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.

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

REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO DEFENDANTS' CROSS-MOTION

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GLOSSARY

2020 NBPP	*Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020*, 84 Fed. Reg. 17,454 (Apr. 25, 2019), the preexisting rule amended by the rule challenged in this case.
2021 NBPP	*Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans*, 85 Fed. Reg. 29,163 (May 14, 2020), the rule challenged in this case.
ACA	Patient Protection and Affordable Care Act
CMS	Defendant Centers for Medicare and Medicaid Services
DLC	Plaintiff Diabetes Leadership Council
DPAC	Plaintiff Diabetes Patient Advocacy Coalition
HDHP	High deductible health plan
HHS	Defendant U.S. Department of Health and Human Services
HSA	Healthcare savings account

INTRODUCTION

1. In the regulation challenged here, defendants the U.S. Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) have affirmatively authorized health insurance companies to impose a practice that is indisputably harmful to patients—particularly those, like the individual plaintiffs here, who require lifechanging (and sometimes expensive) specialty medications to treat their chronic health conditions. That practice, known as a copay accumulator adjustment program, allows an insurer to refuse to credit copay assistance amounts from drug manufacturers against patients' deductibles and out-of-pocket maximums; results in a one-for-one transfer of value from the patient to her insurer; and all too frequently leaves patients unable to afford their medications at all. *See, e.g.*, AR002184 (comment of the American Medical Association in opposition to the 2021 NBPP, explaining that "[w]hen the copay coupon expires or runs out . . . the patient is faced with a sudden—and often massive—increase in financial responsibility for a drug, as the coupons have not counted toward his/her deductible. This could result in some patients deciding not to take or continue taking their medications with severe adverse health consequences.").[1]

It is hard to overstate the real-world interests present in this case: The government's policy broadly authorizing insurance companies to use copay accumulators inevitably leads to Americans across the country being unable to afford specialized, life-changing medications prescribed by

[1] The government attempts to chide us for saying "that insurance companies 'collect' the value of manufacturer coupons through their accumulator adjustment programs." Gov't Br. 4-5. But the government acknowledges that such programs "seek to shift drug costs from insurers to patients and manufacturers." *Id.* at 5 (quoting *Pharm. Rsch. & Mfrs. of Am. v. Becerra*, 2022 WL 1551924, at *2 n.1 (D.D.C. 2022)); *see also Pharm. Rsch.*, 2022 WL 1551924, at *5 (through accumulators, "health plan[s] ha[ve] devised a way to capture" "[a] manufacturer's financial assistance to an insured patient."). Nor does the government dispute our citation to record evidence illustrating how the imposition of an accumulator costs the patient money, and allows her insurer to collect additional money in the exact same amount. *See* Pls. Br. 7-8 (reproducing diagram from AR004150). Thus, while the government may be right in some technical sense that accumulators "do not result in insurance companies 'collecting' the coupon amounts" directly (Gov't Br. 5), the net economic result is precisely the same. For another description of how copay accumulator programs operate, see Trialcard, Inc. Am. Br. (Dkt. 19) at 6-10.

their doctors. *See, e.g.*, AR002463 (Comment of the American College of Rheumatology: "Without the assistance of manufacturer copay coupons, our patients will be forced to delay treatment, ration their medication, forfeit treatment entirely, or experience incredible financial hardships to pay for their treatment."). The implications for patients—including the three named plaintiffs in this litigation—are dire.

Thus, while the government and regulated industry may prefer to frame this dispute as a purely economic struggle between drug manufacturers and insurance payors (*see, e.g.*, Gov't Br. 3-5 ("[t]his dispute between drug manufacturers and health plans"); *see generally* AHIP Am. Br. (Dkt. 30)), it is the *patients* who are caught in the middle, with the most devastating potential consequences. *See* TrialCard, Inc. Am. Br. (Dkt. 19) at 10-16 (explaining the well-documented link between copay accumulators, prescription drug abandonment, and patient mortality, which hits "the sickest, most vulnerable patients [the] hardest"); Aimed Alliance Am. Br. (Dkt. 18) at 16-21 (similar). And it is the patients and their representatives who seek to vindicate their rights through this lawsuit.

2. In our opening brief, we explained that the agencies' approval of copay accumulator programs in the 2021 NBPP is unlawful: That action is contrary to the Affordable Care Act's (ACA) statutory definition of cost sharing (Pls. Mem. 13-18); it is even more clearly contrary to the existing regulatory definition of cost-sharing, which the agencies have not purported to amend or interpret (*id.* at 18-21); and it is arbitrary and capricious for a whole host of reasons (*id.* at 22-38).[2]

Rather than meet these arguments head-on, the government centers its opposition and cross-motion around a curious contention: It claims that the 2021 NBPP challenged here did not actually do *anything*. According to the government, although the 2021 NBPP amends the Code of Federal Regulations to explicitly provide that manufacturer copay assistance amounts "are not required to be[] counted toward the annual limitation on cost sharing" (45 C.F.R. § 156.130(h);

[2] Our opening brief also demonstrated that plaintiffs have standing to bring this lawsuit, which the government does not dispute. Pls. Mem. 38-42; *cf. generally* Gov't Mem.

2021 NBPP, 85 Fed. Reg. at 29,261), thereby authorizing insurers to impose copay accumulators without limitation, the agencies' action is *actually* a "decision *not* to set definitive standards in this area." Gov't Mem. 1. And according to the government, that means not only that this lawsuit is not justiciable, but that plaintiffs' challenges fail on the merits as well.

The government's central contention, however, is meritless. The 2021 NBPP manifestly changed the law: Prior to its promulgation, it was a clear regulatory violation for an insurer to use a copay accumulator program in circumstances where no generic drug equivalent was available and appropriate; after the 2021 NBPP, that very same conduct is expressly permitted by regulation. The government cannot escape this unavoidable fact, and with it, both the government's threshold arguments and the bulk of its merits contentions fall away. The 2021 NBPP is unlawful, and must be set aside.

ARGUMENT

I. PLAINTIFFS' CLAIMS ARE JUSTICIABLE.

The government begins with two justiciability arguments—but both lack any possible merit.

A. The government first contends that the 2021 NBPP "is essentially a decision to decline to set rules in this area and therefore does not constitute final agency action subject to review under the APA." Gov't Mem. 12; *see Bennett v. Spear*, 520 U.S. 154, 177-178 (1997) (to be final, "the action must mark the 'consummation' of the agency's decisionmaking process" and "must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'") (first quoting *Chi & S. Air Lines, Inc. v. Waterman S.S. Corp.*, 333 U.S. 103, 113 (1948), then quoting *Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970)). That argument is wrong on several counts.

First, the premise of this argument—that the 2021 NBPP "is essentially a decision to decline set rules"—is impossible to square with the facts. The 2021 NBPP does *not* decline to set rules; it revises the Code of Federal Regulations to explicitly permit copay accumulator programs: "[A]mounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct

support offered by drug manufacturers for specific prescription drugs . . . *are not required to be*[] counted toward the annual limitation on cost sharing." 45 C.F.R. § 156.130(h) (emphasis added); *see* 2021 NBPP, 85 Fed. Reg. at 29,261. There is a monumental difference between not having any rule with respect to certain conduct—particularly when, as the government concedes here, the statute reasonably could be interpreted to *prohibit* that conduct—and having a regulation explicitly permitting the conduct. *See, e.g.*, *Scenic Am., Inc. v. U.S. Dep't of Transp.*, 836 F.3d 42, 56 (D.C. Cir. 2016) (agency action that "create[d] a safe harbor such that" conduct adhering to its guidelines would not be disapproved had "legal consequences" and was final under the *Bennett* test). And in any event, "[i]t is well settled that the promulgation and publication of a final regulation after formal notice and comment is 'final' agency action"—which is precisely what occurred here. *Beverly Entrs., Inc. v. Herman*, 50 F. Supp. 2d 7, 12 (D.D.C. 1999).

Second, while it is enough the 2021 NBPP expressly authorizes certain conduct by regulated parties, it also affirmatively *rescinded* a prior regulatory prohibition, which independently qualifies as final agency action. That is, the 2021 NBPP legalizes conduct that was expressly illegal prior to the rule. As we have explained, the prior version of Section 156.130(h) provided that only manufacturer assistance amounts "for specific prescription brand drugs *that have an available and medically appropriate generic equivalent* are not required to be counted toward the annual limitation on cost sharing." 45 C.F.R. § 156.130(h) (version effective June 24, 2019 to July 12, 2020) (emphasis added); *see* Pls. Mem. 8-9. And the agencies, in adopting that language, made unmistakably clear that, in the absence of a medically appropriate generic equivalent, copay accumulators were unlawful: "Where there is no generic equivalent available or medically appropriate . . . amounts paid toward cost sharing using any form of direct support offered by drug manufacturers *must* be counted toward the annual limitation on cost sharing." 2020 NBPP, 84 Fed. Reg. at 17,545 (emphasis added).

In this way, regardless of whether the 2021 NBPP "require[s]" insurers to "do anything" (Gov't Mem. 13), the rule *permits* conduct that was flatly prohibited under the prior regulations. A rescission of a preexisting legal prohibition necessarily qualifies as final agency action, subject

to judicial review by aggrieved parties; such legalization of previously prohibited conduct by definition "alter[s] the legal regime." *Bennett*, 520 U.S. at 178.

Indeed, the government admits that, at least generally, "abrogation of a rule with final effect could itself constitute final agency action." Gov't Mem. 14. And of course that is correct: "[A]n amendment to a legislative rule must itself be legislative" (*Sierra Club v. EPA*, 873 F.3d 946, 953 (D.C. Cir. 2017)), and "a legislative rule is . . . necessarily final" under *Bennett* and APA Section 704 (*Cal. Communities Against Toxics v. EPA*, 934 F.3d 627, 635 (D.C. Cir. 2019)). Against this settled law, the government cannot seriously contend that a revision to the Code of Federal Regulations removing a legal prohibition that previously restrained the conduct of regulated parties lacks the kind of "legal consequences" that make an agency's action final. *Bennett*, 520 U.S. at 178. Unsurprisingly, the government has identified no case standing for that rather outlandish proposition.

For its part, the government concedes that its argument "is somewhat complicated by the fact" that the 2021 NBPP rescinded a previously existing legal prohibition. Gov't Mem. 14. That is quite an understatement—the 2021 NBPP's rescission of a prior legal prohibition flatly guts its justiciability argument.

The government's only argument to the contrary is its claim that "the 2020 Rule"—which had expressly prohibited accumulators except where a generic alternative was available and appropriate—"was effectively suspended and never actually enforced." Gov't Mem. 14; *see* AR004321 (August 2019 guidance document stating that "the Departments will not initiate an enforcement action" against insurers utilizing copay accumulators even where "there is no medically appropriate generic equivalent available."); Pls. Mem. 9 (discussing guidance).

Whatever it may have said about the agencies' enforcement discretion, however, this guidance did not alter the legal prohibition on copay accumulators contained in the 2020 NBPP—because it could not lawfully have done so. It is beyond cavil that, when a regulation is promulgated through notice and comment rulemaking, the only lawful way for an agency to suspend or rescind that regulation is through a new round of notice and comment. *See, e.g.*, *Clean Air Council*

v. Pruitt, 862 F.3d 1, 9 (D.C. Cir. 2017) ("[A]n agency issuing a legislative rule is itself bound by the rule until that rule is amended or revoked" and "may not alter such a rule without notice and comment.") (alteration incorporated, internal quotation marks omitted); *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 113 (2d Cir. 2018) (notice-and-comment "requirements apply with the same force when an agency seeks to delay or repeal a previously promulgated final rule," because "altering the effective date of a duly promulgated standard could be, in substance, tantamount to an amendment or rescission of the standards.") (quoting *Nat. Res. Def. Council v. Abraham*, 355 F.3d 179, 194 (2d Cir. 2004)); *Envt'l Def. Fund, Inc. v. EPA*, 716 F.2d 915, 920 (D.C. Cir. 1983) ("The suspension or delayed implementation of a final regulation normally constitutes substantive rulemaking under APA § 553," thus requiring "notice and comment"); *Nat'l Venture Capital Ass'n v. Duke*, 291 F. Supp. 3d 5, 15 (D.D.C. 2017) ("'An agency . . . may not alter [a legislative] rule without notice and comment,' nor does it have any inherent power to stay a final rule.") (quoting *Clean Air Council*, 862 F.3d at 9).

Thus, even if the agencies were not *enforcing* the 2020 NBPP's prohibition of copay accumulators, that prohibition remained on the books and remained binding on regulated parties until it was rescinded by the 2021 NBPP—the very agency action challenged here. *See, e.g.*, *Nat'l Ass'n of Mfrs. v. SEC*, __ F. Supp. 3d ___, 2022 WL 16727731, at *3-4 (W.D. Tex. 2022) (setting aside as *ultra vires* an agency's attempt to suspend the effectiveness of an existing regulation without notice and comment). Again, the government cites no case for its novel contention that the rescission of a legal prohibition somehow lacks finality if it is preceded by a decision not to enforce that prohibition.

In sum, the 2021 NBPP plainly "alter[s] the legal regime" governing copay accumulators (*Bennett*, 520 U.S. at 178) by revising the Code of Federal Regulations to explicitly authorize insurers to impose them. The test for final agency action demands nothing more—indeed, it demands substantially less. The agencies' action is final.

B. The government also briefly gestures at an argument that the issuance of the 2021 NBPP is unreviewable as "agency action committed to agency discretion by law" (5 U.S.C. § 701(a)(2)),

because (the government says) "it represents an exercise of HHS's discretion not to regulate." Gov't Mem. 15.

As just discussed, however, the 2021 NBPP is plainly *not* a decision "not to regulate"; it does not, for example, say "we decline to decide whether manufacturer assistance must be counted toward the cost sharing cap." Instead, it explicitly *permits* insurers to utilize copay accumulators by providing that manufacturer copay assistance amounts "*are not* required to be[] counted toward the annual limitation on cost sharing." 45 C.F.R. § 156.130(h) (emphasis added); *see* 2021 NBPP, 85 Fed. Reg. at 29,261.

In other words, Plaintiffs do not challenge the agencies' decision *whether or not* to regulate. *Cf.* Gov't Mem. 15-16 (arguing that the ACA "leaves to the Secretary's sole judgment to 'determine[]' when it is 'appropriate' to issue regulations"). Rather, Plaintiffs challenge the *product* of that decision, which is a binding legal pronouncement that, for the first time, insurers "are not required" to count manufacturer copay assistance "toward the annual limitation on cost sharing," without regard for the availability of a generic equivalent. 45 C.F.R. § 156.130(h); *see* 2021 NBPP, 85 Fed. Reg. at 29,261. And as to that action, there is most certainly "a meaningful standard against which to judge" its legality (Gov't Mem. 15 (quoting *Webster v. Doe*, 486 U.S. 592, 599-600 (1988))): *viz.* the statutory and regulatory definitions of cost sharing and the arbitrary and capricious standard. The "committed to agency discretion" exception to judicial review is thus plainly inapplicable here. There is no impediment to review of the 2021 NBPP.

II. THE 2021 NBPP IS CONTRARY TO BOTH STATUTE AND REGULATION.

On the merits, we explained that the 2021 NBPP's legalization of copay accumulator programs conflicts both with the statutory definition of cost sharing under the ACA, and even more plainly with the pre-existing regulatory definition, which the NBPP does not purport to amend or reinterpret.

In order to protect patients and ensure that healthcare does not become unaffordable, the ACA sets an annual limit on the cost sharing (deductibles, co-insurance, and the like) that an insurer may require of a covered patient. *See* 42 U.S.C. § 18022(c)(1) (providing that "cost-sharing

. . . shall not exceed" the result of a statutory formula). Once that limit is reached, the insurer must cover the remainder of the patient's medical costs for the year at 100 percent, and the patient cannot be required to pay anything more out of pocket. As we, and multiple *amici*, have explained, accumulator programs are an attempt to game this system: They refuse to credit amounts paid by a patient using manufacturer assistance against this annual maximum, with the result that the patient is actually required to obtain and pay substantially more than what the ACA permits. *See generally* Pls. Mem. 6-8, TrialCard Am. Br. (Dkt. 19) at 6-10. But, if the statutory definition of "cost sharing" in the ACA (or the regulatory definition in the agencies' pre-existing regulations) in fact encompasses amounts for which the patient is responsible regardless of whether she fulfils that obligation by seeking out and obtaining manufacturer assistance, then the ACA *requires* those amounts to be counted against the annual cost-sharing cap, and copay accumulator programs (which, by definition, exclude them) are unlawful.

As we explained, both the statute and the existing regulations do require manufacturer assistance to be counted as cost sharing. *See generally* Pls. Mem. 13-21. The statute defines "cost-sharing" with a focus on whether the expense is "required of an insured individual" in order to access her prescribed care (42 U.S.C. § 18022(c)(3)(A)), indicating that the relevant question is *whether* the patient must come up with funds before she may receive treatment, not *where* she turns to obtain those funds. Charges that a patient chooses to satisfy by obtaining manufacturer copay assistance are still "required of" the patient and are thus within the definition of cost-sharing, precluding copay accumulator schemes that seek to exclude them from cost-sharing calculations. *See* Pls. Mem. 13-16. And the regulatory definition makes this conclusion even more explicit, defining "[c]ost sharing" to include "any expenditure required by *or on behalf of*" the patient (45 C.F.R. § 155.20 (emphasis added)), a phrase that plainly encompasses payments made by manufacturers "on behalf of" individual patients, in order that those patients may access a drug. *See* Pls. Mem. 19-20.

A. As to the statutory definition, the government tellingly does *not* argue that our proposed interpretation is wrong. *See generally* Gov't Mem. 16-23. Indeed, the government affirmatively

acknowledges that our interpretation "is one possible reading of the statute," and argues only that the statutory definition "permits two interpretations and therefore is ambiguous." Gov't Mem. 16, 19; *see also id.* at 16 (section heading: "HHS correctly concluded that the statutory definition is ambiguous") (capitalization altered).

1. While, as we explain below, the government's claim of ambiguity is incorrect, its argument is non-responsive to our central point. An arguably ambiguous statute is not meaningless; it is simply susceptible to more than one reading. Thus, a reviewing court faced (as here) with a claim that the statute prohibits certain conduct must still render its best interpretation of that statute, even *if* ambiguous, based on the statutory text, structure, history, and precedent. *See, e.g.*, Antonin Scalia & Bryan A. Garner, *Reading Law* 233 (2012) (it is "never" the case that, "after applying all the normal tools of interpretation, an ambiguity cannot be resolved"); *cf.* pages 23-24, *infra*. That is especially so in circumstances where, as the government admits here,[3] there is no applicable deference regime.

And, as we have explained, the best interpretation of the ACA's cost-sharing definition is that it includes amounts, like manufacturer assistance, that are "required of" an insured individual, even if she obtains outside help in satisfying those "require[ments]." 42 U.S.C. § 18022(c)(3)(A).

If we are right that this is the best reading of the statute (and we are), it does not matter that the provision may be described as ambiguous; it still prohibits insurers from refusing to count manufacturer copay assistance against a patient's cost sharing obligations, which is precisely what copay accumulator programs do. The agencies' promulgation of a regulation that expressly permits that very same conduct is therefore contrary to statute, and must be set aside. *See, e.g.*, *Texas v. EPA*, 726 F.3d 180, 195 (D.C. Cir. 2013) (Kavanaugh, J.) ("A valid statute always prevails over a

[3] The government concedes (at 23 n.2) that *Chevron* deference is not warranted here. Nor does it argue for any lesser form of deference (*e.g.*, *Skidmore* deference).

conflicting regulation, and a regulation can never trump the plain meaning of a statute.") (alteration incorporated).[4]

2. Even setting aside the non-responsiveness of the government's ambiguity-based position, its statutory-interpretation points are not persuasive.

First, the government acknowledges that the definitions we cite for the listed terms in Section 18022(c)(3)(A) focus on who "bear[s] responsibility" for payment (Gov't Br. 19 (quoting Insurance, *Black's Law Dictionary* (11th ed. 2019)), but then puzzlingly posits that "nothing . . . suggest[s] that 'bear' in this context has anything to do with 'legal responsibility' . . . rather than who actually pays" (*id.*). But that is simply what responsibility *means*: Just as the Principal Deputy Assistant Attorney General "bears responsibility" for the government's litigation of this case even though he (presumably) did not personally write the briefs, a patient bears responsibility for meeting her coinsurance requirements even though she obtains the funds from a manufacturer, because she can only obtain her drugs upon that obligation being satisfied. *See, e.g.* Responsibility, *Black's Law Dictionary* (11th ed. 2019) ("1. The quality, state, or condition of being duty-bound, answerable, or accountable."). Whether a patient is "duty-bound" or "answerable" for a payment is a completely separate question from how the patient chooses to fund that payment.[5]

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[4] If an interpretive tie-breaker is required, it may be found in the patient-benefitting purpose of the ACA. *See, e.g.*, *Am. Chem. Council v. Whitman*, 309 F. Supp. 2d 111, 115 (D.D.C. 2004) ("When searching for the meaning of an ambiguous statutory provision, a court should focus on the broader structure and purpose of the statute."); *Cutler v. U.S. Dep't of Health & Human Servs.*, 797 F.3d 1173, 1175 (D.C. Cir. 2015) ("Congress enacted the Affordable Care Act in 2010 in an effort to increase the number of Americans covered by health insurance and decrease the costs of health care.") (quotation marks omitted). When interpreting an ambiguous provision intended to reduce patients' out-of-pocket costs and guarantee their access to life-saving treatment, it would be anomalous to choose a construction that permits a maneuver by insurers that significantly *increases* those costs and forecloses needed therapeutics. *See, e.g.*, Pls. Mem. 7 (reproducing table from AR004150, demonstrating how copay accumulators increase patient costs and result in a net transfer of value from the patient to the insurer).

[5] The government also attempts a gotcha, noting that the consumer-facing glossary on HealthCare.gov, which our brief cites for background purposes, refers to copayments and coinsurance as amounts that "you [i.e., the patient] pay." Gov't Br. 19. But a consumer-facing explainer of this type cannot be expected to include the level of legal nuance that is the focus of the dispute in this case.

In any event, the government has *no* response to our most fundamental point: that, even setting aside the definitions of the listed terms in Section 18022(c)(3)(A)(i), the overall provision refers to amounts "required of" the patient, a term that encompasses payment requirements that the patient satisfies by obtaining manufacturer assistance. 42 U.S.C. § 18022(c)(3)(A)(ii); *see* Pls. Mem. 14-15.

Next, the government quibbles at length with our drawing of the inference that, because "qualified medical expense" in clause (ii) is defined by statutory cross-reference not to include amounts "compensated by insurance or otherwise," clause (i), which contains no such cross-reference, is not similarly limited. Gov't Mem. 20-22; *see* Pls. Mem. 15. But the government misunderstands either our argument or the authorities on which it relies: We are not comparing clause (i) with the definition of qualified medical expense; we are comparing clause (i) to clause (ii), which *were* "enacted together" (Gov't Mem. 21), and *do* contain a clear "contrast" (*id.*)—one contains the cross-reference, and the other does not.[6]

Finally, the government asserts that our "interpretation is not internally consistent" because Plaintiffs have challenged only the 2021 NBPP, and not the 2020 NBPP that also permitted copay accumulators, though only where a generic equivalent is available and appropriate. Gov't Mem. 22-23. To be clear, Plaintiffs would be perfectly happy if the 2020 NBPP were set aside as well—they simply chose to focus on the 2021 NBPP's across-the-board approval of copay accumulators because (a) that egregious action is what specifically harms them, and (b) that is the only currently effective regulation. *Cf.* Pls. Mem. 38-42. Our theory is not that the 2021 NBPP is contrary to statute but the 2020 NBPP is not; the statutory validity of the pre-existing regulations is simply not at issue in this case.

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[6] The government's further, passing assertion that the specific-governs-the-general canon has application here (Gov't Mem. 22) is difficult to understand, because it is unexplained. *Cf., e.g.*, *Nat'l Parks Conservation Ass'n v. Semonite*, 422 F. Supp. 3d 92, 95 (D.D.C. 2019) ("It is not enough merely to mention a possible argument in the most skeletal way, leaving the court to do counsel's work.") (quoting *Schneider v. Kissinger*, 412 F.3d 190, 200 n.1 (D.C. Cir. 2005)).

B. As for the existing regulatory definition of cost sharing, the government has even less to say.

As we explained, that definition provides that "any expenditure required by *or on behalf of* an enrollee" counts as "[c]ost sharing" for ACA purposes. 45 C.F.R. § 155.20 (emphasis added); *see* Pls. Mem. 18-20. Even if there were any question whether amounts covered by manufacturer assistance are "required of" the patient under the statute, those copay assistance payments from manufacturers are undoubtedly made "on behalf of" the patient in question, and thus qualify as cost sharing under the existing regulations. *Id.* And because the agencies' approval of copay accumulators in the 2021 NBPP conflicts with that existing regulation—which the agencies have not purported to rescind, amend, or interpret away—the 2021 NBPP is unlawful. *Id.*; *see, e.g.*, *Nat'l Envt'l Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014) ("Although it is within the power of an agency to amend or repeal its own regulations, an agency is not free to ignore or violate its regulations while they remain in effect.") (alterations incorporated); *Huntington Hosp. v. Thompson*, 319 F.3d 74, 75 (2d Cir. 2003) (where an agency has promulgated "two separate [and concurrently effective] regulations construing the same act of Congress in a totally inconsistent manner[,] [s]uch administrative rulemaking cannot stand.").

The government does not dispute that, if the approval of copay accumulators in the 2021 NBPP conflicts with the pre-existing regulatory definition of cost sharing, it must be set aside. *See generally* Gov't Mem. 23-25. Instead, its only response, contained in a single paragraph of reasoning, is to quote the 2021 NBPP's conclusion that, while "[t]he value of the direct drug manufacturer support *can* be considered part of the overall charges incurred by the enrollee as the consumer cannot obtain the drug without providing the full amount owed," it also "could 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." 2021 NBPP, 85 Fed. Reg. at 29,234 (emphasis added); *see* Govt Mem. 24-25.

But this contention too is a non-sequitur, both when the agencies first made it in the 2021 NBPP and when the government invokes it now. First, this argument invokes a false dichotomy,

not present in the regulation, between "costs incurred by or charged to enrollees" on the one hand, and "a reduction . . . in the amount that the enrollee is required to pay" on the other. 2021 NBPP, 85 Fed. Reg. at 29,234. While that framework may be at least arguably coherent in analyzing the *statutory* definition—which, as discussed, focuses on expenditures "required of" the patient (*see* pages 8-11, *supra*—it does not address the regulations' "on behalf of" language whatsoever. *Cf.* 2021 NBPP, 85 Fed. Reg. at 29,231 (discussing this theory in connection with the "proposed interpretation" "of the PPACA" that the agencies ultimately declined to promulgate).

That is, *even if* a copay assistance payment is deemed to cause "a reduction . . . in the amount that the enrollee is required to pay at the point of sale" rather than representing a "cost[] incurred by" that patient (2021 NBPP, 85 Fed. Reg. at 29,234), that would do nothing to dispel the conclusion that a copay assistance payment from a manufacturer with respect to an individual patient remains an "expenditure required . . . *on behalf of* [that patient] with respect to essential health benefits," and therefore falls within the plain terms of the existing regulatory definition of "[c]ost sharing." 45 C.F.R. § 155.20 (emphasis added). In other words, the government has *still* not offered, either in the NBPP or in its brief, a text-based reading of the regulations under which a copay-assistance payment is *not* an "expenditure required . . . on behalf of" the patient. That failing is fatal to its position here, and to the lawfulness of the 2021 NBPP.

Finally, the government may not rest on its belated contention that the regulatory definition of cost sharing should be interpreted to focus on the "actual economic impact" on "the *drug manufacturer*" (Gov't Mem. 25 (emphasis added))—as opposed to the economic impact on the *patient*. That contention is an "impermissible 'post hoc rationalization'" (*DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1908-1909 (2020)) that was never raised by the agencies during the regulatory process.[7] And it is wrong in any event, because the regulatory text gives absolutely no indication that the "cost sharing" between patients and their insurers should actually be defined with reference

[7] *Cf.* 2021 NBPP, 85 Fed. Reg. at 29,233 (discussing, in the context of the purported conflict with IRS guidance, "the true economic cost *to the individual*") (emphasis added).

to the economic impact on third-party drug manufacturers or medical service providers. 45 C.F.R. § 155.20.

In sum, the agencies' authorization in the 2021 NBPP for insurers to utilize copay accumulator programs conflicts with the governing statute—and even if it did not, it absolutely conflicts with the pre-existing regulations that continue to bind the agencies. As to the latter point, the government hardly even offers a retort. That relative silence is telling. The Court should set aside the 2021 NBPP as "not in accordance with law." 5 U.S.C. § 706(2).

III. THE 2021 NBPP IS ARBITRARY AND CAPRICIOUS.

Our brief also explained that, apart from its conflict with both statute and regulation, the 2021 NBPP is arbitrary and capricious in multiple glaring respects. *See generally* Pls. Mem. 22-38. The theme of the government's response, again, is to assert that the 2021 NBPP does not actually do anything (and therefore cannot be objectionable); as the government would have it, the 2021 NBPP was simply "a decision not to resolve the ambiguity in the statute" (Gov't Mem. 25); a "continu[ation] [of] the policy of flexibility that pre-dated the 2020 Rule" (*id.* at 33); or a "decision to decline to set a definitive rule in this area" (*id.* at 35).

As we have already explained, none of that is true. Even setting aside the effect of the 2020 NBPP, which the 2021 NBPP explicitly reversed, prior to the agencies' action here there was no regulation either allowing or disallowing copay accumulators, and only a statute that (in the government's view) was "ambiguous" as to their permissibility. After the 2021 NBPP, there is now a binding regulation that *expressly permits* insurers to impose copay accumulators in any State that does not prohibit them. That is hardly a "decision to decline to set a definitive rule"; rather, it is a declaration that federal law does not prohibit accumulators, and that insurers are free to utilize them unless a particular State says otherwise. The 2021 NBPP represents a major change in the law—and as we have explained, one that was adopted through an arbitrary and capricious process.

A. To begin, we explained that the 2021 NBPP is fundamentally unlawful because it is premised on the notion that the same statutory text—the ACA's cost-sharing definition—can simultaneously both include and not include manufacturer copay assistance. Pls. Mem. 20-21; *see*

United States v. Santos, 553 U.S. 507, 522 (2008) (Supreme Court has "forcefully rejected" "giving the same word, in the same statutory provision, different meanings in different factual contexts") (citing *Clark v. Martinez*, 543 U.S. 371, 386 (2005)); *see also Clark*, 543 U.S. at 386 (rejecting the "dangerous principle that judges can give the same statutory text different meanings in different cases").

The government's response is again to attempt to recast what the agencies did here, asserting that they have "simply declined to step in and resolve statutory ambiguities as the issue continues to percolate among the states." Gov't Mem. 26. As an initial matter, the government's repeated references to state regulation are completely beside the point; the question in this case (and for the agencies in the rulemaking process) is the meaning of *federal* law—*i.e.*, whether the ACA and existing federal regulations define "cost sharing" in a way that permits insurers to utilize copay accumulators, or instead requires manufacturer copay assistance to be counted as cost sharing. Regardless of whether States choose to independently ban copay accumulators under state law, the interpretation of federal statutes and regulations is not subject to "percolat[ion] among the states."[8]

Moreover, as noted above, the challenged action here is *not* a decision not to decide. The agencies' reasoning, as reflected in the 2021 NBPP, was not simply that the ACA has nothing to say about this question one way or another, so regulated parties are free to do as they please; it was that the statute can be read in two different ways, *and regulated parties are free to choose which interpretation applies to them*:

[8] The regulated industry's related contention that copay accumulators are actually good because "most [States] opt to allow them" (AHIP Am. Br. (Dkt. 30), at 3)—apart from being irrelevant to the legal issues presented in this case—is misleading. Copay accumulators are a relatively new and little-known phenomenon and state legislatures are not agile institutions; even with those constraints, however, momentum is growing as more and more States take action to ban or restrict accumulators. *See, e.g.*, *More States Ban Harmful Co-Pay Accumulator Programs*, Health Policy Today (Sept. 7, 2022) (explaining that fifteen states plus Puerto Rico have enacted bans in the four years since the first state ban in 2019), perma.cc/Z3AW-EZ4M.

> For issuers who elect to include these [copay assistance] amounts towards a consumer's annual limitation on cost sharing, the value of direct drug manufacturer support would be considered part of the overall charges incurred by the enrollee. For issuers who elect to not count these amounts towards the consumer's annual limitation on cost sharing, the value of the direct drug manufacturer support would be considered a reduction in the amount that the enrollee incurs or is required to pay.

2021 NBPP, 85 Fed. Reg. at 29,234. Plainly, that is not a reservation of the question for future regulatory action; it is a blessing for regulated entities to use *either* interpretation of the statute and regulation (*i.e.*, either that manufacturer copay assistance is encompassed within the "cost sharing" definition, or that it is not) as they see fit. And that reasoning is carried out in the final regulation, which does *not* say, for example, that the agencies take no position on whether the ACA requires copay assistance to be counted as cost sharing; instead, it affirmatively states that copay assistance amounts "are not required to be[] counted toward the annual limitation on cost sharing." 45 C.F.R. § 156.130(h); *see* 2021 NBPP, 85 Fed. Reg. at 29,261.

Although the agencies' lawyers may now wish it were otherwise, the 2021 NBPP thus affirmatively authorizes copay accumulators if insurers choose to implement them; it does not simply reserve the interpretive question for a later date. And it does so by telling those insurers that they get to choose which of two competing statutory interpretations applies to them. As we have explained, no principle of law permits a single statutory provision to simultaneously mean two diametrically opposed things—much less that each regulated party gets to choose which of these conflicting interpretations applies to it. The 2021 NBPP must be set aside on this basis, as well.

B. We also demonstrated that the agencies reversed course from the 2020 NBPP—which limited the use of copay accumulators to drugs for which a generic equivalent was available and medically appropriate—without justifying their departure from their prior factual findings that, in the absence of an available generic, "the use of the manufacturer coupon would not disincentivize a less expensive choice," and thus would not "distort the market," which was the agencies' entire rationale for permitting copay accumulators in the first place. 2020 NBPP, 84 Fed. Reg at 17,545; *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-516 (2009) ("[A] reasoned explanation is

needed for disregarding facts and circumstances that underlay . . . the prior policy."); *see* Pls. Mem. 32-34. Moreover, we explained that the only point raised in the 2021 NBPP that could even conceivably justify its about-face without a repudiation of those factual findings—a potential conflict with tax law—was illusory, and the agencies' reliance on that supposed conflict would thus require setting aside the rule. Pls. Mem. 23-29.

In response, the government makes a curious maneuver. It says that the 2021 NBPP did *not* actually determine that there was a conflict between the tax laws and the 2020 NBPP's prohibition of copay accumulators in the absence of a generic equivalent. Gov't Mem. 29 ("HHS did not, and was not required, as Plaintiffs imply, to find that the IRS rule directly conflicted with the 2020 rule or to delve into the sources or correctness of the IRS's interpretation."). Instead, the government says, "HHS felt that, as a matter of policy, it preferred not to require issuers and plans to follow a course that created a *potential* conflict." *Id.* (emphasis added).[9] This argument by the government runs into at least three fundamental problems.

First, the government's after-the-fact account of the agencies' decisionmaking—*i.e.*, that they "did not . . . find that the IRS rule directly conflicted with the 2020 Rule" (Gov't Br. 29)—is at odds with what the agencies said at the time. In the 2021 NBPP itself, the agencies explained their action by stating, in declaratory language, that "section 223 of the [Internal Revenue] Code" does not permit a high-deductible health plan (HDHP) "to credit the deductible in a manner that does not reflect the actual cost of medical care to the individual." 2021 NBPP, 85 Fed. Reg. at 29,233. Thus, they went on, "[i]f a third party . . . such as a drug manufacturer, has arranged for a rebate or discount . . . whether via a drug discount card or a drug coupon, the true economic cost

[9] The government also finds it "[n]otabl[e]" that "Plaintiffs themselves have not challenged the IRS guidance itself" (Gov't Mem 29), but does not explain either (a) why that might be relevant, or (b) how Plaintiffs could have "challenged" a guidance document that is neither final agency action nor within the statute of limitations, having been issued in 2004. *See, e.g.*, *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014) ("[G]eneral statements of policy," such as guidance documents, are not "subject to pre-enforcement judicial review."); *Peri & Sons Farms, Inc. v. Acosta*, 374 F. Supp. 3d 63, 70 (D.D.C. 2019) (APA claims "are subject to the [six-year] statute of limitations set forth in 28 U.S.C. § 2401.").

to the individual is the net amount incurred. Accordingly, to meet the requirements of section 223 of the Code, an HDHP *may only* take into account that net amount when determining whether the individual has satisfied the deductible." *Id.* (emphasis added).

The next sentence: "Therefore, a conflict between the HHS policy finalized in the 2020 Payment Notice and the provisions of section 223 of the Code and the IRS guidance may exist for issuers who elect to include drug manufacturer support amounts towards the consumer's deductible and annual limitation on cost sharing if the consumer is enrolled in an HDHP coupled with an HSA." 2021 NBPP, 85 Fed. Reg. at 29,233.

That language speaks for itself: When issuing the 2021 NBPP, the agencies determined that—under their interpretation of tax law—"an HDHP may only take into account [a patient's] net" costs for a drug, after netting out any manufacturer assistance, because "section 223" prohibits HDHPs from "credit[ing] the deductible in a manner that does not reflect the actual cost of medical care to the individual." 2021 NBPP, 85 Fed. Reg. at 29,233. That is not tentative language; it is a declarative statement about what tax law requires, and it is flatly inconsistent with crediting manufacturer assistance against patients' deductibles, which is precisely what the 2020 NBPP required insurers to do unless a generic equivalent was available and medically appropriate. *See* 2020 NBPP, 84 Fed. Reg. at 17,545 ("Where there is no generic equivalent available or medically appropriate . . . amounts paid toward cost sharing using any form of direct support offered by drug manufacturers *must* be counted toward the annual limitation on cost sharing.") (emphasis added). Thus, in the agencies' view, "a conflict . . . may exist" between the 2020 NBPP and "the provisions of section 223 of the Code and IRS guidance." 2021 NBPP, 85 Fed. Reg. at 29,233.

In view of these unequivocal statements that the tax law is incompatible with the 2020 NBPP's requirements, the government's current litigation stance that the agencies "did not . . . find that the IRS rule directly conflicted with the 2020 Rule" (Gov't Br. 29), is "impermissible 'post hoc rationalization,'" and cannot rescue the agencies' erroneous tax-law analysis. *Regents*, 140 S. Ct. at 1909; *see also id.* at 1908 ("It is a 'foundational principle of administrative law' that judicial review of agency action is limited to 'the grounds the agency invoked when it took the action.'")

(quoting *Michigan v. EPA*, 576 U.S. 743, 758 (2015)); *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943); *Sea-Land Serv., Inc. v. Dep't of Transp.*, 137 F.3d 640, 646 (D.C. Cir. 1998) ("An agency action, however permissible as an exercise of discretion, cannot be sustained 'where it is based not on the agency's own judgment but on an erroneous view of the law.'") (quoting *Prill v. NLRB*, 755 F.2d 941, 947 (D.C. Cir. 1985)).

Second, even taking the government at its word that the agencies did *not* actually determine that there was a conflict and instead simply acknowledged the possibility, the 2021 NBPP would then be arbitrary and capricious for a different reason: failure to adequately respond to the "many commenters" who explained to the agencies "that the rule does not conflict with rules relating to HDHPs with HSAs." 2021 NBPP, 85 Fed. Reg. at 29,233; *see, e.g.*, AR003575 (comment explaining that no conflict exists); AR002674 (same); *see also* Pls. Mem. 27-28 (collecting additional examples). As the D.C. Circuit has repeatedly explained, an agency "must respond to comments that can be thought to challenge a fundamental premise underlying the proposed agency decision" (*Carlson v. Postal Reg. Comm'n*, 938 F.3d 337, 344 (D.C. Cir. 2019)), and "[n]odding to concerns raised by commenters only to dismiss them in a conclusory manner" does not satisfy this obligation (*Gresham v. Azar*, 950 F.3d 93, 103 (D.C. Cir. 2020), *vacated as moot*, 142 S.Ct. 166 (2022)). In the government's current counterfactual view, the agencies responded to comments asserting that there is no conflict by simply observing that there is confusion about whether a conflict exists, without taking a position on whether the conflict is actually real. That non-sequitur cannot satisfy the agencies' obligation to provide reasoned responses to important comments.

Third, even if all of the above were wrong, the result of the government's argument is the following: (1) the agencies have previously said that a policy (allowance of copay accumulators) is only justified as a policy matter in one narrow circumstance (where a generic is available, *see* page 16, *supra*); (2) then, *without* repudiating that factual finding, the agencies have now extended that policy to *all other* circumstances (*i.e.*, circumstances where it is *not* justified); and (3) the government's sole rationale for doing so is the existence of what it now claims are *unsubstantiated* concerns about a potential conflict between the narrow policy and the tax law. If that truly is the

scope of the agencies' action here, it fails the most fundamental requirement of "reasoned decisionmaking": that the decision "be both reasonable and reasonably explained." *Villareal-Dancy v. U.S. Dep't of Air Force*, __ F. Supp. 3d ___, 2022 WL 4482597, at *9 (D.D.C. 2022) (quoting *Ind. Boxcar Corp. v. R.R. Ret. Bd.*, 712 F.3d 590, 591 (D.C. Cir. 2013)).

In other words, if the government is right, then the agencies threw the baby out with the bathwater when they jettisoned any connection between the justification of the policy and the policy's scope, all because of the *potential* for a legal conflict that the government now says the agencies never confirmed to actually exist. In that case, the agencies have failed to "dr[a]w a 'rational connection between the facts found and the choice made," and their action cannot be sustained. *Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 41 F.4th 586, 595 (D.C. Cir. 2022) (quoting *Motor Vehicles Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).[10]

C. We further explained that the agencies' treatment of the costs to patients from their approval of copay accumulators is arbitrary and capricious. In particular, the agencies essentially assumed away the predictable costs to patients by asserting that insurers would act against their economic interests by failing to take advantage of the newly legalized copay accumulators. Pls. Mem. 29-32; *see, e.g.*, *Am. Trucking Ass'ns, Inc. v. Fed. Motor Carrier Safety Admin.*, 724 F.3d 243, 248 (D.C. Cir. 2013) ("[W]e think it 'a hardly-speculative exercise in naked capitalism' to suggest motor carriers would respond to the hours-increasing provisions by requiring their drivers to use them and work longer days.") (quoting *Abigail Alliance for Better Access to Dev. Drugs v. Eschenback*, 469 F.3d 129, 135 (D.C. Cir. 2006)).

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[10] The government also now suggests that the agencies' "[f]irst" justification was "administrative difficulties posed by the 2020 rule." Gov't Br. 27. But that notion appears in only a single sentence in the 2021 NBPP, which merely states that comments were received along those lines, and does not assert that the agencies were adopting those concerns as the basis of their action. *See* 2021 NBPP, 85 Fed. Reg. at 29,233 ("For example, stakeholders raised questions related to certain administrative issues related to how to determine and apply the net amount to the deductible when an individual receives this type of payment."). Even if the government's current contention were credited, the addition of a single sentence regarding "questions related to certain administrative issues" does not meaningfully change the calculus.

In response, the government contends that it was reasonable for the agencies to assume insurers would not adopt copay accumulators *en masse* because, "[u]p through the 2019 plan year, HHS had not regulated the use of copay accumulator programs, and therefore plans or issuers were free to adopt them," but "not all had done so." Gov't Br. 34. But this argument does not account for the difference, in terms of the impact on insurers' incentives, between a situation with no regulation one way or the other regarding the legality of copay accumulators (and, per the government, a statute that could reasonably be read to prohibit them), and the post-2021 NBPP world in which federal regulators have explicitly approved their use. In the former situation, a risk-averse company would have doubts about imposing what might be an unlawful practice on patients; in the latter, the insurer would have no such concerns.

In any event, we further demonstrated that the incentives for insurers to adopt copay accumulators after the 2021 NBPP were not merely hypothetical; instead, the undisputed evidence in the comment record before the agency was that insurers had *already begun* to adopt more accumulators after the agencies announced they would not be enforcing the 2020 NBPP's general prohibition on such schemes. Pls. Mem. 30-31. Thus, while courts may generally credit agencies' "predictions regarding the actions of regulated entities" (Gov't Mem. 34 (quoting *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin*, 374 F.3d 1251, 1260-1261 (D.C. Cir. 2004)), here those predictions were contrary not only to economic logic and common sense, but to record evidence as well, making this case far from "routine[]" (*id.*). *See also, e.g.*, *State Farm*, 463 U.S. at 43 ("Normally, an agency rule would be arbitrary and capricious if the agency . . . offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."). The government does not respond. This failure of reasoned decisionmaking, too, demands vacatur.[11]

[11] The government also invokes the agencies' statement that, "[g]iven the multitude of variables and considerations that are out of HHS's control, we cannot predict th[e] burden [on patients] with sufficient certainty." 2021 NBPP, 85 Fed. Reg. at 29,232; *see* Gov't Mem. 35. But that subsequent assertion cannot change the fundamental failing that occurred earlier in the agencies' analysis:

D. Finally, we explained that the agencies' reasoning was arbitrary and capricious in two additional respects: The agencies failed to analyze whether their prohibition on copay accumulators (except where generic alternatives were available) in the 2020 NBPP had generated reliance interests that had to be taken into account (Pls. Mem. 34-36); and, 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, the agencies failed "to treat like cases alike" (*Nat'l Weather Service Emps. Org. v. Fed. Labor Relations Auth.*, 966 F.3d 875, 883 (D.C. Cir. 2020); *see* Pls. Mem. 36-38).

The government asserts that the agencies did not need to consider reliance on "the 2020 Rule, which was never enforced,"[12] and that "the evidence Plaintiffs cite . . . does not show harm caused by decisions made *as a result of reliance* on the 2020 Rule." Gov't Mem. 32. As the Supreme Court observed in *Regents*, however, these objections "are surely pertinent in considering the strength of any reliance interests, but that consideration *must be undertaken by the agency in the first instance*, subject to normal APA review." 140 S. Ct. at 1913-1914 (emphasis added); *see also id.* (setting aside agency action because "[t]here was no such consideration in the [challenged document]"). Indeed, the Court explained, it is "the agency's job"—not that of its counsel in later litigation—to affirmatively evaluate the existence and strength of any reliance interests: "[B]ecuase DHS was not writing on a blank slate, it *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. But just like in *Regents*, the agencies here failed to demonstrate that they did any of these things—and the absence of any inquiry into reliance interests renders their decision arbitrary and capricious. *See id.* ("Acting Secretary Duke should have considered those matters but did not. That failure was arbitrary and capricious in violation of the APA.").

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assuming, contrary to both logic and record evidence, that insurers would generally act against their economic interests by declining to institute copay accumulator programs.

[12] As noted above, an agency's decision not to enforce a rule does not deprive that rule of binding legal effect on regulated parties (*see* pages 5-6, *supra*), and thus cannot foreclose the existence of reliance interests as a legal matter.

As for treating like cases alike, the government goes back to the well of claiming that the 2021 NBPP does not actually do anything, asserting that, because "[t]he rule provides complete flexibility" over whether to count manufacturer assistance against a patient's cost-sharing obligations, "all forms of assistance are, for the time being, treated the same under HHS's regulations." Gov't Br. 37-38. Again, however, this argument disregards the difference between an *actual* lack of regulation regarding a practice—such as the agencies' current approach to non-manufacturer patient assistance, whose ability to be excluded from cost-sharing is governed only by a statute the government says is ambiguous—and the *existence* of regulation affirmatively *permitting* regulated parties to engage in that practice, notwithstanding a statute that could reasonably be read to prohibit it. With that difference in mind, the agencies have failed "to treat like cases alike," in violation of a "fundamental norm of administrative procedure." *Nat'l Weather Service Emps. Org.*, 966 F.3d at 883. And as for the government's assertion that agencies need not "resolve massive problems in one fell regulatory swoop" (Gov't Mem. 38 (quotation marks omitted)), that may be so—but when such an "incremental" approach (*id.*) results in "treating similarly situated parties differently," the agency still "must provide an adequate explanation to justify" that disparate treatment. *Wilhelmus v. Geren*, 796 F. Supp. 3d 157, 162 (D.D.C. 2011) (quoting *Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 776 (D.C. Cir. 2005)). It is the lack of any such "adequate explanation," not the disparate treatment itself, that renders the agencies' action arbitrary and capricious here.

IV. THE COURT SHOULD VACATE, NOT "REMAND THE CASE TO THE AGENCY FOR FURTHER RULEMAKING."

In its final section, the government requests that, "[i]f the Court agrees that the statute is ambiguous but concludes that the agency's rule is nevertheless arbitrary and capricious, it should remand to the agency for further rulemaking, rather than attempting to arrive at its own interpretation." Gov't Br. 39; *see, e.g.*, *Teva Pharm. USA, Inc. v. FDA*, 441 F.3d 1, 4-5 (D.C. Cir. 2006) ("We . . . generally remand for an agency to make the first interpretation of an ambiguous statutory term when it has failed to do so previously.").

First of all, this principle is inapplicable here. Though the government claims the 2021 NBPP does not interpret the ACA, the rule expressly provides that manufacturer assistance amounts "are not required to be[] counted toward the annual limitation on cost sharing" (45 C.F.R. § 156.130(h); *see* 2021 NBPP, 85 Fed. Reg. at 29,261), and thus plainly contains at least an implicit interpretation that the ACA's definition of cost-sharing is compatible with that exclusion. Plaintiffs challenge that interpretation of the statute and claim that the ACA does *not* permit manufacturer assistance to be excluded from cost sharing. Unlike in the government's cases, therefore, that statutory interpretation question is properly teed up for this Court's review. That is, "[t]he actual holding of *Prill* and the cases following it"— the line of cases on which the government relies here— "is this: when an agency incorrectly concludes that Congress mandated a particular regulatory interpretation of a statute—and the agency therefore stops itself at *Chevron* step one—this court will vacate and remand." *Noble Energy, Inc. v. Salazar*, 671 F.3d 1241, 1246 n.5 (D.C. Cir 2012). That situation is not presented here.[13]

Moreover, unlike the remand-without-vacatur doctrine (*see, e.g.*, *Allied-Signal, Inc. v. U.S. Nuclear Reg. Comm'n*, 988 F.2d 146, 150-151 (D.C. Cir. 1993)), the cases make plain that the result of the government's argument, even if it did apply, would be that "this court will vacate *and* remand." *Noble Energy*, 671 F.3d at 1246 n.5 (emphasis added); *accord, e.g.*, *Teva*, 441 F.3d at 5 ("We therefore vacate the district court's judgment and remand with instructions to vacate the FDA's decision and remand to the agency for further proceedings."). This argument therefore does not permit the 2021 NBPP's approval of copay accumulator programs to remain in place during

[13] If the Court were to disagree, Plaintiffs further preserve the argument that the *Prill-Teva* line of cases—premised, as it is, on *Chevron*'s notion that "[w]hen a statute is ambiguous, Congress has left a gap for the agency to fill," and that a reviewing court's interpretive role is therefore constrained (*Teva*, 441 F.3d at 4-5)—is inconsistent with "the judicial duty to provide an independent judgment of the law's meaning in the cases that come before the Nation's courts," and should therefore be overturned or reconsidered. *Buffington v. McDonough*, 143 S. Ct. 14, 14-22 (2022) (Gorsuch, J., dissenting from denial of certiorari).

the pendency of any further proceedings before the agency, should the Court find remand appropriate.

CONCLUSION

For the foregoing reasons, the Court should grant summary judgment in favor of Plaintiffs, deny the government's cross-motion, and set aside the 2021 NBPP's authorization of copay accumulator programs.

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Respectfully submitted,

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