United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued January 13, 2020 Decided June 16, 2020

No. 19-5222

MERCK & CO., INC., ET AL.,
APPELLEES

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,
APPELLANTS

Appeal from the United States District Court
for the District of Columbia
(No. 1:19-cv-01738)

Ethan P. Davis, Principal Deputy Assistant Attorney General, U.S. Department of Justice, argued the cause for appellants. With him on the briefs were *Scott R. McIntosh* and *Joshua Revesz*, Attorneys, U.S. Department of Justice, and *Robert P. Charrow*, General Counsel, U.S. Department of Health and Human Services.

Barbara Jones, *William Alvarado Rivera*, *Kelly Bagby*, and *Maame Gyamfi* were on the brief for *amici curiae* AARP and AARP Foundation in support of appellants and reversal.

Richard P. Bress argued the cause for appellees. With him on the brief were *Daniel Meron*, *Caroline A. Flynn*, *Gregory*

B. in den Berken, *Robert Corn-Revere*, *Ronald G. London*, and *Annie M. Wilson*.

Cory L. Andrews was on the brief for *amicus curiae* Washington Legal Foundation, et al. supporting appellees and affirmance.

Jeffrey S. Bucholtz, *Joel McElvain*, and *Daryl L. Joseffer* were on the brief for *amicus curiae* Chamber of Commerce of the United States of America in support of appellees and affirmance. *Steven P. Lehotsky* entered an appearance.

Kevin King, *Rick Chessen*, and *Jared S. Sher* were on the brief for *amicus curiae* NCTA – The Internet & Television Association in support of appellees and affirmance.

Stephen B. Kinnaird and *Jerianne Timmerman* were on the brief for *amicus curiae* National Association of Broadcasters in support of appellees and affirmance.

Sean Marotta and *Ilya Shapiro* were on the brief for *amicus curiae* the Cato Institute in support of appellees and affirmance.

Timothy Sandefur and *Jonathan Riches* were on the brief for *amicus curiae* Goldwater Institute in support of appellees and affirmance.

Before: HENDERSON and MILLETT, *Circuit Judges*, and EDWARDS, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* MILLETT.

MILLETT, *Circuit Judge*: In May 2019, the United States Department of Health and Human Services' Centers for

Medicare and Medicaid Services published a rule that broadly requires drug manufacturers to disclose in their television advertisements the wholesale acquisition cost of many prescription drugs and biological products for which payment is available under Medicare or Medicaid. *See* Regulation to Require Drug Pricing Transparency, 84 Fed. Reg. 20,732 (May 10, 2019) ("Disclosure Rule" or "Rule"). In the overwhelming majority of cases, the price that the Disclosure Rule compels manufacturers to disclose bears little resemblance to the price beneficiaries actually pay under the Medicare and Medicaid programs.

A number of drug manufacturers challenged the rule on statutory and constitutional grounds, and they prevailed in district court. We affirm. The Department acted unreasonably in construing its regulatory authority to include the imposition of a sweeping disclosure requirement that is largely untethered to the actual administration of the Medicare or Medicaid programs. Because there is no reasoned statutory basis for its far-flung reach and misaligned obligations, the Disclosure Rule is invalid and is hereby set aside.

I

A

The Social Security Act, 42 U.S.C. §§ 301–1397mm, created the Medicare and Medicaid programs. *See id.* §§ 1395–1395*lll* (Title XVIII of the Social Security Act); *id.* §§ 1396–1396w-5 (Title XIX of the Social Security Act). Medicare is "a nationwide, federally funded health insurance program for the elderly and individuals with disabilities." *Anna Jacques Hosp. v. Burwell*, 797 F.3d 1155, 1156 (D.C. Cir. 2015). Medicaid "is a federal subsidy program that underwrites participating States' provision of medical services to 'families with dependent children and [to] aged, blind, or disabled

individuals, whose income and resources are insufficient to meet the costs of necessary medical services.'" *Salazar ex rel. Salazar v. District of Columbia*, 896 F.3d 489, 492 (D.C. Cir. 2018) (quoting *Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378, 1382 (2015)).

The Centers for Medicare and Medicaid Services ("Centers") administer Medicare and "the federal side" of Medicaid, *Ipsen Biopharmaceuticals, Inc. v. Azar*, 943 F.3d 953, 954 (D.C. Cir. 2019). *See Anna Jacques Hosp.*, 797 F.3d at 1157.

This case involves two provisions of the Social Security Act.

First, as relevant here, 42 U.S.C. § 1302(a) empowers the Secretary of Health and Human Services to "make and publish such rules and regulations, not inconsistent with [the Social Security Act], as may be necessary to the efficient administration of the functions with which [the Secretary] is charged" under the Medicare and Medicaid statutes. 42 U.S.C. § 1302(a).

Second, 42 U.S.C. § 1395hh(a)(1) provides that the "Secretary shall prescribe such regulations as may be necessary to carry out the administration of the [Medicare] insurance programs[.]" 42 U.S.C. § 1395hh(a)(1).

B

After undertaking the notice and comment process, the Centers published the Disclosure Rule in May 2019. *See* 84 Fed. Reg. 20,732 (May 10, 2019). The Rule requires pharmaceutical manufacturers to disclose pricing information in all of their television advertisements for any prescription drugs or biological products "distributed in the United States

for which payment is available, directly or indirectly," under Medicare or Medicaid. *Id.* at 20,732, 20,758 (codified at 42 C.F.R. § 403.1200 (2019)); *see id.* at 20,735. Specifically, television advertisements for covered pharmaceuticals must include a textual statement disclosing "the current list price for a typical 30-day regimen or for a typical course of treatment[.]" *Id.* at 20,758 (codified at 42 C.F.R. § 403.1202). The only exception is for drugs with a list price of "less than $35 per month for a 30-day supply or typical course of treatment[.]" *Id.* at 20,732, 20,758 (codified at 42 C.F.R. § 403.1200).[1]

The Rule defines "[l]ist price" as "the wholesale acquisition cost" for the pharmaceutical. 84 Fed. Reg. at 20,758 (codified at 42 C.F.R. § 403.1201(c)). "Wholesale acquisition cost" is, in turn, defined as "the manufacturer's list price for the prescription drug or biological product to wholesalers or direct purchasers[,] * * * not including prompt pay or other discounts, rebates or reductions in price[.]" *Id.* (codified at 42 C.F.R. § 403.1201(d)). The Rule acknowledges that the price manufacturers must disclose "may be different" from what consumers actually pay. *Id.* (codified at 42 C.F.R. § 403.1202).

The Disclosure Rule identifies 42 U.S.C. §§ 1302 and 1395hh as the sources of authority for the obligations it imposes. 84 Fed. Reg. at 20,757. In the Department's view, the Rule falls within those provisions because it "will improve the efficient administration of the Medicare and Medicaid programs by improving drug price transparency and informing

[1] The Disclosure Rule requires that the advertisements state in full: "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." 84 Fed. Reg. at 20,758 (codified at 42 C.F.R. § 403.1202) (brackets in original).

consumer decision-making, both of which can increase price competition and slow the growth of federal spending on prescription drugs." *See id.* at 20,732.

C

On June 14, 2019, pharmaceutical manufacturers Merck & Co., Inc., Eli Lilly and Company, and Amgen Inc., as well as the Association of National Advertisers, Inc., (collectively, "Manufacturers") filed suit challenging the lawfulness of the Disclosure Rule. They alleged that the Rule violates the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551 *et seq.*, because it (i) exceeds the Department's statutory authority, (ii) is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and (iii) violates the First Amendment. The same day they filed their complaint, the Manufacturers moved to stay the Rule pending judicial review and to expedite proceedings on the motion to stay. The district court promptly granted the motion to expedite and held a hearing two weeks later.

On July 8, 2019, the day before the Rule was to go into effect, the district court granted the motion to stay based on the merits of the statutory APA arguments and entered an order vacating the Rule. *See Merck & Co. v. HHS*, 385 F. Supp. 3d 81, 98 (D.D.C. 2019).

The district court ruled that neither Section 1302(a) nor Section 1395hh(a)(1) authorized the Department to impose the challenged disclosure requirement. *Merck*, 385 F. Supp. 3d at 90–98. Quite the opposite, the district court concluded that, "when viewed as a whole, the [Social Security Act] unambiguously does not delegate to [the Department] the power to promulgate the [Disclosure Rule]." *Id.* at 92.

The district court held that both Sections 1302(a) and 1395hh(a)(1) authorize the Secretary only to undertake the "administration" of the Medicare and Medicaid statutes. *Merck*, 385 F. Supp. 3d at 90. The court reasoned that those general grants of authority were limited "to establish[ing] rules and regulations for 'running' or 'managing' the federal public health insurance programs[.]" *Id.* The court concluded that the Rule exceeded that authority by regulating market actors (*i.e.*, pharmaceutical manufacturers) "that are not direct participants in the Medicare or Medicaid programs." *Id.* at 90–91; *see also id.* at 94 (finding that the Rule "regulates primary conduct several steps removed from the heartland of [the Department's] authority under the Social Security Act") (internal quotation marks omitted).

The district court added that, usually when Congress authorizes an agency to regulate direct-to-consumer advertising of pharmaceutical products, it says so directly. In the court's view, "Congress knows how to prescribe the content of drug advertising when it chooses to do so," and it did not use such language in Section 1302(a) or Section 1395hh(a)(1). *Merck*, 385 F. Supp. 3d at 95–96.

Finally, the district court emphasized that the Disclosure Rule "moves [the Department] into regulating the marketing of products that comprise 'a significant portion of the American economy[,]'" and that Congress would not have authorized such sweeping and substantial regulatory power in a statutory provision that merely grants general administrative authority. *Merck*, 385 F. Supp. 3d at 97 (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000)). Otherwise, the district court concluded, the Department could promulgate any rule "that might reasonably result in cost savings to the Medicare and Medicaid programs[.]" *Id.* at 98.

Having concluded that the Disclosure Rule exceeds the Department's statutory authority under the Social Security Act, the district court declined to reach the Manufacturers' other challenges. *Merck*, 385 F. Supp. 3d at 84, 98.

The Department timely filed a notice of appeal on August 21, 2019.

II

The first question presented—and the only one we need to resolve—is whether the Secretary properly relied on Sections 1302(a) and 1395hh(a)(1) to enact the Disclosure Rule. *See Louisiana Public Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) ("[A]n agency * * * has no power to act[] * * * unless and until Congress confers power upon it.").

In answering that question, we review the district court's interpretation of the Medicare and Medicaid statutes *de novo*. *See Loving v. IRS*, 742 F.3d 1013, 1016 (D.C. Cir. 2014). We approach that statutory interpretation task through the lens of *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). That means that, at what is known as *Chevron* Step One, we apply ordinary tools of statutory construction to determine "whether Congress has directly spoken to the precise question at issue." *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013) (internal quotation marks omitted). If the statute resolves it, that is the end of the matter. We enforce the statute as Congress directs. *Id.* (Courts "must give effect to [this] unambiguously expressed intent[.]"). If, however, the statute is ambiguous on the question at hand, we proceed to *Chevron* Step Two. There, we will generally uphold the agency's construction of the statute so long as it is a "reasonable interpretation." *See id.*

The Department acknowledges that *Chevron* governs this case, but then argues that its regulation must be upheld if it is "reasonably related to the purposes of the enabling legislation[.]" Department Br. 22 (quoting *Thorpe v. Housing Authority of the City of Durham*, 393 U.S. 268, 280–281 (1969)); *see also Mourning v. Family Publications Serv., Inc.*, 411 U.S. 356, 369 (1973) (Where the empowering provision of a statute authorizes an agency to make "such rules and regulations as may be necessary to carry out the provisions of th[e] Act," the Court will generally uphold regulations that are "reasonably related to the purposes of the enabling legislation.") (internal quotation marks omitted).

Even assuming that there is material distance in this case between *Mourning* and *Thorpe*'s "reasonably related" test and the well-established *Chevron* Step Two reasonableness inquiry, the government overreads those pre-*Chevron* cases. *Mourning* and *Thorpe* do not "state[] a canon of statutory interpretation for general rulemaking provisions." *Colorado River Indian Tribes v. National Indian Gaming Comm'n*, 466 F.3d 134, 139 (D.C. Cir. 2006) (quoting *Mourning*, 411 U.S. at 369). Instead, in "determining whether the agency's interpretation is permissible[,] * * * we must employ all the tools of statutory interpretation, including text, structure, purpose, and legislative history." *Loving*, 742 F.3d at 1016 (internal quotation marks omitted). After all, agencies are "bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes." *Colorado River*, 466 F.3d at 139–140 (quoting *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 231 n.4 (1994)); *see also Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 92 (2002) (explaining that *Mourning* does not authorize agencies to "contravene Congress' will").

III

The district court ruled at *Chevron* Step One that the Medicare and Medicaid statutes unambiguously foreclose the Secretary from requiring price disclosures in consumer advertising. *Merck*, 385 F. Supp. 3d at 92 ("[W]hen viewed as a whole, the [Social Security Act] unambiguously does not delegate to [the Department] the power to promulgate the [Disclosure Rule]."); *see also* Manufacturers Br. 22–35. But we need not decide whether Sections 1302(a) and 1395hh(a)(1) unambiguously foreclose *any* regulation of pharmaceutical advertisements or price disclosure requirements. Even assuming that the statutory provisions confer some relevant regulatory authority in those areas, the Disclosure Rule's blunderbuss operation falls beyond any reasonable exercise of the Secretary's statutorily assigned power.[2]

Recall that, as relevant here, Section 1302(a) directs the Secretary to "make and publish such rules and regulations, not inconsistent with [the Social Security Act], as may be *necessary to the efficient administration of the functions* with which [the Secretary] is charged under" the Medicare and Medicaid programs. 42 U.S.C. § 1302(a) (emphasis added). Similarly, Section 1395hh(a)(1) directs the Secretary to "prescribe such regulations as may be *necessary to carry out the administration of the insurance programs* under" the Medicare Act. *Id.* § 1395hh(a)(1) (emphasis added).

The Department argues that, under *Chevron* Step Two, it reasonably concluded that the Disclosure Rule is "necessary"

[2] Although the Manufacturers primarily advance their statutory construction arguments under *Chevron* Step One, they argue in the alternative that, "[f]or many of the same reasons, * * * [the Disclosure Rule] should fail at *Chevron* Step Two." Manufacturers Br. 35 n.22.

to the "efficient administration" of the Medicare and Medicaid programs because the "price transparency" that it introduces will "improve the efficiency of Medicare and Medicaid programs by reducing wasteful and abusive increases in drug and biological product list prices[.]" Department Br. 22–25 (quoting 84 Fed. Reg. at 20,733). In particular, the Secretary reasons, the Disclosure Rule will (i) incentivize manufacturers "to reduce their list prices by exposing overly costly drugs to public scrutiny," thereby reducing program costs, and (ii) provide "consumers with more information to better position them as active and well-informed participants in their health care decision-making." 84 Fed. Reg. at 20,733.

Neither of those arguments holds up. The Secretary's administrative authority is undoubtedly broad. *See Thorpe*, 393 U.S. at 277 n.28; *see also National Welfare Rights Org. v. Mathews*, 533 F.2d 637, 640 (D.C. Cir. 1976). But it is not boundless. To qualify as administering the Medicare or Medicaid statutes, a program of such intrusive regulation must do more than identify a hoped-for trickle-down effect on the regulated programs.

Instead, to fall within the Secretary's regulatory authority, rules must be "*necessary to the efficient administration* of the functions with which [the Secretary] is charged[,]" 42 U.S.C. § 1302(a) (emphasis added), or "*necessary to carry out the administration* of the insurance programs under" the Medicare subchapter of the Social Security Act, *id.* § 1395hh(a)(1) (emphasis added). "[A]dministration" is the central focus of both definitions. When the Social Security Act was enacted in 1935, this meant "the practical management and direction of"

its various programs (including eventually Medicare and Medicaid), as well as their "management" and "conduct."[3]

So for a regulation to be "necessary" to the programs' "administration," 42 U.S.C. §§ 1302(a), 1395hh(a)(1), the Secretary must demonstrate an actual and discernible nexus between the rule and the conduct or management of Medicare and Medicaid programs. The regulation's operational focus must also be on those two programs, and the rule's effect must be more than tangential. For example, the Secretary would be hard pressed to defend as necessary to program administration a rule forbidding vending machines or smoking breaks at

[3] *Administration*, BLACK'S LAW DICTIONARY 58 (3d ed. 1933) ("In public law. The administration of government means the practical management and direction of the executive department, or of the public machinery or functions, or of the operations of the various organs of the sovereign."); *Administration*, WEBSTER'S NEW INTERNATIONAL DICTIONARY 34 (2d ed. 1941) (defs. 1a, 2) (defining "administration" as the "[a]ct or process of administering" or "[t]he managing or conduct of an office or employment; the performance of the executive duties of an institution, business, or the like").

The term had essentially the same meaning in 1965 when Section 1395hh(a)(1) was enacted. *See Administration*, BLACK'S LAW DICTIONARY 65 (4th ed. 1951) (defining "administration" as the "[m]anaging or conduct of an office or employment"); *id.* ("In public law, the administration of government means the practical management and direction of the executive department, or of the public machinery or functions, or of the operations of the various organs of the sovereign[.]"); *see also Administration*, THE OXFORD ENGLISH DICTIONARY 163 (2d ed. 1989) (defs. 3, 4) (defining "administration" as "management" of either business or public affairs, relying on historical usage dating back to the Fourteenth Century).

businesses that employ Medicare or Medicaid recipients just because those measures could promote healthier living and thereby reduce program costs. In other words, the further a regulation strays from truly facilitating the "administration" of the Secretary's duties, the less likely it is to fall within the statutory grant of authority.

The Disclosure Rule strays far off the path of administration for four reasons.

First, disclosure of a pharmaceutical's "list price"—its wholesale acquisition cost, 84 Fed. Reg. at 20,758—bears little meaningful relationship to the price that either the federal government or Medicare and Medicaid beneficiaries pay for drugs. The Department conceded at oral argument that reimbursement under Medicare Part B "in most cases" is tied "to the average sales price of [a] drug" rather than to the wholesale acquisition cost. Oral Arg. Tr. 5:3–7. Occasionally, cost-sharing prices might also be "based on" the wholesale acquisition cost, but that is the exception rather than the rule. *See* 84 Fed. Reg. at 20,740; *cf.* Oral Arg. Tr. 6:4–20, 19:2–4 (asserting that, when there is no "established [average sales price,]" Part B reimbursements "can be" based on the wholesale acquisition cost).

The amount that Medicare *beneficiaries* pay under Part B is even further removed from the wholesale acquisition cost. As of 2019, Part B beneficiaries' annual deductible was only $185. Oral Arg. Tr. 19:20–21.[4] Once their deductibles are met, beneficiaries typically pay 20 percent coinsurance for prescription pharmaceuticals. Oral Arg. Tr. 19:20–20:12; *see*

[4] *See also* Disclosure Rule, 84 Fed. Reg. at 20,740; Centers for Medicare & Medicaid Services, *2019 Medicare Parts A & B Premiums and Deductibles*, https://www.cms.gov/newsroom/fact-sheets/2019-medicare-parts-b-premiums-and-deductibles.

also Disclosure Rule, 84 Fed. Reg. at 20,740. Therefore, even in the limited circumstances where the wholesale acquisition cost comes into play, consumers often are shielded from paying that amount. Moreover, the Rule did not rest on any finding that Medicare consumers are generally aware of how their payments are computed in relationship to the wholesale acquisition cost.

The Department also admitted that, under Medicare Part D, insurance plans typically do not pay the full wholesale acquisition cost. Rather, plan administrators and pharmacies actively negotiate over the appropriate price. *See* Oral Arg. Tr. 7:4–7. And again, beneficiaries typically pay only a fraction of this negotiated price, either in the form of a copay or coinsurance.[5]

The Secretary nonetheless insists that the wholesale acquisition cost is closely connected to the price Medicare participants pay, explaining that Part D beneficiaries who are responsible for coinsurance "effectively pay[] a percentage of a metric that is closely related" to the wholesale acquisition cost. Oral Arg. Tr. 7:9–12. But to state that what *some* Medicare beneficiaries pay is at best three steps removed from the disclosed wholesale acquisition cost only highlights the

[5] *See* Juliette Cubanski et al., Kaiser Family Foundation, *Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing*, figure 9 (May 17, 2018), https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing; Juliette Cubanski et al., Kaiser Family Foundation, *Medicare Part D: A First Look at Prescription Drug Plans in 2019* (Oct. 16, 2018), https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2019.

gulf between the Disclosure Rule and the actual operation of the Medicare program.

The relationship between wholesale acquisition cost and Medicaid is also quite attenuated. Under Medicaid, States develop plans to implement the Medicaid statute and to provide healthcare services to covered populations, subject to the Secretary's approval. 42 U.S.C. § 1396a(a), (b). At oral argument, the Department explained that each plan establishes the applicable drug prices to be paid under Medicaid in that State. Oral Arg. Tr. 16:1–8. When pressed, the Department said that it was unaware of any State that had adopted the wholesale acquisition cost as the applicable price, and that it was "unlikely" any had. Oral Arg. Tr. 16:9–15. Moreover, the Manufacturers note—and the Department does not contest—that the vast majority of Medicaid beneficiaries pay at most a nominal copayment for prescription drugs. *See* J.A. 250; *see also* Oral Arg. Tr. 59:8–24. And, again, the Secretary made no finding that Medicaid consumers were generally aware of any relationship between what they pay and the wholesale acquisition cost.

To be sure, the Secretary determined that "*some* consumers" will find that their coinsurance payments "increase as the [wholesale acquisition cost] increases." Disclosure Rule, 84 Fed. Reg. at 20,733 (emphasis added). That is so, the Secretary said, because patients will often pay *either* the wholesale acquisition cost or a cost-sharing amount of that price "when drugs are purchased early in the year before a deductible has been met, or during the plan year when coinsurance applies, or at any time when a drug is not covered by insurance[.]" *Id.* at 20,740. But it is not at all clear that this point specifically refers to Medicare or Medicaid consumers, as opposed to medical consumers generally. *See id.* at 20,740 ("A drug's [wholesale acquisition cost] has relevance as a

benchmark in both federal *and commercial* health care programs.") (emphasis added).

In any event, the Secretary's "either" reference again fails to show that any substantial number of Medicare or Medicaid consumers would pay the wholesale acquisition cost, or would even understand the relationship between what they pay and the price the Rule orders disclosed. In fact, the Centers admitted at oral argument that the wholesale acquisition cost is "a price that's rarely paid[.]" Oral Arg. Tr. 39:1. On this record, it is difficult to see how requiring the disclosure of wholesale acquisition cost to consumers generally promotes price transparency in any material way, or how it is otherwise related to the "administration" of either Medicare of Medicaid.

Second, similarly attenuated is the Secretary's claim that disclosure of the wholesale acquisition cost "*may* inform" consumers' "critical health care decisions related to their treatment with prescription drugs or biological products[.]" Disclosure Rule, 84 Fed. Reg. at 20,733 (emphasis added).

For starters, the Rule again leaves unclear if this point is aimed at Medicare and Medicaid consumers, or consumers generally. *See* 84 Fed. Reg. at 20,740. If the latter, as the Federal Register suggests, that would underscore the Rule's administrative overreach.

Anyhow, while agencies often can regulate based on educated judgments about probabilistic outcomes, that is not what is going on here. "May[be]" informing consumers about a price that Medicaid and Medicare customers will almost never pay, and that they are unlikely to understand, unlashes the disclosure from its claimed administrative mooring.

Worse still, the Secretary candidly acknowledged that the disclosure could just as well backfire. "[C]onsumers,

intimidated and confused by high list prices, may be deterred from contacting their physicians about drugs or medical conditions[,]" and may be "discourage[d] * * * from using beneficial medications." Disclosure Rule, 84 Fed. Reg. at 20,756. That, in turn, could "potentially increase [the] total cost of care" under the Medicare and Medicaid programs. *Id.* The Secretary also admitted a "lack [of] data to quantify these effects." *Id.* Generating potentially harmful confusion through disclosures to the general public of information that is largely disconnected from Medicare and Medicaid pricing is not a plausible means of administering the programs.

Third, the Disclosure Rule regulates advertising directed at the general public and not communications targeted specifically, or even predominantly, to Medicare or Medicaid recipients. *See* 84 Fed. Reg. at 20,732, 20, 758. That further increases the distance between the Disclosure Rule and any actual administration of those programs. Standing alone, that factor might not foreclose the Secretary's interpretation of his authority, but it opens another fissure between the required disclosure and the programs' administration, particularly when combined with the marginal relevance of the wholesale acquisition cost in the first place.

Fourth, and finally, the sweeping "nature and scope of the authority being claimed by the" Department underscores the unreasonableness of the Department's claim that it is just engaged in general "administration." *Loving*, 742 F.3d at 1021. As the Supreme Court has explained, "courts should not lightly presume congressional intent to implicitly delegate decisions of major economic or political significance to agencies." *Id.* (citing *Brown & Williamson*, 529 U.S. at 160); *see also Utility Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2444 (2014) ("When an agency claims to discover in a long-extant statute an unheralded power to regulate 'a significant portion of the

American economy,' we typically greet its announcement with a measure of skepticism.") (citation omitted) (quoting *Brown & Williamson*, 529 U.S. at 159–160).

The Department's construction of the statute would seem to give it unbridled power to promulgate any regulation with respect to drug manufacturers that would have the arguable effect of driving down drug prices—or even healthcare costs generally—based on nothing more than their potential salutary financial benefits for the Medicare or Medicaid program. This suggests a staggering delegation of power, far removed from ordinary administration. Could the Department dictate salaries at pharmaceutical companies that make or sell products "for which payment is available, directly or indirectly, under" Medicare or Medicaid, 84 Fed. Reg. at 20,758? Could it superintend pharmaceutical companies' business operations to cut costs? Surely not. But the Department's reasoning suggests that such regulations would be fair game as long as they ultimately resulted—even indirectly—in reduced Medicare or Medicaid expenditures or increased price competition.

The Department counters that *this* rule is not of major significance because compliance costs would be low. But that is hardly the only measure of significance. The Disclosure Rule at least implicates a substantial constitutional question concerning the government's authority to regulate the public speech of companies just because some percentage of the audience is involved in a governmental program from which the businesses indirectly derive financial benefit. *See AFL-CIO v. FEC*, 333 F.3d 168, 179–180 (D.C. Cir. 2003) (striking down the agency's construction under *Chevron* Step Two because the agency's approach raised "serious constitutional difficulties") (internal quotation marks omitted); *id.* (agency's construction was "properly addressed at *Chevron* [S]tep

[T]wo" because the statute was subject to "more than one constitutionally permissible interpretation").

In any event, the breadth of the Secretary's asserted authority is measured not only by the specific application at issue, but also by the implications of the authority claimed. *See Gonzales v. Oregon*, 546 U.S. 243, 248–249, 267–268 (2006) (rejecting the argument that Congress implicitly delegated the authority to "prohibit doctors from prescribing regulated drugs for use in physician-assisted suicide" in part because, under the Government's theory, the Attorney General would have broad power to "decide whether *any* particular drug may be used for any particular purpose," and whether "a physician who administers any controversial treatment could be" punished) (emphasis added).

In closing, we emphasize that nothing in this opinion holds that the Secretary is categorically foreclosed from regulating pharmaceutical advertisements. We leave that question for another day and hold only that no reasonable reading of the Department's general administrative authority allows the Secretary to command the disclosure to the public at large of pricing information that bears at best a tenuous, confusing, and potentially harmful relationship to the Medicare and Medicaid programs. Although the Secretary's regulatory authority is broad, it does not allow him to move the goalposts to wherever he kicks the ball.

IV

For the foregoing reasons, we affirm the district court's judgment vacating the Rule.

So ordered.