No. 22-339

IN THE
Supreme Court of the United States

PFIZER INC,
Petitioner,
v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

MOTION OF THE NATIONAL MINORITY QUALITY FORUM FOR LEAVE TO FILE BRIEF AMICUS CURIAE AND BRIEF AMICUS CURIAE IN SUPPORT OF PETITIONER

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Pursuant to Rule 37.2 of the rules of this Court, the National Minority Quality Forum ("NMQF") respectfully moves this Court for leave to file the attached brief *amicus curiae* in support of the petition for a writ of certiorari to review the judgment of the U.S. Court of Appeals for the Second Circuit in *Pfizer, Inc.* v. *HHS*, 42 F.4th 67 (2d Cir. 2021). Counsel of record for all parties received timely notice of NMQF's intent to file the attached brief as required by Rule 37.2(a). Counsel for Respondents withheld consent, so NMQF is filing this motion for leave to file the attached brief *amicus curiae* pursuant to Rule 37.2(b).

In this case, the Second Circuit endorsed the government's overbroad construction of the Anti-Kickback Statute to bar petitioner's co-pay assistance program for certain Medicare beneficiaries. NMQF's brief *amicus curiae* will assist the Court in understanding how this overbroad construction will exacerbate racial disparities in access to medical care and jeopardize a whole range of charitable programs that would otherwise help individuals and families who face wholly unaffordable Medicare co-pays that place out of reach the Medicare benefits they are entitled to receive.

Accordingly, NMQF respectfully requests that the Court grant this motion for leave to file a brief *amicus curiae*.

Respectfully submitted.

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INTEREST OF AMICUS CURIAE[1]

The National Minority Quality Forum ("NMQF" or "the Forum") is a nonprofit, nonpartisan research and educational organization dedicated to ensuring that

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[1] No counsel for any party authored this brief in whole or in part, and no other entity or person made any monetary contribution toward the preparation and submission of this brief. Counsel for Respondents withheld consent, so NMQF has filed a motion for leave to file this *amicus curiae* brief. Sup. Ct. R. 37.2(b).

high-risk racial and ethnic populations and communities receive optimal health care. NMQF integrates data and expertise in support of initiatives to eliminate health disparities that affect disadvantaged groups. The grim results of these disparities are well known and widely documented, and yet do not—and should not—cease to shock our collective conscience.

Racial and ethnic minorities suffer from disproportionately high rates of chronic disease and premature death. Black men are more than 50% more likely than whites to die prematurely from stroke,[2] Hispanic children and adolescents have the highest prevalence of obesity,[3] and Black women are more than twice as likely to die from complications of pregnancy than white women.[4] Black and Hispanic Medicare beneficiaries are far less likely than white beneficiaries to receive flu vaccinations, and even those who are vaccinated are far less likely than white program beneficiaries to receive the forms of the vaccine that are most effective for

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[2] Office of Minority Health, U.S. Dep't of Health & Hum. Servs., *Stroke and African Americans*, http://bit.ly/3EogcW5 (last visited Nov. 11, 2022).

[3] National Ctr. For Health Stats., DHHS Pub'n No. 2016-1232, *Health, United States, 2015*, at 26 (June 22, 2017), http://bit.ly/3A7UeUN; Guerrero et al., *Racial and Ethnic Disparities in Early Childhood Obesity: Growth Trajectories in Body Mass Index*, 3 J. Racial & Ethnic Health Disparities 129 (2016); Isasi et al., *Health Issues in Hispanic/Latino Youth*, 4 J. Latinx Psychol. 67 (2016).

[4] Hoyert & Minino, *Maternal Mortality in the United States: Changes in Coding, Publication, and Data Release, 2018*, 69 Nat'l Vital Stats. Reps. 1, 5 (2020), https://stacks.cdc.gov/view/cdc/84769.

older Americans.[5] These and other healthcare metrics attest to a simple but grave truth: High-risk racial and ethnic populations lack equal access to health care in the United States.

Over the years, NMQF has focused primarily on pursuing change through policy and organizing. For example, NMQF has hosted discussions regarding diversity in the health care workforce, organized community health clinics, and facilitated summits throughout the country to provide youth with mentorship, leadership training, and resources to make positive changes in their communities.[6] NMQF's preferred method of effecting change is written advocacy, intended for a general audience, and focused on exposing various aspects of the large-scale disadvantages of inadequate access to optimal health care. For example, the Forum has published articles revealing the lack of adequate proper access to dental care for low-income and Medicare beneficiaries[7] and explaining how out-of-pocket payments for the fixed-dose combination of Hydralazine and Isosorbide Dinitrate (BiDil), a heart medication, negatively affect Black populations specifically.[8]

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[5] Mahmud et al., *Effect of Race and Ethnicity on Influenza Vaccine Uptake Among Older US Medicare Beneficiaries: A Record-Linkage Cohort Study*, 2 The Lancet E143 (2021).

[6] National Minority Quality Forum, *2019 Annual Report* 1, 4, 14 (2020), http://bit.ly/3hCdDah.

[7] National Minority Quality Forum, *Reassessing the Dental Care Paradigm: A National Minority Quality Forum White Paper* (Nov. 2015), http://bit.ly/3O2ujnh.

[8] National Minority Quality Forum, *Out-of-Pocket Payments for the Fixed-Dose Combination of Hydralazine and Isosorbide Dinitrate (BiDil)* (Mar. 8, 2017), http://bit.ly/3G4bYV3.

In this case, the Forum decided to engage in courtroom advocacy for the first time in its history, beginning in the district court, then the Second Circuit, and now in support of Pfizer's petition for a writ of certiorari in this Court. The Forum's decision to enter the courtroom fray, and its continued support of Pfizer's appeals, reflects the importance of this case for the issues that are NMQF's focus. While it is clear that the issues surrounding health care access for minority communities do not begin or end with the interpretive decisions of the U.S. Department of Health and Human Services, NMQF believes that the Department's decision to prohibit Pfizer's patient subsidy initiative for a breakthrough drug to treat a serious heart disease will exacerbate existing disparities. It is imperative that this Court intervene now to review the decisions below.

INTRODUCTION AND SUMMARY OF ARGUMENT

Approximately 100,000 individuals suffer from Transthyretin Amyloid Cardiomyopathy ("ATTR-CM"), a progressive and potential fatal heart disease that in certain hereditary forms disproportionately afflicts Black men. Without the Court's intervention, many will have to forgo treatment that could meaningfully prolong their lives, simply because they cannot afford the co-pays necessary for Medicare to pick up the rest of the tab, and because the government will bar manufacturers from assisting with those co-pays. This amounts to a triple-blow for Black communities and Black families. First, their husbands, sons, and fathers are more likely to suffer from hereditary ATTR-CM. Second, because relatively few people in the population as a whole suffer from ATTR-CM, the costs of developing treatments are high, and the resulting price tag and co-pays for the drugs are high. Third, the effects of the persistent racial wealth gap then come into play—Black families have less wealth than majority families with comparable levels of income, and are thus more likely to be financially impacted by co-pays, no matter the amount.[9]

Given these sources of structural inequality, the government's overbroad construction of the Anti-Kickback Statute (AKS) will continue to exacerbate disparities in access to medical care by denying minority persons co-pay assistance and, by extension, denying them access to Medicare benefits that would be theirs if they could afford the co-pay. As Pfizer aptly describes in its petition, the government's approach to the AKS effectively "outlaws a wide swath of routine, beneficial conduct." Pet. 2. If the Second Circuit's opinion is left to stand, it risks chilling a whole range of charitable programs that would otherwise help individuals and families to access Medicare benefits that they have a lawful right to receive but are practically out of reach because the required Medicare co-pays are wholly unaffordable.

In practical terms, the government's interpretation of the AKS punishes patients for being both too poor to afford treatment, but not poor enough to warrant the government's assistance. Pet. 16-17. That approach is neither wise nor equitable; it exacerbates the inequities many low-income minorities already face in the healthcare system by preventing them from receiving life-saving medical treatment at a lower cost. That is the opposite of what Congress intended when it created Medicare, and more recently, when it directed the

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[9] Tanzi, *Five Charts That Show the Extent of the Black Wealth Gap in U.S.*, Bloomberg (July 18, 2020), http://bit.ly/3UucFeN.

Department to avoid the disparate treatment of minorities in the provision of health care benefits. There is simply no sound reason to treat the AKS as requiring, or permitting, that dramatically inequitable result.

Indeed, the district court recognized the potentially catastrophic consequences that the government's interpretation of the AKS would have on low-income minorities, explaining that "it is impossible entirely to eliminate the financial impact" of Pfizer's lifesaving drug, and that "economic hardship may result in patients with debilitating illness foregoing treatment that otherwise might assist them." Pet. App. 62a. Despite thus acknowledging that it is the sick and the dying who stand to suffer if the government prevails in its view that Pfizer's co-pay assistance program is unlawful, the district court—and the Second Circuit—nonetheless found themselves bound to sustain the government's position. NMQF writes to underscore the policy consequences of the government's position, as well as the disconnect between the government's pro-equity rhetoric and legal commitments and its insufficient concern for equity when making concrete health policy decisions on which minority lives and minority families depend.

ARGUMENT

I. HHS HAS A RESPONSIBILITY TO ENSURE THAT PROGRAM BENEFICIARIES FROM HISTORICALLY DISADVANTAGED COMMUNITIES ENJOY EQUAL ACCESS TO MEDICARE BENEFITS.

As originally enacted, the Medicare statute had a deceptively modest statement of purpose—"[t]o provide a hospital insurance program for the aged under the Social Security Act with a supplementary medical benefits program and an expanded program of medical assistance." Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286. As it exists today, Medicare has grown to "provide health insurance for nearly 60 million aged or disabled Americans, nearly one-fifth of the Nation's population." *Azar* v. *Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). The scope of the program is wide, providing access to life-saving treatments for "all elderly, as well as the disabled." *Allina Health Servs.* v. *Sebelius*, 746 F.3d 1102, 1105 (D.C. Cir. 2014). Given the inclusive set of beneficiaries for whom Medicare is intended, and given that "[o]ne way or another, Medicare touches the lives of nearly all Americans," *Azar*, 139 S. Ct. at 1808, the need to ensure equality of access to care for all sectors of the beneficiary population is a paramount one.

Indeed, Medicare (and Medicaid) have furthered equality of access to medical care across many dimensions of society, including along racial lines. For instance, in 1969 the IRS issued Revenue Ruling 69-545, which developed what is still known as the "community benefit standard" for determining whether a hospital qualified as a charitable organization. Importantly, that standard required hospitals seeking to avail themselves of the exemption to "operat[e] an emergency room open to all persons" and "provid[e] hospital care for *all* those persons in the community able to pay the cost thereof either directly *or through third party reimbursement*." Rev. Rul. 69-545, 1969-2 C.B. 117 (emphases added). The ruling also makes clear that "able to pay" includes payment through Medicare. *Id.* In other words, the combination of Medicare and the tax laws opened the doors of healthcare facilities to all eligible beneficiaries, regardless of race.[10]

More recently, in January of 2021, President Biden issued an Executive Order that instructed the federal government to "pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality."[11] In response to this Order, in April 2022, the Centers for Medicare & Medicaid Services published the "CMS Framework for Health Equity 2022–2032," which notes the "critical importance" of CMS's "responsibility to increase access to health care coverage for underserved populations" and "adapt policies to continue to make coverage across [federal healthcare programs] more affordable and available."[12] Both the Executive Order, and the Center for Medicare & Medicaid Services' response, highlight the government's consistent position that it is responsible for enhancing racial equity in health care and mitigating the disparities that underserved communities face in accessing affordable health care.

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[10] *See also* IRS, *Charitable Hospitals—General Requirements for Tax-Exemption Under Section 501(c)(3)* (last updated Aug. 3, 2021) ("Once a determination is made that a particular patient is covered by health insurance, governmental program or otherwise has sufficient resources to pay for health care, and the hospital has the available space and can provide the appropriate medical services, the patient should be admitted to the hospital in a nondiscriminatory manner."), http://bit.ly/3tkLaZ9.

[11] Exec. Order No. 13985, 86 Fed. Reg. 7009 (Jan. 25, 2021).

[12] Centers for Medicare & Medicaid Servs., *CMS Framework for Health Equity 2022–2032*, at 18 (Apr. 2022) http://bit.ly/3A4Y7dq.

For two reasons, a concern for equal access should be front and center in this case, in which the government is attempting to defend its decision to block Pfizer from providing a form of financial assistance to patients who otherwise may have difficulties affording the Medicare co-pays for tafamidis, the Pfizer-made drug designed to treat ATTR-CM. First, a sustained body of research—including publications from the Center for Medicare & Medicaid Services—reveals that as a factual matter, members of minority groups face significant disparities in access to and quality of care received through Medicare. Second, the agency has an obligation, as referenced in the preceding paragraph, as a matter of law and stated policy, to eliminate these disparities. And yet the government's approach to interpreting the AKS displays no evident concern for equality of access, and to the contrary, will perpetuate unwarranted disparities unless this Court intervenes.

A. Minority individuals and families are significant contributors to Medicare, but lack equal access to program benefits.

Research demonstrates that Medicare beneficiaries belonging to minority groups consistently lag behind white counterparts in terms of access to quality healthcare services. In fact, in 2019, the Department published a study concluding that minority Medicare beneficiaries—across multiple racial and ethnic groups, including Black beneficiaries—faced substantial disparities in quality of care according to a wide range of patient-reported and clinical measures.[13] This reality is

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[13] *See* Office of Minority Health, Centers for Medicare & Medicaid Servs., *Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage*, at vi-vii (Apr. 2019) (noting that "Black and Hispanic beneficiaries received worse clinical care than

exacerbated by disparities across racial lines in income, debt, and other measures of wealth,[14] which conspire to ensure that minority communities regularly endure worse health outcomes.

Minority groups, and Black Americans in particular, already fare worse than white Americans across a wide range of health measures including life expectancy, rates of chronic disease, and cancer mortality rates.[15] They also are more likely to be uninsured and rely on public health programs like Medicare as compared to white Americans.[16] A lack of insurance, in addition to other factors, often means Black Americans struggle to afford healthcare costs and shoulder a disproportionate share of medical debt.[17] Studies also

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White beneficiaries on a large portion of the clinical care measures examined"), http://bit.ly/3DXF7OV.

[14] McIntosh et al., *Examining the Black-White Wealth Gap*, The Brookings Inst. (Feb. 27, 2020), http://bit.ly/3AbdEIq.

[15] Hillet et al., *Key Facts on Health and Health Care by Race and Ethnicity: Health Status, Outcomes, and Behaviors, Kaiser Family Foundation Study* (Jan. 26, 2022), http://bit.ly/3WRL2hc.

[16] Keisler-Starkey & Bunch, *Health Insurance Coverage in the United States*: *2021*, at 1, 7, 12-13, U.S. Census Bureau (Sept. 2022), http://bit.ly/3hDKDio.

[17] *See* Perry et al., *The Racial Implications of Medical Debt: How Moving Toward Universal Health Care and Other Reforms Can Address Them*, The Brookings Inst. (Oct. 5, 2021) ("According to our analysis, 17.4% of households with insurance have medical debt compared to 27.9% of households without insurance … . Nearly 80% of medical debt is held by households with zero or negative net worth. The blame for a lack of health care coverage should not be rigidly characterized as a class issue. Black households are more likely to hold medical debt. Twenty-seven percent of Black households hold medical debt compared to 16.8% of non-Black households.), https://bit.ly/3TvQi7p.

establish that households with medical debt typically delay or avoid seeking health care for otherwise treatable health conditions,[18] meaning vulnerable communities are caught in a vicious cycle of poor health outcomes due to an inability to pay. In other words, the racial wealth gap further entrenches the well-documented racial health gap.

Researchers have consistently identified racial disparities in prescription drug access in Medicare.[19] These disparities include access to medications for cardiovascular disease.[20] In part, these disparities in access to pharmaceuticals are caused by disparities in the ability to afford medications. As one study reports, "[e]lderly black Medicare beneficiaries are more than twice as likely as white beneficiaries to not have

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[18] Hamel et al., *The Burden of Medical Debt: Results from the Kaiser Family Foundation/New York Times Medical Bills Survey, Section 3: Consequences of Medical Bill Problems*, Kaiser Family Found. (Jan. 5, 2016), http://bit.ly/3G8kySA; Patel et. al., *Association of Social Risks With Avoiding or Delaying Health Care and With Emergency Department Visits: Evidence From 2017 Ohio Medicaid Assessment Survey*, 27 Am. J. of Managed Care 115 (2021).

[19] Schore et al., *Racial Disparities in Prescription Drug Use Among Dually Eligible Beneficiaries*, 25 Health Care Fin. Rev. 77, 77-79 (2003), (noting multiple studies demonstrating disparities in prescription drug use among Medicare beneficiaries, and observing that "members of racial minorities are less likely than those of non-minorities to receive appropriate medications for cardiovascular disease and AIDS"), http://bit.ly/3G5YyYv.

[20] U.S. Gen. Acct. Off., GAO-03-862R, *Health Care: Approaches to Address Racial and Ethnic Disparities* 10-11 (July 8, 2003) (noting racial and ethnic disparities in "appropriate medication" and "procedures" relating to cardiovascular disease), https://www.gao.gov/assets/gao-03-862r.pdf.

supplemental insurance and to not fill prescriptions because they cannot afford them."[21]

As the Department and multiple other sources have demonstrated, the COVID-19 pandemic further underscored the role that socioeconomic status and race play in shaping health outcomes.[22] Prior to the pandemic, Black households already had disproportionately less wealth than their white counterparts.[23] In 2020,

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[21] Schore, 25 Health Care Fin. Rev. at 77; *see also* Briesacher et al., *Racial and Ethnic Disparities in Prescription Coverage and Medication Use*, 25 Health Care Fin. Rev. 63, 63-64, 73-74 (2003), http://bit.ly/3to5g4x; Reed et al., *Issue Brief: Unequal Access: African-American Medicare Beneficiaries and the Prescription Drug Gap* 1-2, Center for Studying Health Sys. Change (July 2003) (noting that "[t]he different pattern of supplemental coverage for elderly black and white Medicare beneficiaries helps to explain the prescription drug access gap between blacks and whites" and "[t]he lower incomes of older African Americans partially explain why they are less likely than whites to fill all of their prescriptions"), http://bit.ly/3EpXvBy.

[22] *See e.g.*, Simmons et al., *Issue Brief*: *Health Disparities by Race and Ethnicity During the COVID-19 Pandemic: Current Evidence and Policy Approaches*, Office of the Asst. Sec. for Plan. and Evaluation, U.S. Dept. of Health & Hum. Serv. (Mar. 16, 2021) ("The COVID-19 pandemic has highlighted stark health disparities among Black, Hispanic, Native American, and Native Hawaiian/Pacific Islander populations in several areas, including infections, hospitalizations, death rates, and vaccination rates."), http://bit.ly/3UT8KYN.

[23] *See e.g.*, Bhutta, et. al., *Disparities in Wealth by Race and Ethnicity in the 2019 Survey of Consumer Finances*, Board of Governors of the Federal Reserve System (2020), https://doi.org/10.17016/2380-7172.2797; Grutman, *The Racial Wealth Gap Is a Racial Health Gap*, 110 Ky. L.J. 723, 726 (2021) ("As in years prior, 2020 median household income differed dramatically by race. Households headed by those who self-identified as Asian had the highest median income ($94,903), compared to

65.2 percent of unemployed Black households could not produce $400 in emergency savings, as opposed to 46.7 percent of unemployed white households.[24] This meant that Black communities, in addition to experiencing higher coronavirus morbidity due to their vulnerable socioeconomic status, were also less equipped to weather the financial consequences of the pandemic.[25] There is therefore more reason than ever to conclude that racial and ethnic disparities in health—including disparities in access to prescription medications—represent a problem that public officials, including HHS, should be striving to address.

B. Congress and HHS have acknowledged these disparities and the agency's obligation to address those disparities at an operational level.

The agency's paramount obligation to avoid perpetuating racial and ethnic disparities in access to Medicare benefits derives from at least three sources. *First*, Congress has spoken on the issue. The Patient Protection and Affordable Care Act, enacted in 2010, provides that "an individual shall not, on the ground

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white, non-Hispanics ($74,912), Hispanics of any race ($55,321) and Blacks ($45,870)).

[24] Board of Governors of the Federal Reserve System, *Survey of Household Economics and Decisionmaking* (calculations based on data collected in April 2020 and July 2020), http://bit.ly/3tpGzow.

[25] *See* Perry, *The Racial Implications of Medical Debt: How Moving Toward Universal Health Care and Other Reforms Can Address Them*, *supra* note 17 (explaining that Black people are disproportionately frontline and essential workers, and consequently experienced higher rates of COVID-19 infection, due to decades of discrimination in the labor market).

prohibited under title VI of the Civil Rights Act of 1964 … be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance [including Medicare Part D] or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments)." 42 U.S.C. § 18116(a). Title VI, in turn, has been construed to reach "unintentional, disparate-impact discrimination as well as deliberate racial discrimination." *Guardians Ass'n* v. *Civil Serv. Comm'n of City of N.Y.*, 463 U.S. 582, 593 (1983) (plurality opinion); *see* 45 C.F.R. § 80.3(b)(2) (effectuating Title VI and forbidding "criteria or methods of administration" that produce disparate impact discrimination).

The 2010 provision is a natural extension of Medicare's promise to provide life-saving treatments and medications to "*all* elderly, and the disabled," and underscores that the law requires more than that Medicare policies be neutral on their face. In end effect too, Medicare policies must work equitably, just like all other governmental policies subject to Title VI. *See, e.g.*, *Lau* v. *Nichols*, 414 U.S. 563, 566 (1974) (noting that under Title VI "there is no equality of treatment merely by providing students with the same facilities, textbooks, teachers, and curriculum" where those students "do not understand English," since "those who do not understand English are certain to find their classroom experiences wholly incomprehensible and in no way meaningful"), *abrogated on other grounds by Alexander* v. *Sandoval*, 532 U.S. 275 (2001).

Second, HHS's own description of its goals highlights the importance of ensuring equal access to

Medicare benefits across all members of the beneficiary population. In 2011, HHS published the HHS Action Plan to Reduce Racial and Ethnic Disparities. That document expressed the Department's commitment to "continuously assessing the impact of all policies and programs on racial and ethnic health disparities" and sought to explain how "the Department can leverage" the Affordable Care Act and other initiatives "in its effort to reduce racial and ethnic health disparities."[26]

Third, the HHS OIG itself has adopted a policy posture that rightfully places it at odds with decisions or actions that perpetuate or exacerbate racial and ethnic health disparities. Thus, OIG's strategic plan for 2020–2025, published during the Trump Administration, describes one of its primary goals as to "promote quality, safety, and value in HHS programs," notes that those programs "provide critical services to diverse populations," and commits OIG "to providing oversight that helps HHS improve its programs and ensure that eligible beneficiaries receive appropriate services."[27] Similarly, its mission statement explains its role as "provid[ing] objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve."[28] Such goals are fundamentally inconsistent with an approach that fails to attend to

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[26] U.S. Dep't of Health & Human Servs., *HHS Action Plan to Reduce Racial and Ethnic Health Disparities* 1, 7 (Apr. 2011), https://bit.ly/3EmABuT.

[27] Office of Inspector Gen., U.S. Dep't of Health & Human Servs., *HHS-OIG Strategic Plan 2020–2025*, at 12 (2020), http://bit.ly/3AaVrLk.

[28] *Id.* at 3.

disproportionate and negative effects on the ability of minority populations to access care.

In the Second Circuit, the government sought to justify the dramatically inequitable consequences of its position by pointing to what it described as the cost implications of allowing those with good intentions to help patients pay for live-saving medications. According to the government, the criminal law must be leveraged to prevent that outcome because, although Pfizer's proposed co-pay program would assist needy patients in accessing its lifesaving drug for "virtually free," the program would "leav[e] the bill with federal healthcare programs." C.A. Respondents Br. 50. This argument, of course, completely disregards the non-discrimination command of the Patient Protection and Affordable Care Act and the pro-equity goals that HHS emphasizes when it does not have cost-savings in mind.

The argument is also unsound in its own right. As the D.C. Circuit recently admonished in rejecting a different HHS policy, also notionally aimed at reducing drug prices, the agency cannot construe a statute to give it "unbridled power to promulgate any regulation with respect to drug manufacturers that would have the arguable effect of driving down drug prices—or even healthcare costs generally—based on nothing more than their potential salutary financial benefits for the Medicare or Medicaid program." M*erck & Co., Inc.* v. *HHS*, 962 F.3d 531, 540 (D.C. Cir. 2020). This Court should likewise grant review to reject the agency's interpretation of the AKS in a manner that increases the health risks that patients face and exacerbates racial inequities in access to life-saving medication. And in doing so, the Court should be clear-eyed about the source of the cost savings that the government is touting. Those "savings" would be derived by denying life-saving medical care to elderly taxpayers who have paid into the system, likely for decades, in their hour of most urgent need. A desire for cost-savings cannot remotely justify the government's contention that Congress made it a crime to help Medicare beneficiaries access life-saving care.

II. HHS HAS HISTORICALLY MADE POLICY DECISIONS INCONSISTENT WITH THE NEEDS OF DISADVANTAGED COMMUNITIES.

OIG's rejection of Pfizer's patient subsidy program is just the latest example of how HHS has made coverage and other program decisions that work at cross purposes with its responsibility to further equal access to medical care for historically disadvantaged communities. The Black community in particular has borne the brunt of these shortcomings. In addition to tafamidis, which combats ATTR-CM arising in a hereditary form that primarily afflicts Black men, HHS has discouraged doctors from prescribing BiDil, a drug proven effective at treating heart failure in Black people.

Heart failure is a condition in which the heart is unable to pump enough blood to meet the body's demands. Black people face a heightened risk of heart failure, in part because high blood pressure and diabetes are more common among them and because, some scientists suspect, they may have lower levels of nitric oxide.[29] BiDil represents a significant medical advance for Black people in particular because the most effective drugs for combatting heart failure in the general

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[29] Arbor Pharms., LLC, *Heart Failure Is Different for African Americans* (2018), https://www.bidil.com/about-heart-failure/african-americans.

population—angiotensin-converting enzyme (ACE) inhibitors—have been less effective for Black people, for reasons that are not yet fully understood.[30] BiDil is the result of a search for drugs that would address this effectiveness gap. The study that supported BiDil's FDA approval shows a 43% improvement in survival and a 33% reduction in first-time hospitalizations for heart failure compared to a treatment of a placebo and standard therapy.[31]

Instead of promoting this breakthrough medication, HHS discouraged doctors' prescriptions by encouraging Medicare Part D insurers to exclude BiDil from their formularies and by encouraging generic substitution of an unproven combination of drugs.[32] Medicaid programs and private insurers followed suit and imposed similar reimbursement limitations for BiDil, to the detriment of Black patients who would benefit enormously from increased access to BiDil.[33]

For BiDil, like tafamidis, HHS staked its position on the high cost of the drug. That stance made no sense as a matter of policy because it failed to take account of cost savings that patients derive from taking a more effective medication. For example, economic analysis

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[30] Letter from Daniel J. Popeo & Richard A. Samp, Wash. Legal Found. to Kerry N. Weems, Acting Adm'r, Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., Re: Petition to Revise CMS Reimbursement Policies Regarding BiDil®, at 3 (Aug. 7, 2008), http://bit.ly/3UObpCS.

[31] *Id.* at 3-4 (citing Taylor et al., *Combination of Isosorbide Dinitrate and Hydralazine in Blacks with Heart Failure,* 351 N. Eng. J. Med. 2049 (2004)).

[32] *Id.* at 6.

[33] *Id.*

published in December 2005 shows that prescribing BiDil to Black heart failure patients as an add-on to standard therapies resulted in many fewer medical expenditures than when it was not prescribed.[34] Moreover, a myopic focus on price will have the end effect of exacerbating disparities in access to medical care because it ignores the reality that drugs that serve a minority of patients can be expensive to research on the front end and difficult to affordably price on the back end because of smaller user pools. Had the agency focused instead on the enormous heart-health benefits that BiDil could provide to a minority population that has historically received less than its fair share of Medicare expenditures, it appears very likely that the decision would have been different. One would have expected the Department to have learned its lesson from BiDil, but by all appearances, it is determined to commit the same fundamental error again.

III. HHS'S INTERPRETATION OF AKS LIABILITY—NOW ENDORSED BY THE SECOND CIRCUIT—FURTHER PERPETUATES DISPARITIES IN HEALTHCARE ACCESS RESULTING FROM THE RACIAL HEALTH AND WEALTH GAPS.

ATTR-CM exemplifies the ongoing, interrelated nature of disparities in access to health care and wealth for minority populations. ATTR-CM afflicts people of all racial and ethnic backgrounds, but the hereditary type disproportionately afflicts Black men. That means Black men are more often sick with the disease, and

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[34] *Id.* at 7 (citing Angus et al., *Cost-Effectiveness of Fixed-Dose Combination of Isosorbide Dinitrate and Hydralazine Therapy for Blacks with Heart Failure*, 112 Circulation: J. of Am. Heart Assoc. 3745 (2005)).

more often in need of access to expensive medications. For reasons deeply (and tragically) rooted in our nation's history, they are persistently among the least likely to be able to afford those medications, and to need to rely on Medicare benefits to access them. And for those same reasons, they are among the least likely to be able to access their benefits, because a benefit premised on a co-pay in the thousands is still beyond their reach—like trying to scale a wall using a ladder that starts more than halfway up.

Co-pay assistance programs represent one means of extending that ladder. They represent one tool that could break the cycle detailed above, responding directly to the issue of disparities in the case of ATTR-CM specifically and with respect to other diseases more generally. But the government's chosen position—now endorsed by the Second Circuit—removes that tool, thereby allowing this manifestation of the racial health and wealth gap to endure. That decision has enormous human consequences. The American Heart Association characterizes ATTR-CM as an "underdiagnosed and potentially fatal disease,"[35] and untreated patients suffering from hereditary ATTR-CM can expect to live an average three years after diagnosis.[36] Given that tafamidis is the only FDA approved drug on the market, affordable access to this medication through co-pay programs like those proposed by Pfizer is a matter of

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[35] American Heart Ass'n, *What is Transthyretin Amyloid Cardiomyopathy (ATTR-CM)?* 1 (2019), https://www.heart.org/-/media/files/health-topics/answers-by-heart/what-is-attrcm.pdf.

[36] Hafeez & Bavry, *Diagnosis of Transthyretin Amyloid Cardiomyopathy,* 9 Cardiology & Therapy 85 (2020) https://link.springer.com/article/10.1007/s40119-020-00169-4.

life and death for diagnosed patients and affected communities.

For reasons that Pfizer articulated below and in its petition, the agency's interpretation is neither compelled by nor permitted under the law. *See* Pet. 4 ("To conclude that the AKS criminalizes any financial assistance—no matter how benign—respondents, with the court of appeals' approval, failed to consider properly the text, structure, and history of the AKS, which demonstrate the statute's focus on corrupt transactions."). It is also incompatible with the agency's obligations to ensure equitable program access and to safeguard equally the wellbeing of all beneficiaries. This Court should grant Pfizer's petition in order to ensure that HHS operates with the proper sense of its authority and responsibilities under the law, imposing neither burdens more onerous nor consequences more dire than what Congress prescribed.

CONCLUSION

The Court should grant the petition for a writ of certiorari should be granted.

Respectfully submitted.

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