Oral Argument Not Yet Scheduled

No. 19-5222

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

BRIEF OF *AMICUS CURIAE* NATIONAL ASSOCIATION OF BROADCASTERS IN SUPPORT OF APPELLEES

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PARTIES, RULINGS, AND RELATED CASES

Plaintiffs below, and appellees here, are Merck & Co., Inc.; Eli Lilly and Company; Amgen Inc.; and the National Association of Advertisers. Defendants below, and appellants here, are the United States Department of Health and Human Services and Alex M. Azar II in his official capacity as Secretary thereof, and the Centers for Medicaid & Medicaid Services and Seema Verma in her official capacity as Administrator thereof. The American Association of Retired Persons is *amicus curiae* in support of appellants. The National Association of Broadcasters ("NAB"), the Goldwater Institute, the Cato Institute, NCTA – The Internet and Television Association, and the U.S. Chamber of Commerce are *amici curiae* in support of appellees filing separate briefs.

Appellees seek affirmance of the United States District Court for the District of Columbia's July 8, 2019 opinion and order: *Merck & Co., Inc. v. U.S. Dep't of Health & Human Servs.*, 385 F. Supp. 3d 81 (D.D.C. 2019) (Mehta, J.) (J.A. __-__). NAB is not aware of any related cases.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Local Rule 26.1, *amicus curiae* makes the following disclosures regarding its corporate status: NAB is a nonprofit, nonpartisan corporation organized under Section 501(c)(6) of the

Internal Revenue Code. It does not have a parent corporation, does not issue stock, and no publicly held corporation has any form of ownership interest in it.

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

All parties have consented to the filing of this brief. NAB certifies that no party or party's counsel authored this brief in whole or in part, or contributed money intended to fund its preparation or submission. NAB also certifies that only it provided funds to prepare and submit this brief. Fed. R. App. P. 29(c)(5). Pursuant to D.C. Circuit Rule 29(d), NAB certifies that a separate brief is necessary to provide the perspective of the broadcast industry that is directly affected by the discriminatory rule under review.

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GLOSSARY OF ACRONYMS AND ABBREVIATIONS

APA	Administrative Procedure Act
CMS	Centers for Medicare & Medicaid Services
DTC	Direct-to-consumer
DTC Rule	42 C.F.R. § 403.1202
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
HHS	Department of Health and Human Services
HUD	Department of Housing and Urban Development
SSA	Social Security Act
WAC	Wholesale acquisition cost

STATUTES AND REGULATIONS AT ISSUE

All applicable statutes, etc., are contained in the Brief for Plaintiffs-Appellees.

INTEREST OF *AMICUS CURIAE*

NAB is a non-profit incorporated trade association representing television broadcasters across the United States. NAB advocates for its membership before Congress, the courts, the Federal Communications Commission ("FCC"), and other governmental entities. NAB's membership will be adversely affected if this Court disturbs the district court's correct and well-reasoned decision to set aside a recent Department of Health and Human Services ("HHS") regulation requiring disclosure of list prices in direct-to-consumer ("DTC") pharmaceutical advertising on television. *Merck & Co. v. United States Dep't of Health & Human Servs.*, 385 F. Supp. 3d 81 (D.D.C. 2019) (invalidating 42 C.F.R. § 403.1202 as *ultra vires*).

Specifically, HHS, via the Centers for Medicare & Medicaid Services ("CMS"), recently enacted a regulation (the "DTC Rule") requiring "[a]ny advertisement for any prescription drug or biological product on television" to "contain a textual statement indicating the current list price for a typical 30–day regimen or for a typical course of treatment." 42 C.F.R. § 403.1202. The "list price" is defined as "the wholesale acquisition cost" ("WAC"), which means "the manufacturer's list price for the prescription drug or biological product to wholesalers or direct purchasers . . . not including . . . discounts, rebates or reductions in price." 42 C.F.R. § 403.1201(c)-(d). HHS did not require this disclosure in other media. If this Court allows the rule to stand, NAB members

risk suffering injury if prescription drug manufacturers shift advertising spending from television to unregulated media.

SUMMARY OF ARGUMENT

The district court correctly held that regulation of DTC pharmaceutical advertising is outside the scope of HHS's authorizing statutes, which empower the agency to make rules relating to the "administration" of the Medicare and Medicaid programs. HHS's rulemaking authority pertains only to the operations of Medicaid and Medicare; the agency has no power to regulate private actors' commercial speech. Indeed, although HHS claims the required disclosures are modest, its conception of its power is effectively unbounded: it may regulate any economic activity with a derivative effect on health care costs covered by Medicare or Medicaid. Nothing in the Social Security Act ("SSA") vests HHS with such extraordinary powers—particularly not with regard to pharmaceutical prices. Congress specifically forbade HHS to set pharmaceutical prices or to interfere with price negotiations of pharmacy benefit managers and pharmaceutical companies under Part D of Medicare, preferring to leave price determination to private competition. Congress did not grant HHS the power to accomplish indirectly what it is forbidden to do directly.

Even if the scope of the authorizing statutes were ambiguous, that would not entitle HHS's interpretation to deference. To avoid First Amendment concerns,

this Court presumes Congress does not vaguely grant agencies the power to regulate speech; this canon trumps *Chevron* deference. Only a clearly stated authorization, which HHS acknowledges it lacks, could work as even a first step to justifying compelled speech.

The presumption is particularly important here because it would be strange for Congress to convey power to regulate drug advertising in a statute authorizing rulemaking for the administration of Medicare and Medicaid, and yet deny that power in authorizing other forms of drug advertising regulation under the Federal Food, Drug, and Cosmetic Act (FDCA). CMS, the agency to which the Secretary delegated the administration of the Medicare and Medicaid programs, has no expertise in the regulation of consumer behavior and commercial advertising. The DTC Rule reflects that lack of expertise. Far from promoting rational consumer choice about pharmaceuticals, it is likely to *mis*inform consumers and *counteract* the proven benefits of DTC pharmaceutical advertising—alleviation of underdiagnosed and undertreated conditions, improved doctor-patient communication, and consumer education. CMS did not even consider the economic ramifications of its discriminatory rule, giving no coherent reason (and none exists) to single out television platforms, despite receiving comments observing that multiple forms of media are identically situated in terms of the

stated purposes of the rule. Congress simply did not give HHS the power to regulate commercial speech through administration of Medicare and Medicaid.

ARGUMENT

I. THE DISTRICT COURT CORRECTLY HELD THAT THE RULE EXCEEDS THE AGENCY'S STATUTORY AUTHORITY

"It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988); *see also Motion Picture Ass'n of Am., Inc. v. F.C.C.* ("*MPAA*"), 309 F.3d 796, 801 (D.C. Cir. 2002) ("An agency may not promulgate even reasonable regulations that claim a force of law without delegated authority from Congress."). Therefore the Administrative Procedure Act ("APA") directs courts to "hold unlawful and set aside agency action . . . found to be . . . in excess of statutory jurisdiction." 5 § U.S.C. 706(2)(C). In so deciding courts apply the two-step *Chevron* test, first asking whether Congress spoke clearly about the agency's authority and only then, if the question remains ambiguous, deferring to reasonable interpretations of the ambiguity. *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984); *see also City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290 (2013) (two-step *Chevron* inquiry applies to agency jurisdiction questions). "The controlling principle of *Chevron* is that when the statute, viewed in light of its legislative history and the traditional tools of statutory construction, is ambiguous, the administering agency is entitled to make a

reasonable policy choice." *Wagner Seed Co. v. Bush*, 946 F.2d 918, 920 (D.C. Cir. 1991) (citation omitted).

HHS would derive authority to promulgate the rule from two SSA provisions. One directs the Secretary of HHS (among others) to make "such rules and regulations . . . as may be necessary to the efficient administration of [his] functions" under the SSA. 42 U.S.C. § 1302(a). The other more specifically directs the Secretary to "prescribe such regulations as may be necessary to carry out the administration of" Medicare and Medicaid. 42 U.S.C. § 1395hh(a)(1). Since these authorizing statutes are not ambiguous as to whether HHS has the power to regulate DTC pharmaceutical advertising, the district court's invalidation of the DTC Rule as *ultra vires* should be affirmed.

A. The Plain Meaning of "Administration" of Public Health Insurance Programs Excludes Regulation of Broadcast Speech

HHS jumbles together inapposite pre-*Chevron* precedent and unconvincing glosses on "efficient administration" in arguing that the SSA authorizes regulation of DTC pharmaceutical advertising. The announcement of the final rule, for example, declared it permissible at *Chevron* step one "because Congress did not directly speak to the question . . . and nothing in the text or structure of the Medicare statute prohibits" it. 84 Fed. Reg. 20,732, 20,737 (May 10, 2019); *see also* HHS Br. at 33 (claiming an agency with general-purpose authority may make all rules except those "Congress clearly disallowed").

This Court unequivocally rejects such a position. The "failure to negate regulation" in an area is not an "ambiguity that supports an implicit congressional delegation of authority to the agency" to regulate in that area. *Am. Bar Ass'n v. F.T.C.* ("*ABA*"), 430 F.3d 457, 468–69 (D.C. Cir. 2005). That is because "[w]ere 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* and quite likely with the Constitution as well." *Ethyl Corp. v. E.P.A.*, 51 F.3d 1053, 1060 (D.C. Cir. 1995) (emphases in original); *see also MPAA*, 309 F.3d at 805-6; Op. at 16 (J.A. __-__) ("An agency's general rulemaking authority plus statutory silence does not [] equal congressional authorization.").

The SSA's "efficient administration" language clearly limits the agency's authority to regulation directly related to Medicaid and Medicare operations—the provision of covered medical goods and services to beneficiaries. *See* Op. at 12-13 (J.A. __-__) (the term "administration" confers only the power to "control[] the operation of something over which a person has executive authority"). HHS strains to expand the term's meaning to sweep in economic policy more broadly, noting one dictionary's definition of "efficient" as "producing effectively at minimum . . . *expense*," HHS Br. at 25 (emphasis in original), and citing another to propose that "administration" plausibly "encompasses . . . all the actions . . . of a

government or state in the exercise of its duties," *id.* at 28 (citation omitted). But those definitions confirm that the agency's power is only to promulgate rules governing cost-effective performance of Medicare and Medicaid services by program actors; they do not suggest *carte blanche* to regulate private activity to reduce Medicare and Medicaid expenses.

HHS forgets, moreover, that at *Chevron* step one courts do not "examin[e] . . . statutory provisions in isolation" and that "[t]he meaning—or ambiguity—of certain words or phrases may only become evident when placed in context." *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132–33 (2000). In addition to being unable to regulate in explicit contravention of an authorizing statute, an agency may not regulate "inconsistent[ly] with the administrative structure that Congress enacted." *ETSI Pipeline Project v. Missouri*, 484 U.S. 495, 517 (1988). All the contextual and structural factors—including those HHS discusses—foreclose any inference that the power to "efficient[ly] administ[er[" Medicare and Medicaid encompasses compulsory price disclosures in DTC pharmaceutical advertising. As the district court pointed out, each existing piece of the administrative structure HHS cited to support its position in fact "concerns the day-to-day running and operation of Medicare and Medicaid" and "is directed in some way to a program participant or the program itself." Op. at 15 (J.A. __-__).

The same is true of HHS's citations on appeal. *See* HHS Br. at 26-27.[1] Legislation and regulation aimed at private drug companies, as HHS's brief also shows, *see id.* at 26-27, 32, are closely tethered to the administration of the Medicare and Medicaid programs. Thus pharmaceutical manufacturers must "offer . . . outpatient drugs for purchase at or below [an] applicable ceiling price," 42 U.S.C. § 256b(a)(1), and must "report *to the Secretary*" periodically on the prices of covered drugs, *id.* § 1396r-8(3)(A) (emphasis added); *see also* 42 C.F.R. § 414.806 (penalizing "misrepresentation in the reporting of [price] data" to HHS). All of the marketing regulations HHS cites reach the program operators themselves. *See, e.g.*, 42 C.F.R. § 422.2260 (defining "marketing" as "activities . . . [c]onducted by the [Medicare] organization").

The DTC Rule succumbs in any case to the well-established principle that an agency does not "possess[] plenary authority to act within a given area simply because Congress has endowed it with some authority to act in that area." *Ry. Labor Executives' Ass'n v. Nat'l Mediation Bd.*, 29 F.3d 655, 670 (D.C. Cir.), *as amended*, 38 F.3d 1224 (D.C. Cir. 1994) (en banc). HHS's claim of broad

[1] HHS cites a statute directing States "to assure that payments are consistent with efficiency, economy, and quality of care," 42 U.S.C. § 1396a(a)(30)(A); a statute allowing the Secretary to deem certain payments "grossly excessive or grossly deficient," *id.* § 1395u(b)(8); various provisions "aim[ing] to minimize waste in the Medicare and Medicaid programs," PBr. at 26; and various provisions "reflect[ing] a commitment to informing beneficiaries about their benefits," *id.* at 27. None of those concerns regulation of private economic activity.

authority to drive down pharmaceutical prices rings particularly hollow, as Congress specifically forbade the Secretary to set drug prices or interfere in the price negotiations between pharmacy benefit managers and pharmaceutical companies under Medicare Part D, which accounts for most Medicare prescription drug spending.[2] *See* 42 U.S.C. § 1395w-111(i). Congress instead developed an alternative scheme to rely on private competition. *See* Juliette Cubanski et al., *What is the Latest on Medicare Drug Price Negotiations?* (Oct. 17, 2019), https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/ ; *see also* John F. Wasik, *Why Medicare Can't Get the Lowest Drug prices*, Forbes (Aug. 10, 2018), https://www.forbes.com/sites/johnwasik/2018/08/10/why-medicare-cant-get-the-lowest-drug-prices/#7834bfdf302b . Whether the current scheme is working well or not, Congress surely did not give HHS roundabout powers to regulate extrinsic activity to accomplish indirectly something that Congress forbade it to regulate directly under Part D.

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[2] In 2016, Medicare spent $99.5 billion on prescription drugs under Part D (prescription drug coverage administered by private stand-alone drug plans and Medicare Advantage drug plans), and $29.1 billion under Part B (outpatient medical care). *See* Kaiser Family Foundation, "10 Essential Facts about Medicare and Prescription Drug Spending" (Jan. 29, 2019), *https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/*

As the district court also explained, *see* Op. at 20-22 (J.A. __-__), Congress's separate regulation of DTC pharmaceutical advertising in the FDCA hurts rather than helps HHS's position. Substantive provisions of the FDCA directly address misleading advertising and labeling, *see also* 21 U.S.C. §§ 321(n), 331(n), 352(a), 352(n), and the Secretary has authority to enforce those rules, *see id.* §§ 352(n), 371(a). Notably, when Congress authorized HHS to require preclearance of pharmaceutical DTC television advertising, it carefully limited HHS's authority to making recommendations on certain topics, and prohibited changes unless accompanied by a "determin[ation] that the advertisement would be false or misleading without a specific disclosure about a serious risk listed in the labeling of the drug involved" or the date of the drug's approval. *See* 21 U.S.C. § 353c(b), (c), (e). This suggests that Congress legislates specifically and with circumspection when authorizing entrenchment on commercial speech about prescription drugs—further evidence that SSA's "administration" cannot suddenly be taken to mean blanket authorization for such regulation.

Critically, the Food and Drug Administration ("FDA"), the expert subagency to which the Secretary delegated FDCA authority, has long declared that the FDCA did not confer the power to require drug pricing disclosures. *See Reminder Labeling and Reminder Advertisements for Prescription Drugs*, 40 Fed. Reg. 58,794, 58,794 (Dec. 18, 1975). It defies logic that Congress would grant explicit

but highly circumscribed authority under the FDCA to regulate pharmaceutical advertising (but not to compel pricing disclosures), and yet impliedly grant uncircumscribed authority to regulate all pharmaceutical advertising merely by authorizing the Secretary to administer Medicare and Medicaid. *See Federal Maritime Comm'n v. Seatrain Lines, Inc.*, 411 U.S. 726, 742-744 (1973) (rejecting agency's claim of authority to approve mergers and acquisitions because "when Congress meant to require agency approval for mergers and acquisitions" in other statutes "it did so unambiguously"). When Congress intends to authorize the regulation of DTC pharmaceutical advertising, "it knows how to do so." *Nat'l Rifle Ass'n of Am., Inc. v. Reno*, 216 F.3d 122, 127 (D.C. Cir. 2000); *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1626 (2018) (examples of explicit dispute resolution procedures in different statutes "is further evidence that Section 7 does nothing to address the question of class and collective actions").

The case law HHS cites does not support its reading of the scope of "administration." HHS relies on two pre-*Chevron* cases, *Mourning v. Family Publications Services, Inc.*, 411 U.S. 356 (1973), and *Thorpe v. Housing Authority of City of Durham*, 393 U.S. 268 (1969), claiming "the scope of the authority conferred on HHS by sections 1302(a) and 1395hh(a)(1) is informed, and in important respects controlled, by" those decisions. HHS Br. at 19-20. HHS believes those cases stand for the general proposition that "the validity of a

regulation promulgated thereunder will 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*, 393 U.S. at 280-81)). HHS then argues that reduced prescription drug costs are reasonably related to the SSA's purposes, and therefore the DTC Rule "comes within the scope of the agency's rulemaking authority." *Id.* at 22.

HHS misinterprets *Mourning* and *Thorpe*, conflating two distinct inquiries. The scope of the agency's regulatory power is a question of statutory interpretation under *Chevron*. The "reasonable relationship" test described in *Mourning* and *Thorpe* addresses whether a particular rule is a valid exercise of the power granted, and depends on the nature of the statutory grant.

Mourning approved Federal Reserve Board rules implementing the Truth in Lending Act, which among other things required disclosures of transactions involving finance charges. 411 U.S. at 361. The Board's authorization was to "prescribe regulations to carry out the purposes" of the Act, including "regulations necessary or proper . . . to prevent circumvention or evasion thereof." *Id.* at 361-62 (quoting 15 U.S.C. § 1604). The Board, recognizing creditors could disguise finance charges in a cash price, promulgated a rule requiring disclosure both of overt finance charges and charges payable over four installments. *Id.* at 362. The Supreme Court affirmed that the Board had statutory authority to promulgate the

rule under the Act's expansive grant of authority: "Congress was clearly aware that merchants could evade the reporting requirements of the Act by concealing credit charges. In delegating rulemaking authority to the Board, *Congress emphasized the Board's authority to prevent such evasion*." *Id.* at 371 (emphasis added). "The language of the enabling provision preclude[d]" the Court from finding the rule outside of the Board's power. *Id.* Because "some remedial measure was authorized, the question remaining is whether the measure chosen is reasonably related to its objectives," and "where reasonable minds may differ as to *which of several remedial measures* should be chosen, courts should defer to the informed experience and judgment of the agency *to whom Congress delegated appropriate authority*." *Id.* at 371-72 (emphases added). Thus the Court, applying traditional tools of construction, first determined the Board was "delegated appropriate authority" to promulgate rules preventing evasion of the Act, and then applied a "reasonable relationship" test to find the particular measure a valid exercise of that power. *Mourning* does not suggest (as HHS contends) that the scope of an agency's power is anything reasonably related to legislative purpose.

HHS likewise misreads *Thorpe*, which approved Department of Housing and Urban Development ("HUD") notification requirements for local housing authorities conducting evictions. Congress had authorized HUD to "make . . . such rules and regulations as may be necessary to carry out" the Housing Act. 42

U.S.C. § 1408 (Supp. III 1964). The Court first found that HUD had statutory authority to promulgate the rule, finding untenable "the contention that the [rule] violates the congressional policy of allowing local authorities to retain maximum control over the administration of federally financed housing projects …." 393 U.S. at 278. After rejecting the authority's additional argument that the rule violated the Due Process Clause, the Supreme Court held that "the only remaining inquiry is whether it is reasonably related to the purposes of the enabling legislation under which it was promulgated." *Id.* at 280-21. The Court found that an eviction notification requirement easily fit the Act's purpose of providing housing assistance to families in need. *Id.* at 281. There was no question of HUD's statutory authority to promulgate procedural rules for eviction; the reasonable-relationship test pertained only to whether the particular rule was a valid exercise of that power. *Thorpe* thus provides no support for HHS's attempt to bootstrap the SSA's limited authorization to promulgate rules for the "administration" of Medicare and Medicaid into a broad authority to regulate pharmaceutical advertising.[3] Nothing in the SSA confers *carte blanche* upon HHS

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[3] HHS cites one recent case from this Court, *Doe, 1 v. Fed. Election Comm'n*, 920 F.3d 866 (D.C. Cir. 2019), that it alleges proves the vitality of its interpretation of *Mourning* and *Thorpe*. *Doe, 1* examined an attempt to enjoin the Federal Election Commission from releasing information identifying a trust and trustee found to have misreported campaign contributions. There this Court mentioned *Mourning* in rejecting "[p]laintiffs' theory . . . that [the Federal Election Campaign Act's]

to regulate any sector of the economy plausibly linkable to the costs of the program administered.

B. HHS's Interpretation of the Scope of "Efficient Administration" Is Unlawfully Expansive

Deference at *Chevron* step two "is premised on the theory that a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps." *Brown & Williamson*, 529 U.S. at 159. But it is well-established that at *Chevron* step one courts should "hesitate before concluding that Congress [] intended such an implicit delegation" where an agency precipitously "assert[s] jurisdiction to regulate . . . a significant portion of the American economy." *Id*; *see also Util. Air Regulatory Grp. v. E.P.A.*, 573 U.S. 302, 324 (2014) (agency may not "bring about an enormous and transformative expansion in [its] regulatory authority without clear congressional authorization"); *MCI Telecomm. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994) (power of agency to "modify [] requirement[s]" used to administer statute did not give it

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specification of what the Commission is required to disclose deprives the Commission of authority to disclose anything else." *Id.* at 870. But the circumstances of *Doe, 1* reveal that (much like *Mourning* and *Thorpe*) it is entirely inapposite to justify the jurisdictional expansionism HHS claims here. The Commission was implementing a statute that "affirmatively and unambiguously provide[d] for" disclosing the results of investigations. *See id.* at 869-70. It was *not* creating a wholly novel disclosure obligation justified solely by a broad "all rules necessary and proper" or "efficient administration" type of authorizing statute.

"authority to make [] basic and fundamental changes in the scheme"). The risk of such "attempted turf expansion" via regulation, *ABA*, 430 F.3d at 467, is why "[a]gency authority may not be lightly presumed," *Michigan v. E.P.A.*, 268 F.3d 1075, 1082 (D.C. Cir. 2001). So too here. HHS's interpretation of "administration" arrogates itself vast powers to regulate any aspect of industry not specifically barred from its jurisdiction by Congress so long as there are arguable spillover effects on Medicare and Medicaid costs. This theory would ostensibly permit the agency to regulate doctors' private fees or malpractice insurance, or even fast food advertising, because of potential derivative effects on public health insurance spending. *See Gonzales v. Oregon*, 546 U.S. 243, 262–63 (2006) (rejecting logically "unrestrained" agency interpretation of mandate that would "claim[] extraordinary authority").

HHS, as one might expect, does not believe the slope to be so slippery. *See* HHS Br. at 40. But it presents no creditable argument as to limiting principles. First, HHS attempts to distinguish this case from *Brown & Williamson* (FDA lacks power to regulate tobacco products) and *Utility Air Regulatory Group* (Clean Air Act does not authorize EPA to regulate greenhouse gases). Unlike those cases, HHS claims, this one "does not involve policy initiatives of vast economic and political significance." HHS Br. at 40. That qualification does not exactly gel with the agency's explanation of the need for the rule—the "crisis of prescription drug

costs" "rising at rates greater than inflation with no end in sight" and "threaten[ing] Medicare and Medicaid's sustainability." HHS Br. at 1. This Court should not expect an agency anticipating an insolvency "crisis" for major social programs to limit itself to regulating at the margins. Regardless, the question is not whether this particular rule is modest (and it is not). The question is the scope of the power HHS claims to justify that rule: it claims any rule that reduces health-care costs is "reasonably related" to Medicare and Medicaid administration, no matter the *activity* regulated. The upshot is that HHS may regulate any economic activity in pursuit of "keep[ing] Medicare and Medicaid costs low." HHS Br. at 16.

HHS underlines the alleged "[in]significance" of the rule's anticipated cost to pharmaceutical companies—"a pittance compared to" what they spend on advertising. HHS Br. at 41. But that too is the wrong question. The measure of a regulation's overreach per *Brown & Williamson* and its progeny is not exclusively the financial significance of the particular rule. It is the breadth and tenuousness of the newly claimed authority.

This Court's decision in *Loving v. I.R.S*, 742 F.3d 1013 (D.C. Cir. 2014) (Kavanaugh, J.), is illustrative. In *Loving* tax preparers challenged an IRS regulation requiring they pass a qualifying exam, pay an annual fee, and take continuing education courses. This Court affirmed an injunction against the rule, holding that IRS's statutory authorization to "regulate the practice of

representatives of persons before the Department of the Treasury" did not extend to tax preparers. The Court deemed the regulation invalid at *Chevron* step one despite finding that the "exact scope" of the terms "practice . . . before" and "represent" might "var[y] depending on the context." *Id.* at 1017-1018. Under the agency's construction it "would be empowered for the first time to regulate hundreds of thousands of individuals in the multi-billion dollar tax-preparation industry" even though "nothing in the statute's text or the legislative record contemplates that vast expansion of the IRS's authority." *Id.* at 1021. Therefore the *Brown & Williamson* framework applied, as the Court was "confident that . . . Congress did not intend to grow such a large elephant in such a small mousehole." *Id.* (referencing *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress does not alter the fundamental details of a regulatory scheme in vague or ancillary provisions—it does not . . . hide elephants in mouseholes.")). Notably, the *Loving* Court did not propose that the new regulations would force any persons or firms (let alone any whole industry) out of business. The "vast economic and political significance" was baked into the jurisdictional expansion. HHS's incursion into television speech is analogously improper: "if accepted it would virtually free the [agency] from its congressional tether." *Comcast Corp. v. F.C.C.*, 600 F.3d 642, 655 (D.C. Cir. 2010); *see also Am. Library Ass'n v. F.C.C.*,

406 F.3d 689, 703 (D.C. Cir. 2005) (APA review must "impose[ ] meaningful limits on the scope of the [agency's] general jurisdictional grant").

HHS suggests its authority would remain limited by the "arbitrary and capricious" standard of review of the APA itself. HHS Br. at 42-43. But agencies do not have a free hand to regulate so long as they do not do so arbitrarily, and this restriction (applicable to all agencies) does not speak to whether agencies have overstepped the authority delegated by Congress. And HHS's final suggestion—that there are already limiting principles in specific statutory prohibitions (for example, forbidding interference with doctors' prescribing decisions), *see* HHS Br. at 43—merely highlights the problem. There HHS essentially admits it considers itself empowered to regulate in any area plausibly linked to prescription drug prices "absent an express withholding of such power," *Ethyl Corp.*, 51 F.3d at 1060 (emphasis removed), a proposition this Court has squarely foreclosed.

II. NO CLEAR STATEMENT FROM CONGRESS AUTHORIZES THE AGENCY'S COERCION OF PRIVATE SPEECH

A. Congress Is Presumed Not to Grant the Power to Regulate Speech by Implication

Even accepting, *arguendo*, HHS's proposition that the scope of "efficient administration" vis-à-vis DTC advertising is ambiguous, the agency's interpretation still would not deserve deference. Because of the importance of First Amendment protections, and the rarity of any adequate nexus between speech

restriction (or compulsion) and legitimate governmental interest, *see*, *e.g.*, *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 578–79 (2011) (state's attempt "to tilt public debate in a preferred direction" by controlling pharmaceutical marketing was unconstitutional); *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2377 (2018) (invalidating a "government-scripted, speaker-based disclosure requirement . . . wholly disconnected from [the government's] informational interest"), courts do not readily infer that Congress grants administrative agencies the power to regulate speech.

Accordingly, Congress cannot be deemed implicitly to authorize infringements on private speech via a general grant of rulemaking authority. It may only bestow that power expressly, as this Court's ruling in *MPAA* illustrates. There the FCC promulgated mandatory video description rules under the all-purpose Section 1 authorization of the Communications Act. 47 U.S.C. § 151 (empowering FCC to "execute and enforce the provisions" of the Act "for the purposes of regulating . . . commerce in communication"). This Court set the rules aside, noting that the agency's attempt to link them to the statutory authorization "completely ignore[d] the fact that [the] regulations significantly implicate [television] program content." *MPAA*, 309 F.3d at 803. As this Court then explained, "[t]o avoid potential First Amendment issues, the very general provisions of" the FCC authorizing statute "have not been construed to . . .

authorize the FCC to regulate program content. Rather, Congress has been scrupulously clear when it intends to delegate authority to the FCC to address areas significantly implicating program content." *Id.* at 805; *see also Turner Broad. Sys., Inc. v. F.C.C.*, 512 U.S. 622, 651 (1994) (explaining the presumption "that Government regulation over the content of broadcast programming must be narrow"); *F.C.C. v. League of Women Voters of California*, 468 U.S. 364, 378 (1984) (because "broadcasters are engaged in a vital and independent form of communicative activity . . . the First Amendment must inform and give shape to the manner in which Congress exercises its regulatory power in this area").

Thus even the FCC, whose core jurisdiction *is* communications regulation, has only been allowed to regulate speech under specific authorization from Congress. *MPAA*, 309 F.3d at 805 (citing statutes). The same is true of the Federal Election Commission, whose regulatory bailiwick is inherently First Amendment-adjacent. *See, e.g.*, 52 U.S.C. §§ 30104(f)(2) (requiring disclosure to agency of information about electioneering expenditure), 30120 (requiring identifying disclosures and disclaimers in campaign advertising). Certainly, the same standard should govern HHS, which does *not* possess a general statutory authorization to regulate the marketplace of ideas.

B. Nothing in the SSA Overcomes the Presumption Against Implied Grants of Authority to Regulate Speech

The presumption is particularly important given HHS's strained theory that the power to regulate all DTC pharmaceutical advertising is implicit in SSA's directive to make rules for the efficient administration of Medicare and Medicaid. The SSA's delegated regulatory field is the administration of public social insurance programs; Congress would not have hidden a delegation to regulate private advertising to *all* pharmaceutical consumers in a statute that by definition applies only to government provision to a subset of them.

Congress understands that the Secretary delegated its FDCA authority to the FDA, and that the FDA is the agency within HHS with expertise in pharmaceutical advertising to consumers. Congress legislates against that backdrop. *See* 21 U.S.C. §§ 352(n) (requiring published advertisements to direct consumers to FDA's website), 379d-5 (HHS "shall issue guidance that describes Food and Drug Administration policy regarding the promotion, using the Internet (including social media), of medical products that are regulated by such Administration"); 393 ("[m]ission" of FDA includes "taking appropriate action on marketing of regulated products").

By contrast, Congress cannot be deemed to have conferred a broad power to regulate commercial speech simply by granting HHS the authority to make rules for the administration of Medicaid and Medicaid. Because marketing of

commercial speech is far afield from the administration of federal medical insurance programs, it is unsurprising that CMS, to which the Secretary has delegated authority to administer Medicare and Medicaid, has no expertise in DTC marketing. *Cf. King v. Burwell*, 135 S. Ct. 2480, 2489 (2015) (it was "especially unlikely that Congress would have delegated [a] decision [requiring] expertise in crafting health insurance policy" to the IRS).

The DTC Rule clearly reflects CMS's lack of expertise. First, the rule falls well short of improving rational economic choice by prescription drug consumers—indeed, the rule is likely to *mis*inform and confuse them, making them *less* likely to get needed medical care. The DTC Rule requires disclosure of the list price for wholesalers or direct purchasers, 42 C.F.R. §§ 403.1201(c)-(d), 403.1202, but because third-party payment arrangements mean consumers rarely pay the list price, there is no reasonable link between WAC and customer behavior. *See* Appellees' Br. 6-11. Indeed, CMS straightforwardly conceded (both in its notice and in the final rule) that it lacks any understanding of customer response to pharmaceutical pricing information:

> This rule may improve price transparency for consumers . . . On the other hand, consumers, intimidated and confused by high list prices, may be deterred from contacting their physicians about drugs or medical conditions. Consumers might believe they are being asked to pay the list price rather than a co-pay or co-insurance and wonder why they are paying so much when they already paid a premium for their drug plan. This could discourage patients from using beneficial medications, reduce access and potentially increase total cost of care.

83 Fed. Reg. at 52,797-52,798; *see also id.* at 52,789-52,790 (noting the possibility that ten customers "could get the exact same product and all ten could pay a different price"); 84 Fed. Reg. at 20,756.

Indeed, post-comment, having received no economic information on which to found its rule, CMS defended WAC as merely "the most commonly used benchmark" and "an important factor for determining the final price that patients will pay." 84 Fed. Reg. at 20,739. That does not explain as a matter of consumer behavior why the rule would be efficacious rather than counterproductive.

To the contrary, the rule threatens to reduce or eliminate the proven benefits of DTC pharmaceutical advertising, which raises awareness about medical conditions and treatment options, and spurs consumers to action. *See* FDA, *Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results* (Nov. 19, 2004) at 2 ("DTC advertisements prompted a sizable percentage of patients to seek additional information about the drug, the condition it treats, or health in general"); Frank Auton, *The Case for Advertising Pharmaceuticals Direct to Consumers*, 1(4) Future Med. Chem. 587 (2009) (benefits of DTC pharmaceutical advertising include decreasing undertreated and undiagnosed disease, improving patient compliance with treatment regimens, and improving doctor-patient relationships); C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or*

Toxic?, 36 Pharmacy & Therapeutics 669, 672-673 (2011) ("Most health care professionals seem to agree that DTC pharmaceutical advertising is beneficial because it promotes dialog with patients," "help[s] patients ask more thoughtful questions," and "[r]emoves the stigma associated with certain diseases"). HHS's regulation could deter DTC pharmaceutical advertising on television altogether, or at least confuse consumers and dissuade them from discussing treatment that seems prohibitively expensive.

CMS's lack of expertise in regulating communications, especially broadcasting, is manifest in the agency's indifference to the competitive effects of its rule. This further underscores why Congress cannot be deemed implicitly to have authorized general regulation of DTC advertising through the SSA. *Burwell*, 135 S. Ct. at 2489. In response to comments of NAB and others that singling out television was unfair and unjustifiable when the value of disclosure was not media-specific, CMS merely postulated that "[b]ecause of the value and return on investment related to DTC advertising, it is unlikely that adding the list price of pharmaceuticals to DTC television advertising will significantly affect the amount spent by that sector on television advertisements." 84 Fed. Reg. at 20,746 (footnotes omitted). With regard to the discriminatory treatment of television, CMS declared that "we want to apply this rule as narrowly as possible to achieve

our goal of promoting price transparency and reducing drug costs, with minimal burden on those providing the information." 84 Fed. Reg. at 20,748.

These responses are wholly inadequate. With regard to the first, CMS elsewhere contradicts its speculation that the DTC Rule is "unlikely" to "significantly affect" television spending on DTC advertising. *See id.* at 20,756 ("For some affected entities, this may mean substantially changing their advertising paradigm" and thus "may affect the number of televised DTC advertisements"). The second is simply an abdication. Sparing pharmaceutical companies from some burdens does not justify singling out television and ignoring the competitive effects of this discriminatory rule.

It is perverse to single out television as a platform, especially free over-the-air broadcasters, whose advertising revenues are uniquely linked to the efficient distribution of a public good. Television broadcasters rely primarily on advertising revenues to support local news and public affairs programming, including coverage of weather disasters and other emergencies. Both Congress and the Supreme Court recognize that broadcasters perform an important public service by delivering free information. *See, e.g., Turner*, 512 U.S. at 662-63 (discussing benefits of "free, over-the-air local broadcast television"); 47 U.S.C. § 521, notes (Congressional finding 12) ("Broadcast television programming [] supported by revenues generated from advertising . . . is otherwise free to those who own television sets

and do not require cable transmission to receive broadcast signals. There is a substantial governmental interest in promoting the continued availability of such free television programming, especially for viewers who are unable to afford other means of receiving programming."). Yet in its "anticipated effects" section, CMS does not even mention television broadcasting as an affected business, let alone attempt to assess the rule's impact on the targeted medium. *See* 84 Fed. Reg. at 20,755.

The DTC Rule interferes with the broadcast television industry's primary revenue source, threatening local stations' ability to provide important services to the public. Pharmaceutical manufacturers already spend around one-fourth of their advertising budgets on media other than television. 83 Fed. Reg. at 52,792. Faced with the prospect of altering advertisements to incorporate government-scripted messages they consider misleading to consumers, companies may well choose to reallocate marketing budgets to print, internet, or social media platforms. Broadcast television already competes with an ever-increasing array of other media for advertising dollars. By disincentivizing televised DTC pharmaceutical advertising, the rule threatens broadcast stations' leading source of revenue, contrary to important governmental interests asserted by Congress and upheld by the Supreme Court. Television should be able to compete on an equal footing for DTC pharmaceutical advertising revenue, and television viewers should not

arbitrarily receive weakened access to the public benefits of that advertising. Yet CMS considered none of that.

CMS has no expertise in consumer economic behavior, and no understanding of the communications industry or the competition therein for advertising dollars. Congress's authorization of rulemaking powers in the SSA relates to the administration of Medicare and Medicaid; it does not convey the power to regulate private economic activity and speech simply because they may have a derivative effect on Medicare and Medicaid costs.

CONCLUSION

This Court should affirm the judgment below.

Respectfully submitted,

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Stephen B. Kinnaird

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Dated: November 19, 2019

/s/ Stephen B. Kinnaird

Stephen B. Kinnaird