No. 20-1374

In the Supreme Court of the United States

CVS PHARMACY, INC., et al.,

Petitioners,

v.

JOHN DOE, ONE, et al.,

Respondents.

On a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS AND REVERSAL

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes and regulations

Statutes and regulations—continued

Other authorities

Other authorities—continued

Other authorities—continued

Other authorities—continued

SUMMARY OF ARGUMENT AND INTEREST OF THE *AMICUS CURIAE* *

The petition for a writ of certiorari in this case presented two questions: first, whether Section 504 of the Rehabilitation Act, as incorporated by Section 1557 of the Patient Protection and Affordable Care Act (ACA), provides for a disparate-impact cause of action alleging disability discrimination; and second, whether the recognition of such a right of action would invalidate the facially neutral terms and conditions of most prescription drug benefit plans. See Pet. i. The Court granted review of the first question alone. But the two questions are analytically linked, and the possibility that an affirmative answer to the first question may compel an affirmative answer to the second question weighs heavily in favor of petitioners and reversal.

The work of designing and implementing a prescription drug benefit plan is complex and multifaceted. The sponsors of prescription drug plans, often working with a third-party pharmacy benefit manager (PBM), must identify which drugs to cover, determine how costs will be shared between the plan and its participants, identify and negotiate discounts and rebates from hundreds of pharmaceutical manufacturers, and negotiate the terms of reimbursement with thousands of pharmacies. This is not a one-size-fits-all undertaking. Insurers and employers typically offer, and consumers have come to expect, a range of options that balance the size and scope of the benefit (which drugs are covered, at what pharmacies, on what terms) with

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* No counsel for a party authored this brief in whole or in part, and no party other than *amicus* or its counsel contributed financially to the preparation or submission of the brief. All parties have consented to the filing of this brief.

overall cost (the size of premiums and amount of cost sharing) in varying ways.

Congress recognized the value of the private market's approach to prescription drug coverage. It therefore incorporated market competition and benefit-management tools into the Medicare Part D program and the health insurance marketplaces offered under the ACA—both of which are governed by the nondiscrimination mandate of Section 1557. See *Nondiscrimination in Health and Health Education Programs or Activities*, 85 Fed. Reg. 37,160, 37,174 (June 19, 2020). In designing these federally subsidized health insurance programs, Congress intended for market forces to control costs and to foster consumer choice, subject to minimum federal protections. Consumers thus can choose among plans with greater levels of coverage for greater cost and those with lower levels of coverage for lower cost, depending on what fits their needs and budgets.

Reading a disparate-impact cause of action into the Rehabilitation Act, and consequently into Section 1557, would frustrate Congress's purpose in structuring the ACA exchanges and Medicare Part D program around patient choice, and would cripple the design of prescription drug benefits. There is no indication in the text, structure, or history of Section 1557 that Congress intended to gut these programs by authorizing condition-by-condition exceptions to the coverages that the plan designed and the consumer chose.

To be sure, the Nation's antidiscrimination laws require plan sponsors to treat participants equally, using facially neutral plan terms, without regard for disability. But they do not require plan sponsors to guarantee equally convenient access to all prescription drugs, regardless of important differences in the cost or

complexity of handling, dispensing, delivering, and administering such drugs.

Taken to its logical conclusion, the Ninth Circuit's contrary position would arguably invalidate the substantive terms of most prescription drug plans, compelling plan sponsors to tailor all benefits to the "unique pharmaceutical needs" of those with the most complex medical conditions. Pet. App. 15a. Because some disabling illnesses necessitate especially expensive or high-risk medications, participants with such illnesses will almost always find themselves disproportionately required to use prior authorizations, specialty pharmacies, mail services, and other benefit-management features. Under the Ninth Circuit's reasoning below, that represents an unlawful disparate impact, necessitating condition-by-condition exceptions to the use of essential and well-established benefit management tools. The exceptions would become the rule, and benefit design would be a matter principally for judges rather than plan sponsors.

Such an outcome would threaten the viability of prescription drug benefit plans and the ways they are designed and managed throughout the country. Mail-service and specialty pharmacies, for example, are essential for promoting plan participants' compliance with prescription drug regimens, ensuring quality control for drugs that require special handling, and containing the cost of expensive medications. The Ninth Circuit held, in practical effect, that these commonplace, yet essential, benefit management features are unlawful under Section 1557 because they discriminate among different classes of drugs—resulting, in turn, in a "disparate impact" on participants who depend on particularly expensive drugs to manage disabling health conditions. The Ninth Circuit's decision threatens the ongoing viability of a wide range of common

prescription drug benefit management tools and would deny consumers the benefit design choices they made when selecting their insurance coverage.

The Pharmaceutical Care Management Association (PCMA) is the national trade association representing the interests of PBMs. PCMA's members design and administer prescription drug benefits for more than 266 million Americans who have health insurance through employer-sponsored health plans, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans, and others. As part of its mission, PCMA seeks to promote and defend pharmacy benefit management tools proven to lower prescription drug costs while increasing access to drugs and improving plan-participant safety and adherence.

PCMA and its members know firsthand the value of being able to design prescription drug plans in varying ways to meet the needs of consumers with different medical needs and budgets. Benefit design features like preferred pharmacy networks, formularies, prior authorizations, step therapy protocols, specialty pharmacies, and mail-service programs contribute to PBMs' ability to deliver (on behalf of plan sponsors) cost effective prescription drug benefits with improved plan-participant access and outcomes. That is so despite the fact that these features may, as a practical matter, affect the ways in which certain plan participants receive the drugs they need.

PCMA and its members are firmly opposed to disability discrimination and committed to the principle that prescription drug benefit plans must use facially neutral and consistent rules. See PCMA, *Working Together for a More Equitable Health Care System*, https://perma.cc/AU7F-4C46. PCMA promotes policies designed to discover and to address disparities and inequities in care. This includes policies to make cover-

age more affordable for individuals with medical conditions that cause extremely high drug costs. *Id.* at 7-8. The mail-service and specialty pharmacy provisions at issue here are in keeping with that commitment.

In holding that these benefit management tools can produce unlawful disparate impacts nonetheless, the decision below poses a serious threat to the viability of countless other benefit design features and, with them, insurers' and employers' ability to control prescription drug spending and quality and consumers' ability to access medically necessary drugs at affordable costs. Because neither the Rehabilitation Act nor Section 1557 supports such a drastic result, the Court should reverse.

ARGUMENT

I. FEDERALLY SUBSIDIZED PRESCRIPTION DRUG INSURANCE PROGRAMS ARE PREMISED ON COMPETITIVE MARKET FORCES AND PATIENT CHOICE

Federally subsidized prescription drug insurance coverage begins with a plan sponsor, the organization that offers a prescription drug plan to consumers. The plan sponsor is ultimately responsible for furnishing and designing the coverage that it will offer to those who choose to join its plan. To do so, a plan sponsor (typically in conjunction with a third-party administrator) must carefully calibrate its plan to strike the right balance between coverage on the one hand and premiums and costs on the other hand. To meet that objective, a single plan sponsor might offer multiple options—for example, one plan with broad coverage of drugs and a large pharmacy network with a higher premium and copays, and a second plan with narrower drug coverage and a smaller pharmacy network, but lower premiums and copays. If a plan offers coverages that are either too expensive or too restrictive, it may

not attract enough participants to support it. It is thus incumbent on plan sponsors to design coverage that Americans want. The key point is that market competition drives sponsors to offer plans with varying features designed to optimize consumer choice, access, safety, and affordability. And consumers are free to choose from among those offerings, with their varying features, to select the plan best suited to their unique needs and budget.

Plan sponsors are aided in this endeavor in the prescription drug coverage market by PBMs. PBMs play a critical role in maximizing the value the plans can deliver at a sustainable cost. To do so, PBMs offer many innovative benefit-management tools that a plan sponsor can integrate into the design of its plan to control costs, improve patient outcomes, and increase safety and quality of care. These tools have proven effective time and again at controlling costs while expanding benefit access, quality, and convenience. And the evidence is unequivocal that Congress intended to harness the market forces that have driven the development and wide adoption of these tools when it designed the Medicare Part D program and ACA exchanges.

A. PBMs offer a wide range of innovative benefit management features to maximize benefits, services, quality, and cost-containment

In an effort to reign in skyrocketing prescription drug costs driven primarily by pharmaceutical manufacturers, PBMs have continually innovated within the prescription drug market over the past several decades. This case concerns two of the many tools that PBMs, on behalf of their health-plan clients, use to ensure broad access to prescription drug benefits and improved plan-participant outcomes while containing the otherwise prohibitive cost of prescription drug cover-

age. At the same time, the decision below implicates an even broader range of essential prescription benefit design features.

Pharmacy networks generally. PBMs develop the networks of pharmacies that plan sponsors use to determine where plan participants can fill their prescriptions. Networks benefit plan sponsors, plan participants, and pharmacies alike. Pharmacies compete for inclusion in PBM networks. They often accept reduced reimbursement rates in exchange for the prospect of a steady stream of business from plan participants and access to PBMs' instant, point-of-sale reimbursement processes. See Fed. Trade Comm'n, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* 4-5 (Aug. 2005), perma.cc/4F6K-USVC. About 95% of all retail pharmacies throughout the Nation are included in one or more PBM networks. David A. Hyman, *The Unintended Consequences of Restrictions on the Use of Maximum Allowable Cost Programs ("MACs") for Pharmacy Reimbursement* 5 (Apr. 2015), perma.cc/-LPX5-RFP6. Plan sponsors and participants benefit from lower negotiated reimbursement rates that networks make possible.

Plan sponsors can (and typically do) offer a range of plans with different network options. Some plans use large and embracive pharmacy networks that include virtually all pharmacies willing to provide discounts to the plan. Other plans use significantly narrower pharmacy networks through which they can achieve deeper discounts, offering participants a narrower benefit at lower cost. Still other plans use a tiered network, which includes both "preferred" in-network pharmacies and regular in-network pharmacies. Preferred pharmacies offer more favorable discounts in exchange for preferred status and thus higher patient volume. Plan participants then pay

smaller copays or lower coinsurance at preferred pharmacies, while still enjoying the option of using a wide range of other pharmacies at somewhat higher cost-sharing levels if they choose.

Mail-service pharmacies. PBMs often encourage the use of mail-service pharmacies that dispense prescriptions through the mail. Receiving regularly needed medications by mail serves the convenience of consumers and promotes better adherence by eliminating barriers to access. *E.g.*, Elena V. Fernandez et al., *Examination of the Link Between Medication Adherence and Use of Mail-Order Pharmacies in Chronic Disease States*, 22 J. Managed Care & Specialty Pharmacy 1247 (2016), perma.cc/2RM2-KP7C; John D. Jones, *Managed Care Pharmacy: The Past and Present*, *in Handbook of Pharmaceutical Policy* 227, 237-238 (2007).

Mail-service pharmacies are especially important for individuals with limited transportation options (including consumers in rural areas) or health conditions that restrict their mobility. Indeed, researchers have found statistically significant improvements in compliance for consumers receiving medications for a variety of afflictions, including hypertension, high cholesterol, and diabetes, from mail-service drug delivery. Fernandez, *supra*, at 1254. The flexibility to receive prescriptions by mail has also been critical to many during this global pandemic, in particular, given that simply picking up a prescription at a pharmacy has presented a substantial health risk in its own right.

Because they are able to fill prescriptions on a larger scale, mail-service pharmacies can also implement computer-controlled quality processes, robotic dispensing, and advanced workflow practices that dispense prescriptions with greater accuracy and reduce medication errors. For the same reason, mail-service

pharmacies also produce substantial plan savings through greater discounts made possible by their scale. See Ctrs. for Medicare & Medicaid Servs., *Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies* (Dec. 2013), perma.cc/ZY46-9CZL.

Specialty pharmacies. PBMs also frequently partner with specialty pharmacies to dispense and manage drug regimens for rare or particularly complex health problems. Specialty drugs often entail unique consumer education protocols, complex or unusual storage or shipment requirements, or unusually high costs.

Specialty pharmacies have specialized credentials to manage such complicated drug regimens safely and effectively. Typical retail pharmacies are not equipped to manage the complex logistics or monitoring necessary to ensure safe and effective specialty drug use. By leveraging scale and expertise, specialty pharmacies dramatically improve patient outcomes and reduce costs for those with conditions like HIV, multiple sclerosis, or some cancers. Jun Tang et al., *Effects of Specialty Pharmacy Care on Health Outcomes in Multiple Sclerosis*, 9 Am. Health & Drug Benefits 420 (2016) (finding that specialty pharmacy care significantly lowers risk for relapse in multiple-sclerosis patients compared with community pharmacy care); Suzanne J. Tschida et al., *Outcomes of a Specialty Pharmacy Program for Oral Oncology Medications*, 4 Am. J. Pharmacy Benefits (2012) (finding that specialty pharmacy programs improved adherence and reduced overall medical costs in oral oncology patients).

Formularies. In addition to the tools respondents challenge in this particular case, PBMs use a variety of other methods to structure prescription drug benefits and ensure that drugs are used in an efficient and ef-

fective manner. Formularies, for example, are lists of prescription drugs that a plan covers. To create and manage formularies, PBMs convene panels called "pharmacy and therapeutics" or P&T committees comprising experts who are qualified to select the most clinically appropriate drugs for a given drug class and indication. Formularies encourage clinically sound and cost-effective prescription drug coverage. See Fed. Trade Comm'n, *supra*, at 6.

This is no easy task. "Plan members often want unfettered access to the newest and most heavily marketed prescription drugs," which may include categories of drugs for conditions like nail fungus or eczema that may be troublesome but not warrant high-cost prescription drugs, or to "lifestyle drugs" like for male pattern baldness. Jones, *supra*, at 231-232. Plans must carefully balance these "patient demands against limited benefit dollars" and the need to provide access to essential drugs for many medical conditions when designing formularies. *Ibid.*

Plans can also use formularies to promote safety and patient adherence by prioritizing drugs that are easier to use or less likely to have adverse interactions with other drugs. Jones, *supra*, at 232. Incentivizing the selection of medications that are easier to use or have fewer side effects encourages plan participants to keep taking their medication as prescribed. By improving outcomes, plans indirectly reduce costs by keeping plan participants healthier and less likely to need more expensive hospital or medical services.

Plans must customize their formularies to their own preferences and the needs of their plan participants. Some plans may choose an open formulary, according to which the plan sponsor covers most or all prescription drugs. Other plans may choose a more limited, closed formulary that covers a narrower range

of drugs listed on the formulary in favor of lower overall pricing. And still other plans may choose a tiered formulary in which preferred drugs come with lower cost-sharing or other financial incentives, even though the plan may still offer some coverage for non-preferred drugs at higher cost-sharing levels. As with pharmacy networks, consumers have come to expect a range of options, balancing convenience and medical need with overall cost.

Prior authorizations and step therapy. PBMs also offer plans the option to administer prior authorization, step therapy, and other utilization management protocols as methods to reduce potentially unnecessary use of especially high-risk or high-cost drugs. See 2018-2019 AMCP Pharmacy Prof'l Practice Comm., *Prior Authorization and Utilization Management Concepts in Managed Care Pharmacy*, 25 J. Managed Care & Specialty Pharmacy 641, 641 (2019) (explaining that prior authorization helps "optimiz[e] patient outcomes and reduc[e] waste, error, unnecessary drug use, and cost").[2] Prior authorization means that a plan must preapprove a drug before the pharmacy is permitted to dispense it as a covered drug. For those drugs with a high risk of abuse, prior authorization may help prevent the development of substance abuse problems.[3]

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[2] Accord Jones, *supra*, at 233-235 (explaining that in properly structured prior authorization programs, prior authorization should rarely be required but still generate substantial savings).

[3] *E.g.*, Johns Hopkins Bloomberg School of Pub. Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* 32 (Nov. 2015), perma.cc/P9MU-P884 (observing that one PBM's use of "prior authorization for more than 30 days of opioid therapy" helped "to reduce inappropriate prescribing" by 6.6 million pills over an 18-month period); Bill Preston et al., *Strategies for Stemming the Opioid Epidemic*, Deloitte Insights (May 18, 2018), perma.cc/BL47-5DPK; Daniel M. Hartung et al., *Effect of a High Dos-*

For drugs with particularly troublesome side effects, prior authorization encourages better consumer education and understanding before a drug is dispensed.[4] And for drugs with unusually high costs, prior authorization may promote the use of less expensive alternative medications first. See 2018-2019 AMC Pharmacy Prof'l Practice Comm., *supra*, at 641.

A related protocol—step therapy—affirmatively requires plan participants to try a medically appropriate alternative drug, like the generic version of a branded drug, when starting a new prescription regimen. See generally Brenda R. Motheral, *Pharmaceutical Step-Therapy Interventions: A Critical Review of the Literature*, 17 J. Managed Care Pharmacy 143 (2011); Michael A. Fischer & Jerry Avorn, *Step Therapy – Clinical Algorithms, Legislation, and Optimal Prescribing*, 317 J. Am. Med. Ass'n 801 (2017). Step therapy encourages both plan participants and prescribers to evaluate appropriate therapeutic alternatives before immediately selecting the most risky or most expensive option first.

The Centers for Medicare and Medicaid Services (CMS) recently acknowledged that introduction of prior authorization and step therapy protocols in Medicare

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age Opioid Prior Authorization Policy on Prescription Opioid Use, Misuse, and Overdose Outcomes, 39 Substance Abuse 239, 243-245 (2018).

[4] *E.g.*, Patrick P. Gleason et al., *Dalfampridine Prior Authorization Program: A Cohort Study*, 19 J. Managed Care Pharmacy 18, 18-19 (2013) (detailing the use of prior authorization to prevent seizure side effects in individuals with multiple sclerosis); Catherine I. Starner et al., *Rosiglitazone Prior Authorization Safety Policy: A Cohort Study*, 18 J. Managed Care Pharmacy 225, 226 (2012) (finding that prior authorization for rosiglitazone, a drug for type 2 diabetes, reduced the risk of dangerous drug interactions).

Advantage plans "will lower costs" and "promot[e] better clinical decisions," overall "improv[ing] the quality of care for Medicare beneficiaries." CMS, *Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs* (Aug. 7, 2018), perma.cc/G3ZF-FEXV.

Generic drug utilization. PBMs also encourage generic drug utilization as a general matter through formulary tiers and preferential cost-sharing terms. Generics offer the same form, safety, strength, quality, performance, and intended use as a branded drug, but almost always at a far lower cost. Encouraging generic drug utilization saves money for plans and consumers and promotes greater access to drugs. See Jones, *supra*, at 236-237 (explaining that a midsize employer that implemented a generic incentive program increased utilization from 47.5 to 51.9% and saved nearly $300,000 in a year).

B. Congress designed the ACA exchanges and Medicare Part D plans to capitalize on private market forces to expand coverage

Prescription drug costs in the United States have ballooned over the past two decades. Price increases have been driven in part by year-over-year price increases for brand name drugs already on the market. Inmaculada Hernandez et al., *The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Cost of Drugs*, 38 Health Affairs 76 (Jan. 2019).

PBMs have played a constant and critical role in controlling those costs and keeping prescription drug coverage more affordable. By one estimate, PBMs reduce prescription drug spending by 30%. Joanna Shepherd, *The Fox Guarding the Henhouse: The Regulation of Pharmacy Benefit Managers by a Market Adversary*, 9 Nw. J. L. & Social Policy 1, 22 & n.143 (2013). To put this in perspective, the United States spent an estimated $369.7 billion on prescription drugs in 2019.

CMS, *NHE Fact Sheet*, perma.cc/D3NW-6X9Y. PBMs use drug benefit management tools like those we have described because they work for plans and consumers alike. They control prescription drug spending while ensuring safe and generous access to prescriptions.

When designing federally subsidized prescription drug insurance programs under Medicare Part D and the ACA exchanges, Congress intended to harness these private market forces and allow consumers the freedom to choose plans they prefer. It thus gave plans and their PBMs leeway to design different benefit-management tools, leaving to consumers to choose plans with the mix of coverage, tools, and out-of-pocket costs they prefer. But Congress did not leave this discretion unfettered; it even built some of these benefit management tools into the Part D program and ACA exchanges to ensure minimum beneficiary protections and coverage standards.

1. Take first the Medicare Part D program, which like the ACA exchanges is governed by Section 1557. Medicare is the federal health insurance program for people aged 65 or older or with certain disabilities or end-stage renal disease. Medicare comprises four parts: Parts A, B, C, and D. *See* 42 U.S.C. § 1395 *et seq.*

Medicare Part A is the hospital insurance program, which covers inpatient hospital care and similar services. 42 U.S.C. § 1395c *et seq.* Medicare Part B is the medical insurance program, which generally covers outpatient care and related supplies and services. *Id.* § 1395j *et seq.* Coverage under Parts A and B is known as traditional or original Medicare, and Part A is provided premium-free by the federal government. See CMS, *Medicare & You* 22 (Dec. 2020), perma.cc/EK88-LS9Z. Under the traditional Medicare program, the federal government pays covered provider costs using a fee-for-service schedule. See CMS, *Fee Schedules*—

General Information (Nov. 11, 2019), perma.cc/P9XD-68UK.

In 1997, Congress established the Medicare Part C program, today known as Medicare Advantage. See Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251. Part C gives Medicare-eligible individuals an alternative to traditional Medicare, allowing them to select plans offered by private companies that offer access to Part A coverage bundled with supplemental coverages. See *Northeast Hosp. Corp.* v. *Sebelius*, 657 F.3d 1, 2-3 (D.C. Cir. 2011).

By the early 2000s, Congress was exploring how to add prescription drug coverage to the Medicare program. A 2002 report by the Congressional Budget Office (CBO) detailed the available options. See CBO, *Issues in Designing a Prescription Drug Benefit for Medicare* (Oct. 2002), perma.cc/QB54-MSY6. Potential structures ranged from a regional single-payer model to an approach like Part C, using private companies to offer plans that would compete for participants. *Id.* at 14-15, 36-42.

The CBO foresaw that Medicare spending would "soar over the next three decades" and that PBMs would play an essential role in containing those costs. CBO, *supra*, at xiii. It concluded that "[a]ctive cost management by the entities administering the Medicare drug benefit could encourage the use of few or less-expensive drugs." *Ibid*. That is, "[t]he degree to which PBMs [can] effectively control Medicare drug costs would depend on their being allowed and encouraged to aggressively use the various tools at their disposal" for keeping costs down, including the ones we have discussed above. *Ibid.*

Around the same time, the Government Accountability Office (GAO) surveyed the effectiveness of PBMs in serving the Federal Employees Health Benefit Pro-

gram. GAO, *Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies* (Jan. 2003), perma.cc/P3TX-YP8Q. The GAO similarly found that, when PBMs put to use the tools we have described here, plan participants get "wide access to retail pharmacies, coverage of most drugs, and benefit[] from cost savings." *Ibid.* at Highlights; see also *id.* at 15-17. Plan participants "typically pa[y] lower out-of-pocket costs for prescriptions filled through mail-order pharmacies and benefit[] from other savings that reduce[] plans' costs and therefore help[] to lessen rising premiums." *Ibid.* at Highlights; see also *id.* at 17-19.[5]

Against this background, there is no denying that Congress understood that utilization of tools like "formularies * * * and related approaches that steer demand to preferred drugs, networks of pharmacies, disease-management programs, and efforts to educate patients and physicians" is essential to effectively controlling prescription drug spending, and in turn making more generous prescription drug benefits widely available and accessible. CBO, *supra*, at xiii.

Congress ultimately passed the Medicare Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. Among other things, the act added a new Part D prescription drug benefit.

Consistent with the CBO's findings, Congress structured Part D as a privatized program, meaning that the federal government would not administer the benefit itself. See *Cares Cmty. Health v. United States Dep't of Health & Human Servs.*, 944 F.3d 950, 954 (D.C. Cir. 2019). Medicare beneficiaries instead receive

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[5] The GAO made similar findings more recently. See GAO, *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization* 26 (July 2019), perma.cc/K49G-KRPJ.

Part D drug benefits by enrolling in a privately sponsored Part D prescription drug plan, a Medicare Advantage plan that includes a Part D component, a Program of All-Inclusive Care for the Elderly organization, or a cost plan offering qualified prescription drug coverage. See 42 C.F.R. § 423.4 (defining Part D plan).

Congress did not leave consumers without protections, however. Notably, it set minimum coverage and cost-sharing obligations. 42 U.S.C. § 1395w-102. And it has built some of the available benefit-management tools into the Part D program. For example, the statute directs plans to develop networks of pharmacies (*id.* § 1395w-104(b)(1)) and to develop a formulary using a pharmacy and therapeutic committee (*id.* § 1395w-104(b)(3)). It also directs plan sponsors to put in place utilization management programs that offer incentives to reduce costs and prevent abuse. *Id.* § 1395w-104(c).

But Congress otherwise gave substantial flexibility to Part D plan sponsors to design and manage their plans. Congress codified its goal of "promot[ing] competition" under the Part D program by expressly providing that the administering agency may neither "interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors" nor "require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i). Simply stated, Congress left it to market forces to dictate appropriate outcomes for the delivery of prescription drug benefits using the tools available.

2. Congress pursued a similar design when it enacted the ACA in 2010. The ACA was intended to create "near-universal" and strengthened health insurance coverage in the United States (42 U.S.C. § 18091(2)(D)) through a series of measures built upon the existing private insurance market. To make insur-

ance more widely available to the uninsured, the ACA required the creation of new health insurance marketplaces or "exchanges" in each state. Individuals and small businesses can purchase health insurance coverage through these exchanges. Insurers do not have to offer plans on the exchange, but if they do, they may only offer "qualified health plans" that meet minimum requirements. See 42 U.S.C. § 18031(b), (c).

Consistent with its design for Medicare Part D, Congress intended to promote consumer choice and insurance competition through the exchange structure. See ACA, Pub. L. No. 111-148 at Part II, 124 Stat. 119, 173 (2010). Congress generally gave ACA plan sponsors the ability to design their plans in market-efficient ways, provided they offer the essential health benefits. 42 U.S.C. § 18022(a), (b). Plans set premiums and cost-sharing levels and choose the level of coverage that the plan will offer, whether bronze, silver, gold, or platinum. See *id.* § 18022(a). They design their own provider networks, subject to minimum adequacy requirements. *Id.* § 18031(c).

Specific to prescription drug coverage, plan sponsors contract with PBMs to take advantage of the many benefit-management tools that PBMs make available. Qualified health plans are thus meant to control costs and improve patient outcomes like any other prescription drug benefit plan, by using formularies, designing pharmacy networks, and encouraging use of generics.

Because the ACA exchanges (like Medicare Part D) are premised on plan competition and consumer choice, a plan can choose to offer a higher level of coverage with fewer restrictions and higher premiums and copays, or a plan may offer a lower level of coverage with more restrictions and a lower premium and cost-

sharing. Consumers may then choose the plan that best suits their personal situations.

In short, Congress incorporated private market forces into the Part D program and the ACA exchanges precisely because it wanted these federally subsidized programs to benefit from the PBM benefit-management tools available in the private market.

II. A DISPARATE-IMPACT THEORY OF LIABILITY IS INCOMPATIBLE WITH CONGRESS'S DESIGN FOR FEDERALLY SUBSIDIZED PRESCRIPTION DRUG COVERAGE

Against this background, disparate-impact liability is incompatible with the statutory design for the federally subsidized prescription drug benefit programs covered by Section 1557. Congress could not have intended to foster, and sometimes even to require, the use of innovative benefit-design tools to manage prescription drug costs while at the same time specifying, by incorporating the Rehabilitation Act, that those tools are unlawfully discriminatory. If allowed to stand, the Ninth Circuit's misguided construction of Section 1557 and the Rehabilitation Act will imperil the innovative benefit-design tools that Congress meant to encourage.

A. The disparate-impact standard for disability discrimination is an analytical mismatch in the healthcare context

Section 1557 prohibits discrimination under any health program receiving federal funds on a ground prohibited by four federal anti-discrimination statutes, including Section 504 of the Rehabilitation Act. 42 U.S.C. § 18116. Rather than establish its own nondiscrimination standards, Section 1557 instead incorporated the substantive standards existing under these other statutes.

Relevant here, Section 504 of the Rehabilitation Act prohibits a recipient of federal funds from discriminating against an individual "solely by reason of her or his disability." 29 U.S.C. § 794(a). That clear language does not reach conduct with a disparate impact on individuals with a disability. Petitioners explain why at length in the merits brief. Pet. Br. 13-40. Section 504 straightforwardly precludes an entity receiving federal funds from excluding, denying, or discriminating against someone "*solely* by reason of his or her disability." 29 U.S.C. § 794(a) (emphasis added). That the prohibited ground is the "sole" reason for the alleged discrimination suggests intentionality, and not merely incidental impacts. Accord *Doe v. BlueCross BlueShield of Tenn., Inc.*, 926 F.3d 235, 241 (6th Cir. 2019). Put another way, it is impossible to have a "sole" reason for doing something that wasn't intentionally considered. If it was not considered, some other reason must have motivated the action.

That conclusion is supported by the other statutes that Congress incorporated into Section 1557. None of the other provisions—Title VI of the Civil Rights Act, Title IX of the Education Amendments of 1972, or the Age Discrimination Act of 1975—extends to disparate-impact liability, either. See Pet. Br. 28-33; *BlueCross*, 926 F.3d 235 at 240-241 (collecting cases).

And it is further supported by the ACA's context more generally. It is imperative in the health-insurance context—as the Court previewed in *Alexander* v. *Choate*, 469 U.S. 287 (1985)—that liability not be premised on a disparate-impact liability theory. The *Choate* Court declined to decide the question whether Section 504 authorizes disparate-impact liability because it was torn between two compelling, but competing, policy considerations. On the one hand, the Court thought Congress perceived that disability dis-

crimination is "most often the product, not of invidious animus, but rather of thoughtlessness and indifference." *Choate*, 469 U.S. at 295-297. On the other, the Court recognized that, in the context of disability discrimination, a disparate-impact theory would be essentially impossible to manage given the inherent inability to make all individuals with a disability "similarly situated" to those without. *Id.* at 298-299.

Choate thus rejected application of a disparate-impact theory in the insurance-coverage context with respect to state Medicaid programs:

> Section 504 does not require the State to alter this definition of the benefit being offered simply to meet the reality that the handicapped have greater medical needs. To conclude otherwise would be to find that the Rehabilitation Act requires States to view certain illnesses, i.e., those particularly affecting the handicapped, as more important than others and more worthy of cure through government subsidization.

469 U.S. at 303-304; see also *BlueCross*, 926 F.3d at 242 (noting "[t]he oddity of applying disparate-impact discrimination in this area").

That same observation holds true here. A disparate-impact theory cannot sensibly apply in the context of the health-insurance markets envisioned by the ACA and Medicare Part D. If Congress had truly intended that every individual with a disabling condition who needs a particularly expensive, sensitive, and difficult-to-administer drug for a serious medical condition must be able to do so on the same terms as a person requiring (say) a 7-day basic antibiotic prescription for a sinus infection, the ACA and Medicare Part D would have looked wildly different.

B. The disparate-impact standard threatens the viability of prescription drug benefit plans, jeopardizing access to care

For all of the foregoing reasons, the decision below threatens the validity of each of the benefit-management tools that we described above. Because some disabling illnesses necessitate especially expensive or high-risk medications, plan participants with such illnesses will almost always find themselves disproportionately required to use those tools, which necessarily affect the way in which they access their medications. Under the Ninth Circuit's reasoning below, that represents an unlawful disparate impact, necessitating condition-by-condition exceptions to the enforceability of agreed plan terms. If that were the law, courts rather than plans and their PBMs would come to administer prescription drug benefits.

For example, individuals with a relevant disability could challenge the exclusion of drugs from plan formularies, significantly limiting the point of a formulary to begin with. An individual could also challenge placement of a drug on a more expensive formulary tier, undermining a plan's ability to bargain for cost savings through the use of tiers.

A participant with a disabling condition requiring prior authorization likewise could challenge that requirement as having a disparate impact on her and all other individuals with the same condition. After all, individuals with non-disabling prescription drug needs can typically obtain their routine medicines without prior authorization.

Step therapy faces the same problem. An individual with a condition that requires her to try a less expensive alternative medication first could claim a disparate impact not experienced by non-disabled par-

ticipants able to obtain their drugs of choice without such a requirement.

And then there is this case—in which participants with a disabling condition challenge the obligation to acquire covered specialty drugs through mail-service or a drop-shipment. A plan's rules for acquiring covered specialty drugs will virtually always have a disparate impact on individuals with conditions that necessitate taking specialty drugs.

The decision below would invalidate each of these facially neutral, nondiscriminatory mechanisms that are essential to the economical design of prescription drug benefits. On a condition-by-condition and tool-by-tool basis, disparate-impact liability would slowly carve away all limitations, resulting in unfettered access to all drugs as covered drugs irrespective of plan cost. The decision below thus imperils the full range of prescription drug benefit-management tools that plan sponsors rely on to provide cost-effective coverage.

These critical tools that keep premiums and cost-sharing lower for all consumers, including individuals with disabilities, would be effectively stripped from the tool chest. The Court need not take our word for it: States have already taken steps to expedite the implementation of the Ninth Circuit's logic. In reliance on the decision below, California Senate Bill 524 proposes to bar PBMs from requiring consumers to use mail-service or specialty pharmacies for any drug regimens. *See* Cal. S. Bill No. 524 (Sept. 3, 2021)..

As we have said, PCMA and its members are deeply committed to nondiscrimination, and they are devoted to promoting access to and delivering meaningful, safe, and cost-effective prescription drug coverage to all the plan participants they serve. But the effects of healthcare policies, cost-management tools, and benefit-design features will inevitably fall in different ways

on different patients depending on their medical conditions. That is to say, disparate impacts based on health condition are inevitable precisely because patients with different health conditions require different treatment, implicating different levels of access to different kinds of care, under different practical circumstances.

To hold that that Section 1557 imports a disparate-impact standard for disability discrimination would portend great harm to millions of Americans who receive prescription drug insurance coverage through a federally subsidized program, leading to runaway prescription drug costs, higher premiums, higher cost-sharing, and less generous benefits. Over the long term, disparate-impact liability may well render prescription drug benefits too expensive for sponsors to continue offering at all.

Disparate-impact liability additionally threatens sponsors' ability to accurately spread risk, which is an essential component for any insurance coverage premised on pooling healthier and less-healthy patients together. Respondents' claim of entitlement to coverage that guarantees unfettered access to all prescription drugs regardless of condition would thus paradoxically threaten access prescription drug coverage writ large. The adverse effects would fall most immediately on those with disabling conditions in greater need of drug coverage.

Accepting the Ninth Circuit's holding would also upend Congress's design for federally subsidized health insurance programs. The ACA exchanges and Medicare Part D were designed to allow patients to choose the level of services that they want, balanced against the cost of the plan. Congress requires plan sponsors to use at least some of these benefit-management tools in offering coverage under these programs. Accord 42 U.S.C. § 1395w-104(b)(1), (b)(3), (c). The Ninth Cir-

cuit's decision below fundamentally disrupts that design. A disparate-impact analysis would effectively allow any patient to gain unrestricted access to coverage through litigation, notwithstanding the plan terms that she chose during open enrollment. That is not what Congress intended.

No matter what the Court may conclude about the disparate-impact standard for disability discrimination generally, Congress cannot have meant to import that standard into the healthcare context through Section 1557. To reach that conclusion, one would have to believe that Congress, while expressly preserving and encouraging the competitive market forces that gave rise to these essential benefit management tools, simultaneously meant to outlaw their use. But it is rote that statutes must be read to avoid absurd results. *Milavetz* v. *Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 246-247 (2010). Here, that requires reversing the Ninth Circuit's conclusion that the ACA authorized a disparate-impact cause of action targeting health plans and their service providers.

CONCLUSION

The Court should reverse the judgment below.

Respectfully submitted.

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