[ORAL ARGUMENT NOT SCHEDULED]

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

BRIEF FOR APPELLANTS

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici

Plaintiffs in district court, and appellees here, are Merck & Co., Inc.; Eli Lilly and Company; Amgen Inc.; and Association of National Advertisers, Inc.

Defendants in district court, and appellants here, are the United States Department of Health and Human Services; Alex M. Azar II, in his official capacity as Secretary, 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.

B. Rulings Under Review

Defendants-appellants seek review of the July 8, 2019 opinion and order of the United States District Court for the District of Columbia. *See Merck & Co., Inc. v. U.S. Dep't of Health & Human Servs.*, 385 F. Supp. 3d 81 (D.D.C. 2019) (Mehta, J.), reproduced at J.A. __-__.

C. Related Cases

The case on review has not previously been before this Court or any other court, save the district court where it originated. Counsel for the government is not aware of any related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

/s/ Joshua Revesz
Joshua Revesz

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GLOSSARY

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

INTRODUCTION

The nation is experiencing a crisis of prescription drug costs. Americans currently spend nearly $450 billion on prescription drugs each year, with the federal health insurance programs, Medicare and Medicaid, paying over half that amount. Those costs are rising at rates greater than inflation with no end in sight, and the problem is exacerbated by drug companies spending billions of dollars annually on direct-to-consumer television advertising, often on their most profitable products. Yet despite this deluge of marketing, patients remain ill-informed about the costs of prescription drugs and are therefore unable to make informed choices about the cost-effectiveness of available treatments. This lack of transparency threatens Medicare and Medicaid's sustainability and comes at the expense of American taxpayers.

As part of its efforts to mitigate this increasingly serious problem, the Department of Health and Human Services (HHS)—invoking its statutory authority to promote the efficient administration of the Medicare and Medicaid programs—issued a new rule that seeks to improve price transparency by requiring the disclosure of list prices in direct-to-consumer (DTC) television pharmaceutical advertisements. This rule (the "DTC rule") is based on the elementary principle that markets function better when they are more transparent, and that consumers generally make better decisions about the products they purchase when they have more information about how those products are priced.

Three major pharmaceutical companies and a trade association have sued HHS, claiming that the rule is unlawful. The district court, although acknowledging the severity of the policy problem, agreed with plaintiffs that HHS lacked statutory authority to promulgate this rule. That holding is wrong.

The Secretary issued the rule pursuant to his broad statutory authority to make rules "as may be necessary to the efficient administration" of the Medicare and Medicaid programs. 42 U.S.C. § 1302(a); *see id.* § 1395hh(a)(1). The Supreme Court has long held that, absent congressional intent to the contrary, regulations issued under such statutes will be sustained so long as they are "reasonably related" to the purposes of those statutes. *Mourning v. Family Publn's Serv., Inc.*, 411 U.S. 356, 369 (1973); *Thorpe v. Housing Auth. of City of Durham*, 393 U.S. 268, 280-81 (1969). The DTC rule does not contravene congressional intent and is reasonably related to promoting the efficient administration of the Medicare and Medicaid programs. HHS therefore had statutory authority to promulgate the rule.

The district court erred in concluding that the DTC rule is unrelated to the "efficient administration" of the Medicare and Medicaid programs. The court wrongly believed that drug manufacturers are not "direct participants" in the Medicare and Medicaid programs, even though those manufacturers must enter into contracts with HHS in order for their drugs to be eligible for coverage. The district court was additionally mistaken to conclude that some other, unidentified part of the Medicare or Medicaid statutes precluded HHS from acting, and that a different

statute, the Federal Food, Drug, and Cosmetic Act, limits the authority of HHS under the Medicare and Medicaid provisions of the Social Security Act. Finally, the district court erred in treating the DTC rule as an agency policy of vast economic and political significance to which more stringent standards of judicial review apply, given that the DTC rule will cost pharmaceutical companies only a tiny fraction of what they pay on television advertising.

STATEMENT OF JURISDICTION

Plaintiffs assert claims against HHS under the Administrative Procedure Act, 5 U.S.C. § 706. The jurisdiction of the district court was invoked under 28 U.S.C. § 1331. The district court entered a final order and judgment on July 8, 2019. J.A. __. The government filed a timely notice of appeal on August 21, 2019. J.A. __; *see* Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

Whether HHS has statutory authority to promulgate a rule requiring pharmaceutical companies whose drugs are covered by the Medicare or Medicaid programs to disclose the list prices of certain drugs to consumers in the companies' television advertisements.

PERTINENT STATUTES AND REGULATIONS

42 U.S.C. § 1302(a) provides: "The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services, respectively, shall make and publish such rules and regulations, not inconsistent with this chapter [*i.e.*, the Social

Security Act], as may be necessary to the efficient administration of the functions with which each is charged under this chapter."

42 U.S.C. § 1395hh(a)(1) provides in relevant part: "The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter [*i.e.*, Medicare]."

42 C.F.R. § 403.1202 provides in relevant part:

> Any advertisement for any prescription drug or biological product on television (including broadcast, cable, streaming, or satellite) must contain a textual statement indicating the current list price for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast, as follows: "The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different."

STATEMENT OF THE CASE

A. Statutory Background

1. As part of the Social Security Amendments of 1965, Congress created the Medicare program "[a]s a means of providing health care to the aged and disabled." *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 404 (1993); *see* 42 U.S.C. § 1395 *et seq.* The program reimburses medical providers for services that they supply to Medicare enrollees. 42 U.S.C. § 1395g(a); *see Good Samaritan Hosp.*, 508 U.S. at 404. Nearly all individuals over the age of 65, as well as certain disabled or sick individuals, are eligible for Medicare. 42 U.S.C. § 1395c.

The Medicare program assists enrolled individuals in defraying the cost of prescription drugs. Medicare part A provides insurance coverage for prescription drugs administered during inpatient hospital care, home healthcare, or hospice services. *See* 42 U.S.C. § 1395d. Medicare part B covers a limited number of outpatient prescription drugs, typically administered by doctors. *See id.* § 1395*l*. And Medicare part D, enacted in 2003, provides subsidized access to prescription drugs more generally. *See id.* § 1395w-101 *et seq.* For Parts B and D, Medicare beneficiaries generally have a deductible—an amount that must be paid for services before the insurance plan starts to pay. 84 Fed. Reg. 20,732, 20,740 (May 10, 2019) (J.A. __). And, for each drug purchased, Medicare beneficiaries generally must pay either a co-payment (a fixed dollar amount) or a coinsurance payment (a percentage of the drug's total cost). *Id.*

The Social Security Amendments of 1965 also created the Medicaid program "for the purpose of providing federal financial assistance to States that choose to reimburse certain costs of medical treatment for needy persons." *Harris v. McRae*, 448 U.S. 297, 301 (1980); *see* 42 U.S.C. § 1396 *et seq.* States enjoy flexibility to develop plans to implement the Medicaid statute and to provide healthcare services to covered populations. 42 U.S.C. § 1396a(a). But every State's plan must be approved by HHS. *Id.* § 1396a(b). As part of a State's Medicaid plan, a State may offer outpatient prescription drug coverage, although the precise coverage requirement and copayments vary by State. *Id.* § 1396d(a)(12).

Congress has given HHS broad authority to promulgate rules to implement the Medicaid and Medicare programs. 42 U.S.C. § 1302(a), applicable to both Medicare and Medicaid, authorizes the Secretary of HHS to "make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which each is charged under this chapter." And 42 U.S.C. § 1395hh(a)(1), applicable to Medicare, empowers the Secretary to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter."

2. HHS's Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs. As part of that responsibility, CMS enters into Medicaid drug rebate agreements with pharmaceutical manufacturers. Manufacturers must enter into those agreements in order for payment to be available under Medicaid and Medicare part B for covered outpatient drugs; the relevant agreements include a Medicaid drug rebate agreement, under which manufacturers pay rebates to States, and a program participation agreement under the "340B program," under which they must offer certain prices to that program's covered entities. *See* 42 U.S.C. §§ 256b(a)(1), 1396r-8(a); 42 C.F.R. §§ 447.501-.510. Manufacturers with these agreements also must report to HHS their average sales prices for certain drugs covered under Medicare part B. 42 U.S.C. §§ 1395w-3a(f), 1396r-8(b)(3); 42 C.F.R. §§ 414.800-.806. Under Medicare part D, in order for their brand name drugs to be covered, manufacturers must enter into a Medicare Coverage

Gap Discount Program Agreement under which they agree to pay discounts on those drugs to a subset of part D enrollees. 42 U.S.C. §§ 1395w-114a(a); 1395w-153; 42 C.F.R. §§ 423.2300-.2345. CMS disburses federal funds to cover the costs of services, including prescription drugs, provided under Medicare and Medicaid.

B. Rising Costs for Prescription Drugs

Over the past decade, the cost of prescription drugs "has increased dramatically, and prices are projected to continue to rise faster than overall health spending." 84 Fed. Reg. at 20,733 (J.A. __). Approximately thirty percent of those increased costs may be attributed to "changes in the composition of drugs prescribed towards higher price products or price increases for drugs." *Id.* (citing HHS, *Issue Brief: Observation on Trends in Prescription Drug Spending* (Mar. 8, 2016), https://go.usa.gov/xVmqn). As a result of these phenomena, drug expenditures are rising well in excess of general inflation. *Id.*

CMS is the nation's single largest drug payor. In 2016, CMS and its beneficiaries spent $174 billion on drugs covered under Medicare Parts B and D, and $64 billion on drugs covered under Medicaid. 83 Fed. Reg. 52,789, 52,792 (Oct. 18, 2018) (J.A. __). CMS spent approximately fifty-three percent of the total amount spent on prescription drugs in the United States that year. *Id.* And CMS's overall expenditures on drugs have increased at rates greater than inflation both in the aggregate and on a per-beneficiary basis. *Id.* These "spiraling drug costs" are "passed

on to federal healthcare program beneficiaries and American taxpayers more broadly." 84 Fed. Reg. at 20,733 (J.A. __).

C. The DTC Rule

In recent years, HHS has pursued a number of initiatives to help combat rising drug prices. The Food and Drug Administration (FDA) has worked to accelerate its approval of generic drugs. The approval of generic drugs in 2017 alone saved American consumers nearly $9 billion in 2017. HHS, *American Patients First: The Trump Administration Blueprint To Lower Drug Prices and Reduce Out-of-Pocket Costs* 18 (May 2018), https://go.usa.gov/xVEux. The FDA has also taken several steps to encourage generic drug development, including publishing the names of drugs with no generic competitors and closing loopholes that allow brand-name drug companies to forestall the generic competition that Congress intended. *Id.* And CMS has promulgated a regulation that makes it easier for generic drugs to enter Medicare formularies, thereby allowing Medicare beneficiaries to benefit from those drugs. *Id.* at 19; *see* 83 Fed. Reg. 16,440, 16,606-08 (Apr. 16, 2018).

This case concerns another rule that HHS (acting through CMS) promulgated to help lower prescription drug prices. *See* 84 Fed. Reg. 20,732-58 (J.A. __-__) (final rule); 83 Fed. Reg. 52,789-52,799 (J.A. __-__) (proposed rule). The rule requires direct-to-consumer (DTC) television advertisements for prescription drugs covered by the Medicare or Medicaid programs to include the "list price" of the advertised drug for a thirty-day supply or typical course of treatment. 42 C.F.R. § 403.1202. The rule

exempts drugs with a list price under $35 per month or course of treatment. *Id.* § 403.1200(a)-(b). The list price is defined as the cost that wholesalers or direct purchasers pay for the drugs, without any discounts. *Id.* § 403.1201(c)-(d). HHS recognized that individuals covered by insurance will rarely pay a drug's list price. 84 Fed. Reg. at 20,739 (J.A. __). As a result, the rule requires the list price statement to include a qualifier: "The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different." 42 C.F.R. § 403.1202.

In both the proposed and final rules, HHS explained how this "price transparency" will "help improve the efficiency of Medicare and Medicaid programs by reducing wasteful and abusive increases in drug and biological product list prices." 84 Fed. Reg. at 20,733 (J.A. __). First, HHS noted that transparency "will provide manufacturers with an incentive to reduce their list prices by exposing overly costly drugs to public scrutiny." *Id.* Second, HHS observed that the disclosure requirement "will provide some consumers with more information to better position them as active and well-informed participants in their healthcare decision-making." *Id.*; *see id.* (noting that "the coinsurance borne by some consumers will increase as the [list price] increases"). And third, HHS suggested that market transparency will encourage manufacturers "to compete based on list price" and will "likely motivate manufacturers to be less willing to raise prices." 83 Fed. Reg. at 52,790 (J.A. __)

(citing John F. Cady, *An Estimate of the Price Effects of Restrictions on Drug Advertising*, 44 Economic Inquiry 493 (1976)).

HHS based its authority to promulgate the rule on 42 U.S.C. §§ 1302(a) and 1395hh(a)(1). 84 Fed. Reg. at 20,732, 20,735-38 (J.A. __, __-__); 83 Fed. Reg. at 52,790-91 (J.A. __-__). As noted above, section 1302(a) authorizes HHS to issue such rules "as may be necessary to the efficient administration of the functions" with which the agency is charged under the Social Security Act, including the Medicare and Medicaid programs, and section 1395hh(a)(1) authorizes HHS to promulgate such regulations "as may be necessary to carry out the administration of the insurance programs" under Medicare.

HHS explained that its rule would "improve the efficient administration of the Medicare and Medicaid programs by improving drug price transparency and informing consumer decision-making, both of which can increase price competition and slow the growth of federal spending on prescription drugs." 84 Fed. Reg. at 20,732 (J.A. __). HHS further stated that the two statutes "authorize regulations that the Secretary determines are necessary to administer" Medicare and Medicaid. *Id.* at 20,736 (J.A. __); *see id.* at 20,737 (J.A. __) ("Congress has explicitly directed the Secretary to operate the Medicare and Medicaid programs efficiently and has expressly authorized regulations necessary to that purpose, so long as they are not inconsistent with the Social Security Act. Promoting pricing transparency, and thus efficient

markets, for drugs funded through those programs falls within the scope of the Secretary's mandate.").

In assessing its authority to promulgate the rule, HHS was guided by the Supreme Court's decisions in *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). Those cases, HHS explained, "stand for the proposition that a grant of broad rulemaking authority," such as the grants in sections 1302(a) and 1395hh(a)(1), "permits regulations that are reasonably related to the purposes of the programs for which rulemaking is authorized, and that the Secretary has discretion to determine which rules are necessary." 84 Fed. Reg. at 20,736 (J.A. __) (citing *Mourning*, 411 U.S. at 369; *Thorpe*, 393 U.S. at 277 n.28). HHS concluded that the DTC rule meets this standard, "given the clear nexus between this requirement [to include list price in certain DTC ads] and Congress's recognition throughout the Social Security Act of administering the Medicare and Medicaid programs in a manner that minimizes unreasonable expenditures." *Id.* at 20,735-36 (J.A. __-__).

In addition, HHS explained that the DTC rule complies with the "two-part Chevron test." 84 Fed. Reg. at 20,736 (J.A. __). HHS observed that its rule passes the first step of that test "because Congress did not directly speak to the question of requiring the disclosure of the list price in DTC television advertisements, and nothing in the text or structure of the Medicare statute prohibits this rule." *Id.* at 20,737 (J.A. __). And the rule "is a permissible interpretation of the Secretary's broad

authority to regulate for the efficient administration of the Medicare and Medicaid programs," particularly given that both *Mourning* and *Thorpe* "hold that broad rulemaking authority permits regulations reasonably related to program purposes." *Id.*

After responding to numerous public comments on the proposed rule, HHS issued the final rule on May 10, 2019. 84 Fed. Reg. 20,732 (J.A. __). As required by law, HHS conducted a regulatory impact analysis and determined that the "total administrative costs of the rule are estimated to be $5.2 million in 2020 and $2.4 million in subsequent years." *Id.* at 20,754 (J.A. __). Those sums, HHS noted, are a small fraction of the $4.2 billion spent annually on television advertising for prescription drugs. *Id.*; *see id.* at 20,734 (J.A. __). HHS scheduled the rule to take effect on July 9, 2019. *Id.* at 20,732 (J.A. __).

D. Prior Proceedings

Plaintiffs are three pharmaceutical companies—Merck & Co., Eli Lilly and Co., and Amgen Inc.—as well as an advertising industry association, the Association of National Advertisers. *See* Compl. ¶¶ 1, 18-21 (J.A. __). Plaintiffs filed their complaint on June 14, 2019, five weeks after the publication of the final DTC rule. Plaintiffs asserted that the rule is in excess of HHS's statutory authority, arbitrary and capricious, and contrary to the First Amendment. Compl. ¶ 111 (J.A. __); *see* 5 U.S.C. § 706(2)(A)-(C). Plaintiffs moved to stay the rule pending judicial review, relying on their statutory authority and First Amendment claims.

On July 8, 2019, the district court granted plaintiffs' motion to stay the rule. The court ruled that HHS lacked statutory authority to promulgate the DTC rule, without reaching the other legal theories in plaintiffs' complaint. Op. 2 (J.A. __). With the government's consent, and over plaintiffs' objection, the district court consolidated the stay motion with the merits and entered a final judgment vacating the rule. *See id.* at 7-8 (J.A. __).

The district court began its opinion by asserting that *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), governed the question of whether HHS had statutory authority to promulgate the rule. Op. 9-10 (J.A. __-__). The court noted HHS's view that *Mourning* and *Thorpe* established the governing framework for assessing the scope of an agency's regulatory authority under broad rulemaking provisions like those in this case. *Id.* at 9 (J.A. __). But it rejected that view, indicating instead that *Mourning* and *Thorpe* might apply at *Chevron*'s second step, which asks whether an agency's interpretation is reasonable. *Id.* at 10 (J.A. __).

The district court then turned to the text of 42 U.S.C. §§ 1302(a) and 1395hh(a)(1). The court acknowledged that the statutes "are broad grants of rulemaking authority." Op. 12 (J.A. __). But it suggested that under section 1302(a), which allows HHS to make rules "as may be necessary to the efficient administration of" the Medicare and Medicaid programs, the term "administration" confers only the power to "control[] the operation of something over which a person has executive authority." *Id.* at 12-13 (J.A. __-__). In the district court's view, HHS lacked

executive authority over drug manufacturers because those manufacturers "do not receive payment for their products from CMS," and so their "decisions impact program costs in an indirect way." *Id.*

The district court drew the same inference from the structure of the Medicare and Medicaid programs. The district court observed that no provision of the Social Security Act "authorize[s] HHS, in the name of attempting to reduce the costs, to regulate the health care market itself or market actors that are not direct participants in the insurance programs." Op. 15 (J.A. __). Accordingly, the court determined, *Thorpe* and *Mourning* were distinguishable because, in those cases, "the agency aimed its rule at either the very actors that Congress empowered the agency to regulate . . . or the agency's own operations." *Id.* at 18-19 (J.A. __-__).

The district court also looked to other statutes to confirm its conclusion. The court noted that the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, empowers the FDA to impose certain requirements on prescription drug advertisements. Op. 21 (J.A. __) (citing 21 U.S.C. § 352(n)). That grant of authority, the district court opined, demonstrates that "Congress kn[ew] how to prescribe the content of drug advertising when it chooses to do so." *Id.*; *see also id.* at 22 (J.A. __) (making a similar point as to 21 U.S.C. § 353c, which allows FDA to require pre-review of television advertisements).

Finally, the district court ruled that "[t]he subject matter of the [DTC rule] also leads to the conclusion that Congress did not delegate authority under the [Social

Security Act] to compel drug price disclosures." Op. 22 (J.A. __). The district court suggested that the "magnitude of the pharmaceutical industry" means that "[c]ommon sense dictates that Congress would not have authorized such a dramatic seizure of regulatory power based solely on general rulemaking authority." *Id.* at 24 (J.A. __). Relatedly, the district court found it relevant that, in its view, HHS had never previously attempted to use its rulemaking authority to "directly regulate the market for pharmaceuticals." *Id.*

SUMMARY OF ARGUMENT

In creating the Medicare and Medicaid programs, Congress delegated to HHS the power to enact all rules "necessary to the efficient administration" of those programs. Addressing similar enabling language in other statutes, the Supreme Court has concluded that such language grants the agency "broad authority," and that a regulation promulgated under such provisions "will be sustained as long as it is reasonably related to the purposes of the enabling legislation." *Mourning v. Family Publ'ns Serv., Inc.*, 411 U.S. 356, 365, 369 (1973) (quotation marks omitted). Under the traditional framework of *Chevron* deference, HHS's interpretation of the scope of its rulemaking authority must be upheld so long as the statute is ambiguous and the agency's interpretation is reasonable.

Mourning and *Chevron* together make clear that HHS had statutory authority to promulgate the DTC rule. The rule is aimed at the problem of rising drug prices—a critical problem for the Medicare and Medicaid programs, and for American

consumers and taxpayers more generally. It addresses that problem through a disclosure requirement that will enable consumers to better understand their out-of-pocket costs and make choices informed by knowledge of those costs. That solution is reasonably related to the purpose of those programs: in numerous provisions of the Social Security Act, Congress expressed concern both for keeping the costs of Medicare and Medicaid low and for ensuring that those programs' enrollees were adequately informed of the nature of their benefits. The DTC rule advances both of those goals.

The district court's contrary conclusion is incorrect. The court determined that requiring pharmaceutical companies to publicly disclose the list prices of their prescription drugs unambiguously falls outside the scope of the "administration" of Medicare and Medicaid. But this Court has recognized that an agency's general rulemaking authority is not confined to those actors whose conduct is expressly addressed by the statute, and here, Congress has permitted CMS to impose conditions on drug companies that want their drugs to be eligible for Medicare and Medicaid coverage. The court also suggested that the structure of the Medicare and Medicaid statutes foreclose the DTC rule, but never pointed to any feature of those statutes that would support that conclusion.

Additionally, the district court failed to analyze correctly the scope of the FDCA. While that act permits the FDA to require advertisements for prescription drugs to include disclosures related to safety and efficacy, nothing in it prohibits CMS

from requiring different disclosures to advance different goals under a different statute. Finally, the district court was wrong to treat this rule as if it were initiating a revolution in health insurance and medical care. Far from imposing novel and far-reaching economic burdens or fundamentally reshaping the marketing of prescription drugs, the rule imposes adds a limited disclosure obligation to existing advertising, and the cost of complying with the rule is extremely modest relative to the pharmaceutical industry's advertising spending. For all of these reasons, HHS has reasonably concluded that the rule is within the scope of its general rulemaking authority under the Medicare and Medicaid statutes, and the rule should accordingly be upheld.

STANDARD OF REVIEW

This Court reviews de novo the district court's statutory interpretation. *Loving v. IRS*, 742 F.3d 1013, 1016 (D.C. Cir. 2014).

ARGUMENT

In enacting the Medicare and Medicaid statutes, Congress gave HHS authority to "make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration" of HHS's functions under the Medicare and Medicaid programs. 42 U.S.C. § 1302(a); *see id.* § 1395hh(a)(1) (authority to promulgate regulations "necessary to carry out the administration" of Medicare insurance programs). That authority permits HHS to require the disclosure of price information by drug companies whose drugs are covered by Medicare and Medicaid. HHS has determined that the unprecedented rise in prescription drug costs

poses a grave threat to Medicare and Medicaid, and it promulgated the DTC rule to help protect those programs' fiscal viability. The text of sections 1302 and 1395hh vests HHS with broad rulemaking authority, and neither the structure of the Medicare and Medicaid statutes, nor any other statutory provision, disables HHS from exercising that broad authority to require drug companies to inform Medicare and Medicaid beneficiaries of the prices of their drugs.[1]

I. HHS IS ENTITLED TO DEFERENCE IN INTERPRETING THE SCOPE OF ITS RULEMAKING AUTHORITY.

The sole question presented by the decision below is whether HHS has statutory authority under sections 1302(a) and 1395hh(a)(1) to promulgate regulations that require pharmaceutical companies to disclose to consumers information about the prices of drugs that are covered by the Medicare and Medicaid programs. Although plaintiffs' complaint also contended that the present rule is arbitrary and capricious and that it violates the First Amendment, the district court did not address either of those claims. Op. 6-7 (J.A. __-__). Its decision rests entirely on its conclusion that rules requiring pharmaceutical manufacturers to disclose the price of their

[1] We note that one of the plaintiffs, the Association of National Advertisers, failed to demonstrate its standing in the complaint. "[W]hen a petitioner claims associational standing, it is not enough to aver that unidentified members have been injured. Rather, the petitioner must specifically identify members who have suffered the requisite harm." *Sorenson Commc'ns LLC v. FCC*, 897 F.3d 214, 224 (D.C. Cir. 2018). The Association of National Advertisers did not identify any such members in the complaint or accompanying declarations, and therefore lacks standing to press its claims.

drugs are beyond the scope of HHS's authority to promulgate rules "necessary to the efficient administration" of the Medicare and Medicaid programs. 42 U.S.C. § 1302(a); *see* 42 U.S.C. § 1395hh(a)(1).

In reviewing the interpretation of regulatory statutes by the agencies charged with administering them, this Court applies the familiar standards of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). The Court first asks whether "the intent of Congress is clear," in which case it must "give effect to Congress's clear intent." *Village of Barrington v. Surface Transp. Bd.*, 636 F.3d 650, 659 (D.C. Cir. 2011) (quoting *Chevron*, 467 U.S. at 842). But if there is "statutory ambiguity," the Court "defer[s] to the agency's permissible interpretation" so long as "the agency has offered a reasoned explanation for why it chose that interpretation." *Id.* at 363. The fact that this case involves questions regarding the scope of HHS's rulemaking authority does not alter the applicability of this framework, for "a court must defer under *Chevron* to an agency's interpretation of a statutory ambiguity that concerns the scope of the agency's statutory authority." *City of Arlington v. FCC*, 569 U.S. 290, 296-305 (2013); *New England Power Generators Ass'n, Inc. v. FERC*, 757 F.3d 283, 289 (D.C. Cir. 2014). In determining whether a statute is ambiguous, this Court employs the "traditional tools of statutory construction." *Chevron*, 467 U.S. at 843 n.9.

In this case, the scope of the authority conferred on HHS by sections 1302(a) and 1395hh(a)(1) is informed, and in important respects controlled, by the Supreme Court's decisions in *Mourning v. Family Publications Service, Inc.* and *Thorpe v. Housing*

Authority of the City of Durham. In those cases, the Court addressed the scope of authority conferred by general rulemaking provisions closely resembling those involved here. In *Thorpe*, the United States Housing Act authorized the Department of Housing and Urban Development to "make . . . such rules and regulations as may be necessary to carry out the provisions of this Act." 393 U.S. 268, 277 & n.28 (1969) (citing 42 U.S.C. § 1408 (Supp. III 1964)). In *Mourning*, the Truth in Lending Act similarly authorized the Federal Reserve Board to "prescribe regulations to carry out the purposes of" the Act. 411 U.S. 356, 361 (1973) (citing 15 U.S.C. § 1604).

In both cases, the Court rejected arguments that particular regulations were beyond the scope of the rulemaking authority conferred by these provisions. In so doing, the Court construed the terms of the rulemaking provisions. The Court explained that general rulemaking provisions of this sort confer "broad authority" on the agency. *Mourning*, 411 U.S. at 365; *see Thorpe*, 393 U.S. at 280-81; *National Welfare Rights Org. v. Mathews*, 533 F.2d 637, 640 (D.C. Cir. 1976). More specifically, "[w]here the empowering provision of a statute states simply that the agency may 'make . . . such rules and regulations as may be necessary to carry out the provisions of this Act,'" the Court held 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.'" *Mourning*, 411 U.S. at 369 (quoting *Thorpe*, 393 U.S. at 280-81). Just months ago, this Court applied the "reasonably related" standard of *Mourning* and *Thorpe* to uphold a Federal Election Commission regulation that required disclosure of

documents identifying a campaign contributor. *Doe, 1 v. FEC*, 920 F.3d 866, 870-71 (D.C. Cir. 2019).

Here, Congress has authorized HHS to promulgate whatever regulations may be "necessary to the efficient administration of the functions" of the Medicare and Medicaid programs, 42 U.S.C. § 1302(a), or "necessary to carry out the administration of the insurance programs" of Medicare, *id.* § 1395hh(a)(1). The Supreme Court has previously recognized that § 1302(a) confers "broad rule-making powers . . . in substantially the same language" as the rulemaking provision in *Thorpe* itself. *Thorpe*, 393 U.S. at 277 n.28; *see also Blum v. Bacon*, 457 U.S. 132, 140 n.8 (1982) (same). HHS has interpreted this language to provide the agency, which is paying hundreds of billions of dollars for drugs on behalf of Medicare and Medicaid beneficiaries, with the authority to require pharmaceutical companies to disclose to consumers the list price of those drugs. *Chevron*, *Mourning*, and *Thorpe* collectively provide the framework for judicial review of that interpretation.

The district court concluded that §§ 1302(a) and 1395hh(a)(1) unambiguously withhold from HHS the authority to promulgate a rule requiring public disclosure of price information by pharmaceutical companies, and therefore the agency's assertion of rulemaking authority fails at step one of *Chevron*. That conclusion is incorrect. Contrary to the district court's belief, neither the text of the rulemaking provisions themselves (Op. 12-20 (J.A. __)), nor other statutory provisions (Op. 20-23 (J.A. __)), nor the subject matter of the rule (Op. 23-26 (J.A. __)) demonstrate that Congress

"directly addressed the precise question at issue." *Chevron*, 467 U.S. at 843. As a result, the question whether HHS's statutory rulemaking authority extends to rules such as this one is a question on which the agency is entitled to deference. As we now show, the agency permissibly—indeed, quite correctly—determined that requiring public disclosure of drug price information in DTC television advertising is, following the standard articulated by the Supreme Court in *Mourning* and *Thorpe*, "reasonably related to the purposes of the enabling legislation," *Thorpe*, 393 U.S. at 280-81, and therefore comes within the scope of the agency's rulemaking authority.

II. HHS REASONABLY DETERMINED THAT ADDING PRICE INFORMATION TO DTC ADVERTISING IS "NECESSARY TO THE EFFICIENT ADMINISTRATION" OF THE MEDICARE AND MEDICAID PROGRAMS.

HHS has statutory authority to regulate price information in DTC pharmaceutical advertising because doing so is "necessary" to the "efficient administration" of the Medicare and Medicaid programs. 42 U.S.C. § 1302(a); *see id.* § 1395hh(a)(1). The rising cost of drugs is placing an increasingly serious financial burden on the federal government, as well as individual patients, and providing consumers with information about the cost of drugs has the potential to reduce that burden by supporting informed consumer choices and increasing competition. The Supreme Court and this Court have explained that regulations issued pursuant to broad grants of rulemaking authority such as section 1302(a) and section 1395hh(a)(1) are within the scope of an agency's authority as long as they are reasonably related to

the purposes of the statutes that the agency administers. Here, the Medicare and Medicaid statutes leave no doubt that disclosure requirements designed to curb skyrocketing drug prices are reasonably related to the efficiency and transparency goals of those statutes.

A. As the final rule explains, the United States is experiencing a crisis in prescription drug costs. Every year, the prices of necessary medicines increase faster than the rate of inflation. *See supra* pp. 7-8. Medicare and Medicaid, as the federal health insurance programs for the elderly, needy, and disabled, pay over half of the total amount spent on prescription drugs each year. 84 Fed. Reg. at 20,733 (J.A. __). The dramatically increasing costs of those drugs are an acute threat to the sustainability of the Medicare and Medicaid programs. *Id.*

The problem of rising drug prices is exacerbated by the lack of transparency in the market for pharmaceutical products. In a typical market, consumers are provided with prices of the goods they consider purchasing, and they can take price into account in choosing among products. 84 Fed. Reg. at 20,735 (J.A. __). By contrast, consumers of prescription drugs are missing this information, even though many consumers have potentially significant cost-sharing obligations (like coinsurance) for the drugs they buy. *See id.* As a result, consumers are unable to identify and evaluate lesser-cost alternatives that may satisfy their medical needs. Pharmaceutical manufacturers exacerbate this problem when they engage in direct-to-consumer

advertising that promotes their most profitable products while keeping patients in the dark about those products' costs.

Requiring price disclosures for prescription drugs aims to reduce those market distortions and thereby reduce costs for the Medicare and Medicaid programs as well as for individual consumers. Price information will help patients and prescribers to be better informed as to the costs associated with their healthcare choices. *See* 84 Fed. Reg. at 20,734 (J.A. __). And empowering consumers to make better-informed decisions will "increase price competition and slow the growth of federal spending on prescription drugs." 84 Fed. Reg. at 20,732 (J.A. __).

B. In promulgating the DTC rule, the Secretary used the broad authority given to him by Congress to "make and publish such rules and regulations . . . as may be necessary to the efficient administration" of the Medicare and Medicaid programs, and to "prescribe such regulations as may be necessary to carry out the administration" of Medicare. 42 U.S.C. §§ 1302(a), 1395hh(a)(1). As noted above, these grants of rulemaking authority closely parallel the rulemaking statutes at issue in *Mourning* and *Thorpe*. Indeed, the Supreme Court specifically observed in *Thorpe* that 42 U.S.C. § 1302 confers "broad rulemaking authority" on HHS in "substantially the same language" as the rulemaking provision at issue in that case. 393 U.S. at 277 n.28. This Court has characterized the rulemaking authority conferred by § 1302(a) as "far-ranging," and has observed that "[a] more plenary [grant] of rule-making power would

be difficult to devise." *National Welfare Rights Org.*, 533 F.2d at 640 (quoting with approval *Serittella v. Engleman*, 339 F. Supp. 738, 752 (D.N.J. 1972)).

The question of statutory authority therefore turns on whether HHS reasonably determined that the DTC rule is "reasonably related" to the "efficient administration" of Medicare and Medicaid. *See Chevron*, 467 U.S. at 842; *Mourning*, 411 U.S. at 369. And the answer to that question is plainly yes. HHS adopted the DTC rule to "promote transparency, efficiency, and the responsible use of federal funds, in particular the Medicare trust funds," by enabling "[Medicaid and Medicare] beneficiaries to make more informed decisions" about the drugs they are prescribed. 84 Fed. Reg. at 20,736 (J.A. __). As described above, HHS determined that increased transparency will "improv[e] drug price transparency and inform[] consumer decision-making, both of which can increase price competition and slow the growth of federal spending on prescription drugs." 84 Fed. Reg. at 20,732 (J.A. __); *see supra* pp. 9-11.

The fiscal health of these insurance programs is intimately related to the programs' "efficient administration." As a matter of common usage, "efficient" means "[a]cting or producing effectively with a minimum of waste, *expense*, or unnecessary effort." *American Heritage Dictionary of the English Language* (5th ed. 2019) (emphasis added); *see* 84 Fed. Reg. at 20,733 (J.A. __) (explaining that the DTC rule "will help improve the efficiency of Medicare and Medicaid programs by reducing wasteful and abusive increases in drug and biological product list prices"). And as a programmatic matter, both the Medicare and Medicaid statutes reflect the importance

of administering those programs in a manner that minimizes unnecessary expenditures. For example, the Medicaid statute requires States to "safeguard against unnecessary utilization of [Medicaid] care and services and to assure that payments are consistent with efficiency, economy, and quality of care." 42 U.S.C. § 1396a(a)(30)(A). The Medicare statute authorizes the Secretary to determine which part B payments are "grossly excessive or grossly deficient," and therefore "not inherently reasonable." 42 U.S.C. § 1395u(b)(8). And other portions of the Social Security Act similarly aim to minimize waste in the Medicare and Medicaid programs. *See, e.g.*, 42 U.S.C. § 1395w-104(c)(3) (Medicare part D drugs); *id.* § 1395ddd (Medicare Integrity Program). These provisions demonstrate that Congress, in creating and reforming the Medicare and Medicaid programs, has charged HHS with avoiding unnecessary program costs. As a result, HHS reasonably determined that the DTC rule's effort to restrain drug costs through greater transparency was "reasonably related to the purposes of the enabling legislation." *Thorpe*, 393 U.S. at 280-81.

Congress has expressed the same focus on cost reduction in statutes concerning prescription drugs. In particular, drug manufacturers must commit not to charge covered entities more than the average manufacturer price of certain drugs, minus a rebate percentage, in exchange for having those drugs covered by Medicaid and Medicare part B. 42 U.S.C. § 256b(a)(1); *see id.* § 1396r-8(a). Congress has also required manufacturers of those drugs to "furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug . . . that, according to the

manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug." *Id.* § 256b(a)(1).

Finally, the Medicare and Medicaid statutes also reflect a commitment to informing beneficiaries about their benefits. *See, e.g.*, 42 U.S.C. § 1395b-3 (outreach to beneficiaries); *id.* § 1395b-7 (explanation of benefits); *id.* § 1395w-104(a) (explanation of part D benefits); *id.* § 1396d(u)(2) (information for beneficiaries). That commitment includes the regulation of advertising for Medicare participants. *See* 42 U.S.C. § 1395w-21(h)-(j); 42 C.F.R. §§ 422.2260-.2276; *see also* 42 C.F.R. § 423.2268(a)(2) (obligations on part D sponsors); *id.* § 423.505(i)(3) (derivative obligations on downstream entities). Administering a benefits program requires helping beneficiaries understand what costs are borne by the program *and* what costs they have to bear themselves, particularly when they may bear coinsurance obligations for the drugs that they use. The DTC rule advances that congressional goal by placing beneficiaries in a better position to assess the cost of prescription drugs. It thus falls well within the authority granted by sections 1302 and 1395hh.

III. THE DISTRICT COURT'S ANALYSIS OF HHS'S RULEMAKING AUTHORITY WAS INCORRECT.

A. The "efficient administration" of the Medicare and Medicaid extends to drug manufacturers who supply drugs to Medicare and Medicaid enrollees.

The Medicare and Medicaid programs pay hundreds of billions of dollars each year for drugs administered to Medicare and Medicaid beneficiaries. The district court

concluded that this colossal flow of federal funds to pharmaceutical companies does not implicate the "efficient administration" of the Medicare and Medicaid programs, and hence rules requiring drug manufacturers to disclose their prices to consumers are beyond the authority of HHS to promulgate. Op. 13-15 (J.A. __-__). The district court reached that remarkable conclusion in two steps. First, it interpreted the word "administration" to confine HHS's authority to "direct participants in the Medicare or Medicaid programs." Op. 13 (J.A. __). Second, it concluded that pharmaceutical manufacturers, unlike "health care providers, private plan carriers, or beneficiaries," do not "play[] a direct role in the public health insurance programs." *Id.*

The district court erred at each step of its analysis. To begin, nothing about the meaning of "administration" supports, much less compels, confining HHS's regulatory authority to parties that play a "direct role" in the regulatory scheme. Even the dictionary definitions relied on by the district court do not suggest such a limitation. The term encompasses, *inter alia*, "all the actions that are involved in managing the work of an organization." Op. 13 (quoting *Black's Law Dictionary* (11th ed. 2019)); *see also American Heritage Dictionary of the English Language* (5th ed. 2019) (defining "administration" as "[t]he activity of a government or state in the exercise of its powers or duties"). Where, as here, "the work of [the] organization" includes disbursing hundreds of billions of dollars for prescription drugs, the "efficient administration" of that vast undertaking necessarily extends to the firms whose products (and whose advertising practices) account for that spending.

More generally, an agency's general rulemaking authority "may be exercised to regulate circumstances *or parties* beyond those explicated in a statute." *National Ass'n of Mfrs. v. SEC*, 748 F.3d 359, 366 (D.C. Cir. 2014) (emphasis added), *overruled on other grounds by American Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).[2] Thus, for example, this Court has rejected a statutory challenge to a conflict-minerals disclosure requirement that applied to non-manufacturers, even though the statute that the agency sought to implement covered only manufacturers of minerals. *Id.* at 367-68 ("[S]ilence allows the Commission to use its delegated authority in determining the rule's scope . . . ."). Here, likewise, Congress has given HHS broad authority to regulate in furtherance of the effective administration of Medicare and Medicaid, and Congress did not qualify that "far-ranging" grant of authority, *National Welfare Rights Org.*, 533 F.2d at 640, by excluding from its reach private firms whose activities directly and profoundly affect the operation and financial stability of the programs.

But even if the district court were correct that HHS's authority to adopt rules to further the "efficient administration" of Medicare and Medicaid was confined to entities that play a "direct role" in those programs, it still erred in concluding that advertising by drug manufacturers to Medicare and Medicaid beneficiaries is outside

[2] In *American Meat Institute*, this Court overruled a portion of *National Association of Manufacturers* involving a First Amendment challenge to a compelled disclosure. *See* 760 F.3d at 22-23. But the en banc Court did not overturn or alter the statutory holdings in *National Association of Manufacturers*. *See National Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015) (denying panel rehearing).

the scope of the agency's rulemaking authority. The district court assumed that pharmaceutical manufacturers are not "direct participants in the insurance programs." Op. 15 (J.A. __). That assumption is incorrect.

As discussed above, in order for payment to be available under Medicare part B and Medicaid for their covered outpatient drugs, pharmaceutical manufacturers must enter into agreements with HHS under which they must pay certain rebates to States and must offer their covered outpatient drugs to covered entities at or below a ceiling price. *See* 42 U.S.C. §§ 256b(a)(1), 1396r-8(a); *supra* pp. 6-7. They must also agree to report to HHS their average sales price data for certain types of drugs. *See* 42 U.S.C. §§ 1395w-3a(f), 1396r-8(b)(3); 42 C.F.R. §§ 414.800-.806. In addition, Congress has mandated that as a condition of coverage of their brand name drugs, manufacturers must commit to participating in a program under which they pay discounts on such drugs to certain part D enrollees. 42 U.S.C. §§ 1395w-114a(a), 1395w-153.

Those provisions, among others, demonstrate that the district court misunderstood the role that pharmaceutical companies play in the Medicare and Medicaid programs. Those companies are not strangers to the Medicare and Medicaid programs, nor are they subject to regulation under sections 1302(a) and 1395hh(a)(1) solely because they are "market actors." Op. 13, 15 (J.A. __, __). Rather, Congress itself determined that drug manufacturers must enter into direct dealings with HHS and assume prescribed obligations in exchange for having the government subsidize their products for Medicare and Medicaid enrollees. In

promulgating the DTC rule, HHS merely imposed an additional obligation, one that is perfectly consistent with that congressional scheme.

The district court also assigned weight to the fact that drug manufacturers "do not receive payment for their products from CMS." Op. 13 (J.A. __). It is true that drug manufacturers are not paid directly by CMS; they are paid by healthcare providers and other private parties, who are ultimately reimbursed by HHS. But those healthcare providers—who unquestionably may be regulated under HHS's general rulemaking authority, as the district court acknowledged—do not receive payment for their services directly from CMS. Rather, Medicare reimbursement for healthcare providers typically "is handled by fiscal intermediaries, such as private insurance companies." *HCA Health Servs. of Okla., Inc. v. Shalala*, 27 F.3d 614, 615 (D.C. Cir. 1994); *see Baptist Memorial Hosp. v. Sebelius*, 603 F.3d 57, 60 (D.C. Cir. 2010). And Medicaid reimbursement is made by the States who then receive federal funds on a quarterly basis. 42 U.S.C. § 1396b(a)(1). Thus, almost all of the actors who "play[] a direct role in the public health insurance programs" are generally not paid directly by HHS. Op. 13 (J.A. __).

Once the relationship between pharmaceutical companies and the Medicare and Medicaid programs is understood, the district court's efforts to distinguish this case from *Mourning*, *Thorpe*, and *Doe, 1* collapse. The district court viewed those cases as distinguishable because "the agency aimed its rule at either the very actors that Congress empowered the agency to regulate . . . or the agency's own operations." Op.

18-19 (J.A. __-__). Here too, drug companies are "actors that Congress empowered the agency to regulate." Congress imposed conditions on drug manufacturers in the Medicare and Medicaid contexts, and HHS has previously promulgated rules to implement those conditions. *See* 42 C.F.R. §§ 414.800-.806, 423.2300-.2345, 447.501-447.510. Therefore, even on the district court's unduly restrictive understanding of "efficient administration," the DTC rule falls within the scope of HHS's rulemaking authority.

At the very least, the district court erred in concluding that the term "administration" unambiguously and categorically excludes DTC drug advertising from HHS's regulatory authority. At a minimum, the district court should have proceeded to *Chevron*'s second step, which asks "whether the agency's answer" to an interpretive question "is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. And, given the role that pharmaceutical companies play in the Medicare and Medicaid schemes, HHS's interpretation of the term, and the associated scope of the agency's rulemaking authority, was entirely reasonable and should be upheld.

B. Nothing in the Medicare or Medicaid statutes prohibits the DTC rule.

Rather than looking to *Mourning* and *Thorpe* for guidance, the district court looked to two other lines of cases. The first line of cases holds that an agency may not rely on a general grant of rulemaking authority to sustain a specific regulation

when the statutory scheme, read as a whole, disables the agency from taking that action. The second line of cases stands for the proposition that, in the absence of general rulemaking authority, an agency cannot act without a more specific grant statutory authority. Neither line of cases supports the district court's ruling. Nothing in the Medicare or Medicaid statutes precludes HHS from requiring drug companies to disclose their prices to consumers, and HHS properly used its general rulemaking authority here.

1. The district court primarily relied on cases holding that a congressional grant of general rulemaking authority does not give an agency "carte blanche" to "promulgate rules on any matter relating to its enabling statute." Op. 16 (J.A. __) (quoting *Citizens To Save Spencer Cty. v. EPA*, 600 F.2d 844, 873 (D.C. Cir 1979)). That is correct: because an agency cannot act contrary to the "unambiguously expressed intent of Congress," *Chevron*, 467 U.S. at 842-43, it may not make rules that Congress clearly disallowed. For that reason, this Court has observed that general rulemaking authority does not permit an agency to make rules that "conflict[] with the plain meaning" of a statute. *National Mining Ass'n v. U.S. Dep't of the Interior*, 105 F.3d 691, 694 (D.C. Cir. 1997). And "it is well established that an agency may not circumvent specific statutory limits on its actions by relying on separate, general rulemaking authority." *Air Alliance Hous. v. EPA*, 906 F.3d 1049, 1061 (D.C. Cir. 2018) (per curiam). That principle is embodied in the text of section 1302(a) itself: the provision authorizes HHS to promulgate rules and regulations that are necessary for the

efficient administration of the Medicare and Medicaid programs, but stipulates that the rules may "not [be] inconsistent with this chapter" (*i.e.*, the Social Security Act, which includes the Medicare and Medicaid programs).

But these principles, and the cases that rely on them, do not support the district court's decision here, for the simple reason that the DTC rule does not conflict with any other provisions of the Medicare and Medicaid statutes. Indeed, the district court never identified any statutory limitation in the Medicare or Medicaid statutes that would disable HHS from regulating DTC drug advertising. Nor did it identify anything else to support the notion that the DTC rule would be "inconsistent" with the Medicare or Medicaid statutes.

The district court also relied on *Colorado River Indian Tribes v. National Gaming Commission*, 466 F.3d 134, 135-37 (D.C. Cir. 2006). But that case is inapposite for similar reasons. The statute at issue in *Colorado River* empowered a federal agency to regulate certain "class II gaming" activities in tribal casinos, but left the regulation of "class III gaming" to tribes in compact with States. *Id.* at 290. The Court determined that the agency could not use its general rulemaking authority under this scheme to regulate class III gaming, because Congress had explicitly chosen not to authorize federal involvement in that area, leaving regulation to a different set of regulators. *Id.* at 293-94. In sum, the Court determined that the structure of the relevant act clearly precluded the promulgated rule. *See id.* at 294.

This case is nothing like *Colorado River*. 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. To the contrary, as discussed above, the DTC rule is consistent with the structure of those statutes because it advances their efficiency and transparency goals. *Supra* pp. 9-11, 25. 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.

The district court acknowledged "the absence [here] of the kind of statutory structural feature that was present in *Colorado River*." Op. 20 (J.A. __). The court dismissed that point on the ground that "the mere absence of an express statutory restriction is not a blank check" for agency regulations. *Id.* But HHS is not relying on "the mere absence of an express statutory restriction"; it is relying on a broad affirmative grant of rulemaking authority. Contrary to the district court's suggestion, HHS is not "appropriat[ing] the power to regulate simply because Congress has not explicitly taken that power away." *Id.* Congress has explicitly *granted* the power to regulate. While Congress was free to qualify that grant in other provisions of the Medicare and Medicaid statutes, it has not done so.

2. The district court also cited several cases for the proposition that this Court will not "presume a delegation of power merely because Congress has not expressly

withheld such power." Op. 17 (J.A. __) (quoting *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1060 (D.C. Cir. 1995)). That proposition is unremarkable: except for powers that inhere in Article II, the Executive Branch can act only "*within the bounds of its statutory authority*." *City of Arlington v. FCC*, 569 U.S. at 297. But none of the cases of this type that the district court cited involves statutes like sections 1302 and 1395hh, which give HHS broad authority to "publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration" of Medicare and Medicaid. 42 U.S.C. § 1302(a). In delegating such broad authority, Congress authorized HHS to make any regulation "reasonably related" to the purposes of those programs. *Thorpe*, 393 U.S. at 280. Thus, this case is not an example of an agency relying on the "absence of an express limitation" to make rules. Op. 17 (J.A. __). Instead, HHS has relied on Congress's express and affirmative grant of broad general rulemaking authority. As long as an exercise of rulemaking authority falls within the general scope of that grant, HHS is not under any additional obligation to show that Congress intended the specific exercise of its rulemaking authority.

C. The terms of FDA's authority over drug advertising under the FDCA do not govern HHS's authority under the Medicare and Medicaid statutes.

The district court also looked to statutes other than the Medicare and Medicaid statutes to illuminate—and in the court's view, to constrain—HHS's authority under sections 1302 and 1395hh. *See* Op. 20 (J.A. __) (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132-33 (2000)). The district court noted that Congress has

amended the Federal Food, Drug, and Cosmetic Act to regulate certain aspects of television drug advertisements. *Id.* at 20-22 (J.A. __-__). Because "Congress deliberately and precisely legislated in the area of drug marketing under the FDCA," the court inferred "that Congress knows how to speak on that subject when it wants to," and that the absence of any comparable provisions under the Medicare and Medicaid statutes reflects an absence of authority under those statutes. *Id.* at 23 (J.A. __). The district court's leap from the FDA's regulatory authority under the FDCA to HHS's authority under the Medicare and Medicaid statutes is unsupportable, particularly at *Chevron*'s first step.

The FDCA's provisions relating to drug advertising are part and parcel of that statute's general regulatory focus on medical product safety and efficacy. The FDCA requires prescription drug advertisements to provide a drug's established name, ingredients, and information regarding "side effects, contraindications, and effectiveness." 21 U.S.C. § 352(n). In 2007, Congress amended the FDCA to empower the FDA to require the pre-dissemination submission of any television drug advertisement for advance review and to recommend, *inter alia*, changes that are "necessary to protect the consumer good and well-being" and the inclusion of information about "the specific efficacy of the drug as it relates to specific population groups." *Id.* § 353c(b)(1)(A), (b)(2). Congress authorized FDA to require inclusion of "a specific disclosure about a serious risk listed in the labeling of the drug" if the advertisement would be false or misleading without such a disclosure, but otherwise

limited FDA's role in pre-dissemination review of an advertisement to making recommendations. *Id.* § 353c(c), (e). In enacting these provisions, Congress sought to ensure that drug advertisements are consistent with the goals of the FDCA, a statute that is "designed primarily to protect the health and safety of the public at large." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 108 (2014).

If HHS were invoking its general rulemaking authority under sections 1302(a) and 1395hh(a)(1) to impose requirements on drug advertising related to a drug's safety or efficacy, the existence of the drug advertising provisions in the FDCA, and the limited scope of those provisions, might have some bearing on HHS's authority. But the DTC rule is directed at an entirely different problem, one that has no relation to the FDCA's public health concerns relating to safety and efficacy of medical products. It is intended to further the efficient administration of Medicare and Medicaid, not to protect the public health and safety. That Congress expressly provided FDA (which does not account for costs as part of its safety mission) with limited authority to regulate drug advertising in the interests of public health has no bearing on HHS's authority to regulate drug advertising for entirely different reasons.

The district court reasoned that because Congress "deliberately and precisely legislated in the area of drug marketing under the FDCA," Congress must have implicitly disallowed HHS from regulating as to drug marketing under other authority and for other purposes. Op. 23 (J.A. __). But this Court has repeatedly disavowed that approach. It has held that "a congressional decision to prohibit certain activities

does *not* imply an intent to disable the relevant administrative body from taking similar action with respect to activities that pose a similar danger." *Texas Rural Legal Aid, Inc. v. Legal Servs. Corp.*, 940 F.2d 685, 694 (D.C. Cir. 1991); *see Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 697 (D.C. Cir. 2014) ("The *expressio unius* canon is a 'feeble helper in an administrative setting, where Congress is presumed to have left to reasonable agency discretion questions that it has not directly resolved.'" (quoting *Cheney R.R. Co. v. ICC*, 902 F.2d 66, 68-69 (D.C. Cir. 1990))). And *Mourning* itself rejected the argument that, "in requiring disclosure as to some transactions, Congress intended to preclude the [agency] from imposing similar requirements as to any other transactions," ruling that such a theory "would undermine the flexibility sought in vesting broad rulemaking authority in an administrative agency." 411 U.S. at 372. Accordingly, the district court erred in treating the FDCA as a limitation on HHS's powers under sections 1302 and 1395hh, and thereby preventing HHS from using "means that Congress has generally endorsed . . . to advance an end that Congress endorsed." 83 Fed. Reg. at 52,791 (J.A. __); *see Colorado River*, 466 F.3d at 139-40 (noting that agencies are bound "by the means [Congress] has deemed appropriate").

D. The scope of the DTC rule does not call HHS's statutory authority into question.

Finally, the district court concluded that the "subject matter" of the DTC rule "also leads to the conclusion that Congress did not delegate authority under the [Social Security Act] to compel drug price disclosures." Op. 23 (J.A. __). The district

court cited *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000), for the proposition that Congress must speak clearly before a court will infer that Congress has delegated a policy decision of vast economic and political magnitude to an administrative agency. *See also Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014) (similar). But this rule does not involve policy initiatives of vast economic and political significance, and upholding does not mean giving HHS the power to pursue such initiatives in the future.

1. This case "is a far cry from *FDA v. Brown & Williamson*." *Verizon v. FCC*, 740 F.3d 623, 638 (D.C. Cir. 2014). In *Brown & Williamson*, the Supreme Court held that Congress had not authorized FDA to regulate tobacco products as drugs or devices. The Court emphasized that "FDA had not only completely disclaimed any authority to regulate tobacco products, but had done so for more than eighty years, and that Congress had repeatedly legislated against this background." *Id.* (citing *Brown & Williamson*, 529 U.S. at 143-59). The Court "also observed that the FDA's newly adopted conclusion that it did in fact have authority to regulate this industry would, given its findings regarding the effects of tobacco products and its authorizing statute, logically require the agency to ban such products altogether, a result clearly contrary to congressional policy." *Id.* (citing *Brown & Williamson*, 529 U.S. at 135-43).

The Court's decision in *Utility Air Regulatory Group* was very similar. There, the Court determined that allowing EPA to regulate greenhouse gases under the Clean Air Act "would be inconsistent with—in fact, would overthrow—the Act's structure and

design." 573 U.S. at 321. Among other things, the Court noted the EPA's interpretation would mean that "annual permit applications would jump from about 800 to nearly 82,000; annual administrative costs would swell from $12 million to over $1.5 billion; and decade-long delays in issuing permits would become common, causing construction projects to grind to a halt nationwide." *Id.* at 322. And the newly regulated entities "would face permitting costs of $147 billion." *Id.* These consequences, the Court held, would be fundamentally incompatible with "the substance of Congress' regulatory scheme." *Id.* (quoting *Brown & Williamson*, 529 U.S. at 156).

"The circumstances here are entirely different." *Verizon*, 740 F.3d at 638. HHS "never disclaimed authority to regulate" prescription drug advertising, "nor is there any similar history of congressional reliance on such a disclaimer." *Id.* Moreover, HHS's rule would not have any consequence even remotely akin to the banning of tobacco products in *Brown & Williamson* or the thousand-fold increase in annual permit applications and the imposition of more than a hundred billion dollars in permitting costs in *Utility Air Regulatory Group*. On the contrary, the DTC rule would impose only $2.45 million in annualized compliance costs—a pittance compared to the $4.2 billion spent on direct-to-consumer television advertising in 2017. *See* 84 Fed. Reg. at 20,755-56 (J.A. __-__). And the rule would require only two additional textual sentences to appear in television advertisements that are already highly regulated because of the nature of the products they advertise.

2. The district court acknowledged that "the costs imposed by [the DTC rule] amount to a rounding error for the pharmaceutical industry." Op. 26 (J.A. __). But it reasoned that upholding HHS's authority to adopt this rule "would swing the doors wide open to any regulation, rule, or policy that might reasonably result in cost savings to the Medicare and Medicaid programs, unless expressly prohibited by Congress." *Id.*

There is no basis for the district court's concern. The court was wrong to suggest that there is no "limiting principle" that would allow a court to uphold this rule without opening the floodgates to any regulatory initiative that would reduce Medicare and Medicaid expenses. *See* Op. 26 (J.A. __). *Brown & Williamson* provides one such limiting principle: general grants of rulemaking authority may not support regulatory initiatives of vast "economic and political significance," 529 U.S. at 160, especially where the agency has previously disavowed such power. The Administrative Procedure Act, 5 U.S.C. § 706, supplies another: regardless of the scope of its rulemaking authority under sections 1302(a) and 1395hh(a)(1), HHS may not adopt regulations that are arbitrary and capricious or "not in accordance" with other statutes or other provisions of the same statute.[3] And, of course, sections 1302

[3] Below, plaintiffs advanced claims that the DTC rule is arbitrary and capricious and in violation of the First Amendment. The district court did not reach those claims, and this Court need not address them in the first instance on appeal. If the Court agrees with HHS that the DTC rule is within the scope of the agency's general rulemaking authority, plaintiffs are free to renew their other claims in any further proceedings below.

and 1395hh give HHS "authority to promulgate only those regulations that it establishes will fulfill [its] specific statutory goal" of ensuring the efficient administration of Medicare and Medicaid. *Verizon*, 740 F.3d at 640.

Finally, Congress has already prohibited HHS from taking the extraordinary steps that the district court feared. *See* Op. 26 (J.A. __). The Medicare statute prohibits the federal government from "exercis[ing] any supervision or control" over doctors' prescribing decisions or medical administration. 42 U.S.C. § 1395. Nor may the government "interfere with the negotiations between drug manufacturers and pharmacies" and Medicare part D insurers. *Id.* § 1395w-111(h)(i)(1). Requiring drug manufacturers to *disclose* their prices does not imply the existence of authority to *control* drug prices.

3. The district court also criticized the DTC rule on the grounds that it is "far afield of any other type of rulemaking authority HHS has previously exercised" under the Social Security Act. Op. 25 (J.A. __). The factual basis for the district court's assertion is unclear; as discussed above, several HHS rules impose requirements on pharmaceutical companies in connection with their participation in the Medicare and Medicaid programs. *See supra* pp. 6-7. But, even if HHS's regulation were novel, an agency's interpretation of its own authority "cannot be rejected simply because it is new." *Verizon*, 740 F.3d at 636 (citing *National Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005)). There is no desuetude principle in administrative law, and the district court was mistaken to suggest otherwise.

CONCLUSION

The judgment of the district court should be reversed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 10,955 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Garamond 14-point font, a proportionally spaced typeface.

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CERTIFICATE OF SERVICE

I hereby certify that on September 23, 2019, I electronically filed the foregoing brief 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. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

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