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.

Civil Action No. 1:22-cv-2604 (JDB)

REPLY IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiffs paint an overly simplistic picture of the health insurance industry and the legal requirements that govern it. They contend that the U.S. Department of Health and Human Services, through the Centers for Medicare & Medicaid Services (collectively, "HHS"), issued a rulemaking that fundamentally alters the legal landscape for insurers, at the expense of patients in need of certain medications. They insist that drug manufacturer assistance can only be viewed as a kind of contribution to a patient's payment for drugs, just like assistance that a patient receives through family, crowdfunding, and other sources for purposes of paying their medical bills. And, in accordance with this view, Plaintiffs maintain that the Affordable Care Act ("ACA"), 42 U.S.C. §§ 18001 *et seq*., and its implementing regulations foreclose the agency's sound policy judgment in the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Government Plans, 85 Fed. Reg. 29,164 (May 14, 2020) ("2021 NBPP"). In the alternative, Plaintiffs argue that the 2021 NBPP fails to account for factors that the agency (in their view) was required to consider, such as reliance interests that resulted from the agency's prior policy judgment in the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, 84 Fed. Reg. 17,454 (Apr. 25, 2019) ("2020 NBPP"). The facts of this case are much more complicated than Plaintiffs let on, however, and HHS's consideration of the relevant issues in the 2021 NBPP was reasonable.

As HHS explained in the 2021 NBPP, a rule requiring insurers to count some drug manufacturer assistance towards patients' cost-sharing obligations could create a conflict with existing IRS policies. That potential conflict caused confusion in the immediate aftermath of the 2020 NBPP, which prompted HHS to reconsider the rule. Moreover, under the ACA and its

implementing regulations, there is a strong case for viewing drug manufacturer assistance as reducing a patient's up-front costs, rather than contributing to a patient's payment for drugs. For that reason, HHS concluded that the statute and regulations are ambiguous and declined to interpret them. And numerous commenters emphasized that barring copay accumulators could lead to higher drug costs in general for all patients due to market distortion. Faced with these complexities, which HHS explained in the Federal Register, the 2021 NBPP imposed no legal requirements on insurers regarding specific types of drug manufacturer financial assistance. Instead, the rule made explicit the agency's goal of affording states and insurers flexibility in deciding whether to adopt copay accumulators—the same flexibility that insurers have always had, including during the brief period where the 2020 NBPP imposed a different requirement (because that requirement was never enforced).

The 2021 NBPP is neither contrary to law nor arbitrary and capricious. For those reasons, the Court should grant Defendants' cross-motion for summary judgment.

ARGUMENT

I. THE 2021 NBPP IS NOT CONTRARY TO THE AFFORDABLE CARE ACT.[1]

Plaintiffs have failed to grapple with HHS's central contention regarding the multiple potential meanings of "cost sharing" under the ACA. Plaintiffs proceed from the assumption that drug costs covered by manufacturer assistance programs are part of the "amounts for which the patient is responsible," which (in their view) must be "counted against the annual cost-sharing

[1] For the reasons stated herein and in Defendants' opening brief, Defendants maintain that the 2021 NBPP is not contrary to law or arbitrary and capricious. If, however, the Court is inclined to agree with Plaintiffs that the rule is arbitrary and capricious, Defendants respectfully request that the Court resolve the case on those grounds without reaching the question whether the policy articulated in the 2021 NBPP is foreclosed by the ACA or by 45 C.F.R. § 155.20.

cap" under the ACA's definition of "cost sharing." Reply in Supp. of Pls.' Mot. for Summary Judgement & Opp'n to Defs.' Cross-Mot. at 7-9, ECF 33 ("Pls. Reply"). Relying on that assumption, Plaintiffs assert that the key question is whether such costs should be credited towards cost sharing even if they are paid for by the drug manufacturer, and not by the patient.

HHS, however, disagrees with Plaintiffs' assumption that patients are necessarily "responsible" for such costs in the first place. As HHS explained in the final rule, although the "value of the direct drug manufacturer support" could be understood in that way, it could also be "viewed as representing a *reduction*, by drug manufacturers, in the amount that the enrollee is *required to pay* at the point of sale in order to obtain the drug." 85 Fed. Reg. at 29,234 (emphasis added). Suppose, for example, that a brand name drug requires a $50 co-pay, and the drug manufacturer offers the patient a $20 coupon. If the coupon results in a "reduction . . . in the amount that the [patient] is required to pay at the point of sale"—thereby reducing the cost paid by the patient from $50 to $30—then the patient would be "responsible" for payment in the amount of $30, and not for the full cost of the brand name drug.[2] *See* 85 Fed. Reg. at 29,234. Because drug manufacturer assistance could be viewed either as part of the "cost incurred by or charged to enrollees" or as a "reduction" of those costs, HHS concluded that the term "cost sharing" as applied to such assistance is "subject to interpretation." *Id*.

Plaintiffs do not address the "reduction" view of drug manufacturer assistance, let alone explain why the statute's definition of "cost sharing" precludes it. Instead, they offer several

[2] This view is not only plausible, but compelling. When a person uses a manufacturer coupon to buy a product at a grocery store, it is likely that the value of the coupon is simply discounted from the sale price of the product at the cash register. In that scenario, it would be rather unusual to interpret that the provider of the coupon has contributed a portion of the customer's payment for full-priced groceries.

assertions regarding the statute's meaning. These assertions do not establish that the final rule conflicts with the statute.

First, Plaintiffs argue that the Court must "render its best interpretation of the statute, even *if* ambiguous." Pls. Reply at 16. Even if that were true, the question remains whether, under the statute, drug manufacturer assistance should be viewed as part of the amount "required of" an insured individual or as a "reduction" of that amount. Plaintiffs offer no explanation why the former interpretation should trump the latter. HHS maintains that the statute is susceptible to both interpretations, and "[t]o provide maximum flexibility for states and issuers," it declined to finalize an interpretation of the statute that would adopt only the "reduction" view of drug manufacturer assistance. 85 Fed. Reg. at 29,234.

Second, Plaintiffs point to the ACA's use of the term "required of," 42 U.S.C. § 18022(c)(3)(A)(ii), as textual evidence that the definition of "cost sharing" "encompasses payment requirements that the patient satisfies by obtaining manufacturer assistance," Pls. Reply at 11. Again, Plaintiffs offer no explanation for why, under the statute, such assistance is used to "satisf[y]" "payment requirements." *Id*. If drug manufacturer assistance is treated as altering the patient's payment requirements in the first instance by reducing the cost of a drug for a patient—as HHS observed that it may be treated under the statute——then it is far from clear why the value of the assistance is "required of" the patient. *Id*. (quoting 42 U.S.C. § 18022(c)(3)(A)(ii)).

Third, Plaintiffs emphasize the "contrast" between clauses (i) and (ii) of the ACA provision that contains the definition of cost sharing. The statute defines "cost-sharing" to include—

> (i) deductibles, coinsurance, copayments, or similar charges; and
> (ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of Title 26) with respect to essential health benefits covered under the plan.

42 U.S.C. § 18022(c)(3)(A). Section 223(d)(2) of Title 26 excludes from the definition of "qualified medical expenses" any "amounts paid by [a] beneficiary for medical care" that are "compensated for by insurance or otherwise." 26 US.C. § 223(d)(2)(A). Plaintiffs' concede that the cross-referenced language "look[s] to whether the beneficiary is 'compensated' for an expense" by drug manufacturer assistance instead of "pay[ing] it out of pocket"—that is, patient costs that are compensated by third parties may be excluded. Pls.' Mot. for Summary Judgement at 15, ECF 13 ("Pls. Mem."). But Plaintiffs argue that the cross-reference to Title 26 is "not present in clause (i)" and thus does not apply to any expenses that fall within clause (i). *Id.*; Pls. Reply at 11.

Plaintiffs' reliance on the "contrast" between clauses (i) and (ii) is inconsistent with their other statutory arguments. Elsewhere, Plaintiffs import the "required of" language from clause (ii) into clause (i), even though that language appears only in clause (ii). They argue that the "statutory text . . . sweeps within the definition of 'cost-sharing' any 'deductibles, coinsurance, copayments, or similar charges' [described in clause (i)] that are 'required of' the insured individual in order to access her healthcare [according to clause (ii)]." Pls. Mem. at 15 (quoting 42 U.S.C. § 18022(c)(3)(A)); *see also* Pls. Reply at 11 (the "overall provision" of the statutory definition of cost sharing "refers to amounts 'required of' the patient" (quoting 42 U.S.C. § 18022(c)(3)(A)(ii)). This is so, Plaintiffs say, because clause (ii) "follows the enumerated categories of charges in clause (i)." Pls. Mem. at 14 (citing *Dong v. Smithsonian Inst.*, 125 F.3d 877, 880 (D.C. Cir. 1997) ("[T]he phrase 'A, B, or any other C' indicates that A is a subset of C.")). Accordingly, on Plaintiffs' logic, the cross-reference to Title 26 in clause (ii)—which also "follows the enumerated categories" in clause (i) and simply modifies the "required of" language that Plaintiffs import into

clause (i)—*does* apply to the entire definition of "cost-sharing." Pls. Mem. at 14-15 (citations omitted). Plaintiffs' efforts to import one part of clause (ii) into the entire statutory definition while rejecting the application of another part of the same clause makes little sense.

Accordingly, the ACA does not require that insurers count drug manufacturer assistance towards "cost-sharing" maximums. Nor does it foreclose HHS's analysis of the statute as being "subject to interpretation," thereby providing flexibility to insurers. *Id*. at 11 (citation omitted).

II. THE 2021 NBPP DOES NOT VIOLATE HHS REGULATIONS.

For similar reasons, the 2021 NBPP does not run afoul of HHS's regulatory definition of cost sharing. That definition encompasses "any expenditure required by or on behalf of an enrollee with respect to essential health benefits." 45 C.F.R. § 155.20. In arguing that the regulation requires that cost sharing include the value of drug manufacturer assistance, Plaintiffs make the same error that they made with respect to the statute: they assume that drug manufacturer assistance constitutes part of the cost incurred by an enrollee, and they posit that such assistance qualifies as "payments . . . made 'on behalf of'" a patient. Pls. Reply at 12. Again, Plaintiffs fail to explain why it is not equally plausible, in the alternative, to view drug manufacturer assistance as a "reduction[] by [the] drug manufacturer[]" of a drug cost for the patient. 85 Fed. Reg. at 29,234.

Plaintiffs do acknowledge HHS's observation that drug manufacturer assistance may be viewed as a "reduction . . . in the amount that the enrollee is required to pay at the point of sale." Pls. Reply at 13 (quoting 85 Fed. Reg. at 29,234). But Plaintiffs then dismiss this analysis out of hand, positing (without explanation) that this understanding of drug manufacturer assistance "would do nothing to dispel the conclusion" that such assistance "remains an 'expenditure required

. . . *on behalf of* [a patient] with respect to essential health benefits.'" *Id.* (quoting 45 C.F.R. § 155.20). Plaintiffs are mistaken. Under the "reduction" view of drug manufacturer assistance, the assistance amount would be viewed as a reduction "by drug manufacturers" of the cost "incurred by an enrollee under the health plan." 85 Fed. Reg. at 29,231. Such a price reduction may not involve any "expenditure[s]" on anyone's behalf; at least in some cases, the drug manufacturer may merely reduce the amount required to be paid by the purchaser. *See* 85 Fed. Reg. at 29,234. Viewed in this light, it is unclear why drug manufacturer assistance programs must necessarily fall under the regulatory definition of cost sharing.

Accordingly, like the statute, the regulation does not compel Plaintiffs' preferred interpretation.

III. THE 2021 NBPP IS NOT ARBITRARY AND CAPRICIOUS.

1. HHS was not required to determine conclusively whether a conflict existed between IRS guidance and the 2020 NBPP.

Plaintiffs do not dispute that HHS was not required to find that the IRS rule directly conflicted with the 2020 NBPP. An agency may change its policy as long as "the new policy is permissible under the statute," there are "good reasons for it," and "the agency believes it to be better." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). For the reasons outlined in Defendants' motion, each of those requirements is satisfied here.

Nevertheless, Plaintiffs insist that the 2021 NBPP should be vacated because the agency erroneously represented that there was a conflict between the 2020 NBPP and IRS policy. The agency did not make any such representation. In the final rule and the materials cited therein, HHS repeatedly used equivocal language regarding the "possibility" of a conflict between existing IRS guidance and the 2020 NBPP. 85 Fed. Reg. at 29,231. The requirements in the 2020 NBPP "could

create a conflict," *id.*; AR4320 (same); an insurer "could be put in the position" of complying with different requirements, 85 Fed. Reg. at 29,231; and HHS "underst[ood] that the policy advanced by the 2020 NBPP and prior IRS guidance related to HDHPs *may* conflict," AR 4320 (emphasis added). Absent from the administrative record is any representation that there was *certainly* a conflict between the policies. It is enough that the agency was concerned about a "possible" conflict and the confusion that could—and did—flow from that possibility. *See* 85 Fed. Reg. at 29,233 ("In the proposed rule and this final rule, we seek to clarify the HHS policy and address the confusion, including the potential conflict, identified by stakeholders.").

Plaintiffs' fallback argument is that the 2021 NBPP is arbitrary and capricious because HHS purportedly failed to address "many comment[s]" that alleged that the 2020 NBPP did not conflict with IRS policy. Pls. Reply at 19 (citation omitted). That argument is meritless. In the final rule, HHS noted that "[m]any commenters requested that HHS clarify that the [2020 NBPP] does not conflict with rules relating to HDHPs with HSAs." 85 Fed. Reg. at 29,233. HHS then proceeded to explain, in three fulsome paragraphs, that (1) the 2020 NBPP was "ambiguous;" (2) it could lead to a "potential conflict" with IRS policy (which HHS described at length); and (3) accordingly, HHS was modifying the rule to eliminate confusion and "avoid this type of conflict for those situations where it may arise." *Id.* That is a far cry from "[n]odding to concerns raised by commenters only to dismiss them in a conclusory manner." Pls. Reply at 19 (quoting *Gresham v. Azar*, 950 F.3d 93, 103 (D.C. Cir. 2020), *vacated & remanded sub nom.*, *Becerra v. Gresham*, 142 S. Ct. 1665 (2022)). And again, it is undisputed that HHS was not *required* to take a position on whether the 2020 NBPP did, in fact, conflict with IRS policy. Acting in response to the concern about the potential conflict and related public confusion was sufficient.

2. HHS adequately considered the potential cost to patients.

Plaintiffs argue that it was arbitrary and capricious for HHS to conclude, based on insurers' longstanding practices, that insurers would not "adopt copay accumulators *en masse*" following the 2021 NBPP. Pls. Reply at 21. Plaintiffs also contend that the record "demonstrate[s]" that this *en masse* adoption of copay accumulators was "not merely hypothetical," but was already happening when HHS issued the final rule. Both arguments are flawed. *Id*.

First, contrary to Plaintiffs' assertion, the administrative record does not demonstrate "*en masse*" adoption of copay accumulators after the agencies announced that they would not be enforcing the 2020 NBPP. As HHS noted in the final rule, "no comments submitted by the health insurance industry on this policy in the 2021 Payment Notice proposed rule expressed a desire to change their current practices." 85 Fed. Reg. at 29,232 n.150. Plaintiffs do not dispute that point. Instead, they cite to four comments in the record from organizations that represent and advocate on behalf of patients and providers. *See* Pls. Mem. at 31 & n.10 (citing AR 2209, AR 2701, AR 404, and AR 2719). Only one of those comments cited to a report concluding that "an issuer"—that is, a single insurer—intended to "revert[] to broadly banning all copay assistance" after the agencies indicated that they would not enforce the 2020 NBPP. AR 2209. But one insurer reverting to an old copy accumulator policy does not mean that other insurers will adopt new ones. Another comment cited the same evidence for the proposition that most Florida providers had copay accumulators in their health plans as of 2020; the cited evidence does not indicate, however, that those providers changed their plans in response to the agencies' actions. AR 2701. And the remaining comments cited by Plaintiffs merely speculate that insurers will embrace copay accumulators. *See* AR 404 (noting that it "seems unlikely" that insurers will choose not to embrace

copay accumulators); AR 2719 (expressing a "belie[f]" that the proposed rule would "result in more plans utilizing copay accumulators").[3]

The cited comments thus suggest, at most, that *some* insurers might change their policies. HHS considered that possibility and acknowledged that "some issuers or group health plans may make changes to their plan designs to exclude direct drug manufacturer support amounts from the annual limitation on cost sharing." 85 Fed. Reg. at 29,232. The agency concluded, however, that "the multitude of variables and considerations that are out of HHS's control" made it impossible to project cost-related burdens on patients "with sufficient certainty." *Id.* Nothing in the record contradicts that conclusion, which was the result of the agency's considered judgment.

Second, in the absence of an actual showing of *en masse* changes in policy, the Court should reject Plaintiffs' invitation to speculate about how insurers will react to the 2021 NBPP. "[P]redictions regarding the actions of regulated entities are precisely the type of policy judgments that courts routinely and quite correctly leave to administrative agencies." *Public Util. Comm'n of State of Cal. v. Fed. Energy Regulatory Comm'n*, 24 F.3d 275, 281 (D.C. Cir. 1994); *accord Mozilla Corp. v.* FCC, 940 F.3d 1, 50 (D.C. Cir. 2019). After careful consideration, the agency concluded that it is "unlikely that issuers will choose to change their longstanding practices." 85 Fed. Reg. at 29,232. In Plaintiffs' view, that conclusion "does not account for the difference" between "a situation with no regulation one way or the other regarding the legality of copay accumulators" and "the post-2021 NBPP world in which federal regulators have explicitly approved their use." Pls. Reply at 21. But Plaintiffs offer no support for this assertion. Absent

[3] These comments also acknowledge that states have been active in enacting legislation to prohibit copay accumulator programs. *See, e.g.*, AR 404. It was therefore reasonable for HHS to emphasize the importance of state law in this area.

record evidence, the Court is not best positioned to make findings about how insurers will react to the 2021 NBPP. This is especially true in the health insurance field, which is highly complex. Accordingly, Plaintiffs cannot establish that the agency's policy judgment was arbitrary and capricious.[4]

3. Plaintiffs' emphasis on reliance interests is misplaced.

HHS finalized the 2020 NBPP on April 25, 2019. *See* 84 Fed. Reg. 17,454. Just four months later—and before the beginning of the open enrollment process to sign up for any plans governed by the 2020 NBPP's finalized regulation on the use of drug manufacturer coupons[5]—the agencies issued FAQ 40, in which they announced that they "intend[ed] to undertake rulemaking in the forthcoming HHS [NBPP] for 2021" to address confusion about the 2020 NBPP and would not enforce it in the meantime. AR 4320-21. The 2020 NBPP was thus never enforced, and it was clear almost immediately after the 2020 NBPP became final that the issue would be reconsidered as part of the 2021 NBPP. The agency recounted this history of non-enforcement in the final rule. It was reasonable for the agency to not expound further on whether "serious reliance interests" might have been affected by the change in agency policy. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016) (citation omitted).

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[4] It also bears note that, even assuming some insurers change their policies, the costs to patients resulting from the 2021 NBPP is not obvious. Indeed, the record indicates that precluding copay accumulator programs could result in drug price and premium increases. Defs. Cross-Mot. for Summary Judgement at 5, ECF 27 (discussing comments); Br. of America's Health Insurance Plans as Amicus Curiae in Supp. of Defs.' Cross-Mot. for Summary Judgement & Opp. to Pls.' Mot. for Summary Judgement at 2, ECF No. 30 ("[C]oupons 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.").

[5] The regulation codified in the 2020 NBPP specified that it applied for plan years beginning on or after January 1, 2020. 45 C.F.R. § 156.130(h). The open enrollment period for that plan year began on November 1, 2019.

Contrary to Plaintiffs' suggestion, *Regents* does not compel a different result. In *Regents*, the Supreme Court considered DHS's termination of the Deferred Action for Childhood Arrivals ("DACA") program. *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1901 (2020). For years, DACA had enabled some 700,000 noncitizens to seek forbearance of removal, work authorization, and other federal benefits. *Id.* The respondents and *amici* in *Regents* described at length the concrete familial, educational, economic, and other interests that had crystallized in the years since DACA's inception. *Id.* at 1914. Against that backdrop, the Court held that DHS was "required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Id.* at 1915. The Court did not, however, establish a generally applicable rule that agencies must discuss potential reliance interests in *all* instances where they seek to change existing policy.

Regents is distinguishable from this case. Given that the 2020 NBPP was not enforced, and that the agency almost immediately announced its intention to reconsider the rule, it was not necessary for the agency explicitly to consider and reject the potential reliance interests involved. Moreover, the agency did consider the possibility that insurers would change their previous policies—which would have been the source of any potential reliance interests—and it concluded that no significant changes were likely to occur. *See supra* at pp. 9-11; *see also* 85 Fed. Reg. 29,232 ("We do not expect any significant increases in patient costs or non-adherence to medications if issuers choose to continue their current behavior."). Because *Regents* does not stand for the broad proposition that an agency must always discuss potential—or even hypothetical—reliance interests

whenever it seeks to change a policy, HHS did not run afoul of *Regents* in the 2021 NBPP.[6]

4. The "treat like cases alike" doctrine is not implicated here.

Plaintiffs argue that HHS has failed to "treat like cases alike" by "permitting insurers to disregard manufacturer copay assistance when calculating deductibles and out-of-pocket maximums but not doing the same for other forms of patient financial assistance." Pls. Reply at 22. That argument betrays a misunderstanding of the principle that agencies generally ought to "treat like cases alike." *Nat'l Weather Serv. Emps. Org. v. Fed. Labor Rels. Auth.*, 966 F.3d 875, 883 (D.C. Cir. 2020) (citation omitted). There is nothing arbitrary and capricious about an agency choosing to regulate certain segments of the market in ways that are informed by its expert judgment, while declining to regulate other parts of the market at the same time.

The D.C. Circuit has recognized that "[a] fundamental norm of administrative procedure requires an agency to treat like cases alike." *Gilbert v. Wilson*, 292 F. Supp. 3d 426, 438 (D.D.C. 2018) (quoting *Westar Energy, Inc. v. Fed. Energy Regulatory Comm'n*, 473 F.3d 1239, 1241 (D.C. Cir. 2007)). That norm is rooted in the importance of adhering to precedent when adjudicating cases; if an agency "glosses over or swerves from prior precedents without discussion[,] it may cross the line from the tolerably terse to the intolerably mute." *Id.* (quoting *Hall v. McLaughlin*, 864 F.2d 868, 872 (D.C. Cir. 1989)). Accordingly, the norm typically arises

[6] Plaintiffs urge that reliance interests existed "as a legal matter," even if they did not exist in practice because the 2020 Rule was never enforced. Pls. Reply at 22. It is not clear what Plaintiffs mean in referring to reliance interests "as a legal matter." *Id.* at 22 n. 12. Whether reliance interests exist is not a question of law, and the mere possibility of such interests is insufficient to challenge agency action. As the D.C. Circuit recently explained, "unidentified and unproven reliance interests are not a valid basis on which to undo agency action. Instead, the harm occasioned must be specifically identified, reasonably incurred, and causally tied" to the agency's actions. *Solenex LLC v. Bernhardt*, 962 F.3d 520, 529 (D.C. Cir. 2020).

in cases where individuals or entities claim that an agency has arbitrarily treated them differently from others when applying agency precedent. In *Westar Energy*, for example, the petitioner argued that the Federal Energy Regulatory Commission "could not permissibly deny its request for a waiver of [a] deadline after it had allowed [another] company to file late." 473 F.3d at 1240. The D.C. Circuit agreed. *Id.* Citing the "treat like cases alike" norm, the court reasoned that "[i]f the agency makes an exception in one case, then it must either make an exception in a similar case or point to a relevant distinction between the two cases." *Id.* at 1241.

The norm that agencies ought to "treat like cases alike" does not extend to agencies' processes for crafting regulations pursuant to their statutory authority (and Plaintiffs cite no cases suggesting otherwise). *Id*. There are no "cases" to compare, nor is there any precedent for the agency to apply. In this context, it is sufficient that HHS considered how appropriately to regulate insurers' treatment of drug manufacturer assistance programs and concluded that there was "no evidence" that other types of cost support identified by Plaintiffs, such as "crowdfunding amounts, waived medical debt, or support toward the purchase of DME," have "similar distortive effects on the market as manufacturer support for brand name prescription drugs." 85 Fed. Reg. at 29,234; *see also Nat'l Ass'n of Broads. v. FCC*, 740 F.2d 1190, 1207 (D.C. Cir. 1984) ("[A]gencies . . . need not deal in one fell swoop with the entire breadth of a novel development."). Plaintiffs' argument that the agency must treat all forms of patient assistance alike is therefore misplaced.

CONCLUSION

For the foregoing reasons, Defendants are entitled to summary judgment as a matter of law.

Dated: July 14, 2023 Respectfully submitted,

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