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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

FINAL REPLY BRIEF FOR APPELLANTS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases: **Page(s)**

Statutes:

Regulations:

Rule:

Other Authorities:

GLOSSARY

DTC	Direct-to-Consumer
HHS	U.S. Department of Health and Human Services

SUMMARY OF ARGUMENT

1. The Department of Health and Human Services (HHS) promulgated the challenged rule (the "DTC rule") to mitigate a crisis in prescription drug costs that threatens the sustainability of Medicare and Medicaid. In promulgating the rule, the agency relied on grants of rulemaking authority that are "far-ranging" in scope. *National Welfare Rights Org. v. Mathews*, 533 F.2d 637, 640 (D.C. Cir. 1976). Indeed, this Court has previously observed that "[a] more plenary [grant] of rule-making power would be difficult to devise." *Id.* Nevertheless, plaintiffs contend that the rule is beyond the limits of this plenary grant of rulemaking authority.

That argument is unsupported by rulemaking provisions' text. Notably, plaintiffs do not defend the district court's reasoning that HHS lacked authority to promulgate the rule because pharmaceutical manufacturers are not direct participants in the Medicaid and Medicare programs. They concede that manufacturers do participate in those government programs, but assert that HHS nevertheless lacks power to require drug-pricing disclosures because it may regulate only in its capacity as insurer. But HHS did regulate here in its capacity as an insurer, tailoring the DTC rule's disclosure mandate to drugs that manufacturers make eligible for Medicaid and Medicare reimbursement. And in any event, plaintiffs provide no textual basis for their "insurer" gloss on the rulemaking provisions, a gloss that is in conflict with this Court's precedent concerning HHS's rulemaking provisions and with the cases plaintiffs themselves cite.

Beyond the text, plaintiffs point to nothing in the structure of the Social Security Act demonstrating that Congress intended to disable HHS from promulgating price-disclosure rules. Rather, plaintiffs note only that Congress chose to specifically require disclosures of certain other information in other contexts. But the fact that Congress required disclosure elsewhere but did not specifically require it in this context does not help plaintiffs here: Congress gave HHS broad rulemaking authority, and there is no evidence that Congress ever considered and precluded the proposal at issue in this case. Plaintiffs' other arguments—that this rule falls within a "major questions" exception to rulemaking authority and that it would create constitutional nondelegation problems—are unsupported by precedent and should be rejected.

2. Plaintiffs also argue on appeal that the rule violates the First Amendment by unconstitutionally compelling their commercial speech. The district court never adjudicated plaintiffs' constitutional claim, and there is no reason for this Court to do so in the first instance. Instead, this Court should reverse the judgment of the district court, which rests solely on that court's mistaken conclusion that HHS lacks statutory authority to promulgate the rule, and remand for further proceedings.

If the Court nevertheless chooses to reach the First Amendment question, it should reject the constitutional challenge. Compelled disclosures of factual and uncontroversial information relating to commercial transactions are generally upheld so long as the regulation is reasonably related to a government interest and does not

unduly burden protected speech. The DTC rule is factual and uncontroversial because it requires only the disclosure of a drug's list price and a disclaimer that accurately notes that consumers' actual drug costs may be different if they have health insurance that covers drugs. And the DTC rule advances the government's interest in improving the efficiency of Medicare and Medicaid and does not curtail any speech. Finally, even if the rule were properly analyzed under the intermediate scrutiny that applies to restrictions on commercial speech, it would pass that scrutiny because the DTC rule directly advances a substantial government interest and restricts no more speech than necessary to serve that interest.

ARGUMENT

I. HHS HAS STATUTORY AUTHORITY TO PROMULGATE THE DTC RULE.

The government's opening brief explained that HHS has authority to promulgate the DTC rule under 42 U.S.C. § 1302(a) and 42 U.S.C. § 1395hh(a)(1), which respectively empower the agency to make rules "as necessary to the efficient administration of the functions with which [it] is charged" under the Social Security Act and "as necessary to carry out the administration of the insurance programs" under Medicare. In response, plaintiffs principally argue (at 21-35) that the DTC rule is unrelated to the "administration" of Medicare and Medicaid. And while they do not directly dispute that the DTC rule is "necessary" to advance the goals of those programs, they argue (at 35-41) that the Supreme Court decisions interpreting similar

language in other rulemaking statutes are inapplicable here. Plaintiffs err on both counts.

A. The DTC rule is reasonably related to the "administration" of Medicare and Medicaid.

The parties agree (*see* Pl. Br. 21-22) that whether the DTC rule relates to the administration of Medicare and Medicaid programs is a question analyzed under the *Chevron* framework. The issue, therefore, is whether the statute "unambiguously forecloses the agency's interpretation, and therefore contains no gap for the agency to fill." *National Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 982-83 (2005). If it does not, then Congress is presumed to have delegated "authority to the agency to fill the statutory gap in reasonable fashion." *Id.* at 980. As the government's opening brief demonstrated, neither the text nor the structure of the Social Security Act unambiguously foreclose HHS from requiring price disclosures in television advertisements for drugs that manufacturers choose to make eligible for Medicare or Medicaid reimbursement.

1. We start with the text. The district court ruled that the term "administration" assigned HHS authority to regulate only "direct participants in the Medicare or Medicaid programs," not "market actors" who "impact program costs in an indirect way." J.A. 23. The government explained (at 29-31) that "administration" sweeps more broadly and that, even if it did not, pharmaceutical manufacturers are direct participants in the Medicare and Medicaid programs. Manufacturers must sign

agreements with HHS in order for their drugs to be eligible for reimbursement, and Congress and HHS have previously imposed numerous conditions as part of those agreements.

Plaintiffs now acknowledge, parting ways with the district court, that they are participants in the Medicare and Medicaid programs. They concede that, as a condition of participating in those programs, they "execute rebate and discount agreements, provide congressionally-mandated information to HHS, and so on." Pl. Br. 26-27. And they do not dispute that the district court was therefore wrong to treat them solely as "market actors" who (unlike "health care providers, private plan carriers, or beneficiaries") do not "play[] a direct role in the public health insurance programs." J.A. 23 (footnote omitted).

Rather than defending the district court's distinction between "direct participants" and "market actors," which actually works in the agency's favor, plaintiffs interpret the "administration" language in sections 1302(a) and 1395hh(a)(1) even more narrowly than the district court. They argue that this language allows HHS to promulgate rules only "in its capacity as insurer." Pl. Br. 23. Even under that proposed reading, plaintiffs concede that sections 1302 and 1395hh would give HHS power to (in at least some cases) "define the coverage of particular products and services" and "require certain agreements related to Medicare and Medicaid to be in writing." *Id.* But, they contend, those provisions would not empower HHS "as insurer" to "regulat[e] how third parties interact with one another." Pl. Br. 23-24.

Plaintiffs' cramped construction of HHS's rulemaking authority is incorrect. It cannot be squared with this Court's observation that "[a] more plenary [grant] of rule-making power [than that provided by HHS's rulemaking provisions] would be difficult to devise." *National Welfare Rights Org.*, 533 F.2d at 640; *accord Thorpe v. Housing Auth. of City of Durham*, 393 U.S. 268, 277 n.28 (1969) (section 1302(a) confers "broad rule-making powers"). And it fails to come to terms with this Court's teaching that agencies may exercise their general rulemaking authority 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), *overruled on other grounds by American Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). As those precedents make clear, and as the statutory language itself provides, HHS has plenary authority to promulgate rules furthering all of "the functions with which [the agency] is charged" under the Medicare and Medicaid statutes, 42 U.S.C. § 1302(a). As demonstrated in the government's opening brief (at 25-27), and as undisputed by plaintiffs, those functions include ensuring cost efficiency for the programs themselves and transparency for Medicare and Medicaid recipients. The DTC rule unquestionably advances those goals.

In any event, HHS's rule would be permissible even accepting plaintiffs' narrow "insurer" gloss. Plaintiffs concede that HHS can, "in its capacity as insurer," "define the coverage of particular products and services." Pl. Br. 23. HHS confined the DTC rule only to pharmaceutical drugs that manufacturers choose to make

eligible for Medicare and Medicaid reimbursement. 42 C.F.R. § 403.1200(a). Under this approach, HHS is simply attaching requirements to insured products for the benefit of Medicare and Medicaid recipients.

The cases that plaintiffs cite further refute their textual theory. For example, in *Cottage Health System v. Sebelius*, 631 F. Supp. 2d 80 (D.D.C. 2009), the district court held that HHS could require hospitals, as a condition of receiving Medicare payments, to maintain written agreements with all "non-hospital sites" that helped train their residents. *Id.* at 86, 91-93. The court ruled that this requirement was proper under section 1395hh because ensuring that hospitals fully bore the cost of medical training for which they were to be reimbursed advanced "the orderly administration of the Medicare program." *Id.* at 92. That reasoning undercuts plaintiffs' argument that HHS categorically lacks general rulemaking authority to "regulate[] how third parties interact with one another" for the "indirect" purpose of "saving program funds." Pl. Br. 24.

2. Plaintiffs' structural arguments fare no better. Plaintiffs point to no limitation in the Medicare or Medicaid statutes indicating that Congress, in enacting sections 1302 and 1395hh, intended to bar HHS from promulgating rules like this one. *Cf. Colorado River Indian Tribes v. National Gaming Comm'n*, 466 F.3d 134 (D.C. Cir. 2006) (discussed in Opening Br. 34-35). The most that they can marshal are statutory provisions showing that Congress *approved* of information disclosure, and specifically empowered HHS to require such disclosures, in other contexts and for other reasons.

But those statutes are irrelevant for the reasons discussed in *Texas Rural Legal Aid, Inc. v. Legal Servs. Corp.*, 940 F.2d 685 (D.C. Cir. 1991). In *Texas Rural Aid*, the Court explained 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." *Id.* at 694. Similarly, a congressional decision to require certain activities does not imply an intent to disable the relevant agency from "taking similar action with respect to activities that pose a similar danger." *See* Opening Br. 38-39.

Plaintiffs have no response to that principle, which forecloses their structural argument. And another case they cite, *Goodman v. Sullivan*, 891 F.2d 449 (2d Cir. 1989) (per curiam), underscores that related congressional action does not disempower HHS from regulating under sections 1302 and 1395hh. There, the Medicare statute provided that HHS should not reimburse items and services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury." *Id.* at 450 (quoting 42 U.S.C. § 1395y(a)(1)(A) (Supp. V 1987)). HHS implemented that statute by prohibiting "payment of benefits for any experimental, investigational, or unproven treatment or diagnostic method not yet generally accepted in the medical profession." *Id.* Although the Second Circuit understood that HHS's rule swept more broadly than the statute, it upheld the rule nevertheless, concluding that Congress, by prohibiting reimbursement for some services, did not intend to disallow HHS from prohibiting

reimbursement for others. *Id.* ("The prohibitory language of [the statute] … is not reasonably interpreted as an affirmative mandate.").

In all events, the statutory provisions that plaintiffs cite are distinguishable even under plaintiffs' framework. First, plaintiffs argue (at 27-28) that the government's position would render superfluous 42 U.S.C. § 1396r-8(b)(3)(A), which provides that all manufacturers "shall report to the Secretary" various types of price information, including the "average manufacturer price … for covered outpatient drugs." But Congress choosing to compel disclosure of some information does not imply that the agency lacks discretionary rulemaking authority to require disclosure of similar information to other parties. It is entirely consistent for Congress to legislate to advance specific priorities (here, the disclosure of certain price data to HHS) while also allowing HHS broad latitude to regulate for changing circumstances.

In arguing to the contrary, plaintiffs invoke (at 28) this Court's decision in *Loving v. IRS*, 742 F.3d 1013 (D.C. Cir. 2014). In that case, the Internal Revenue Service promulgated a rule concerning an issue that Congress repeatedly had addressed. *See id.* at 1020 (noting that Congress has narrowly regulated the behavior of tax preparers). Here, there is no similar evidence that Congress ever considered the extent to which drug manufacturers should be required to disclose prices to consumers. Unlike in *Loving*, there is no basis to conclude that "multiple Congresses have acted as if" HHS lacked authority to issue this rule. *Id.*

Plaintiffs also claim that two other grants of authority to HHS to regulate advertising and marketing materials disable the agency from promulgating this rule. But plaintiffs again overread the provisions they invoke. It is true that a 1997 amendment to the Social Security Act allows HHS to review, and, if appropriate, to "disapprove[] the distribution of" marketing materials prepared by private Medicare Advantage organizations. *See* 42 U.S.C. § 1395w-21(h). That provision was designed to ensure that Medicare beneficiaries were not misled into opting into Medicare Advantage plans, which are plans offered by private insurers under agreements with the government. The provision is focused solely on restricting advertisements relating to private plans; it says nothing (expressly or by implication) about HHS's authority to make public health programs more efficient through the less-intrusive step of requiring disclosures in drug marketing by drug manufacturers. And it was enacted as part of omnibus legislation creating Medicare part C, a legislative undertaking that says nothing about whether HHS could act in another context under its general rulemaking authority. *Cf. Loving*, 742 F.3d at 1019 ("[L]awmakers, like Shakespeare characters, sometimes employ overlap or redundancy so as to remove any doubt and make doubly sure.").

Finally, plaintiffs insist (at 29-30) that Congress's grant of authority to the Food and Drug Administration to regulate drug advertising for safety purposes shows that Congress did not intend HHS to require disclosures in drug advertising for other purposes. As explained in the government's opening brief (at 36-39), that argument is

illogical and contrary to precedent. The only additional authority that plaintiffs provide, *Federal Maritime Commission v. Seatrain Lines, Inc.*, 411 U.S. 726 (1973), is inapposite because that case did not involve any agency rulemaking, and because the Supreme Court determined that unrelated statutory provisions at most rendered a statute "ambiguous." *Id.* at 744. Ambiguity is all that the agency needs to prevail here, where Congress has entrusted HHS to "fill the consequent statutory gap" by promulgating reasonable rules. *Brand X*, 545 U.S. at 997.

3. Plaintiffs also err in suggesting that the "scope" of HHS's asserted rulemaking authority weighs against this rule. Plaintiffs do not dispute that the DTC rule's costs are a pittance compared to plaintiffs' advertising expenditures, or that this rule would not significantly alter the nature of their advertisements. *See* Opening Br. 42. Instead, they argue (at 32) that upholding this rule would embolden the agency to make hypothetical future rules that might have more significant effects.

This Court considered and rejected a similar line of argument in *Verizon v. FCC*, 740 F.3d 623 (D.C. Cir. 2014). There, the Court sustained the FCC's interpretation of statutory provisions that allowed the agency to undertake regulation of broadband Internet providers. *Id.* at 639. The Court did so even though the regulatory initiative there—in contrast to the DTC rule—"certainly involve[d] decisions of great 'economic and political significance.'" *Id.* (quoting *FDA v. Brown & Williamson*, 529 U.S. 120, 160 (2000)). It did so, moreover, even though—again in

contrast to this case—the agency's assertion of authority there was "new," and the agency had previously disavowed the authority it invoked. *Id.* at 636.

The Court dismissed concerns in *Verizon* that the agency's assertion of regulatory authority "would have no limiting principle." 740 F.3d at 639. The limits identified in the government's opening brief in this case are the same limiting principles that satisfied this Court in *Verizon*. First, HHS—like the FCC—must read its rulemaking authority "in conjunction with other provisions of the" statutes it administers. *Id.* at 640; *see* Opening Br. 43 (identifying other provisions that limit HHS's power). And second, HHS may only regulate "to achieve a particular purpose": here, to advance the efficient administrations of the Medicare and Medicaid programs. *Verizon*, 740 F.3d at 640. If those limitations were enough to uphold the assertion of regulatory authority in *Verizon*, then notwithstanding the plaintiffs' objections (at 33-34), they are likewise sufficient here.

4. Finally, plaintiffs suggest that their reading is compelled by principles of constitutional avoidance, because sections 1302 and 1395hh would otherwise "present serious constitutional difficulties under the nondelegation doctrine." Pl. Br. 34-35. There is nothing to that assertion. Under principles of constitutional avoidance, a court may adopt a plausible interpretation of an ambiguous statute only if a different interpretation would raise "serious constitutional concerns." *Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 577 (1988); *see National Mining Ass'n v. Kempthorne*, 512 F.3d 702, 711 (D.C. Cir. 2008) (noting that the canon

of constitutional avoidance does not apply "at the mere mention of a possible constitutional problem"). Here, there is no serious constitutional challenge to these provisions because the Supreme Court has repeatedly rejected nondelegation challenges to similar grants of rulemaking authority. *See, e.g.*, *Skinner v. Mid-America Pipeline Co.*, 490 U.S. 212, 222 (1989) (statute empowering IRS to "prescribe all needful rules and regulations for the enforcement of [the Code]" was "entirely appropriate delegation[] of discretionary authority by Congress" (alteration in original)); *National Broad. Co. v. United States*, 319 U.S. 190, 225-26 (1943) (similar). Plaintiffs have no explanation for why this case is distinguishable from those.[1]

B. The DTC rule is "necessary."

Plaintiffs also attack the government's reliance on *Mourning v. Family Publications Service, Inc.*, 411 U.S. 356 (1973), and *Thorpe v. Housing Authority of City of Durham*, 393 U.S. 268 (1969). In doing so, plaintiffs mischaracterize the nature of the government's reliance on those cases.

The rulemaking provisions in this case authorize HHS to promulgate rules that "may be necessary" for "the efficient administration," 42 U.S.C. § 1302(a), or simply "the administration," *id.* § 1395hh(a)(1), of the Medicare and Medicaid programs. As

[1] Plaintiffs also suggest (at 30-31) that the Court should interpret the statute differently in light of their First Amendment objections to the DTC rule. Whether HHS has the power to require disclosures to Medicare and Medicaid beneficiaries has nothing to do with whether this rule violates the First Amendment for the fact-specific reasons plaintiffs allege. *See infra* Part II.

our opening brief explains (at 19-22), *Mourning* and *Thorpe* speak to whether the DTC rule is "necessary" in the relevant sense of that statutory term, not to whether the rule relates to the "administration" of the Medicare and Medicaid programs. Plaintiffs never argue that the DTC rule is not "necessary," and so appear to concede the interpretive point that *Mourning* and *Thorpe* address. Nevertheless, it is important to clarify some of plaintiffs' misconceptions about those precedents.

First, plaintiffs err in urging this Court to ignore the Supreme Court's teachings in *Mourning* and *Thorpe*. Contrary to their suggestion (at 36), *Mourning* and *Thorpe* have not been overruled by the Supreme Court or subsumed into the *Chevron* framework. On the contrary, they have been applied by this Court several times in the past decade, most recently this year. *Doe, 1 v. FEC*, 920 F.3d 866, 871 (D.C. Cir. 2019); *National Ass'n of Mfrs. v. SEC*, 748 F.3d at 366. And those cases hold that *Mourning* and *Thorpe* do establish the "universally applicable 'reasonable relationship' standard" that plaintiffs deny. *See* Pl. Br. 36. As this Court held in *Doe, 1*, "[w]hen an agency's 'empowering provision' contains such language [as in *Mourning* and *Thorpe*], the courts will sustain a regulation that is 'reasonably related' to the purposes of the legislation." 920 F.3d at 870-71 (quoting *Mourning*, 411 U.S. at 369).

Of course, as plaintiffs note, that is not the end of the matter; not all rules will survive under that standard. *See, e.g.*, *Colorado River*, 466 F.3d at 139. *Motion Picture Ass'n of Am., Inc. v. FCC*, 309 F.3d 796 (D.C. Cir. 2002), which plaintiffs cite (at 38), is an example: there, the Court held that a statute empowering the agency to require

one technology and to "commence an inquiry" into a second technology showed that Congress did not intend the agency to require the second technology by rule.[2] 309 F.3d at 802, 805. But again, plaintiffs identify no similar structural feature that reveals Congress's intent as to the DTC rule. *See supra* pp. 7-11.

Finally, plaintiffs gain no ground by attempting (at 39-40) to minimize the holdings of *Mourning* and *Thorpe* based on their facts. It is true that, in *Thorpe*, the Supreme Court noted that Congress had expressed a policy preference for universal housing and had directed agencies to act "consistently" with that policy. *Thorpe*, 393 U.S. at 281 n.37. But that fact, in the Court's analysis, went to whether the challenged rule was "reasonably related" to the purposes of the statute—not to whether the "reasonably related" standard was the correct one. *Id.* at 280-81.

Similarly, plaintiffs correctly note that, in *Mourning*, the rulemaking provision at issue empowered the agency to make regulations "necessary or proper to effectuate the purposes of (the Act), to prevent circumvention or evasion thereof, or to facilitate compliance therewith." 411 U.S. at 361-62. But, even though plaintiffs describe the "prevent circumvention or evasion" language (which was not present in *Thorpe*) as "crucial[]," Pl. Br. 40, the Court thought otherwise; its analysis section focuses solely on the "necessary" language, never relying on the language that plaintiffs think

[2] Although plaintiffs claim (at 38) that *Motion Picture Ass'n* is a case about general rulemaking authority, the agency in that case "conceded at oral argument[] that the video description rules are arguably justified only" under a provision other than its general rulemaking authority. 309 F.3d at 806.

important. *See* 411 U.S. at 369-78. The facts of *Mourning* and *Thorpe* therefore do not narrow their holdings that a regulation enacted under a general rulemaking provision "will be sustained so long as it is 'reasonably related to the purposes of the enabling legislation.'" *Id.* at 369 (quoting *Thorpe*, 393 U.S. at 280-81) (footnote omitted).

II. THE DTC RULE DOES NOT VIOLATE THE FIRST AMENDMENT.

In addition to challenging the agency's statutory authority to promulgate the DTC rule, plaintiffs assert that the rule violates the First Amendment. The district court did "not reach Plaintiffs' First Amendment challenge," resolving the case solely on the statutory grounds presented in this appeal. J.A. 12. If this Court reverses that statutory holding, the Court should follow its "usual practice" and "decline to address arguments unaddressed by the district court." *Wang ex rel. Wong v. New Mighty U.S. Trust*, 843 F.3d 487, 496 (D.C. Cir. 2016) (alterations adopted). If the Court nevertheless chooses to reach the constitutional issue, it should hold that the DTC rule is consistent with the First Amendment.

A. The required disclosure satisfies review under *Zauderer*.

Plaintiffs concede (at 42) that the DTC rule affects only commercial speech, which is afforded constitutional protection "less extensive than that afforded 'noncommercial speech.'" *Zauderer v. Office of Disciplinary Counsel of the Sup. Ct. of Ohio*, 471 U.S. 626, 637 (1985). And they likewise do not dispute that the DTC rule does not bar plaintiffs from speaking, but instead merely imposes a disclosure requirement. When the government requires that a commercial advertiser "include in [its]

advertising purely factual and uncontroversial information about the terms under which [its] services will be available," the regulation is valid under the First Amendment "as long as disclosure requirements are reasonably related to the State's interest." *Id.* at 651. By their nature, required disclosures of factual information "will almost always demonstrate a reasonable means-ends relationship, absent a showing that the disclosure is 'unduly burdensome' in a way that 'chill[s] protected commercial speech.'" *American Meat Inst. v. USDA*, 760 F.3d 18, 26 (D.C. Cir. 2014) (*AMI*) (en banc) (quoting *Zauderer*, 471 U.S. at 651).

1. This case falls within *Zauderer*'s ambit. The DTC rule requires pharmaceutical advertisers to include two sentences of purely factual and uncontroversial information about drug prices. The first sentence requires advertisers to disclose the list price of the advertised drug. 42 C.F.R. § 403.1202. As HHS explained, a drug's list price is an "objective fact": it is a "manufacturer-specified metric that is commonly used, reported in compendia, defined in statute, and relevant to both federal and commercial healthcare programs." 84 Fed. Reg. 20,732, 20,744 (May 10, 2019) (J.A. 209). And the second sentence, which informs the viewer that "[i]f you have health insurance that covers drugs, your cost may be different," is likewise "undeniably a truthful statement of objective fact." *Id.*; *see* 42 C.F.R. § 403.1202.

Nor is the proposed disclaimer "controversial." In a recent *Zauderer* case, the Supreme Court did not dwell on this requirement, noting that the "essential features"

of *Zauderer* are that the disclosure must involve "only an accurate statement" of "factual information." *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 249-50 (2010). And this Court has explained that factual disclaimers will generally be uncontroversial, although it has left open the possibility that a "required factual disclosure[] could be so one-sided or incomplete that [it] would not qualify as 'factual and uncontroversial.'" *AMI*, 760 F.3d at 27. That potential exception, whatever its scope, is not met here. There is no claim that the disclosure requirement takes a side in a heated political debate. *Cf. NIFLA v. Becerra*, 138 S. Ct. 2361, 2372 (2018) (striking down law that required clinics "to disclose information about state-sponsored services—including abortion, anything but an 'uncontroversial' topic"); *National Ass'n of Mfrs. v. NLRB*, 717 F.3d 947, 958 (D.C. Cir. 2013) (discussing claim that a disclosure "favor[ed] unionization"), *overruled on other grounds by AMI*, 760 F.3d 18. And lack of comprehensiveness in the disclosure is no basis for constitutional objection, because the disclosure requirement "do[es] not prevent [advertisers] from conveying additional information." *Milavetz*, 559 U.S. at 249; *see Spirit Airlines v. U.S. Dep't of Transp.*, 687 F.3d 403, 413-14 (D.C. Cir. 2012) (applying *Zauderer* where the challenged disclosure "does not prohibit airlines from saying anything").

Plaintiffs' arguments to the contrary are insubstantial. Plaintiffs do not dispute the list price of their drugs, or that some drug purchasers will pay the list price. *See* Pl. Br. 8-11. They therefore cannot credibly dispute that the disclaimer concerns "the terms under which [plaintiffs'] services will be available," *Zauderer*, 471 U.S. at 651, or

that it presents purely factual information. Nor do they explain why any alleged incompleteness in the disclosure cannot be addressed, like the disclosure upheld in *Milavetz*, by "additional information." 559 U.S. at 250.

Plaintiffs claim that the disclosure requirement is "subject to misinterpretation by customers" because most individuals will not pay a drug's list price. Pl. Br. 53. Plaintiffs rely on *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), which was overruled in part by *AMI*, and its "misinterpretation" prong may no longer be part of the *Zauderer* analysis. But in any event, plaintiffs overstate the risk of misinterpretation. As HHS explained in its final rule, a drug's list price directly correlates with many insured individuals' out-of-pocket costs, including the prices paid by Medicare part B beneficiaries (who generally pay a twenty-percent coinsurance based on a drug's list price or on a closely related measure) and Medicare part D beneficiaries (who often will be charged thirty-to-fifty-percent coinsurance based on a drug's negotiated price, which closely resembles the list price). 84 Fed. Reg. at 20,740 (J.A. 205). As a result, many Medicare beneficiaries are exposed to out-of-pocket costs that are correlated to the list price, and comparing the list prices of alternative drugs provides useful guidance about the relative out-of-pocket costs. *Id.*

Moreover, the risk of misinterpretation is entirely irrelevant because an advertiser "retains the ability to eliminate all doubt about the [disclosure's] meaning." *National Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 539 (D.C. Cir. 2015) (Srinivasan, J., dissenting). For example, if plaintiffs are concerned that individuals without

insurance will misunderstand the disclosure (Pl. Br. 10-11), nothing stops them from adding a sentence to explain that those individuals may also pay prices below the list price. Similarly, plaintiffs can add accurate language regarding the likelihood that many individuals with insurance will pay significantly less than the list price (*see* Pl. Br. 8-10). And plaintiffs can point consumers to websites that provide consumers with additional pricing information (*see* Pl. Br. 44 n.25). Plaintiffs cannot contend that providing such additional information would be "so burdensome that it essentially operates as a restriction on constitutionally protected speech," *AMI*, 760 F.3d at 27, because pharmaceutical television advertisements already feature numerous textual disclaimers because of the nature of the product. *Zauderer* therefore governs this case.

2. The DTC rule satisfies the *Zauderer* standard. As noted, under *Zauderer*, the Court must uphold the disclosure requirement if it is "reasonably related to the [government's] interest," and not so "unjustified or unduly burdensome" as to "chill[] protected … speech." 471 U.S. at 651; *see AMI*, 760 F.3d at 22-23. Here, plaintiffs do not dispute that the government has a substantial interest in "improv[ing] 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. 198); *see* Pl. Br. 43. Nor do they assert that the disclosure requirement even chills—much less unduly burdens—their speech. *Cf. NIFLA*, 138 S. Ct. at 2378 (noting that the challenged disclosure was so lengthy and prominent as to "drown[] out the facility's own message"). The disclosure requirement therefore satisfies the *Zauderer* test.

Precedent forecloses plaintiffs' theory that the government must present "evidence establishing that disclosure of a drug's [list price] … will reduce overall program spending." Pl. Br. 54. *Zauderer* rejected the argument that the government must "muster substantial evidentiary support for any of the findings" required to support the disclosure. 471 U.S. at 650. And this Court has explained that *Zauderer* does not "require[] evidence of a measure's effectiveness … assuming of course that the reason for informing consumers qualifies as an adequate interest." *AMI*, 760 F.3d at 26. Even were the evidentiary record as weak as plaintiffs suggest (and it is not), the rule would still survive *Zauderer* review.

The post-*AMI* decision in *National Ass'n of Manufacturers* is not to the contrary. There, the challenged rule imposed disclosure requirements on companies that used certain minerals as a way of ameliorating a humanitarian crisis in the Democratic Republic of the Congo. *See* 800 F.3d at 525. The court explained that the rule's asserted effect was "entirely unproven" and "rest[ed] on pure speculation," while "[o]ther post-hoc evidence [threw] further doubt on whether the … rule either alleviates or aggravates the stated problem." *Id.* at 525-26. Here, by contrast, there is evidence that the disclaimer will advance the government's goal, *see infra* p. 23, and there is no contrary evidence in the record. *Zauderer* does not demand more. *See AMI*, 760 F.3d at 26 (disclosures "will almost always demonstrate a reasonable means-ends relationship").

B. The required disclosure would pass muster under *Central Hudson*.

Even if *Zauderer* were inapplicable, the DTC rule would still be constitutional. Government restrictions on commercial speech—and to repeat, the DTC rule does not restrict any speech at all—are ordinarily reviewed under the standards set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). That framework requires courts to ask "whether the asserted governmental interest is substantial," "whether the regulation directly advances the governmental interest asserted," and whether the regulation "is not more extensive than is necessary to serve that interest." *Id.* at 566. As discussed above, plaintiffs do not contest that the government has a substantial interest in improving the efficiency of its benefits programs. And the DTC rule readily satisfies the two remaining prongs of the *Central Hudson* test.

1. To satisfy *Central Hudson*'s "directly advances" prong, the government must "demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 183, 188 (1999) (quotation marks omitted). *Central Hudson* does not require empirical certainty and, while the government's burden "is not satisfied by mere speculation or conjecture," *Edenfield v. Fane*, 507 U.S. 761, 770 (1993), the government can appropriately rely on empirical evidence to determine whether there is a "reasonable risk" of harm that would likely be remedied by the proposed action,

see Action for Children's Television v. FCC, 58 F.3d 654, 657 (D.C. Cir. 1995). *See also Edwards v. District of Columbia*, 755 F.3d 996, 1003 (D.C. Cir. 2014) ("The Supreme Court has permitted litigants to justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and simple common sense." (quotation marks omitted)).

The DTC rule satisfies that standard. HHS determined that "DTC advertising appears to directly affect drug utilization" and that such advertising can lead to increases in the costs of pharmaceuticals. 84 Fed. Reg. at 20,734 & n.12 (J.A. 199) (citing studies). It noted that both prescribers and customers generally lack information concerning the list price and the actual price for drugs. *Id.* at 20,734 (J.A. 199). And it observed that a study shows that including a list price and a disclaimer in advertising makes consumers more price-sensitive. *Id.* at 20,734 & n.18 (J.A. 199) (citing Jace B. Garrett et al., *Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising*, 179 JAMA Internal Medicine 435 (2019) (J.A. 235)). Together, those facts make it more than "mere speculation or conjecture," *Edenfield*, 507 U.S. at 770, that the information required by the DTC rule would enable customers to better understand the prices of pharmaceuticals and, therefore, to avoid costly drugs when less expensive alternatives are available.

Plaintiffs muster only speculation in response. They hypothesize (at 44-48) that consumers will not understand that they may pay less than the drug's list price. But

the prescribed disclaimer language informs consumers of that fact explicitly. *See* 84 Fed. Reg. at 20,741-42 (J.A. 206-07) (discussing JAMA study noting that "the risk of patients not seeking care is mitigated when the advertisement includes a caveat that [out-of-pocket] costs may be less."). And, although they complain that HHS lacks evidence that the DTC rule would "produce overall cost savings," Pl. Br. 49-50, they cite no authority suggesting that the government must know the exact effects of a rule pre-implementation. All that is required is a "reasonable fit," not absolute certainty. *POM Wonderful, LLC v. FTC*, 777 F.3d 478, 502 (D.C. Cir. 2015).

2. The DTC rule satisfies the final prong of *Central Hudson* because it is "not more extensive than is necessary" to serve the government's interest. 447 U.S. at 566. Contrary to plaintiffs' argument (at 50), the Supreme Court has explained that this test does not require the government to employ "the least restrictive means" of regulation or achieve a perfect fit between means and ends. *Board of Trustees of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989). It is sufficient that the government achieve a reasonable fit by adopting regulations "in proportion to the interest served." *Id.*; *see also Greater New Orleans Broad.*, 527 U.S. at 188 (fit need not be "the single best disposition" but only "one whose scope is in proportion to the interest served").

The required disclosure represents a reasonable means-end fit. HHS sought to "narrowly limit[] the amount of information included on the advertisements … to minimize the burden on manufacturers … [and] to only deliver the minimum amount of necessary information." 84 Fed. Reg. at 20,746 (J.A. 211). The rule is limited to

television advertising because HHS again sought "to define the rule as narrowly as possible," and to "have the largest impact with the smallest burden." *Id.* at 20,747 (J.A. 212).

HHS also considered and rejected various alternatives to the disclosure requirement. For example, HHS concluded that allowing pharmaceutical companies to voluntarily disclose their list prices would not be sufficient because "some manufacturers would decline to provide the list price to the patient, and the patient would therefore lack that valuable information." 84 Fed. Reg. at 20,750 (J.A. 215). And it determined that referring patients to drug manufacturers' websites would not work because "there would be a very low conversion of patients" (that is, few patients would access the websites) and because "33 percent of adults surveyed say they do not frequently use the internet." *Id.*

On appeal, plaintiffs suggest yet-more-farfetched alternatives. For example, they propose (at 50-51) that HHS itself could design a website to provide drug-pricing information, even though that proposal faces the same impediments identified by HHS with manufacturer websites. And they suggest (at 51) that HHS should reimburse healthcare providers for including counseling about treatment costs in their patient discussions, but they provide no reason to think that such a reimbursement scheme, which would require HHS to make additional provider payments but would not provide critical pricing information to patients, would actually reduce program costs on balance.

At bottom, plaintiffs misunderstand the First Amendment inquiry. They correctly note (at 52) that "regulating speech must be a last—not first—resort." *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 373 (2002). But that is why, rather than seeking to proscribe drug advertising, HHS mandated a targeted, two-sentence disclosure. As the *Zauderer* Court explained, "all our discussions of restraints on commercial speech have recommended disclosure requirements as one of the acceptable less restrictive alternatives to actual suppression of speech." 471 U.S. at 651 n.14 (citing *Central Hudson*, 447 U.S. at 565). That is what HHS has done here, and its rule comports with the First Amendment.

C. This Court should not grant a stay.

Assuming that this Court reverses the district court's ruling but declines to reach the First Amendment merits, there is no reason for it to stay the DTC rule's effective date pending the district court's resolution of the First Amendment claim, as plaintiffs request. Stay applications ordinarily must be made in the district court in the first instance, and there is no reason to depart from that settled practice in this case. *Cf.* Fed. R. App. P. 8(a)(1). As with the merits of plaintiffs' First Amendment claim, this Court should not rule on the stay question before the district court has an opportunity to do so. *Wang ex rel. Wong*, 843 F.3d at 496. If this Court reverses and remands, plaintiffs will have ample opportunity to ask the district court to stay the rule's effective date. The district court would be able to rule promptly on any

renewed stay motion if this Court remands. This Court can then review that determination through its normal appellate processes.

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 6,498 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 November 25, 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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