IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HIV AND HEPATITIS POLICY INSTITUTE, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No.: 1:22-cv-2604-JDB
	)	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,	)	
	)	
Defendants.	)	
	)	

UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF OF AMERICA'S HEALTH INSURANCE PLANS AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Under Local Rule 7(o), America's Health Insurance Plans, Inc. ("AHIP") moves for leave to file a brief as *amicus curiae* in support of Defendants' Cross-Motion for Summary Judgment and Opposition to Plaintiffs' Motion for Summary Judgment. AHIP's counsel has conferred with counsel for all parties, all of whom consent to this motion. The proposed amicus brief is attached as Exhibit 2 to this motion.

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. AHIP's members have broad experience working with health care stakeholders to ensure that patients have affordable 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.

AHIP recognizes that many Americans struggle to afford prescription drugs. 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 access to needed medication. Substantial research, and AHIP's members' experience, show that unbounded drug manufacturer co-pay coupons are part of the problem—not the solution—to out-of-control drug prices. In fact, co-pay coupons are so problematic that the federal government considers them an illegal kickback in federal programs like Medicare and Medicaid. But neither the challenged rule nor this case is a referendum on the wisdom of co-pay coupons. Rather, the question is whether the government reasonably preserved states' authority to decide whether and when to permit co-pay accumulator programs that protect careful benefit designs and encourage patients to make cost-effective and medically appropriate decisions about their care. The rule under review neither prohibits coupons nor requires accumulators. The rule's sole function is to leave states the flexibility to make case-by-case judgments about when specific circumstances might warrant use of co-pay accumulators. Leaving that judgment to the states—most of which permit co-pay accumulators—was entirely reasonable.

Regarding Local Rule 7(o)(2)'s directive to explain "why an amicus brief is desirable, why the movant's position is not adequately represented by a party, and why the matters asserted are relevant to the disposition of the case," AHIP writes separately to focus on three distinct issues within its expertise that underpin the reasonableness of the government's decision to let states decide whether, and to what extent, co-pay accumulator programs should be allowed. AHIP first explains how drug manufacturers' unconstrained list prices and market manipulation drive higher drug prices, which—given how insurance markets function—lead to higher premiums and cost-

sharing requirements for all consumers. Second, AHIP shares its experience with co-pay coupons, and how such coupons are profit maximizers for drug manufacturers that ultimately hurt, not help, patients. Finally, AHIP explains how accumulator programs work to help control prescription drug prices by preserving health plan benefit designs that encourage high-value, clinically appropriate choices, and how the rule preserves crucial flexibility for states to judge when to permit accumulator programs, as most have chosen to do.

For these reasons, AHIP respectfully requests that this unopposed motion be granted and that it be permitted to file the proposed amicus brief, as provided in the proposed order attached as Exhibit 1 to this motion.

Dated: March 23, 2023

Respectfully Submitted,

/s/Hyland Hunt

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Counsel for *Amicus Curiae*

CERTIFICATE OF SERVICE

On March 23, 2023, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court for the District of Columbia, using the electronic case filing system of the court. I hereby certify that I have served counsel for all parties of record electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/Hyland Hunt
Hyland Hunt

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HIV AND HEPATITIS POLICY INSTITUTE, *et al.*, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	)	Case No.: 1:22-cv-2604-JDB

[PROPOSED] ORDER GRANTING UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF OF AMERICA'S HEALTH INSURANCE PLANS AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Upon consideration of the Unopposed Motion for Leave to File Brief of America's Health Insurance Plans as *Amicus Curiae* in support of Defendants' Cross-Motion for Summary Judgment and Opposition to Plaintiffs' Motion for Summary Judgment, the Court finds that the Motion is hereby **GRANTED**. Accordingly, it is **ORDERED** that the Brief of America's Health Insurance Plans as *Amicus Curiae* is hereby filed.

SIGNED on this ___ day of _____, 2023.

THE HONORABLE JOHN D. BATES
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HIV AND HEPATITIS POLICY INSTITUTE, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No.: 1:22-cv-2604-JDB
	)	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,	)	
	)	
	)	
Defendants.	)	
	)	

BRIEF OF AMERICA'S HEALTH INSURANCE PLANS AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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CORPORATE DISCLOSURE STATEMENT

Under Local Rule 7(o)(5), *amicus curiae* America's Health Insurance Plans, Inc. ("AHIP") submits the following corporate disclosure statement:

AHIP has no parent corporation and no publicly traded company holds 10% or more of AHIP's stock.

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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. AHIP's members have broad experience working with health care stakeholders to ensure that patients have affordable 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.

AHIP recognizes that many Americans struggle to afford prescription drugs. 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 access to needed medication. Substantial research, and AHIP's members' experience, show that unbounded drug manufacturer co-pay coupons are part of the problem—not the solution—to out-of-control drug prices. In fact, co-pay coupons are so problematic that the federal government considers them an illegal kickback in federal programs like Medicare and Medicaid. But neither the challenged rule nor this case is a referendum on the wisdom of co-pay coupons. Rather, the question is whether the government reasonably preserved states' authority to decide whether and when to permit co-pay accumulator programs that protect careful benefit designs and encourage patients to make cost-effective and medically appropriate decisions about their care. The rule under review neither prohibits coupons nor requires

[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.

accumulators. The rule's sole function is to leave states the flexibility to make case-by-case judgments about when specific circumstances might warrant use of co-pay accumulators. Leaving that judgment to the states—most of which permit co-pay accumulators—was entirely reasonable.

INTRODUCTION AND SUMMARY OF ARGUMENT

The rule does nothing more than let states decide whether, and to what extent, co-pay accumulator programs should be allowed. This preservation of state authority makes sense. Plaintiffs seek a *per se* federal rule that would eliminate a tool that most states (and many health insurance providers) judge helpful in addressing ever-increasing prescription drug prices.

No one seems to dispute that drug prices are unsustainably high and that many Americans struggle—and often fail—to afford crucial medications. With reason. Americans pay the highest prices in the world for medications, by a large margin, and the problem gets worse every year. Ever-higher drug prices, in turn, necessarily lead to higher insurance premiums and cost-sharing amounts that impact hardworking American families. And while health insurance providers are strictly regulated to both cover costs and pass on savings, prescription drug prices are left wholly unconstrained based on unilateral price setting by drug manufacturers.

No one should need a coupon to afford a life-saving drug. Far from working to lower the price of drugs, co-pay coupons for brand-name drugs are profit maximizers for drug manufacturers that raise health care costs (and thus health coverage premiums) for everyone, including the patients who are ostensibly helped. Most of the time, coupons are used when a drug faces, or is about to face, competition—*i.e.*, to induce spending on higher-cost drugs when patients and physicians have lower-cost, higher-value therapeutic alternatives. Even when there is no alternative drug, coupons mask the immediate pocketbook impact of extraordinarily high drug prices from patients, while ultimately shifting the higher prices back to patients through higher insurance premiums. This concealment of the true prices shields drug prices from scrutiny while

maximizing drug manufacturer revenues. As drug manufacturers themselves recognize, co-pay coupons are strategic marketing tools designed to generate "significant returns on investment … in the form of increased sales, particularly for drugs approaching loss of exclusivity." H.R. Comm. on Oversight and Reform, 117th Congress, *Drug Pricing Investigation: Majority Staff Report* (Dec. 10, 2021) at xiv, https://tinyurl.com/munrapx ("Congressional Oversight Report").

Co-pay accumulator programs have been developed to mitigate the market distortion that coupons cause. Accumulators operate on a simple premise: when a manufacturer discounts its price through a co-pay coupon, the discount does not require the patient to incur any cost, so it does not count toward a patient's cost-sharing. This preserves important cost-sharing incentives that help nudge patients toward lower cost, higher value choices.

Accumulators thus let patients benefit from the coupon discount—the patient's out-of-pocket spending is still reduced or eliminated whenever a coupon is available, and the accumulator does not change that. Nor does the accumulator provide a windfall to health insurance providers, because the manufacturer pays the value of the co-pay coupon to the pharmacy (not the health insurance provider). The accumulator program simply preserves the benefit design of the health plan, including cost-sharing that encourages high-value, clinically appropriate choices across the board.

The proof is in the pudding. Although states can prohibit co-pay accumulator programs under the rule, most opt to allow them. This is because co-pay accumulators work to help constrain, not inflate, prescription drug prices. The rule reasonably left flexibility to the states to judge how to best mitigate the problem of ever-escalating drug prices and to preserve crucial incentives within health plans for patients and physicians to make high-value treatment choices.

ARGUMENT

I. Co-Pay Coupons Exacerbate the Root Causes of Unaffordable Drugs—High List Prices and Market Manipulation.

A. Ever-Escalating Drug Prices—Unilaterally Set by Manufacturers—Drive Higher Insurance Premiums and Higher Out-of-Pocket Costs.

AHIP shares the concerns of Plaintiffs and their *amici* regarding out-of-reach prescription drug prices. By any measure, Americans are burdened by the high and ever-increasing prices 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. U.S. Dep't of Health & Human Servs., *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. *Id.* at 6.

1. Drug prices are unilaterally set by drug manufacturers, "with no relation to the clinical value of the medication and often far outstripping inflation." *Id*. The House Committee on Oversight and Reform found that "justifications frequently offered by the pharmaceutical industry for raising prices—including research and development (R&D), manufacturing, and other costs—are not supported" by evidence. Congressional Oversight Report, at xv.

Research has shown that innovation is not the primary driver of high drug prices. Net prices (after discounts and rebates) of the top 20 brand-name drugs in the United States are about $116 billion higher than prices for the same drugs in Canada and Europe. And that difference more than covers 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. Drug revenues, in short, dwarf research and development costs. In fact, much more is spent on marketing existing drugs than on inventing

new and better ones. The top ten pharmaceutical companies by revenue spent $36 billion more on 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.[2] And even with these significant expenditures, "the top 25 pharmaceutical companies reported a healthy average operating margin of 22 percent," compared to 5 or 10 percent margins for other types of companies in the top 25 spenders on research and development. *See* 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/bddphrzb.

2. All Americans are affected by high prescription drug prices. About 60% of Americans take at least one prescription drug. Ashley Kirzinger et al., *KFF Health Tracking Poll – February 2019: Prescription Drugs*, Kaiser Family Foundation (Mar. 1, 2019), https://tinyurl.com/5cudcyb9. Nearly a quarter of them reported difficulties in affording their prescription drugs in 2019, *id.*, a share that has only grown since the pandemic, Morning Consult, *Prescription Drug Pricing*, Campaign for Sustainable Rx Pricing (Sept. 2021), https://tinyurl.com/yck9e87r. Beyond their own drug-specific out-of-pocket costs, all consumers pay for the high price of prescription drugs though higher health insurance premiums. Premiums and cost-sharing amounts are set by health insurance providers or health plan sponsors based on the projected costs of medical care, including prescription drug spending. When those costs go up because of ever-increasing drug prices, premiums must rise as well. Prescription drugs are the largest driver of premium costs, representing the largest share of Americans' premiums in the

[2] The United States is one of only two countries in the world to allow direct-to-consumer drug advertising. It is far from clear whether this advertising results in better health outcomes for patients. *See Do not get sold on drug advertising*, Harvard Health Publishing (Feb. 14, 2017), https://tinyurl.com/3jbb69mx; *Cause and Effect: Do Prescription Drug Ads Really Work?*, Knowledge at Wharton (Jan. 4, 2017), https://tinyurl.com/5vwm9zxr.

commercial market (21.5 cents for every premium dollar), higher than the share of premiums going towards inpatient hospital care, physicians, or any other category of medical care. AHIP, *Where Does Your Health Care Dollar Go?*, at 1 (2021), https://tinyurl.com/479usfhx.

High drug prices are also directly correlated to higher deductibles and cost-sharing requirements; deductibles do not go up simply due to health insurance provider pricing decisions. Health plans sold on health care exchanges are classified as bronze, silver, gold, or platinum based on the percentage of health care costs they cover for the average individual. HealthCare.gov, *The health plan categories: Bronze, Silver, Gold & Platinum,* https://tinyurl.com/z9s6rj76. For example, a silver plan must be designed to cover 70% of health care costs, on average. *Id.*; *see also* 42 U.S.C. § 18022(d). When increases in drug price drive up health care costs, some mix of premiums, deductibles, and cost-sharing for silver plans must go up, too, to maintain that 70% level of coverage.

Additionally, health plans—whether sold on or off the exchanges, for individuals or employer group plans—are subject to premium rate reviews by state or federal regulators, *e.g.*, 42 U.S.C. § 300gg-94. Health plans sold in the commercial market must also meet a federal requirement called the "medical loss ratio," limiting health insurance providers' administrative costs and profits, *id*. § 300gg-18(b). In the individual and small group markets (smaller employers), health plans must spend at least 80 percent of premiums on enrollees' health care and quality improvement. *Id.* Plans for larger employers must meet a more stringent 85 percent threshold. *Id.* If, based on a three-year average, health plans expend less than the specified percentage of premiums on their enrollees' health care costs, they are required to pay a rebate to all of their enrollees. *Id.* States may also impose such rebate requirements on plans they directly regulate. Recently, health insurance providers paid more than $2 billion in rebates to nearly 10

million families. *See* Nat'l Ass'n of Ins. Comm'rs, *Medical Loss Ratio* (Oct. 26, 2022), https://tinyurl.com/257rfx5n. As rebates are based on a three-year average, these recent rebates reflect that in early years of the pandemic, Americans used less health care, resulting in fewer claims for health care reimbursement. *Id.*

The bottom line is that health insurance providers work hard within this regulated system to keep premiums and out-of-pocket costs as low as possible given the underlying medical costs, and to give consumers a full range of plan options that carefully balance premiums against anticipated cost-sharing. But unlike premiums, those underlying costs—and especially the brand-name prescription drug prices that are the primary driver of such costs—are wholly unconstrained.

B. Drug Manufacturers Keep Prices Artificially Inflated by Discouraging Market Competition.

Competition can help to bring down drug prices. Generic drugs typically cost one-fifth the price of brand-name drugs. *See* Susie Allen, *Prescription Drug Coupons Actually Increase Healthcare Spending by Billions*, KelloggInsight (Oct. 3, 2017), https://tinyurl.com/yj9e5w5s. But drug manufacturers have developed an arsenal of tactics to evade such competition.

One way that drug manufacturers keep prices elevated is by pursuing overly aggressive strategies to keep competition at bay. 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*: *How Big Pharma Drives Its Higher Revenues Through Patent Gaming and Extending Exclusivity*, at 4 (Dec. 2021), https://tinyurl.com/ypvnpu5p. On average, longer periods of exclusivity mean higher U.S. revenues, with double-than-average revenues for drugs that achieve 17 or more years 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.[3] And—contrary to the assertions of Plaintiffs' *amici*—co-pay coupons, rather than solving the problem, are simply one more tool that manufacturers use to blunt competition and keep prices high.

II. Co-Pay Coupons are Profit Maximizers for Drug Manufacturers that Ultimately Hurt, Not Help Patients.

The legality of co-pay coupon programs is not at issue here. But the pricing distortion they cause explains why HHS preserved states' flexibility to continue using co-pay accumulator programs to mitigate that distortion.

Co-pay coupons are unlawful in federal programs, including Medicare, Medicaid, and health benefits for military members and their families, because a manufacturer subsidizing cost-sharing for its own products "implicate[s] the anti-kickback statute." 70 Fed. Reg. 70,623, 70,625 (Nov. 22, 2005). Yet such subsidies are increasingly common in the commercial market. The share of branded retail spending attributable to drugs with coupons doubled from 2007 to 2010, and nearly doubled again by 2017, so that now 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 ("NBER Paper").

The widespread availability of co-pay coupons in the commercial market "can distort the market and the true cost of drugs," as HHS rightly recognized. 85 Fed. Reg. 29,164, 29,234 (May 14, 2020). "Such direct support from drug manufacturers can add significant long-term costs to

[3] *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).

the health care system … which is passed on to all patients in the form on increased premiums." *Id*. Thus, although coupon programs may "defray some patients' out-of-pocket costs, the overall cost to the health care system increases due to price increases. This cost is in turn passed on to all patients in the form of higher insurance premiums." Congressional Oversight Report, at 159; *see also* NBER Paper, at 2.

Coupons are carefully structured, moreover, to foster this sort of distortion. They are not need-based subsidies. Instead, they are marketing tools designed to maximize profits, crafted to ensure that health plans maximize spending for prescription drugs, while minimizing the amount of manufacturer assistance. This results in drug prices going up for all consumers, including coupon recipients, who ultimately pay higher health insurance premiums. Drug manufacturers generally offer coupons only to patients with commercial insurance, without regard to financial need.[4] Coupons are typically offered for only a set number of uses or a few months a year, or only up to a level that generally corresponds with patient deductibles. *See* Karen Van Nuys et al., *A Perspective On Prescription Drug Copayment Coupons*, USC Schaeffer, at 4 (Feb. 2018), https://tinyurl.com/28jfak9x. After deductibles are met, drugmakers end the coupons and pass along the whole cost of the drug to insurance, with all consumers ultimately bearing the increased costs. Coupons also allow drugmakers to hide their underlying prices from patients, avoiding scrutiny or public censure. Such concealment drives revenue for manufacturers even when there is no competing drug, because coupons mitigate any pressure to reduce extraordinarily high drug prices. *See* Congressional Oversight Report, at 149.

[4] Drug manufacturers sometimes also provide support to charitable patient assistance programs, which, unlike coupons, are "usually … based on a consumer's financial needs," requiring patients to be uninsured or low-income. *See* Jonathan Gray, *Manufacturer Coupons and Patient Assistance Programs*, Actuary Mag. (May 2020), https://tinyurl.com/ymuss74p. Such need-based charitable programs are not at issue here.

But coupons are most often offered when the brand-name drug *does* face competition, from either a generic equivalent, another branded drug in the same class, or a close therapeutic substitute (which may be generic or branded). *See* So-Yeon Kang et al, *Factors Associated With Manufacturer Drug Coupon Use at US Pharmacies,* JAMA Health Forum, at 8 (Aug. 13, 2021) (study finding "manufacturers use coupons to promote sales of high-cost later-in-class-entrants and to compete against new entrants sharing the same mechanisms of action"); Joseph S. Ross & Aaron S. Kesselheim, *Prescription-Drug Coupons—No Such Thing as a Free Lunch*, 369 N. Engl. J. Med. 1188, 1188 (2013) ("62% of coupons for brand drugs had a lower-cost therapeutic alternative available"); Van Nuys, *supra*, at 3 (only 11 of 90 studied couponed drugs (12%) had no generic equivalent or close therapeutic substitute).

Plaintiffs and their *amici* repeatedly assert otherwise—that coupons are mostly offered when a drug faces no competition. *See, e.g.*, Pls.' Summ. J. Br. 37; PhRMA Amicus Br. 6-7. But they can do so only by ignoring most forms of competition and narrowing the lens to only precise generic equivalents. There are many other forms of competition, including close therapeutic substitutes, which are different but similarly effective drugs that work well for many patients. *See* Niteesh K. Choudhry et al., *Improving Adherence to Therapy and Clinical Outcomes While Containing Costs: Opportunities From the Greater Use of Generic Medications*, Annals of Internal Med. (2016), https://tinyurl.com/2p9y658e (noting that "therapeutic interchange … may represent an even greater potential for cost savings" than generic substitution).

Broadening the lens to cover the full spectrum of treatment options, coupons are commonly offered when patients (and their physicians) have another therapeutic alternative. Or when a new choice is just on the horizon. Coupons often appear just as a potential competitor does, as part of manufacturers' efforts to wring every last dollar out of their (already extended) years of

monopolistic pricing power. Investigation by Congress showed that drug companies "strategically use" "co-payment programs to drive demand, particularly after the loss of exclusivity." H.R. Comm. on Oversight and Reform, 116th Congress, *Drug Pricing Investigation: Novartis—Gleevec*, at 36-37 (Sept. 30, 2020), https://tinyurl.com/5ae9j6hm ("Congressional Oversight Report - Novartis"). For instance, Novartis "determined that enhancing the co-pay programs six months before the loss of exclusivity would result in the greatest return on investment by keeping patients on Gleevec before lower-cost generics entered the market." *Id.* Such maneuvers are all too common. In another example, "Pfizer documents emphasized that its copayment program encouraged patients to stay on branded Lyrica even after the entry of generic competition." Congressional Oversight Report, at xiv.

Coupons feed drugmakers' profits by increasing sales volume of the couponed drug, reducing drug manufacturers' willingness to negotiate discounts with health plans, and providing cover for continued price increases. Leemore Dafny et al., *Undermining Value-Based Purchasing—Lessons from the Pharmaceutical Industry*, 375 N. Engl. J. Med. 2013, 2014 (Nov. 2016) (Coupons allow drug manufacturers to "charge insurers the highest price possible … and then use a copayment coupon to promote use."). The end result is higher prices for all. A 2017 study estimated that coupons increased spending for the 23 studied drugs by $700 million to $2.74 billion over 5 years. Leemore Dafny et al., *When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization*, 9 Am. J. of Econ. P. 91, 116 (2017). Similarly, a forthcoming study shows that in the absence of coupons, drug prices for multiple sclerosis alone "would be 8 percent lower, which in the U.S. means about a billion dollars less in spending." Erin O'Donnell, *How Coupons Keep Drugs Costly*, Harvard Mag. (January-February 2023), https://tinyurl.com/yt2mwsb8.

In short, coupons are profit centers, not charity. One company's estimated rate of return for a co-pay assistance program was "$8.90 for every dollar invested." Congressional Oversight Report – Novartis, at iii. Another company's co-pay assistance program "had an average return on investment of 451%." Congressional Oversight Report, at 149; *see also id.* at 154.

III. The Rule Sensibly Lets States Judge the Value of Co-Pay Accumulators for Mitigating Out-Of-Control Drug Prices.

Accumulator programs are a key tool for health insurance providers to blunt drugmakers' efforts to use co-pay coupons to artificially inflate their prices and drive their revenues even higher. HHS sensibly declined to adopt a new federal rule prohibiting co-pay accumulator programs nationwide for qualified health plans, rightly recognizing that allowing accumulators would further the government's efforts to combat the high and rising out-of-pocket costs for prescription drugs. 85 Fed. Reg. at 29,233. Instead, it left flexibility to the states to address whether and when co-pay accumulators should operate. *Id.* That reasoning was sound. Most states allow accumulators, because they defend against some of the ways that coupons drive up prescription drug spending. And the rule preserves states' authority to make case-by-case judgments otherwise.

A. Co-Pay Accumulators Are Key Tools to Limit Distortion without Harming Patients.

Accumulators work by ensuring that a manufacturer's decision to offer a coupon does not distort a health plan's design. Patients still receive the benefit of the coupon. For as long as manufacturers choose to provide co-pay coupons and to the full extent of that discount, patients can use the coupon to reduce the amount they owe to the pharmacy when they pick up the prescription. When manufacturers cease support mid-year—as is usually the case, due to annual limits or coupon use caps—patients are responsible for out-of-pocket costs to the same extent that they always were. If this puts out-of-pocket drug costs out of reach, the problem is not the accumulator—it is the too-high cost of the drug to begin with, or the manufacturer's decision to

cap its financial support. Accumulators do not stand in the way of coupons eliminating any out-of-pocket costs. Manufacturers are not prevented from providing coupons that eliminate out-of-pocket costs. They just can't do so for pennies on the dollar for strategic short-term periods while actually shifting out-of-pocket costs to the patient and all consumers who buy health insurance.[5]

1. To understand how accumulators help keep plans operating as designed, consider how—in the absence of an accumulator—coupons change decision-making. Health plans are designed to encourage the use of clinically appropriate, lower cost drugs, with patients generally asked to pay lower cost-sharing for better value, clinically equivalent alternatives, thereby encouraging cost-effective choices.[6] Consider a hypothetical branded drug with 20% coinsurance and its therapeutic substitute (which is available in a generic), subject to a flat $5 co-pay. Without a coupon, the patient and her medical provider would choose the therapeutic substitute:[7]

Without Coupon			
Brand-Name Drug		*Close Therapeutic Substitute (Generic)*	
Health Plan:	$400	Health Plan	$95
Patient:	**$100**	**Patient:**	**$5**
Total Cost:	$500	Total Cost:	$100
Patient Chooses Generic, Saving $400			

[5] Plaintiffs' *amici* object that patients may be surprised by co-pay accumulators. *See* Trial Card Amicus Br. 10 & n.7. But HHS did not neglect this issue. It "agree[d] with commenters that it is important for issuers and group health plans to be clear and transparent," is monitoring the issue, and "may propose further rulemaking to impose robust disclosure requirements if we find that enrollees are not provided sufficient information on these practices." 85 Fed. Reg. at 29,235.

[6] A formulary is a list of drugs that are covered by a particular health plan. *See In re EpiPen Epinephrine Injection, Mktg., Sales Pracs. & Antitrust Litig.*, 44 F.4th 959, 966 (10th Cir. 2022) . Formularies are typically organized into "tiers," to encourage patients to choose equally effective, lower cost drugs. *Id*. A common structure is to include most generic drugs on the lowest tier, with the lowest cost-sharing; preferred (lower-cost) brand-name drugs on tier two, with medium cost-sharing; and non-preferred brand-name drugs on a third tier, with higher cost-sharing. *Id.* at 967.

[7] Close therapeutic substitutes may be generic or brand-name. *See* Van Nuys, *supra*, at 7. Although close therapeutic substitutes work for most patients, plans have procedures to ensure patients have coverage for more expensive brand-name drugs when medically indicated.

With a coupon, however, the amount spent by the patient out-of-pocket at the pharmacy counter decreases, although the brand-name drug in fact costs four times as much. The coupon does reduce the total amount spent on the brand-name drug, considering the amount paid by the patient and the plan together, but not by nearly enough to make up for the much higher price the plan pays for the drug compared to the substantially less costly generic therapeutic alternative. Thus, the discount directs the patient towards the higher-priced drug, resulting in higher premiums for all—including for that patient.

With Brand-Name Coupon			
Brand-Name Drug with $100 coupon		*Generic Close Therapeutic Substitute*	
Health Plan:	$400	Health Plan	$95
Patient:	**$0**	**Patient:**	**$5**
Total Cost:	$400	Total Cost:	$100
Patient Chooses Brand-Name Drug, Increasing Costs by $300			

2. With an accumulator program, the patient may still choose the higher-priced drug while the coupon is available, because such programs permit patients to benefit from coupon discounts. But the accumulator ensures that when the manufacturer stops offering a coupon, the health plan otherwise operates as designed in terms of cost-sharing and its effect on patient and physician decision-making and health care spending.

To illustrate, consider a silver plan with a $5,000 deductible—about the average in 2023 for silver plans that have a combined medical and prescription drug deductible, as most do.[8]

[8] *See* Kaiser Family Foundation, *Cost-Sharing for Plans Offered in the Federal Marketplace, 2014-2023*, figs. 1-2 (Feb. 2023), https://tinyurl.com/yf7fvt7n.

Imagine a specialty drug costing $48,000 per year, with 25% coinsurance.[9] For such a drug, the manufacturer might well offer a co-pay coupon of $1,000 per month, up to a maximum of $5,000 (not coincidentally, the average deductible).[10]

In the absence of an accumulator, the coupon amount would count toward the patient's deductible, so by May of any given year, the patient would effectively have a $0-deductible plan for the rest of the year, despite incurring no out-of-pocket costs that year. Moreover, this $0 deductible would apply for any medical care, not only prescriptions, given a combined deductible. By comparison, the average gold plan (which required higher premiums) had a $1,650 combined deductible in 2023, well above zero. Kaiser Family Foundation, *supra*, fig. 2.

Without an accumulator program, the patient receives an initial discount in the silver plan, yes, but ultimately pays higher premiums (as do all consumers) because the coupon effectively eliminates the silver plan's cost-sharing design and makes the silver plan cover more out-of-pocket costs than the average gold plan. With an accumulator, on the other hand, the patient still benefits to the full extent of the manufacturer's discount ($5,000), but when the manufacturer's discount stops, cost-sharing functions as it was designed.

Accumulators rightly do not count the manufacturer's coupon towards the patient's out-of-pocket maximum because the patient has incurred no out-of-pocket cost when the manufacturer opts to pick up its own bill. Accumulators thus ensure that patient incentives are aligned with the true cost of prescription drugs. And, as HHS recognized, such alignment of incentives is essential for consumer-directed health plans (also known as high deductible health plans) that are paired

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[9] *See* Sarah Jane Tribble, *Why The U.S. Remains The World's Most Expensive Market For 'Biologic' Drugs*, Kaiser Health News (Dec. 20, 2018), https://tinyurl.com/4e9dae3x (describing drug costing $65,000 per year with $1,300 per month out-of-pocket cost).

[10] *See* Van Nuys, *supra*, at 4 (about half of coupons with published maximums capped coupons between $1,000 and $10,000 per year).

with health savings accounts to qualify for favorable tax treatment. *See* 85 Fed. Reg. at 29,233. Under IRS guidance, a patient's deductible can be credited only in a way that reflects the "actual cost of medical care to the individual"; when a manufacturer pays a portion of the cost or arranges a discount, that amount cannot count toward the deductible. *Id.*

Plaintiffs and their *amici* insist that the possible disqualification of such consumer-directed health plans is no concern because the precise arrangement examined in the IRS guidance was a discount card, not a co-pay coupon. But as HHS recognized, the net-cost principle applies regardless of the program's form. *See id.* Sub-regulatory guidance from the Department of the Treasury has likewise confirmed that any "third-party payment, such as a rebate or coupon, that has the same effect as a discount" cannot be counted toward the deductible. *See* Letter from Office of the Chief Counsel, Dep't of Treasury, to Ill. Dep't of Ins. (Apr. 16, 2021), https://tinyurl.com/y2dmnnyb. HHS rightly avoided adopting a new federal rule that would raise serious compliance concerns for health savings account-eligible consumer-directed health plans, which are favored by about a fifth of American workers, *see* Kaiser Family Foundation, *Employer Health Benefits: 2021 Annual Survey*, at 126 (2021), https://tinyurl.com/4yhzmhtz.

3. While accumulators ensure that patients' cost-sharing accurately reflects the true cost of a drug, they do not confer a windfall on health insurance providers or permit them to "double dip." With accumulators, the coupon amount *never* goes to the health insurance provider; it is paid by the manufacturer to the pharmacy (which applies it towards the cost of the manufacturer's drug). Since coupons reduce the co-pay amount that the patient would otherwise owe the pharmacy, the coupon is not replacing a price that the insurance provider would otherwise have had to pay. It is therefore inaccurate to say that coupons, with accumulators, increase the total amount collected by insurance plans. *See* Pls.' Summ. J. Br. 7.

Instead, accumulator programs simply permit plan enrollees to use co-pay coupons as a discount to reduce what they owe at the pharmacy counter, but not as a credit toward their cost-sharing. Plaintiffs' *amici* claim that a coupon is not a "discount," because it does not reduce the amount the patient owes, but instead provides additional funding to pay that amount. *See, e.g.*, PhRMA Amicus Br. 11. But this distinction between a "discount" and "funding" is nonsensical when the source of the funding is also the seller of the product. Co-pay coupons are discounts. Co-pay accumulator programs do not stop patients from accessing those discounts, but simply ensure that such discounts actually reduce the total amount spent overall by the patient and health plan (and thus all consumers) on prescription drugs, rather than being used to inflate drug prices and drug spending. This is not a "windfall" to health insurance providers. Instead, it lowers the cost of health care for everyone.

B. The Rule Preserves Crucial Flexibility for Plan-by-Plan and State-by-State Judgments Regarding Co-Pay Coupons' Market Distortion, without Impeding Drug Manufacturers' Ability to Support Patient Access to Prescription Drugs.

Although Plaintiffs and their *amici* focus their rhetoric on the benefit of coupons where no generic is available, make no mistake: their statutory arguments would mandate a new federal rule outlawing co-pay accumulators in all circumstances, even when a generic is available. *See, e.g.*, Pls.' Summ. J. Br. 13-16. Regardless, HHS reasonably declined to set a federal rule cabining the use of accumulators to situations where a generic substitute is available, and instead left states free to make their own judgments about the benefits of accumulators. Because co-pay coupons may be launched to deter use of therapeutic substitutes or shortly before the introduction of a generic equivalent, there are myriad situations beyond generic availability where co-pay coupons can cause market distortion. The rule preserves the ability of state regulators to assess when to allow co-pay accumulator programs, without impeding drug manufacturers' ability to support patient access and drug affordability.

The rule's flexibility goes further. It does not require health insurance providers to disregard coupon payments towards the deductible in all circumstances. 85 Fed. Reg. at 29,233. Rather, it permits health insurance providers (subject to state law) to count coupons toward deductibles and out-of-pocket spending when there is no risk of market distortion. *Id.* Many health plans do *not* include co-pay accumulators—only about a third of employers reported having such programs or being unsure. *See* Kaiser Family Foundation, *supra*, at 189–191. And, even when such programs are adopted, they are not one-size-fits-all; health insurance providers have nuanced co-pay accumulator programs that take factors like the (non-)availability of therapeutic alternatives into account.

The rule permits states, too, to make different judgments based on demographic and market considerations in their states. Most states recognize the benefit of co-pay accumulators and permit them in all circumstances. *See* Nat'l Conf. of State Legislators, *Copayment Adjustment Programs* (Feb. 2023), https://tinyurl.com/4x6sw9d8. Some states may avoid the need for co-pay accumulators altogether by banning co-pay coupons in certain situations. *See, e.g.*, Mass. Gen. Laws ch. 175h, § 3; Cal. Health & Safety Code § 132000. A handful of states bar co-pay accumulators even though it will mean higher insurance premiums, making a considered decision to accept higher drug costs in exchange for spreading that burden broadly among all those who pay health insurance premiums. *See, e.g.*, Conn. Public Acts 2021, No. 21-14; 215 Ill. Comp. Stat. 134/30(d); La. Stat. § 22:976; Act of March 27, 2019, 2019 W. Va. Acts 1333. Still others take a middle approach, limiting co-pay accumulators in some but not all cases. *See, e.g.*, Ariz. Rev. Stat. § 20-1126 (ban on accumulators limited to drugs without a generic equivalent or where patient has prior authorization for branded drug); N.C. Gen. Stat. § 58-56A-3 (same); Ky. Rev. Stat. § 304.17A-164 (same). The federal rule affords states the flexibility to assess their market

conditions, examine the extent of the distortions, analyze economic trade-offs, and make these decisions.[11]

While the rule permits states flexibility to use co-pay accumulators to mitigate the price inflation caused by co-pay coupons, the rule does not stand in the way of drug manufacturers assisting patients with prescription drug access and affordability. For starters, drug manufacturers could reduce or discount their list prices, and have ample room to do so given their high profit margins. They could also provide co-pay coupons that continue throughout the year, or without capping the maximum assistance at deductible levels.

Drugmakers generally don't provide open-ended cost-sharing support because the point of coupons is to reap large profits from a small investment by paying co-pays only up until the full cost of the drug shifts to the health insurance provider. This tactic in fact shifts the full cost back to patients, but the cost shifting is concealed. *See* Congressional Oversight Report, at 149 (describing how co-pay coupons reduce negative perception of price increases). It is only by capping support, and tying it to health plan deductibles, that drug manufacturers can achieve 400%-plus returns on their coupon investments. *See id.;* Congressional Oversight Report - Novartis at iii ($8.90 return for every $1 spent). Accumulators permit patients to benefit from the full amount of assistance that drug manufacturers are willing to provide. At the same time, by maintaining plan cost-sharing safeguards, accumulators limit the ability of drug manufacturers to

[11] Plaintiffs' *amici* cite an article that compared average premium increases between states that allow and disallow co-pay accumulator programs to claim that co-pay accumulators do not reduce premiums. *See* Aimed Alliance Amicus Br. 21; Esteban Rivera et al., *Impact of Legislation Protecting Patient Assistance Programs on Health Insurance Premiums*, Global Healthy Living Foundation, https://tinyurl.com/2p8hkjfc. This simple comparison approach is premature, given that most such laws have only recently been enacted; the comparison does not account for other factors that cause premiums to vary between states; and nothing in the analysis negates the overwhelming evidence that co-pay coupons increase costs. *See* pp. 8-11, *supra*.

drive up prices with such minimal investments. The rule reasonably left states the flexibility to continue to use this key tool to fight uncontrolled prescription drug price increases.

CONCLUSION

The Court should deny Plaintiffs' motion for summary judgment and grant Defendants' cross-motion for summary judgment.

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Respectfully Submitted,

/s/Hyland Hunt

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CERTIFICATE OF SERVICE

On March 23, 2023, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, District of Columbia, using the electronic case filing system of the court. I hereby certify that I have served counsel for all parties of record electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/Hyland Hunt
Hyland Hunt