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 WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF OF AMERICA'S HEALTH INSURANCE PLANS AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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TABLE OF CONTENTS

INTEREST OF *AMICUS CURIAE* 1

INTRODUCTION AND SUMMARY OF ARGUMENT 4

ARGUMENT 8

A. Extending Disparate Impact Liability To Facially Neutral Health Plans Will Interfere With Network-Based Coverage, A Critical Feature Of Nearly All Health Plans. 9

1. Provider Networks Manage Costs And Improve Patient Care. 9

2. Networks Cannot Function Properly If Plan Members Can Alter Plan Benefits. 19

B. The Risk Of Disparate Impact Liability Will Undermine Medical Management Tools, Leading To Increased Costs And Heightened Risk To Patients. 20

1. Medical Management Techniques Ensure That Patients Receive Safe And Affordable Care. 20

2. Inviting Disparate Impact Challenges To Medical Management Techniques Will Harm Plan Members And Increase Costs. 24

CONCLUSION 27

TABLE OF AUTHORITIES

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INTEREST OF *AMICUS CURIAE*[1]

America's Health Insurance Plans, Inc. ("AHIP") is the national trade association representing the health insurance community. AHIP advocates for public policies that expand access to affordable health care coverage for all Americans through a competitive marketplace that fosters choice, quality, and innovation. Along with its predecessors, AHIP has over 60 years of experience in the industry.

AHIP has participated as *amicus curiae* in other cases to explain the practical operation and impacts of the Affordable Care Act (ACA) on health insurance providers and the plans they offer. *See, e.g.*, *California v. Texas*, Nos. 19-840, 19-1019 (U.S. May 13, 2020); *Maine Cmty. Health Options v. United States*, Nos. 18-1023, 18-1028, 18-1038 (U.S. Sept. 6, 2019); *King v. Burwell*, No. 14-114 (U.S. Jan. 28, 2015). Likewise here, AHIP seeks to provide the Court with its deep expertise and experience regarding the operation of health plans and benefit design.

AHIP condemns discrimination in all its pernicious forms and supports the nondiscrimination provisions incorporated in Section 1557 of the ACA. AHIP believes that every American deserves affordable health care, regardless of race, color, national origin, sex, gender identity, sexual orientation, age, or disability. AHIP's members work with health care leaders to remove barriers that

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[1] This brief is filed with the written consent of all parties. No counsel for either party authored this brief in whole or in part, nor did any party or other person or entity other than *amicus curiae*, its members, or its counsel make a monetary contribution to the brief's preparation or submission.

impede health care access for all Americans, including those living with HIV/AIDS.

But expanding the Rehabilitation Act to permit disparate impact lawsuits against health plans will instead diminish the public's access to affordable, quality health care. Unless expressly cabined to exclude the health plan context, reading a disparate impact cause of action into section 504 of the Rehabilitation Act—as Respondents ask the Court to do—will create significant uncertainty around many aspects of health care and health plan coverage.

Health care and health plan benefits often apply differently to individuals with disabilities and individuals without disabilities—a natural consequence of the fact that the two groups frequently have different medical needs. Indeed, each enrollee in a health plan is an individual with different needs in any given year. Yet under Respondents' proposed approach, these differences can be the basis for liability under the ACA. The effect will be to reduce the affordability, availability, and quality of health plans and their benefits—contrary to the ACA's (and AHIP's) goal of enhancing public health and access to health care.

If the Ninth Circuit's decision is affirmed—in whole or in part—the new widespread availability of a disparate impact cause of action will invite lawsuits based on commonplace benefit design tools, many of which may affect an enrollee with a particular medical condition (whether a disabled individual or not) differently from another individual enrollee with a different medical condition. Such lawsuits could

conceivably put at risk commonplace benefit designs including (among other things) networks of participating physicians and other health care providers, patient copayments, and drug formulary lists and tiering. The resulting threat of disparate impact liability will have deleterious consequences for patient care, affordability, patient choice, and the stability of the health care system. AHIP's perspective will provide the Court with a comprehensive understanding of these sweeping ramifications.

INTRODUCTION AND SUMMARY OF ARGUMENT

Discrimination is wrong, particularly when it denies equal health care access to vulnerable groups. AHIP and its members work to improve the health of all Americans, including the disabled and those living with HIV/AIDS. AHIP supports efforts—including legislative, judicial, and voluntary industry initiatives—to eliminate discrimination and remove impediments to safe, effective, and affordable health care.

But reading a disparate impact cause of action into section 504 of the Rehabilitation Act and, by extension, into the ACA—at least without restricting its reach to health plans—will not improve health care for vulnerable Americans. Instead, this novel liability theory will impair the availability of affordable, high-quality, patient-focused health plan coverage. The result will be the same regardless of whether the Court expressly ratifies disparate impact claims against facially neutral health plans. Any approach that opens the door to plaintiffs seeking to mandate access to what a court deems "effective treatment"—the linchpin of the Ninth Circuit's decision (Pet. App. 16a)—will undermine the affordability and quality of coverage millions of Americans rely upon and have come to expect.

A decision embracing the Ninth Circuit's reasoning, in whole or in part, will turn topsy-turvy critical tools—like network design, medical management, and evidence-based patient care programs—that health insurance providers use to

promote safety and quality, and to drive value and savings for enrollees, employers, states, and taxpayers. These facially neutral tools, as commonly incorporated into benefit plans, necessarily have different effects among enrollees—regardless of whether they are disabled or not. But if those differences could create exemptions from plan policies—as would potentially follow from a Court decision broadly embracing a disparate impact cause of action under the Rehabilitation Act—the foundation of many aspects of health plan benefit design will crumble. The result: increased health care costs, negative impacts on patient choice, and diminished patient care.

The district court identified these possible ramifications. While acknowledging "the struggles individuals with HIV/AIDS continue to experience in their daily lives" (Pet. App. 39a), the district court recognized that Respondents sought to "change the terms of their benefit plan." *Id.* at 42a. That judicially mandated "rewriting," in the guise of a disparate impact remedy, would be "virtually unworkable" for the plan. *Id.* The district court also cautioned that the "logical extension of Plaintiffs' discrimination challenge could threaten the basic structure" of health maintenance organization (HMO) and preferred provider organization (PPO) managed-care health plans. *Id.* HMOs and PPOs are able to provide comprehensive coverage at favorable rates by directing enrollees to a defined set of in-network physicians. If plan members could "avail themselves of out-of-network providers at in-network rates by contending that in-network care is inferior for any

particular disability, then the basis of the HMO/PPO model would be undermined." *Id.* at 43a.

That prediction risks becoming reality if this Court sanctions the Ninth Circuit's approach. Although the specific facts at issue involve a plan's use of specialty mail-order pharmacies for certain drugs, reading a disparate impact cause of action into section 504—without limiting such claims in the unique health plan context—could permit challenges to various other benefit-design features.

AHIP highlights here as examples two such common plan features: network design and medical management. Network design is a key way that health insurance providers differentiate their offerings, and give employers and enrollees a menu of plan options to suit their particular circumstances. A health insurance provider may offer plans with networks of varying size (some narrower and some broader); some plans may, and others may not, provide reimbursement for services received out-of-network. Based on those varying options, purchasers of coverage (employers, individuals, or other payers) choose a plan based on their needs (medical and financial). Yet all the networks must comply with a vast array of state and federal laws and regulations that impose stringent requirements on access to and the adequacy of such networks. Medical management includes various tools rooted in evidence-based medicine that prioritize safer, less costly treatments over riskier, more expensive approaches. For both networks and other tools, health insurance providers offer enrollees exemption processes that consider both

individualized patient needs and evidence-based treatment options.

Both techniques reflect a profound shift away from the practices of the 1960s, when health care in this country was offered predominately on a fee-for-service basis—a model that experience has since shown incentivizes volume over quality of care. Since the 1980s, health care in our country has shifted to prioritize quality of care, patient outcomes, and affordability. Health insurance providers have helped achieve those ends by designing network-based managed care and leveraging other innovative solutions.

Construing the Rehabilitation Act to permit disparate impact challenges without limitation risks unravelling those innovations. If directed to health plans, disparate impact challenges could seek to transform network-based plans into non-network-based plans; alter cost-sharing tiers for specialty pharmacy products; expand drug formularies; and curtail the use of protocols that prioritize cost-effective treatments. The result will be increased health care costs—one of the biggest problems facing our Nation today—fewer choices and deteriorating patient care.

These effects will manifest even if the Court does not expressly extend disparate impact liability under section 504 to include challenges to health plans specifically. After all, this very case involves prescription drug plan benefits. This case therefore is unlike others where the Court might be inclined to announce a general rule and leave it to other courts to decide when and how that rule applies. To avoid these

cascading consequences for hundreds of millions of Americans, this Court should reverse the Ninth Circuit's judgment or, at a minimum, clarify that any disparate impact liability does not extend to the health plan context.

ARGUMENT

Construing the ACA to permit disparate impact claims in health plan cases threatens serious, far-reaching consequences. If section 504's reach is expanded to permit disparate impact claims without limitation, plaintiffs will seek to challenge facially neutral health plans—like the prescription drug plan at issue in the underlying case—for not providing "effective treatment" to members with disabilities. Pet. App. 14a. If successful, these lawsuits will effectively rewrite the terms of those plans. As the district court recognized, the proliferation of such disparate impact cases will endanger many core aspects of health care plan design and management that enhance affordability, patient choice, and quality of care. AHIP reinforces the district court's warning here by describing several health insurance program elements that an untethered reading of section 504 will undermine—to the detriment of the health care industry, employers (including small businesses), and all Americans.

A. Extending Disparate Impact Liability To Facially Neutral Health Plans Will Interfere With Network-Based Coverage, A Critical Feature Of Nearly All Health Plans.

1. Provider Networks Manage Costs And Improve Patient Care.

Over the last several decades, health insurance providers and employers have explored and implemented a range of strategies designed to improve efficiency, clinical effectiveness, and value in the provision of health care. Key among those strategies has been the creation of network-based managed care that provides individuals and families access to health care providers of all types, including specialty care providers, hospitals, pharmacies, and outpatient services.

a. The central feature of network-based benefit design is a vetted network of medical providers who contract with a health insurance provider to provide services to plan members at agreed-upon rates. Coverage (or level of reimbursement) depends on whether the member uses in-network or out-of-network providers. Plan members have the ability through various exceptions or appeals processes to obtain care from an out-of-network provider at in-network rates in appropriate circumstances.[2]

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[2] *See, e.g.*, 42 C.F.R. 422.112(a)(3) (providing that a Medicare Advantage plan "arranges for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs");

Managed care networks have proven to be a powerful tool through which health plans can obtain lower prices from providers and higher quality care for their members. At the same time, these networks must comply with detailed state and/or federal network adequacy standards intended to ensure that individuals and families have adequate access to a wide spectrum of specialized medical providers and services.

Virtually all private health benefit plans—including private plans in public programs such as Medicare and Medicaid—use provider networks to deliver health care benefits and services. As described below, the most common types of networks are managed care plans, high-value provider networks, and pharmacy benefit plans.

Managed care plans. Managed care plans like HMOs and PPOs rely on networks of contracted providers to deliver affordable, high-quality patient care.[3] PPOs, the most common of these plans, provide subscribers with access to both in-network and out-of-

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National Ass'n of Ins. Comm'rs, *Health Benefit Plan Network Access and Adequacy Model Act*, § 5(c) (2015), *available at* https://content.naic.org/sites/default/files/inline-files/MDL-074_0.pdf ("A health carrier shall have a process to assure that a covered person obtains a covered benefit at an in-network level of benefits, including an in-network level of cost-sharing, from a nonparticipating provider, or shall make other arrangements acceptable to the commissioner[.]").

[3] *See, e.g.*, U.S. Nat'l Library of Med., *Managed Care*, *available at* https://medlineplus.gov/managedcare.html (last visited Sept. 7, 2021).

network care, with lower cost-sharing requirements and out-of-pocket costs when using in-network, preferred providers.[4] PPOs cover approximately 47 percent of Americans who use employer-sponsored health plans.[5] Many other individuals using employer-sponsored plans receive coverage under an HMO plan, which typically requires members to receive care from in-network providers. Fewer than one percent of covered workers use employer-sponsored plans with no network-based structure.[6]

High-value provider networks. Health insurance providers may also contract with more selective groups of providers to offer high-value provider networks. Relying on provider performance data, health insurance providers can identify medical providers with a demonstrated ability to deliver quality health care in an efficient manner. High-value provider networks offer incentives, such as reduced cost-sharing, for plan members to obtain care.

High-value provider networks are typically designed in one of two ways: (1) Health insurance providers create tiers within an existing network based on specified performance metrics, including objective measures of quality care. Plan members who

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[4] HealthCare.gov, *Health Insurance Plan and Network Types: HMOs, PPOs, and more*, *available at* https://www.healthcare.gov/what-are-the-different-types-of-health-insurance/ (last visited Sept. 7, 2021).

[5] Kaiser Family Found., *2020 Employer Health Benefits Survey*, *available at* https://www.kff.org/report-section/ehbs-2020-section-5-market-shares-of-health-plans/ (last visited Sept. 7, 2021).

[6] *Id.*

seek care from providers in a higher-performing tier pay a reduced copayment. (2) Plans create a separate provider network composed of select, high-value providers with track records of providing high-quality patient care. The plan encourages, or requires, members to seek care within this more focused provider network.

Pharmacy benefits plans. Network benefit design is also applied to prescription drug coverage. The pharmacy benefit plan Respondents challenge is an example of such a plan. Pet. Br. 6-7. Pharmacy benefits managers (PBMs)—which contract with health insurance providers or employer plan sponsors to manage prescription drug benefits—assemble networks of retail, specialty, and mail-order pharmacies where covered members can fill prescriptions. Drug plans offer members financial incentives, such as reduced copayments, to fill prescriptions at in-network pharmacies. Many plans use mail-order pharmacies as a component of their networks.

b. All these types of network-based plans achieve benefits in similar ways. Medical providers and pharmacies compete to become contracted network providers with enhanced (or even guaranteed) access to a health plan's members. [7] This competition creates significant incentives for medical providers to offer lower prices and an expansive set of health care

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[7] Joanna Shepherd, *Selective Contracting in Prescription Drugs: The Benefits of Pharmacy Networks*, 15 MINN. J. L., SCI. & TECH. 1027, 1033 (2014).

services.[8] They risk losing patients if they do not join the network, and stand to gain access to a pool of patients if they do.

Network formation has several advantages for health insurance providers, states, employers, and individual consumers alike. One advantage is cost savings, which can be significant.[9] Studies using claims-based modeling have shown that narrower HMO network plans negotiated hospital reimbursement rates 12 percent lower than broader PPO networks.[10] In addition, average Medicare Advantage plan bids (which utilize provider networks) are typically well below traditional Medicare costs—87 percent less based on recent estimates.[11] The cost

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[8] Michael A. Morrisey, *Competition in Hospital and Health Insurance Markets: A Review and Research Agenda*, 36 HEALTH SERVS. RSCH. 191, 192 (2001) ("The general theory is that managed care introduces price competition into health services markets. Such competition among hospitals, physicians, and other providers results in lower prices, or at least less rapidly increasing prices for services.").

[9] Letter from A. Gavil of FTC to Ctrs. for Medicare & Medicaid Servs. (Mar. 7, 2014) (hereafter "FTC Letter"), *available at* http://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers-medicare-medicaid-services-regarding-proposed-rule/140310cmscomment.pdf.

[10] Kate Ho & Robin S. Lee, *Equilibrium Provider Networks: Bargaining and Exclusion in Health Care Markets*, 109 AM. ECON. REV. 473, 477 (2019), *available at* http://www.people.fas.harvard.edu/~robinlee//papers/EqNetworks.pdf.

[11] MedPac, *Report to the Congress: Medicare Payment Policy* 368 (Mar. 2021) (hereafter "Report to the Congress"),

savings have enabled Medicare Advantage enrollees to access plans offering reduced cost sharing and supplemental benefits such as vision, dental, and hearing benefits at no additional premium (beyond the Medicare Part B premium).[12] And in areas where Medicare Advantage enrollment is relatively higher, traditional Medicare spending growth slows as providers employ Medicare Advantage care guidelines for their traditional Medicare patients.[13]

Studies have also shown that basic in-network incentives for hospitals and specialty physicians can result in savings for consumers of approximately 10 percent.[14] High-value networks are even more cost efficient, with studies showing that plan members save up to 25 percent or more on premium costs relative to traditional network plans.[15] As to

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available at http://medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf?sfvrsn=0.

[12] *Id.* at 365.

[13] Garret Johnson et al., *Recent Growth in Medicare Advantage Enrollment Associated With Decreased Fee-For-Service Spending In Certain U.S. Counties*, 35 HEALTH AFFAIRS 1707 (Sept. 2016), *available at* https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.1468.

[14] BlueCross BlueShield of North Carolina, *New BCBSNC Products Offer Cost Savings for Individuals and Employers* (Dec. 12, 2012), *available at* https://mediacenter.bcbsnc.com/news/new-bcbsnc-products-offer-cost-241718.

[15] Duke Helfand, *A Shift Toward Smaller Health Networks*, LOS ANGELES TIMES (Apr. 3, 2011); *see also* McKinsey Ctr. for U.S. Health Sys. Reform, *Hospital networks: Configurations on the exchanges and their impact on premiums* (Dec. 14, 2013), *available at* https://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/healthcare%20systems%20and%20services/p

prescription drug costs, network-based drug plans help individuals and families pay significantly less for medications.[16] Studies also show that Medicaid managed care plans have generated significant savings for state Medicaid programs by negotiating discounts from pharmaceutical manufacturers and encouraging the use of generic drugs.[17] As a result, states using managed care plans to administer Medicaid drug programs have reaped significant savings compared to states using fee-for-service programs.[18]

Savings are also substantial—10-15 percent or more—for plan members using mail-order pharmacies

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dfs/hospital_networks_configurations_on_the_exchanges_and_their_impact_on_premiums.ashx; AHIP, *Milliman Report: High-Value Healthcare Provider Networks* (July 2014), *available at* https://www.ahip.org/milliman-report-high-value-healthcare-provider-networks/.

[16] Shepherd, *supra* note 7, at 1044.

[17] *See, e.g.*, Wakely Consulting Grp., LLC, *The Value of Integrated Pharmacy Benefits in Medicaid Managed Care* (June 15, 2020), *available at* https://www.wakely.com/sites/default/files/files/content/value-integrated-pharmacy-benefits-medicaid-managed-care-20200615.pdf; AHIP, *The Value of Medicaid Managed Care: Making Drugs More Affordable for States and Taxpayers* (Feb. 2020), *available at* https://www.ahip.org/the-value-of-medicaid-managed-care.

[18] *See* Centers for Medicare & Medicaid Servs., *Trump Administration Continues to Keep Out-of-Pocket Drug Costs Low for Seniors* (Jul. 29, 2020), *available at* https://www.cms.gov/newsroom/press-releases/trump-administration-continues-keep-out-pocket-drug-costs-low-seniors.

or participating in narrow pharmacy plan networks.[19] Consumers want these savings: according to a recent poll, a majority (58 percent) prefer "less expensive plans with a limited network of doctors and hospitals" to "more expensive plans with a broader network of doctors and physicians."[20]

Besides cost savings, network-based managed care has a proven track record for enhancing patient care and outcomes. Networks are formed using widely recognized, evidence-based measures of provider performance, including the provider standards set by the National Quality Forum and the Joint Commission on Accreditation of Healthcare Organizations. Health insurance providers can exclude physicians and hospitals that do not meet these standards.

Similarly, health insurance providers use an evaluation tool known as "credentialing" to govern membership in a network. Credentialing looks at a provider's academic background, training, board certification, professional competence, malpractice record, and license history. The process helps patients choose medical providers with the confidence that they have been carefully vetted.

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[19] Pharmaceutical Care Mgmt. Ass'n, *Mail-Service and Specialty Pharmacies Will Save More than $300 Billion for Consumers, Employers, and Other Payers Over the Next 10 Years* (Sept. 2014), *available at* https://www.pcmanet.org/wp-content/uploads/2016/08/pr-dated-09-10-14-visante-pcma-mail-and-specialty-savings.pdf; *see also* FTC Letter, *supra* note 9.

[20] AHIP, *Ask the AHIP Experts: Why Provider Networks are Important* (Dec. 2018), *available at* https://www.ahip.org/ask-the-ahip-experts-why-provider-networks-are-important/.

Importantly, when patients obtain care from their in-network providers, health insurance providers can assess the delivery of that care and hold medical providers accountable for both quality and costs. They can also better facilitate care coordination and disease management for enrollees, including those with chronic conditions.

Medicare Advantage plans outperform traditional Medicare on clinical quality measures,[21] improve survival rates,[22] and reduce hospital readmissions as well as patient days spent in rehabilitation facilities and nursing homes.[23] Studies have also found better outcomes for patients with specific chronic diseases when they are covered by Medicare Advantage.[24]

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[21] Justin W. Timbie et al., *Medicare Advantage and Fee-For-Service Performance on Clinical Quality and Patient Experience Measures: Comparisons from Three Large States*, 52 HEALTH SERVS. RSCH. 2038 (Dec. 2017), *available at* https://pubmed.ncbi.nlm.nih.gov/29130269/.

[22] Aloke K. Mandal et al., *Value-Based Contracting Innovated Medicare Advantage Healthcare Delivery and Improved Survival*, 23 AM. J. MANAGED CARE 41 (Jan. 2017), *available at* https://www.ajmc.com/view/value-based-contracting-innovated-medicare-advantage-healthcare-delivery-and-improved-survival.

[23] Amit Kumar et al., *Comparing post-acute rehabilitation use, length of stay, and outcomes experienced by Medicare fee-for-service and Medicare Advantage beneficiaries with hip fracture in the United States: A secondary analysis of administrative data*, PLOSMED (June 2018), *available at* https://pubmed.ncbi.nlm.nih.gov/29944655/.

[24] *Id.*

Networks benefit patients in other ways as well. Health insurance providers can use network membership as an incentive to encourage medical providers and hospitals to offer additional services and specialty treatments. The network can thus augment the number and types of medical services available in the communities where the health insurance provider offers coverage. The availability of in-network negotiated rates also allows patients to predict more reliably what treatments will cost, and in turn makes them more likely to seek out preventative or early-stage care. Evidence demonstrates that these patients have improved health outcomes.[25]

Finally, network design helps provide consumers with a menu of options to suit their particular needs, both medical and financial. Consumers can choose broader or narrower networks, with varying levels of copayments and specialty coverage, based on their personal circumstances. For example, in the exchange marketplaces, consumers can choose from dozens of available plans based on factors including plan level (from "Bronze" to "Platinum" on the federal exchange), availability of medical providers, hospital network, overall cost, and even particular medical needs.[26] And

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[25] Jonathan Gruber & Robin McKnight, *Controlling Health Care Costs Through Limited Network Insurance Plans: Evidence from Massachusetts State Employees*, 8 AM. ECON. J. ECON. POLICY 219, 221 (May 2016).

[26] HealthCare.gov, *See Plans & Prices*, *available at* https://www.healthcare.gov/see-plans/#/ (last visited Sept. 7, 2021).

on average, 18 Medicare Advantage plans are currently available in each county.[27]

2. Networks Cannot Function Properly If Plan Members Can Alter Plan Benefits.

A Court decision creating disparate impact liability under the Rehabilitation Act and, by extension, the ACA—at least without restricting its reach to health plans—will destabilize the basic principles that help networks function, compromising cost savings, patient choice, and quality of care. If disparate impact liability is available, individuals with disabilities could argue—as they did in this case—that they can receive "effective treatment" only from out-of-network providers. Pet. App. 14a. If successful, those lawsuits would require health insurance providers to cover that treatment at in-network prices. This outcome would effectively rewrite the carefully designed terms of network-based plans and interfere with health insurance providers' ability to contract with hospitals, physicians, and pharmacies. For instance, an individual could select a narrower network plan from his or her employer or an exchange, but then in practice convert that plan into a wider network or non-network-based plan.

The mere possibility of disparate impact claims will threaten the ongoing vitality of plan networks. The economic competition undergirding networks thrives only if access to a network is controlled. Medical providers agree to join a network to have

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[27] *See* Report to the Congress, *supra* note 11, at 365.

special access to an available pool of patients. They compete to offer reduced prices to obtain that access. But if medical providers believe they may be able to access the same pool of patients regardless, they have less reason to join networks and less incentive to discount their prices. In other words, a medical provider's cost-benefit calculation is skewed against networks if it believes those networks can be easily undermined by individuals seeking to redefine the terms of their health plans.

Care standards will suffer the same diminished fate. High-quality providers will have less incentive to join a network or to maintain the high patient-care standards that network membership requires. The end result is that Americans will pay more for reduced-quality care.

B. The Risk Of Disparate Impact Liability Will Undermine Medical Management Tools, Leading To Increased Costs And Heightened Risk To Patients.

1. Medical Management Techniques Ensure That Patients Receive Safe And Affordable Care.

Permitting disparate impact claims will also undermine medical management, also known as care or utilization management. Medical management includes a number of approaches that are all designed to protect patient safety; prevent unnecessary, inappropriate, and potentially harmful care; improve and better coordinate care; and increase health care affordability. In general, these tools—as described below—encourage health care providers to use more

affordable, evidence-based, and proven patient care techniques.

Prior authorization. Prior authorization is a process for providers to request approval from a health insurance provider for a particular item or service before care is delivered to qualify for coverage. The purpose underlying prior authorization is to confirm that a treatment is medically necessary and appropriate for the patient based on clinical evidence. Health insurance providers require prior authorization when medical recordkeeping shows that medical providers are departing at above-average rates from evidence-based requirements. Prior authorization also alerts health insurance providers that an enrollee may need additional care, treatment, or other services. This then allows health insurance providers to help patients maximize their coverage while also minimizing any financial risks. In designing and applying prior authorization, health insurance providers use various sources of evidence-based studies, guidelines, and federal standards.[28]

The benefits of prior authorization are well established. Prior authorization prevents overuse and misuse of ineffective, expensive, or risky treatments and services; protects patients from inappropriate and potentially harmful care; and promotes efficiency and cost savings by requiring providers to explore less costly treatment paths. For example, medical providers are required to recommend physical therapy

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[28] AHIP, *Key Results of Industry Survey on Prior Authorization* (June 2020), *available at* https://www.ahip.org/wp-content/uploads/Prior-Authorization-Survey-Results.pdf.

to a patient with low-back pain before authorizing expensive imaging tests with potential unnecessary exposure to radiation; to avoid prescribing drugs for untested off-label use; and to try non-opioid approaches—like acupuncture, physical therapy, or non-opioid pain medications—to manage pain or to limit opioid dosages or duration.[29] Prior authorization is also used when issuing durable medical equipment (such as wheelchairs, walkers, scooters, and oxygen equipment) to address the rampant problem of fraud, abuse, and other misconduct in connection with those devices.[30]

Step therapy. Similar to prior authorization, step therapy serves a dual function of improving patient safety and reducing unnecessary costs. This medical management tool requires providers to use a safe, effective, and less costly medication before prescribing a higher cost drug. The vast majority of commercial health plans, as well as many state Medicaid programs and Medicare Part D, use step-therapy programs. Typically, these programs encourage prescribers and patients to use generic

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[29] *See* Deborah Dowell, Tamara Haegerich & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016* (Mar. 18, 2016), *available at* http://dx.doi.org/10.15585/mmwr.rr6501e1.

[30] U.S. Dep't of Justice, *Federal Indictments & Law Enforcement Actions in One of the Largest Health Care Fraud Schemes Involving Telemedicine and Durable Medical Equipment Marketing Executives Results in Charges Against 24 Individuals Responsible for over $1.2 Billion in Losses* (Apr. 9, 2019), *available at* https://www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes.

medications as first-line treatment before progressing to brand-name drugs.

Health insurance providers use an evidence-based sequence to promote treatment effectiveness and affordability. This process includes obtaining input from plan pharmacy and therapeutics committees (composed of doctors, pharmacists, and other experts in pharmacy matters), FDA guidelines, and evidence gathered from clinical trials and research. As a result, step therapy helps ensure that patients are prescribed drugs that will provide the greatest clinical benefits with the least accompanying risks.

Prescription formularies. Prescription formularies perform a similar function to step therapy, except they use pricing incentives instead of mandates to enhance access to safer, less expensive prescription drugs. As described in the Petition (at 9-10), drug formularies are one of the most essential tools for managing drug costs. For example, most Medicare Part D plans use a five-tier formulary with differential cost sharing between preferred and non-preferred drugs, and a specialty tier for high-cost drugs.[31] Formularies create tiers reflecting different prices, level of cost-sharing, or availability via specialty pharmacies. Like other medical management protocols, formulary tiers draw on current medical evidence and the input of the plan's pharmacy and therapeutics committee. Drugs are placed in tiers based on their safety, efficacy, and cost-effectiveness. A health insurance provider's ability to manage its

[31] Report to the Congress, *supra* note 11, at 409.

own formularies based on clinical input significantly improves patient safety, reduces drug spending, and, in turn, limits patient cost-sharing and insurance premiums.

"Centers of Excellence" and tiering. Similar to the formulary concept, health insurance providers have begun creating financial incentives for patients to obtain care from certain recognized, high-quality providers. For example, some health benefit plans will cover certain medical or surgical services only if performed at a recognized and contracted Center of Excellence. These facilities have a proven track record of offering high-quality care with minimum complications and use experienced, qualified clinicians. Similarly, other health benefit plans use tiers for medical providers (as well as for prescription drugs), and reduce copayments for members who obtain care from providers and facilities in a higher-performing tier. These protocols, once again, reduce unnecessary costs while directing patients to the highest quality medical care available.

2. Inviting Disparate Impact Challenges To Medical Management Techniques Will Harm Plan Members And Increase Costs.

If the Court holds that the Rehabilitation Act permits disparate impact claims without limitation, it will open the door to challenges to facially neutral medical management techniques, like Petitioners' prescription formulary. Pet. App. 7a-8a. Individuals with disabilities can assert that these techniques impede access to "effective treatment" for their

conditions. As a result, individuals with disabilities could effectively "change the terms of their benefit plan" to expand formularies, change prescription drug and other treatment tiers, or exempt themselves from other core medical management aspects of benefit design. *Id.* at 42a.

Limiting the use of these techniques, even as to only some individuals, will have serious economic consequences. Over $900 billion is wasted annually on unnecessary medical treatment. If health insurance providers cannot employ medical management practices, that amount will surge even higher. And the costs to health insurance providers and their members will be substantial.

Consider prescription drug plans alone. Over $450 billion was spent on prescription drugs in 2015—constituting 16.7 percent of overall health care spending—and medication costs are increasing dramatically every year.[32] Undermining the techniques that help manage these costs will increase the economic burden on insured populations. Indeed, individuals and families are likely to bear the brunt of these economic consequences: The Congressional Budget Office estimates that health benefit plan premiums will rise by 5 to 10 percent or more if plans

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[32] U.S. Dep't of Health and Human Servs., *Observations on Trends in Prescription Drug Spending* 2, 7-8 (Mar. 2016), *available at* https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf.

cannot use common medical management techniques to manage prescription drug costs.[33]

The harm to patients will be even more significant. Medical management ensures that patients receive safe, effective, high-quality care consistent with medical evidence. Patients typically are exempted from these practices only when medical evidence indicates that a different treatment practice is warranted. However, the prospect of liability for disparate impact discrimination will effectively require exemptions from such practices for non-evidence-based reasons, like personal convenience or preferences for certain kinds of medical services (such as prescription counseling from a community pharmacist rather than CVS Pharmacy personnel, as Respondents here argued). Pet. App. 14a, 28a.

The result will be that fewer patients receive purely evidence-based medical treatment and more patients are exposed to riskier and potentially unwarranted medical interventions. This is not an abstract concern: Studies demonstrate that at least 15-30 percent of medical care is unnecessary and that patient requests are a primary reason for overtreatment.[34] The threat of disparate impact liability will make it more difficult for health insurance providers to use common features of

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[33] Congressional Budget Office, *Key Issues in Analyzing Major Health Insurance Proposals* 67 (Dec. 2008), *available at* https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/99xx/doc9924/12-18-keyissues.pdf.

[34] Heather Lyu, *Overtreatment in the United States*, PLOS ONE (Sept. 6, 2017), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5587107/.

benefits plan design—a result that will diminish patient care, not improve it.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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