21-2764

United States Court of Appeals for the Second Circuit

PFIZER, INC.,
Plaintiff-Appellant

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF THE INSPECTOR GENERAL; CHRISTI A. GRIMM, in her official capacity as Principal Deputy Inspector General of and Senior Official in the United States Department of Health and Human Services Office of Inspector General,
Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of New York

BRIEF OF AMERICA'S HEALTH INSURANCE PLANS AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rules of Appellate Procedure 26.1 and 29(a)(4)(A), America's Health Insurance Plans, Inc. states that it has no parent corporation and that no publicly held corporation owns 10% or more of its stock.

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STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

America's Health Insurance Plans, Inc. ("AHIP") is the national trade association representing health insurance providers who provide coverage for hundreds of millions of Americans. AHIP advocates for public policies that expand access to affordable health care coverage to all Americans through a competitive marketplace that fosters choice, quality, equity, and innovation. Along with its predecessors, AHIP has more than 60 years of experience in the industry. AHIP's members offer health and supplemental benefits through employer-provided coverage, the individual insurance market, and public programs such as Medicare and Medicaid. As a result, AHIP's members have broad experience working with virtually all health care stakeholders to ensure that patients have access to needed treatments and medical services. That experience gives AHIP extensive first-hand and historical knowledge about the nation's health care and health insurance systems, and a unique understanding of how those systems work.

Escalating drug prices are a leading driver of rising health care costs, and they are an increasing financial burden for hardworking American families. AHIP is committed to practical solutions that reduce consumer costs and increase patient

[1] No counsel for any party authored this brief in whole or in part, and no person or entity other than the *amicus*, its members, or its counsel made a monetary contribution intended to fund the brief's preparation or submission. All parties have consented to the filing of this brief. *See* Fed. R. App. P. 29(a)(2), (4).

access to needed medication. AHIP's experience shows that unbounded drug manufacturer co-pay assistance programs are part of the problem—not the solution.

The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, as long and reasonably interpreted and applied by the Department of Health and Human Services ("HHS"), contains a pathway for drug manufacturers to assist patients with paying the high prices that manufacturers themselves set and control. At the same time, the statute provides vital guardrails against the risk of fraud, waste, and abuse that otherwise inheres in permitting manufacturers to subsidize patients' up-front costs to induce purchases of their products. These protections are essential because those same patients—and U.S. taxpayers—would otherwise pay the unchecked multi-billion-dollar price tag and resulting higher health insurance premiums.

AHIP agrees with Defendants (Appellees' Br. 24-39) that there is no basis in the statute's text, structure, or purpose for imposing an extratextual requirement that a payment intended to induce a purchase of a manufacturer's product must have the added intent to also "corruptly skew" a prescriber's or purchaser's decision-making to violate the statute. AHIP writes separately to explain how retaining the Anti-Kickback Statute's essential protections against fraud, waste, and abuse will by no means prevent patients from getting help in obtaining extraordinarily expensive drugs.

One better, lawful way to support patient access to essential medications is for drug manufacturers to donate to independent charities—including potentially those targeted for specific diseases, which remains an option for tafamidis itself. Conversely, as experience in the commercial market shows, permitting manufacturers to directly subsidize patients' cost-sharing of their own drugs leads to higher profits for drug manufacturers and higher premiums for everyone, including the patients who are ostensibly helped. Congress has made a reasonable choice to protect American consumers and taxpayers from these harms.

INTRODUCTION AND SUMMARY OF ARGUMENT

There appears to be universal agreement in this case that drug prices are unsustainably high and that many Americans struggle—and often fail—to afford crucial medications. Americans pay the highest prices in the world for medications, by a large margin, and the problem gets worse every year as drug prices rise and rise. These ever-escalating costs are borne by every American business and consumer in the form of higher insurance premiums, and also make higher demands on federal and state taxpayers for programs like Medicare and Medicaid. Drug manufacturers alone set and control the launch price and every price increase for the prescription drugs they sell, and make ample profits doing so. Manufacturers should not be able to leverage the access problems they themselves create to undo a vital protection for

government programs and the beneficiaries who utilize them. Indeed, the Anti-Kickback Statute was designed precisely to address this and similar practices.

Although this urgent affordability problem persists, solutions to delivering patient access to needed medications abound—including many that drug manufacturers could support under current law, if they chose. To start, drug manufacturers could support cost sharing assistance provided by charitable organizations that are free from their influence or control. Drug manufacturers could also reduce their prices—which far outpace what they spend on research and development. They could also refrain from anticompetitive practices that extend the monopolies for brand-name drugs well beyond the timeframes intended by Congress—a solution that would advance innovation and patient well-being.

One thing is clear. Any sustainable solution does *not* lie in opening the door to drug manufacturers paying patients directly if—and only if—the patients purchase that manufacturer's drugs. That "solution" would make the problem of unaffordable prescription drugs worse. It would add yet another mechanism for drug manufacturers to distort the market for their products, alongside unilaterally setting and increasing prices (as the $18,750 monthly cost of tafamidis reflects, SPA-4), and manipulating patent and drug approval processes to extend their monopoly profits.

Opening the door to direct payments from manufacturers to patients furthers the ability of manufacturers to raise the prices of their drugs, with the costs borne by

someone else. Absent the controls provided by the Anti-Kickback Statute, patient-targeted programs that bypass cost-sharing structures (such as co-pay coupons) abound in the commercial market; over 90% of brand-name drug spending involves drugs with co-pay coupons. Experience with co-pay coupons shows that whether "corruptly" intended or not, manufacturer payments to a select group of consumers to induce them to purchase manufacturers' products results in multiple harms. These targeted demand subsidies increase the amount spent on high-cost brand-name drugs (even when lower cost therapeutic equivalents are available), increase the prices negotiated with health insurance providers, and raise health care costs for everyone, without widespread clinical benefit.

Congress reasonably chose to protect federally funded health care programs from similar harms, enacting a broad prohibition on providing *any* remuneration to induce purchases of federally reimbursed health care items or services. Recognizing that some subset of payments might be beneficial yet still fall within the statute's ambit, Congress charged HHS with evaluating the risks and benefits of different health care practices, either for the purpose of adopting regulatory safe harbors or for providing guidance on a case-by-case basis in advisory opinions. HHS has reasonably exercised that authority to hold the line against drug manufacturer subsidies that—unlike donations to independent charities—are prescription-specific

and induce patients to purchase costly medications, bolstering drug manufacturer revenues at the expense of higher health care costs for everyone.

There are several avenues for Pfizer to address the unusual facts of tafamidis—including truly independent charity—without jettisoning a legal rule that has protected federal health programs from fraud, waste, and abuse for decades. Paring back the Anti-Kickback Statute's constellation of statutory and regulatory safeguards for patients, taxpayers, and businesses—designed to keep costs down for all—is not the way to solve the urgent problem of high-priced, unaffordable prescription drug prices.

ARGUMENT

I. Imposing An Extratextual "Corruption" Element On The Anti-Kickback Statute Will Increase Program Costs And Lead To Higher Premiums That Harm Consumers.

The Anti-Kickback Statute prohibits anyone from "knowingly and willfully offer[ing] or pay[ing] any remuneration … to any person to induce such person … to purchase … any good … for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B). In defense of its interest in creating a program controlled by Pfizer and limited only to patients who use Pfizer's drug, Pfizer seeks to impose an additional element that the intent to "induce" must be "improper" or "corrupting," meaning an intent to "skew[] … independent decision-making." Pfizer Br. 27. AHIP agrees with Defendants that the

statutory text and structure cannot support the words Pfizer would add. *See* Appellees Br. 24-39.

Moreover, experience in the commercial market with drug manufacturer coupons demonstrates why donations to independent charities are a better way to address patient access to high-cost drugs. Allowing a drug manufacturer to subsidize its own products, like by offering a coupon that reduces or eliminates a patient's co-pay, raises prescription drug costs and leads to higher premiums for consumers overall.

Congress decided to protect federal health care programs against similar harms through the Anti-Kickback Statute's broad prohibition against remuneration to induce health care purchases. At the same time, Congress granted HHS substantial discretion to shield low-risk beneficial activities through the promulgation of safe harbors or case-by-case evaluation in advisory opinions—as it has repeatedly done for truly independent charitable efforts, as described in Part II. Pfizer effectively seeks to replace this carefully articulated regime with a per se rule that whenever a drug is the "only FDA-approved medicine" for a condition, there is no possibility of improper or over-utilization and therefore induced payments can never violate the Anti-Kickback Statute. *See* Pfizer Br. 53-55. Exercising the careful case-by-case review that Congress contemplated, HHS reasonably concluded otherwise.

Pfizer is wrong (Br. 44-50) that HHS's long-standing interpretation of the statute prevents help for patients in need, simply because it does not give a free pass to a Pfizer-controlled program that supports only those who use (and almost by definition can't afford) Pfizer's tremendously expensive drug. Federal subsidies in Medicare Part D ensure low-income enrollees are required to pay only de minimis amounts for Part D drugs. Cost-sharing is even more sharply limited under Medicaid rules, generally to co-pays of $4 or $8 for most beneficiaries. *See Cost Sharing Out of Pocket Costs*, Medicaid.gov, https://tinyurl.com/32m2tv4y. Further, although Pfizer has priced its drug beyond the reach of even middle-income enrollees, Pfizer can help them through donations to *bona fide*, independent charities. HHS's approach in this matter comports with the law and good policy—leaving room for actual charity, while denying manufacturer efforts to evade the Anti-Kickback Statute's protection against fraud, waste, and abuse.

A. Manufacturer Co-Pay Assistance Benefits Manufacturers with Higher Sales While Burdening Consumers with Higher Prices.

If HHS's long-standing interpretation of the Anti-Kickback Statute is reversed, the future of Medicare drug prices can be glimpsed in the commercial market. There, because the Anti-Kickback Statute does not apply, drug manufacturers generally are allowed to directly subsidize, and thus induce, purchases of their products. Experience in the commercial market shows that the more manufacturers can design around cost-sharing structures with targeted

subsidies like coupon programs, the more opportunity they have to increase prices and profits. Removing statutory protections in the non-commercial market, as Pfizer and its *amici* request, would move drug prices in the wrong direction for the vulnerable patients who benefit from federal health programs.

The use of manufacturer co-pay coupons in the commercial market has increased steadily since coupons were first introduced, with the share of branded retail spending attributable to drugs with coupons doubling from 2007 to 2010, and near doubling again by 2017, so that now the vast majority—over 93%—of brand-name drug spending occurs with couponed drugs. Leemore Dafny et al., *How Do Copayment Coupons Affect Branded Drug Prices and Quantities Purchased?*, NBER Working Paper No. 29735, at 1-2 (Feb. 2022), https://tinyurl.com/4cnmuprt ("Dafny NBER Paper"). Most coupons are offered in situations where the brand-name drug faces competition, from either a generic or another branded drug. *See* Catherine I. Starner et al., *Specialty Drug Coupons Lower Out-Of-Pocket Costs And May Improve Adherence At The Risk Of Increasing Premiums*, 33 Health Affairs 1761, 1762 (2014); Karen Van Nuys et al., *A Perspective On Prescription Drug Copayment Coupons*, USC Schaeffer, at 3 (Feb. 2018), https://tinyurl.com/28jfak9x (only 11 of 90 studied couponed drugs (12%) had no equivalent or close therapeutic substitute).

Coupons work, first and foremost, for the drug manufacturer. They increase sales volume of the couponed drug, increase revenue, and give drug manufacturers free rein to keep raising their prices. Any short-term benefit to patients is overwhelmed by higher total drug costs over time. And patients ultimately pay the price in the form of higher premiums or cost-sharing. Thus, although coupons "may enable individual consumers to access drugs they couldn't otherwise afford, they may also lead to higher medication prices and insurance premiums" for all. Dafny NBER Paper, at 2.

Coupons increase prescription drug costs in various ways. They circumvent formulary design meant to encourage the use of both clinically appropriate and higher value, lower cost drugs through tiered co-payments, with patients generally asked to pay less for lower cost clinically equivalent alternatives, thereby encouraging such cost-effective choices.[2] *Id.* But if a patient has a coupon that reduces or eliminates the co-pay of a brand-name drug, formularies setting the co-

[2] A formulary is a list of drugs that are covered by a particular health plan. *See* Pharmaceutical Care Mgmt. Ass'n (PCMA), *What Is A Formulary?*, https://tinyurl.com/3j5aj3vr. Formularies are typically organized into tiers, through which "[p]lan sponsors offer different copays or other financial incentives to encourage participants to use preferred formulary drugs" in a lower tier. *Id.* ("Formulary Types"). A common structure is to include most generic drugs on the lowest tier, with the lowest co-pay; preferred (lower-cost) brand-name drugs on tier two, with a medium co-pay; non-preferred brand-name drugs on a third tier, with a higher co-pay; and specialty drugs in a fourth tier. HHS, *How Medicare Drug Plans Use Pharmacies, Formularies, & Common Coverage Rules*, at 3 (Jan. 2021), https://tinyurl.com/5n89m5c8.

pays for a brand-name drug at $25 and its generic equivalent at $10 to encourage use of generic drugs probably won't work. Imagine, for example, a manufacturer's coupon that reduces the patient's co-pay for the branded drug to $10, or even $0—never mind that the brand-name drug costs five times more than the generic, on average—the branded drug is now cheaper for the patient, in the short-run at least. Leemore Dafny et al., *When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization*, 9 Am. Econ. J. 91, 92 (2017). In the longer run, the health plan is paying much more for the expensive drug, leading to higher drug costs and higher premiums, which in the end threatens access to health coverage.

For dueling brand-name drugs as well, co-pay coupons inhibit the ability of health insurance providers to negotiate lower prices with manufacturers in exchange for preferred formulary placement. Dafny NBER Paper, at 2. The upshot is that brand-name sales and prices increase, generic sales decrease, and Americans pay the extra cost, with no commensurate clinical benefit.

A 2017 study concluded, for example, that coupons introduced upon the market entry of a generic equivalent increased branded drug sales by more than 60%, compared to what would have been expected in the absence of the coupon. Dafny, 9 Am. J. of Econ. at 93. Prices for couponed drugs also increased faster than non-couponed drugs. *Id.* at 94. All in, the study estimated that coupons increased spending for the 23 studied drugs by $700 million to $2.74 billion over 5 years. *Id.*

at 116. A 2020 Massachusetts study of coupons for drugs with a generic close therapeutic substitute found that the use of branded drugs was higher in the commercial sector compared to Medicare (where the Anti-Kickback Statute has long prohibited them), increasing prescription drug spending in Massachusetts for the 14 studied drugs by 18% or about $45 million a year. Mass. Health Pol'y Comm'n, *Prescription Drug Coupon Study*, at 3 (July 2020), https://tinyurl.com/5f5v9z5y.[3] And the effect of this avoidable drug price inflation is widespread. The availability of coupons for just those 14 drugs added $52 to the average Massachusetts family's health insurance premiums. *Id.*

Even when there is no generic competitor, but there is an alternative brand-name substitute, coupons significantly increase prescription drug spending. Modeling the effect of coupons for a particular class of drugs over time, one study estimates that coupon availability caused an 8% increase in negotiated net prices. Dafny NBER Paper, at 37. A coupon ban, on the other hand, would save nearly $1 billion per year for just one class of drugs, with those savings outweighing forgone out-of-pocket subsidies by four to one. *Id*.

Pfizer indicates there is no other FDA-approved drug for the relevant disease. But coupons can drive up costs even when issued before competitors are approved.

[3] A close therapeutic substitute is not an equivalent, but a drug in the same class that would be appropriate for many patients. *Id.* Massachusetts bars copayment coupons when a generic equivalent is available. *Id.* at 2.

Coupons help drug manufacturers lock up market share that will become resistant to switching to lower cost but similarly effective competitors, artificially inflating demand and revenues for the first entrant even once competitors emerge. For higher cost specialty drugs, in particular, once a patient is adjusted to a particular medication, they are much less likely to try another drug, even if it is therapeutically equivalent and the price is lower. By shielding patients from the immediate cost of purchasing their products, drug manufacturers are able to gain market share even with inflated prices before competitors can emerge, which they can then lock in due to these impediments to switching. Because impediments to switching are so strong, locking up enough market share this way can even discourage market competition from emerging. This would prove very costly to both patients and federal programs.[4]

In sum, if the Anti-Kickback Statute's longstanding protection against programs like coupons that provide remuneration to induce patients to purchase certain drugs is narrowed, the result will be to increase revenue for drug manufacturers, to impose substantially higher health care costs on seniors and other vulnerable participants in federal health programs, and to raise significant roadblocks to lower cost competitors. This is true even when there is not yet an FDA-approved alternative to the drug. In short, manufacturers subsidizing demand for

[4] This is not a hypothetical prospect for tafamidis. In lieu of paying for tafamidis, some patients have enrolled in a phase 3 clinical trial for a different manufacturer's drug which is being studied to treat the same disease. A-210 n.4.

their own drugs does not help solve the problem of unaffordable prescription drugs—it makes things worse.

B. The Anti-Kickback Statute's Inducement Prohibition Protects Federal Health Care Programs from Similar Harms While Permitting Ample Breathing Room for Genuine Patient Assistance.

In enacting the Anti-Kickback Statute, Congress recognized that federally funded health care programs are at particular risk for fraud, waste, and abuse. The statute broadly prohibits "any remuneration" intended to induce the purchase of federally reimbursed health care items and services. 42 U.S.C. § 1320a-7b(b)(2)(B). But, because the statute sweeps broadly, Congress afforded HHS substantial discretion to shape the boundaries of prohibited conduct. In addition to explicitly carving out certain types of discounts, fee waivers, and other forms of remuneration from the statute's coverage, *id.* § 1320a-7b(b)(3), Congress authorized HHS to adopt regulatory safe harbors for other practices where, in the agency's judgment, the benefits outweigh the risk of fraud and abuse, *id.* § 1320a-7d. For practices that do not fall within the statutory or regulatory safe harbors, HHS is authorized to issue case-by-case advisory opinions. *Id.* § 1320a-7d(b)(2)(A).

Exercising this authority, HHS has long recognized the risk of abuse posed by direct payments from manufacturers to patients that are tied to the patient's use of the manufacturer's product. Such subsidies "present all of the usual risks of fraud and abuse associated with kickbacks," including "steering beneficiaries to particular

drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries incentives to locate and use less expensive, equally effective drugs." 70 Fed. Reg. 70,623, 70,625 (Nov. 22, 2005).

Although Pfizer insists that none of those risks are present where a drug has no FDA-approved competitor, the Anti-Kickback Statute does not distinguish between intent to induce purchases based on whether a competitor is already on the market today. Rather, the statute aims to contain costs and prevent payments that distort the market. Congress charged HHS with evaluating the facts, and here, as the district court found, HHS reasonably determined that the current absence of an equivalent drug does not eliminate all risks. *See* Appellee Br. 50. For example, HHS noted that there are alternative treatments for transthyretin amyloid cardiomyopathy (ATTR-CM) (though they are not indicated for all patients depending on which type of the disease they have), A-210, and that patients could become locked into tafamadis even as pharmacological alternatives emerge, A-227-28. Moreover, there is a risk of abuse inherent in the prospect of a manufacturer being able to unilaterally set a list price, shield the decision-makers (patients and doctors) from all price sensitivity, and reap substantial revenues from federal payments. *See* A-219-21. The impact of this very costly drug illustrates the scope of the problem. For this one drug alone, treating the approximately 120,000 patients who have ATTR-CM with tafamidis would increase total U.S. prescription drug spending by 9.3%, adding

nearly $32 billion to prescription drug spending each year. A-219. ATTR-CM disproportionately affects older Americans, SPA-3, and for Medicare-eligible patients, the vast majority of the extra $32 billion per year would be paid by taxpayers, because Medicare covers approximately 75% of premiums and most cost-sharing. SPA-3; Kaiser Family Found., *An Overview of the Medicare Part D Prescription Drug Benefit* (Oct. 13, 2021), https://tinyurl.com/y23kmrpy.

It is not necessary to open the door to the harms caused by direct payments from manufacturers to patients, tied to use of only one manufacturer's product, to help patients. The problem of high-cost drugs is urgent, but there are many other, better paths available that help patients access needed drugs, without causing the same type of market harms.

II. Drug Manufacturers Could Address The Problem Of High-Cost Drugs Without Violating The Anti-Kickback Statute.

A. America Faces an Epidemic of High-Priced Drugs.

By any measure, Americans are burdened by the high and ever-increasing cost of prescription drugs. In 2019, Americans spent over $369 billion on prescription drugs at pharmacies, plus about $144 billion on drugs administered in hospitals and doctors' offices, totaling more than $500 billion in annual prescription drug costs. HHS, *Comprehensive Plan for Addressing High Drug Prices*, at 5-6 (Sept. 9, 2021), https://tinyurl.com/2p826dyk ("HHS 2021 Report"). That represents per capita spending of over $1,500 per American per year. HHS 2021 Report, at 6.

This high-cost trend is unlikely to abate. From 2019 to 2020, the price increases of 23 of the top 25 drugs for Medicare part D outpaced inflation. Juliette Cubanski & Tricia Neuman, *Prices Increased Faster Than Inflation for Half of all Drugs Covered by Medicare in 2020*, Kaiser Family Found. (Feb. 25, 2022), https://tinyurl.com/bdhcuyjf. And that was a relatively good year for Americans' pocketbooks; brand-name drug price increases have been even higher in other years. Stephen W. Schondelmeyer and Leigh Purvis, *Brand Name Drug Prices Increase More than Twice as Fast as Inflation in 2018*, AARP Public Pol'y Inst., at 1 (Nov. 2019), https://tinyurl.com/2vwdretr.

High drug prices harm Americans in several ways. About 60% of Americans, and nearly 90% of adults age 65 and older (and therefore Medicare-eligible), take at least one prescription drug. Ashley Kirzinger et al., *KFF Health Tracking Poll – February 2019: Prescription Drugs* (Mar. 1, 2019), https://tinyurl.com/5cudcyb9. Nearly a quarter of them reported it was difficult to afford their prescription drugs in 2019, *id.*, a share that has only grown during the pandemic, Morning Consult Survey, Campaign for Sustainable Rx Pricing (Sept. 2021), https://tinyurl.com/yck9e87r. "People with low incomes, [and] people with disabilities … bear the brunt of high drug prices resulting from lack of competition in the pharmaceutical supply chain." HHS 2021 Report, at 6. Beyond out-of-pocket costs, all Americans pay for the high cost of prescription drugs though higher health

insurance premiums. Premiums are set by health insurance providers based on the projected costs of medical care. When those costs go up because of ever-increasing drug prices, premiums naturally rise as well. Prescription drugs take the largest share of Americans' premiums in the commercial market (21.5 cents for every premium dollar), ahead of expenses for inpatient hospital care, physicians, or any other medical care. AHIP, *Where Does Your Health Care Dollar Go?* (2021), https://tinyurl.com/479usfhx. Permitting manufacturers to subsidize patients' share of the cost of their own medications on the theory that the subsidies "innocently" but not "corruptly" induce purchases of drugs that are mostly paid by federal funds will only make things worse.

B. Drug Manufacturers Could Help Through Bona Fide Charities and by Reducing List Prices and Embracing Competition.

Pfizer appears to share the concern that prescription drugs are unaffordable for many Americans, but effectively claims powerlessness to help unless it is free to directly pay patients who purchase its products. Not so. Drug manufacturers have many other options to make clinically needed prescription drugs more affordable that don't worsen the problem they themselves created.

For starters, drug manufacturers are free to donate to independent charities that help patients afford out-of-pocket drug costs, and many do. Pfizer notes (Br. 9) that it makes tafamidis available for free to uninsured or underinsured patients with an income up to 500% of the federal poverty level. It is also free to support charities

that provide cost-sharing subsidies, as are all drug manufacturers, if the subsidies are provided by "*bona fide*, independent charities unaffiliated with pharmaceutical manufacturers." 70 Fed. Reg. at 70,624.[5] These independent charities may "reasonably focus their efforts on patients with particular diseases" and manufacturers may even "earmark[]" their donations for certain diseases, though programs may be subject to special scrutiny if the disease is defined so narrowly that it "result[s] in funding exclusively or primarily the products of donors." 79 Fed. Reg. 31,130, 31,121 (May 30, 2014).

Not only is *bona fide*, independent charity an option for prescription drugs generally, it remains an option for tafamidis specifically. In the first instance, Pfizer is free to donate to existing independent charities that focus on supporting patients with amyloidosis (of which ATTR-CM is a type). A-213. Moreover, HHS has not yet rendered an advisory opinion on Pfizer's proposal for a new charity, SPA-7, the district court dismissed claims related to that proposal for lack of prudential ripeness, SPA-17-19, and Pfizer does not appeal that ruling, Br. 13 n.5.

Because truly independent charities (including, potentially, one proposed and funded by Pfizer) are free to support low-income Medicare beneficiaries, the parade

[5] Further, as the HHS Office of the Inspector General has made clear, a drug manufacturer is free to furnish free outpatient prescription drugs outside of the Part D benefit to needy Medicare-eligible patients, so long as certain guidelines are satisfied. 70 Fed. Reg. at 70,627.

of horribles floated by Pfizer and its *amici*—in which the Anti-Kickback Statute "make[s] federal felons out of a charitable family member" (Br. 46)—need not trouble the Court. *See also* Br. of Pharm. Research & Mfrs. of Am. as *Amicus Curiae* at 10-11. The Anti-Kickback Statute does not, under HHS's interpretation, compel a finding of impermissible intent to induce purchases whenever someone pays for part of another's medical care, even if that charitable support makes it possible for the patient to access federally funded health care services that they otherwise would not be able to access. Rather, the statute requires unlawful "willful" intent. 42 U.S.C. § 1320a-7b(b). Families, friends, and independent charities have no financial interest in the medical items a patient chooses to purchase and do not limit the patients' choices to a product that they sell. That makes it highly unlikely that they possess the requisite "willful" intent. *See* Appellees Br. 39-40. Not so for drug manufacturers, which have a financial interest in patients choosing the drugs they sell, and seek to assist only those patients who purchase their products.

For at least 20 years, HHS has consistently interpreted the Anti-Kickback Statute to prohibit manufacturer inducements but permit independent charitable contributions. *See* 70 Fed. Reg. at 70,625 & n.10 (noting that part D guidance draws upon similar advisory opinions issued regarding Medicare part B in 2002). The idea that this purportedly draconian regime chills charitable support for health care needs is belied by the tens of billions of dollars donated by Americans to health care

charities each year, never mind support provided by families, faith-based communities, and through crowd-funding platforms. *See* Non-Profit Source, *Charitable Giving Statistics*, https://tinyurl.com/6tz2kp29 (over $38 billion donated to health care charities in 2017). In fact, the only charitable giving that is chilled is the kind that enriches the donor for their gift.

Beyond bona fide charitable giving, manufacturers could legally increase access to drugs by reducing list prices. And they can do so without impairing innovation. One study compared the net prices (after discounts and rebates) of the top 20 brand-name drugs in the United States to prices in Canada and Europe, and found that the cumulative price difference on those drugs alone—considering only the amount by which U.S. prices exceeded other nations'—was about $116 billion, more than covering the entire $76 billion global research and development budgets of the 15 drug manufacturers that make those top 20 drugs, with $40 billion to spare. Nancy L. Yu et al., *R&D Costs For Pharmaceutical Companies Do Not Explain Elevated US Drug Prices*, Health Affairs Forefront (Mar. 7, 2017), https://tinyurl.com/s4b9aepn.

On average, drug manufacturers earn $18.6 billion in revenues for a new drug, compared to an average $1.8 billion research and development cost per drug, including the cost of risk (*i.e.*, pursuing failed drug candidates). AHIP, *Gaming the System*: *How Big Pharma Drives Its Higher Revenues Through Patent Gaming and*

Extending Exclusivity, at 3 (Dec. 2021), https://tinyurl.com/ypvnpu5p. Collectively, the top ten pharmaceutical companies by revenue spent $36 billion more on selling and marketing than on research and development in 2020. AHIP, *New Study: In the Midst of COVID-19 Crisis, 7 out of 10 Big Pharma Companies Spent More on Sales and Marketing than R&D* (Oct. 27, 2021), https://tinyurl.com/bddnh4vp. With estimated average operating margins for drug manufacturers exceeding 20%, Ezekiel J. Emanuel, *Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up*, The Atlantic (Mar. 23, 2019), https://tinyurl.com/mrjma5dv, there is plenty of room to reduce prices while still funding research and making a healthy profit.[6]

Embracing competition, instead of pursuing overly aggressive strategies to augment already strong intellectual property rights to keep competition at bay for even longer, would also help to solve the problem of unrelentingly high drug prices. Drug manufacturers can protect their drugs from generic competition through patents or certain forms of regulatory exclusivity granted by the FDA. AHIP, *Gaming the System*, at 4. On average, longer periods of exclusivity mean higher U.S. revenues, with double-than-average revenues for drugs that achieve 17 or more years

[6] Tafamidis is the most expensive cardiovascular drug ever launched in the United States. A-219. Given the extraordinary cost, the district court noted that reducing the list price by half would still require Medicare patients to pay an out-of-pocket cost of more than $8,000 per year (instead of $13,000). SPA-4. For such an outlier high-cost drug, reducing the list price will not alone solve the problem—but a near-40% reduction in out-of-pocket costs is significant, and a reduced list price would also help all Medicare beneficiaries save money through lower premiums.

of exclusivity. *Id.* Although exclusivity is meant to promote innovation, brand-name drug manufacturers "sometimes exploit [those] patents and exclusivities … with 'patent thickets,' 'product hopping,' 'pay-for-delay,' and other anti-competitive practices to keep cheaper generics and biosimilars off the market." HHS 2021 Report, at 7. Collectively, these practices cost Americans billions each year.[7]

Ultimately, and even putting other solutions to one side, if the actual problem Pfizer seeks to solve is the affordability of tafamidis, donating to an existing independent charity that supports amyloidosis patients is an immediately available path forward, requiring no regulatory approval. A-213. Pfizer's proposed charity may be another option. Unless and until Pfizer submits a detailed proposal and OIG is able to provide an advisory opinion based on case-specific facts, it is too soon to judge. But one thing is already clear: drug manufacturers don't have to directly pay cost-sharing subsidies to patients who use their products to "help ensure that all Part D beneficiaries can afford medically necessary drugs"; they can achieve that same aim by working with independent charities. 70 Fed. Reg. at 70,624.

[7] *See* Alex Brill, *The Cost of Brand Drug Product Hopping, Coalition for Affordable Prescription Drugs*, at 4 (Sept. 2020), https://tinyurl.com/2p943963 (product hopping involving just five drugs cost $4.7 billion per year in additional health care spending); FTC, *Pay-For-Delay: When Drug Companies Agree Not To Compete*, https://tinyurl.com/yfta3yv5 (estimating that pay-for-delay costs Americans $3.5 billion in higher drug costs per year).

Patients should of course be able to access essential medicines, even expensive ones. Ample avenues exist to help patients afford essential medications without running the risk of giving one entity (the manufacturer) total control over prices, who gets financial assistance, and under what circumstances financial assistance is provided. Such an approach would unnecessarily drive up costs for patients and taxpayers and foreclose competition. Drug manufacturers are free to take other steps to help patients deal with the high prices that those manufacturers alone set, including supporting independent charities that help patients without drug manufacturer control. But the answer is not to exploit the unique facts of this case to push through a legal rule that would disable the Anti-Kickback Statute's critically important protection against fraud, waste, and abuse.

CONCLUSION

The district court's judgment should be affirmed.

April 1, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The foregoing brief is in 14-point Times New Roman proportional font and contains 5,591 words, and thus complies with the type-volume limitation set forth in Rules 21(d)(1) and 29(a)(5) of the Federal Rules of Appellate Procedure and Local Rule 29.1(c).

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April 1, 2022

CERTIFICATE OF SERVICE

I hereby certify that, on April 1, 2022, I served the foregoing brief upon all counsel of record by filing a copy of the document with the Clerk through the Court's electronic docketing system.

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