not only the goals that Congress has directed the agency to pursue but also the manner in which Congress has directed the agency to do so: "[W]e . . . 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." *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 231 n.4 (1994). This Court has repeatedly relied on these principles to reject agencies' attempts to aggrandize their authorities. *See, e.g., Mot. Picture Ass'n*, 309 F.3d at 805 ("The FCC's

position seems to be that the adoption of rules mandating video description is permissible because Congress did not expressly foreclose the possibility. This is an entirely untenable position."); *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1060 (D.C. Cir. 1995) ("Were courts to *presume* a delegation of power absent an express *withholding* of such power, agencies would enjoy virtually limitless hegemony, a result plainly out of keeping with *Chevron* . . . .").

Were the rule otherwise, and CMS had free rein to pursue what it takes to be the goals of the Medicare or Medicaid programs by any means it sees fit, there is no telling where CMS's asserted authority might end. *Gonzales v. Oregon* directs this Court to consider the future implications of the agency's asserted power. 546 U.S. 243, 268 (2006) ("Under the Government's theory, moreover, the medical judgments the Attorney General could make are not limited to physician-assisted suicide. Were this argument accepted, he could decide whether any particular drug may be used for any particular purpose, or indeed whether a physician who administers any controversial treatment could be deregistered."). CMS provides no satisfactory limiting principle for its theory of its statutory powers, and given the wide range of conduct that could possibly

affect the health care market in some tangential way, such a principle is not self-evident.[1]

For example, scientific studies suggest that eating vegetables is healthy and is associated with lower incidence of heart disease,[2] while eating too many candy bars would have essentially the opposite effect. If people ate more vegetables and fewer candy bars, health care costs would probably decrease. And if overall health care costs decreased, Medicare and Medicaid—as parts of the health care market—would probably see

---

[1] Indeed, CMS's recent actions suggest that its reliance on its expansive view of its own rulemaking power was not a one-off event. On November 15, 2019, CMS issued a final rule that relies on 42 U.S.C. § 1302(a) to require hospitals (whether or not they participate in Medicare or Medicaid) to disclose the prices they negotiate with private insurers for medical services that are *not* covered by Medicare or Medicaid. According to CMS, this rule is within its authority to administer Medicare and Medicaid because "there is a direct connection between transparency in hospital standard charge information and having more affordable healthcare and lower healthcare coverage costs," and having lower health care costs outside of Medicare and Medicaid will "promote the efficient administration of the Medicare and Medicaid programs." CMS, *Medicare and Medicaid Programs: Price Transparency Requirements for Hospitals to Make Standard Charges Public*, 84 Fed. Reg. — (to be published Nov. 27, 2019), https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-24931.pdf (p. 62 of the PDF).

[2] *See, e.g.*, Richard L. Pollack, *The effect of green leafy and cruciferous vegetable intake on the incidence of cardiovascular disease: A metaanalysis*, 5 JRSM Cardiovascular Disease 1 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4973479/#.

their costs reduced as well. So, under the authority asserted here, could CMS require manufacturers to affix a label on every candy bar that it might cause disease? Could CMS require a label on vegetables touting their health benefits? It is difficult to see how these labels—a form of compelled speech—are materially different than requiring disclosure of drug prices in ads. Nor, on CMS's rationale, would it have to stop there: CMS's expansive view of its authority would permit the agency to completely ban candy bars or to prohibit stores from selling candy bars unless the customer also buys vegetables. These measures, after all, could be expected to reduce health care costs, including Medicare and Medicaid costs, and neither is explicitly prohibited by the Social Security Act.

Nor would the authority asserted here be cabined even to the context of health care expenditures. Congress routinely uses language similar to that in 42 U.S.C. §§ 1302 and 1395 to describe the scope of the general rulemaking authority that it delegates to federal agencies. If CMS were to prevail here, other agencies could follow its lead to claim that their general rulemaking authority empowers them to regulate primary conduct in novel and surprising ways:

- Congress has accorded the Commissioner of Social Security the power to prescribe rules as he "determines necessary or appropriate to carry out the functions of the Administration." 42 U.S.C. § 902(a)(5). On CMS's theory here, given that the Social Security Trust Funds depend on taxes on income earned through wages, could the Commissioner order an increase in wages in the private market so as to increase the Administration's intake of FICA taxes?
- Similarly, under 7 U.S.C. § 2013(c), the Secretary of Agriculture may issue regulations that he "deems necessary or appropriate for the effective and efficient administration of the Supplemental Nutritional Assistance Program." On CMS's theory, given that SNAP funds are limited, could the Secretary regulate the price of groceries in an effort to increase the purchasing power of food stamps?
- Likewise, the Transportation Security Administration may issue "such regulations as are necessary to carry out the functions of the [TSA]." 49 U.S.C. § 114(l)(1). On CMS's theory, could TSA ban the sale of liquid containers larger than

> 3.4 ounces, on the theory that TSA agents could complete their searches more efficiently if these containers were taken off of the market?

Additional examples abound throughout the United States Code. And it is far from obvious that the answers to these questions would be "no" if CMS were to prevail here. So long as an agency could imagine some way in which a new regulation of primary conduct might further some purpose of the program it administers—and agencies have impressive imaginations when it comes to the breadth of their authority—a generally-worded grant of authority to administer that program would suffice.

C. CMS has no subject-matter expertise in regulating television advertisements.

That CMS has no expertise in television advertisements confirms yet further that Congress could not have meant for CMS to have the authority it sought to exercise in this Rule. When an area is outside an "agency's generally conferred authority," it is unlikely that Congress meant for it to "speak with the force of law" in that area. *See United States v. Mead Corp.*, 533 U.S. 218, 229 (2001).

In *King v. Burwell*, the Supreme Court declined to accord deference to the IRS's views on the availability of health insurance subsidies under the Affordable Care Act, noting that "it is especially unlikely that Congress would have delegated this decision to the *IRS*, which has no expertise in crafting health insurance policy of this sort." 135 S. Ct. at 2489. And in *Gonzales v. Oregon*, the Court refused to interpret the Controlled Substances Act to "cede medical judgments" to the Attorney General; the fact that the Attorney General "lacks medical expertise" confirmed that "[t]he idea that Congress gave the Attorney General such broad and unusual authority through an implicit delegation in the CSA's registration provision is not sustainable." 546 U.S. at 267. In both of these cases, the agency's lack of technical subject-matter expertise provided additional support to the Court's ultimate conclusion that Congress had not implicitly conveyed the claimed authority.

CMS has no expertise or experience regulating the advertisement of prescription drugs under the Social Security Act. Indeed, it appears never to have dawned on CMS that it might be able to assert such

authority until it issued this Rule.[3] Pharmaceutical advertising is regulated instead by FDA under the Food, Drug, and Cosmetic Act. *See* 21 U.S.C. § 321(n) (drugs are misbranded if "advertising" is "misleading"); *see also id.* §§ 331(n), 352(a), 352(n), 353(c). This context makes it clear that Congress knows how to grant authority to regulate drug advertising—and confirms that such authority is important enough to warrant actually mentioning rather than leaving agencies to try to locate it in a generalized administration provision where it supposedly had slumbered unnoticed for decades.

FDA, for its part, has long recognized that it is not empowered to compel price disclosures—which is why HHS had to execute a surprise pivot here and have this Rule come from CMS, despite CMS's lack of relevant expertise. *See* Reminder Labeling and Reminder Advertisements for Prescription Drugs, 40 Fed. Reg. 58,794, 58,794 (Dec. 18, 1975) ("[The] decision to engage in public disclosure of prescription

[3] It is likely a consequence of CMS's lack of expertise in this area that the agency proceeded with its compelled-speech rule without adequately considering the serious First Amendment difficulties the rule poses. *See* Appellees' Br. 41-55. Reading Sections 1302 and 1395 in accordance with their plain meaning also has the virtue of avoiding this additional constitutional problem raised by CMS's interpretation.

drug prices is not for the Food and Drug Administration to make."). And, lately, there have been proposed amendments that would expressly authorize HHS to regulate in this area. *See* S. Amend. No. 3964, 164 Cong. Rec. S5871, S5904, 115th Cong. 2d Sess. (daily ed. Aug. 23, 2018); S. 1437, 165 Cong. Rec. S2775, S2791, 116th Cong. 1st Sess. (daily ed. May 13, 2019). This context makes it exceedingly implausible that the Social Security Act has secretly provided CMS the authority to compel price disclosures all along.

CONCLUSION

This Court should affirm the judgment of the District Court.

Respectfully submitted,

/s/ Jeffrey S. Bucholtz

Jeffrey S. Bucholtz
Joel McElvain
I. Cason Hewgley IV
KING & SPALDING, LLP
1700 Pennsylvania Ave., NW
Washington, D.C. 20006
Telephone: (202) 737-0500
Email: jbucholtz@kslaw.com
Email: jmcelvain@kslaw.com
Email: chewgley@kslaw.com

Counsel for Amicus Curiae

Daryl L. Joseffer
Jonathan Urick
U.S. CHAMBER LITIGATION CENTER
1615 H Street, NW
Washington, DC 20062
Telephone: (202) 463-5337
Email: djoseffer@uschamber.com

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because, as determined by Microsoft Word 2013, it contains 5,630 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionately spaced typeface using Microsoft Word 2013 in 14-point Century Schoolbook font.

/s/ Jeffrey S. Bucholtz
Jeffrey S. Bucholtz
Attorney for Amicus

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing 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, which will effect service on all parties, on November 19, 2019.

/s/ Jeffrey S. Bucholtz
Jeffrey S. Bucholtz
Attorney for Amicus