

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 Petition for 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**

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TABLE OF CONTENTS

Table of Authorities..... ii

Introduction and Interest of the *Amicus Curiae*1

Argument.....4

 The Ninth Circuit’s decision implicates
 matters of significant practical importance
 worthy of further review.....4

 A. The use of innovative network
 management tools is essential to the safe,
 reliable, and cost-effective delivery of
 prescription drugs4

 1. PBMs make available a wide range
 of benefit management features5

 2. Benefit management features like
 specialty pharmacy requirements
 help keep prescription drug costs low....10

 B. The decision below threatens the viability
 of numerous benefit management tools and
 is certain to drive up prescription drug
 costs dramatically12

 C. The use of specialty pharmacies and
 similar network management tools is not
 unlawfully discriminatory.....14

Conclusion18

TABLE OF AUTHORITIES

Cases

<i>Doe v. BlueCross BlueShield of Tennessee</i> , 926 F.3d 235 (6th Cir. 2019).....	14, 15
<i>Modderno v. King</i> , 82 F.3d 1059 (D.C. Cir. 1996)	15

Statutes

42 U.S.C.	
§ 300gg-6(a)	16
§ 18022(b)(1)(F)	16

Other authorities

Brenda R. Motheral, <i>Pharmaceutical Step-Therapy Interventions: A Critical Review of the Literature</i> , 17 J. Managed Care Pharmacy 143 (2011)	10
California Senate Bill 524 Fact Sheet	14
Catherine I. Starner et al., <i>Rosiglitazone Prior Authorization Safety Policy: A Cohort Study</i> , 18 J. Managed Care Pharmacy 225 (2012)	9
Centers for Medicare & Medicaid Services, <i>Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies</i> (Dec. 2013)	7
Centers for Medicare & Medicaid Services, <i>Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs</i> (Aug. 7, 2018)	10
Centers for Medicare & Medicaid Services, <i>NHE Fact Sheet</i> (visited Apr. 16, 2021)	11

Other authorities—continued

Cong. Budget Office, <i>Issues in Designing a Prescription Drug Benefit for Medicare</i> (Oct. 2002)	11, 12
Daniel M. Hartung et al., <i>Effect of a High Dosage Opioid Prior Authorization Policy on Prescription Opioid Use, Misuse, and Overdose Outcomes</i> , 39 <i>Substance Abuse</i> 239 (2018)	9
David A. Hyman, <i>The Unintended Consequences of Restrictions on the Use of Maximum Allowable Cost Programs (“MACs”) for Pharmacy Reimbursement</i> (Apr. 2015)	5
Elena V. Fernandez et al., <i>Examination of the Link Between Medication Adherence and Use of Mail-Order Pharmacies in Chronic Disease States</i> , 22 <i>J. Manag. Care Spec. Pharm.</i> (2016)....	6
Fed. Trade Comm’n, <i>Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies</i> (Aug. 2005)	5, 8
Gov’t Accountability Office, <i>Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies</i> (Jan. 2003)	12
Gov’t Accountability Office, <i>Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization</i> (July 2019)	12
Inmaculada Hernandez et al., <i>The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Cost of Drugs</i> , 38 <i>Health Affairs</i> (Jan. 2019)	11

Other authorities—continued

- Joanna Shepherd, *The Fox Guarding the Henhouse: The Regulation of Pharmacy Benefit Managers by a Market Adversary*, 9 Nw. J. L. Social Policy 1 (2013) 11
- Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (Nov. 2015) 9
- Michael A. Fischer & Jerry Avorn, *Step Therapy – Clinical Algorithms, Legislation, and Optimal Prescribing*, 317 J. Am. Med. Ass’n 801 (2017) 10
- Patrick P. Gleason et al., *Dalfampridine Prior Authorization Program: A Cohort Study*, 19 J. Managed Care Pharmacy 18 (2013) 9
- Pharmaceutical Care Management Association, *PBM Specialty Pharmacies Improve Patient Outcomes and Reduce Costs* (Apr. 2017) 7
- Tricia Lee Wilkins, *Prior Authorization and Utilization Management Concepts in Managed Care Pharmacy*, 25 J. Managed Care & Specialty Pharmacy 641 (2019) 8, 9

**INTRODUCTION AND
INTEREST OF THE *AMICUS CURIAE****

The work of designing and implementing a prescription drug benefit plan is complex and multifaceted. A plan sponsor—typically 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, and identify and negotiate discounts and rebates from pharmaceutical manufacturers and the terms of reimbursement with hundreds or 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 overall cost (the size of premiums and amount of cost-sharing) in varying ways.

At its core, the question presented in this case is whether the design and implementation of such plans is in the hands of plan sponsors and the PBMs they retain, as Congress expressly intended with statutes like the Employee Retirement Income Security Act (ERISA)—or, instead, federal judges. In holding for the first time that disparate-impact disability-discrimination challenges to facially neutral plan terms are cognizable under Section 1557 of the Patient Protection and Affordable Care Act (ACA), the Ninth Circuit has chosen federal judges. And it has done so in a way that threatens the ongoing viability of a wide range of common prescription drug benefit management tools.

* 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.

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 unusually expensive drugs. The Ninth Circuit held, in practical effect, that these commonplace 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 chronic health conditions.

That decision cries out for further review. The Nation's antidiscrimination laws require plan sponsors to treat participants equally, using facially neutral plan terms, without regard for disability. 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 such drugs.

Taken to its logical conclusion, the Ninth Circuit's contrary position would invalidate the substantive terms of most prescription drug plans, compelling plan sponsors to tailor all benefits to the “unique pharmaceutical needs” (Pet. App. 15a) of those with the most complex medical conditions. Anything short of that will have a supposedly unlawful “disparate impact” on disabled plan participants if they are denied the most convenient available method for accessing their drugs—albeit by operation of facially neutral plan terms that they accepted when choosing their coverage. Such an outcome would upend the U.S. healthcare system, which is founded on the notion that plan sponsors are free to offer, and consumers are free to select, plans with benefits that include different terms for the delivery and reimbursement of different drugs.

It would also gut prescription drug coverage as we know it, removing the tools that enable plans to offer affordable prescription drug benefits to consumers, including those with disabilities.

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 the 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 for 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 cost-effective prescription drug benefits with improved plan-participant access and outcomes. That is so despite that these features may, as a practical matter, affect the ways in which plan participants with disabling medical conditions receive the drugs they need.

PCMA is wholeheartedly committed to the principle that prescription drug benefit plans must be designed using facially neutral rules that do not discriminate on the basis of disability or any other inappropriate criteria. The mail-service and specialty pharmacy provisions at issue here are in keeping with that commitment. In holding that these network

management tools can be unlawfully discriminatory 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.

The Court should grant the petition for a writ of certiorari and correct the Ninth Circuit's seriously misguided holding in this case.

ARGUMENT

THE NINTH CIRCUIT'S DECISION IMPLICATES MATTERS OF SIGNIFICANT PRACTICAL IMPORTANCE WORTHY OF FURTHER REVIEW

The question presented in the petition is tremendously important and worthy of this Court's attention. If allowed to stand, it will threaten the ability of insurers and employers to offer appropriately cost-controlled prescription drug benefits while also ensuring a high quality of care. The result will be drastically higher premiums, higher cost-sharing responsibility at the point of sale, and less generous benefits across the board. That is the exact opposite of what Congress intended when it enacted comprehensive health insurance reform, including the ACA's nondiscrimination provisions.

A. The use of innovative network management tools is essential to the safe, reliable, and cost-effective delivery of prescription drugs

This case concerns two of the many tools that PBMs, on behalf of their health-plan clients,² use to

² In the ERISA context, PBMs act at the direction of the plan's fiduciaries to provide services to the plan and to manage benefits in accordance with the contract between the plan and PBM.

ensure broad access to prescription drug benefits and improved plan-participant outcomes while containing the otherwise prohibitive cost of prescription drug coverage. While the facts of this case concern just two of these tools, the lower court's reasoning potentially implicates a broader range of essential prescription benefit design features.

1. *PBMs make available a wide range of benefit management features*

In an effort to reign in skyrocketing prescription drug costs driven primarily by rising manufacturer list prices, PBMs have continually innovated within the prescription drug market over the past several decades. They have created many tools to achieve the goals of lowering consumers' and health plans' prescription drug costs while at the same time increasing access, safety, and adherence.

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 because it attracts a steady stream of business from plan participants and gives pharmacies access to PBMs' instant, point-of-sale reimbursements processes. See Fed. Trade Comm'n, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* 4-5 (Aug. 2005), <https://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), <https://perma.cc/LPX5-RFP6>. For their parts, plan sponsors and participants benefit from lower negotiated reimbursement rates.

Plan sponsors can (and typically do) offer a range of plans with different network options. Some plans use large and embrative 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 fill and deliver 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. Manag. Care Spec. Pharm. 1247-1259 (2016), <https://perma.cc/2RM2-KP7C>.

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 1254. The flexibility to receive pre-

scriptions by mail has been critical to many during a 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 Centers for Medicare & Medicaid Services, *Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies* (Dec. 2013), <https://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 monthly costs.

Specialty pharmacies have specialized credentials to manage such complicated drug regimens safely and effectively. Typical retail or manufacturer-affiliated 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. See PCMA, *PBM Specialty Pharmacies Improve Patient Outcomes and Reduce Costs* (Apr. 2017), <https://perma.cc/4WP6-JECY>.

Formularies. In addition to the tools at issue 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 effective 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 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 at i.

Plans can customize their formularies to their own preferences. 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 a higher cost-sharing level. 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 include prior authorization, step therapy, and other utilization management protocols as methods to reduce the potentially unnecessary use of especially high-risk or high-cost drugs. See Tricia Lee Wilkins, *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”). Prior auth-

orization means that a plan must pre-approve 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 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 Wilkins 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*

³ *E.g.*, Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* 32 (Nov. 2015), <https://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); accord Daniel M. Hartung et al., *Effect of a High Dosage 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).

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) for its part recently acknowledged that introduction of prior authorization and step therapy protocols in Medicare 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), <https://perma.cc/G3ZF-FEXV>.

Generic drug utilization. PBMs also encourage generic drug utilization as a general matter through 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.

2. Benefit management features like specialty pharmacy requirements help keep prescription drug costs low

PBMs use tools like the ones we have just described because they work for plans and consumers alike. They control prescription drug spending while ensuring safe and adequate access to prescriptions. Gutting or limiting the use of these tools would have profound and lasting consequences for the prescription drug market and for consumer access to safe, affordable medications.

It is no secret that prescription drug costs in the United States have dramatically increased 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 81-82 (Jan. 2019), available at <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.05147>. PBMs have played a constant and critical role in controlling those costs and keeping prescription drug coverage more affordable in spite of these price increases. The benefit management tools imperiled by the decision below have time and again proven their utility.

By one estimate, PBMs reduce prescription drug spending by 30% to 35%. 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* (visited Apr. 16, 2021), <https://perma.cc/D3NW-6X9Y>. Without PBMs, that spending level would have been upwards of \$568 billion—meaning that PBMs’ diligent management of prescription drug benefits realized nearly \$200 billion in savings in 2019 alone.

For this reason, the Congressional Budget Office long ago recognized that “[t]he degree to which PBMs [can] effectively control Medicare drug costs . . . depends on their being allowed and encouraged to aggressively use the various tools at their disposal” for keeping costs down. Cong. Budget Office, *Issues in Designing a Prescription Drug Benefit for Medicare*, at xiii (Oct. 2002).

The Government Accountability Office (GAO) similarly has recognized 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.” GAO, *Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies* (Jan. 2003). 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.* The GAO made similar findings more recently, noting that “utilization management services were associated with financial savings or improved beneficiary health indicators.” GAO, *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization* 26 (July 2019), <https://perma.cc/K49G-KRPJ>.

All of this is to say, 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. Cong. Budget Office at xiii.

B. The decision below threatens the viability of numerous benefit management tools and is certain to drive up prescription drug costs dramatically

The decision below threatens the validity of each of the ubiquitous benefit-management tools we have just described. Because some chronic and disabling illnesses necessitate especially expensive or risky medicines, participants with such illnesses will almost always find themselves disproportionately required to

use prior authorizations, specialty pharmacies, mail services, and the like. Under the Ninth Circuit's reasoning below, that represents an unlawful disparate impact, necessitating condition-by-condition exceptions to the use of these tools. But the exceptions would become the rule, and benefits design would be a matter principally for judges rather than plans and PBMs.

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.

A participant with a disabling condition requiring prior authorization (depression or diabetes, for example) 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 participants able to obtain their drugs of choice without such a requirement. On the Ninth Circuit's reasoning, those disabled plan participants would be denied equally "meaningful access" to their drugs.

The decision below thus imperils the full range of prescription drug benefit-management tools laid out above. These critical tools that keep premiums and cost-sharing low 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* California Senate Bill 524 Fact Sheet.

Without these crucial benefit design tools, plans and PBMs will no longer be able to provide plan participants with the same level of safe, effective, and efficient access to prescription drug coverage that they can today. As drug prices continue to rise, health plans and PBMs would increasingly find themselves without the capabilities to control these costs, leaving consumers' access to drugs seriously impaired. If allowed to stand, the decision below is thus certain to harm millions of Americans who receive prescription drug insurance coverage. It will, in turn, lead to runaway prescription drug costs, which will mean higher premiums, higher cost-sharing, and less generous benefits. Over the long term, it may well render prescription drug benefits too expensive for sponsors to continue offering at all. Such a drastic shock to the system by which more than 266 million Americans receive prescription drug coverage warrants this Court's attention.

C. The use of specialty pharmacies and similar network management tools is not unlawfully discriminatory

The petition (at 21-28) lays out persuasively why the decision below is wrong on the merits. So does the Sixth Circuit's well-reasoned opinion in *Doe v. BlueCross BlueShield of Tennessee*, 926 F.3d 235, 241-243 (6th Cir. 2019) (*BCBS*), along with the other decisions discussed at pages 21-23 of the petition. Although we do not repeat those arguments here, two points on the merits bear emphasis.

First, the only question posed by the Rehabilitation Act is whether respondents have been offered the same coverage on the same terms to all participants, regard-

less of disability. See, e.g., *Modderno v. King*, 82 F.3d 1059, 1066 (D.C. Cir. 1996) (Ginsburg, J., concurring). They have, and that ought to be an end to the matter. As the Sixth Circuit explained in *BCBS*, some medicines that plan documents require to be filled by specialty pharmacies “are apt to be used by those with disabilities,” while at the same time, “plenty of others are not.” 926 F.3d at 241. The “common trait linking” drugs that must be filled with specialty mail-service pharmacies is complexity and cost, “not the disabled status of their users.” *Ibid.*

It would be a dramatic expansion of the Nation’s disability laws—one entirely unsupported by the text of any statute—to hold that plans must provide particular levels of prescription drug benefits for disabled persons, so that the unique care they require is no less convenient to obtain on covered terms than the care received by non-disabled persons with fewer and less expensive medical needs. Such a rule would entail reworking virtually all prescription drug benefit plans to give expressly preferential treatment to disabled persons or to remove any tools that effectively control costs for all individuals alike. It also would undermine the safety and efficacy of especially complex drug protocols. That is not what the Rehabilitation Act requires.

Second, and related, the Ninth Circuit wholly misconstrued the law when it held that “the ACA requires * * * health plans [to] cover prescription drugs as an ‘essential health benefit,’” such that all prescription drug plan participants have a statutory right to “meaningful access” to medically necessary drugs under the terms of their plans. Pet. App. 13a-14a (quoting 42 U.S.C. § 18022(b)(1)(F)).

As an initial matter, the ACA’s “essential health benefit” requirement applies only to plans that provide

“health insurance coverage in the individual or small group market[s].” 42 U.S.C. § 300gg-6(a). That describes neither the plans at issue here, nor most plans to which PCMA’s members provide services.

In fact, respondents (and most Americans)—if they sign up for prescription drug benefits at all—are entitled to receive only those prescription drug benefits that they choose to purchase, according to the terms on which they purchase them, and in exchange for the premiums and cost-sharing they agree to pay.

This crucial observation brings the Ninth Circuit’s error into sharp focus. The “benefit” at issue here is not prescription drugs themselves, nor is it any other kind of substantive medical care. See Pet. App. 13a, 16a (incorrectly describing petitioners’ benefit as the right to “meaningful access” to “prescription drug[s]” or to “receiv[e] effective treatment for HIV/AIDS”). Plan sponsors, of course, design their plans with the goal of ensuring that plan participants can afford and access the drugs they need. But a prescription drug benefit is nonetheless something simpler: a contractual entitlement to receive reimbursement for the purchase of a covered drug under the terms specified in the plan documents. The benefit is, in other words, *insurance*, based on the terms of the plan.

Thus, a prescription drug plan’s network—that is, the universe of pharmacies at which a plan participant is entitled to receive reimbursement for particular drugs—is an integral element of the benefit itself. Reimbursements for drugs purchased at non-network pharmacies are not a part of the benefit that the participant has contracted for. The same is true of the requirement to use mail-service and specialty pharmacies in specified circumstances. The benefit is entitlement to reimbursement on the facially neutral terms agreed.

By inventing a new requirement that plans furnish “meaningful access” for each individual participant to any and all medically necessary drugs, the Ninth Circuit’s decision in this case calls for the judicial rewriting of the terms of virtually all prescription drug benefit plans. And it does so on the deeply misguided view that the terms of “access” to particularly specialized and costly drugs is not “meaningful” unless it is precisely the same as the terms of access to ordinary drugs like simple antibiotics and analgesics.

The Rehabilitation Act authorizes no such thing. The ability of plan sponsors and their PBMs to design prescription drug benefits using (among other things) mail-service and specialty pharmacies is elemental to the way that healthcare is delivered and paid for in the United States. The Ninth Circuit’s holding below would turn this system inside out, denying plans the prerogative to design—and participants the prerogative to choose—a more limited benefit at a lower cost. There is no basis in the ACA or the Rehabilitation Act for such a dramatic reconceptualization of the American health-care system.

CONCLUSION

Authorizing lawsuits that challenge plans' facially neutral coverage requirements based on disparate impacts on individuals with particular medical conditions poses a direct and existential threat to the continued viability of prescription drug coverage. The Court should grant the petition and reverse.

Respectfully submitted.

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