UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, *et al.*, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	)	Case No. 1:20-cv-5583-AKH

DEFENDANTS' REPLY IN SUPPORT OF THEIR ASSERTION OF MOOTNESS

It is "a perfectly uncontroversial and well-settled principle of law," *Akiachak Native Cmty. v. U.S. Dep't of the Interior*, 827 F.3d 100, 113-14 (D.C. Cir. 2016), that when "the law that is the basis for the complaint has been replaced by a new law during the case's pendency[,]" the case is moot, *Am. Coll. of Pediatricians v. Becerra ("ACP")*, No. 23-5053, 2024 WL 3206579, at *2 (6th Cir. June 27, 2024) (per curiam). By promulgating the 2024 Rule, HHS has "wiped the slate clean on Section 1557[,]" rendering Plaintiffs' challenge to a prior rule moot. *Id*. at *1.

In opposing dismissal on mootness grounds, Plaintiffs do not focus on the voluntary conduct of the United States Department of Health and Human Services ("HHS"). Rather, Plaintiffs focus entirely on preliminary district court orders that restrain HHS from enforcing certain provisions of the 2024 Rule pending resolution of those cases.[1] But that analysis ignores the "relevant question" in a case like this one, which "is whether the defendant's conduct has been sufficiently altered so as to present a substantially different controversy from the one that existed

[1] Defendants identified those orders in their opening brief. Mem. in Supp. of Defs.' Assertion of Mootness at 5 n.2, ECF No. 180. Since Defendants' opening brief, one of those orders has been modified. Specifically, on August 30, 2024, the district court in *Texas v. Becerra*, No. 6:24-cv-211 (E.D. Tex.), issued an order modifying its earlier order granting the *Texas* plaintiffs preliminary relief. Order Modifying Stay at 4, *Texas v. Becerra*, No. 6:24-cv-211 (E.D. Tex. Aug. 30, 2024), ECF No. 41.

when the suit was filed." *Am. Freedom Def. Initiative v. Metro. Transp. Auth.*, 815 F.3d 105, 109 (2d Cir. 2016) (cleaned up and citation omitted). And by insisting that a live controversy between the parties remains because of preliminary district court orders that HHS opposed, Plaintiffs disregard the adversariness element of an Article III case or controversy. Plaintiffs cite no authority for the premise that they can use this case—where the parties lack any ongoing controversy—to obtain an advisory opinion that HHS's arguments in other courts in defense of provisions of the 2024 Rule are correct. Any relief Plaintiffs still seek would be advisory in nature because it would not affect HHS's conduct in any identifiable way. Because this case is moot, it should be dismissed without prejudice.

ARGUMENT

I. Even Assuming an Existing Controversy, Plaintiffs' Opposition Shows it is Substantially Different from the Controversy that Existed When the Complaint Was Filed.

Assuming some controversy still exists between the parties—and one does not—this case is moot under the governing legal standard. Plaintiffs focus on preliminary district court orders preventing HHS from enforcing a handful of provisions of the 2024 Rule. Pls.' Mem. of Law in Opp'n to Defs.' Assertion of Mootness at 9-13, ECF No. 191 ("Pls.' Mem."). But that emphasis ignores "[t]he relevant question," which "is whether the defendant's conduct has been 'sufficiently altered so as to present a substantially different controversy from the one' that existed when [this] suit was filed." *Am. Freedom Def. Initiative*, 815 F.3d at 109 (quoting *Lamar Advert. of Penn, LLC v. Town of Orchard Park*, 356 F.3d 365, 378 (2d Cir. 2004)). HHS's promulgation of the 2024 Rule meets that standard.

As an initial matter, Plaintiffs' narrow focus on a few claimed "key provisions" of the 2024 Rule ignores the full scope of this case. Pls.' Mem. at 8. This case involves claims having little to do with those provisions. For example, Plaintiffs challenge the 2020 Rule's provisions that (1) addressed the scope of covered entities, Mem. of Law in Supp. of Pls.' Renewed Mot. for Summ. J. on Administrative Procedure Act Claims at 28-36, ECF No. 109; (2) purportedly

incorporated a religious exemption and abortion neutrality provision from Title IX, *id*. at 41-42, 67-70; and (3) governed language access, *id*. at 60-67. Plaintiffs do not dispute that the 2024 Rule superseded those provisions and that no district court order precludes HHS from enforcing the 2024 Rule's provisions in these areas. As Plaintiffs point out, they "sought declaratory and injunctive relief as *to [the entirety of] the 2020 Rule*." ECF No. 191 at 12. For that reason alone, this is "a substantially different controversy from the one that existed when the suit was filed." *Am. Freedom Def. Initiative*, 815 F.3d at 109 (cleaned up).

Plaintiffs' other claims challenging the 2020 Rule similarly do not remain live. Consider, for example, Plaintiffs' claim that "HHS failed to consider *Bostock*'s application to Section 1557." ECF No. 109 at 44. Since this suit was filed, HHS has now considered the impact of *Bostock* for Section 1557 not once but twice. First, in 2021, HHS explicitly considered the *Bostock* decision's impact for Section 1557 in issuing a Notification. Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, 86 Fed. Reg. 27,984, 27,985 (May 25, 2021). That Notification resolved any confusion about HHS's understanding of the scope of discrimination on the basis of sex divined from statements in the preamble to the 2020 Rule. *See* ECF No. 109 at 45.[2] Specifically, the Notification stated that HHS intended to interpret and enforce Section 1557's prohibition on discrimination on the basis of sex to include discrimination on the basis of sexual orientation and gender identity. 86 Fed. Reg. at 27,984. Second, HHS again considered the impact of *Bostock* when it codified that same interpretation as part of the 2024 Rule. *See* 45 C.F.R. § 92.101(a)(2). As the agency explained in the preamble, "the inclusion of 'sexual orientation' and 'gender identity' in § 92.101(a)(2) is consistent with the Supreme Court's reasoning in *Bostock*." 89 Fed. Reg. at 37,574. Given these developments, HHS's "conduct has been sufficiently altered so as to present

[2] Statements in the 2020 Rule's preamble are not themselves the challenged agency action at issue in this case, nor did any such statements dictate the scope of prohibited discrimination before the 2020 Rule was superseded by the 2024 Rule. *Accord Washington v. HHS*, 482 F. Supp. 3d 1104, 1114 n.8 (W.D. Wash. 2020).

a substantially different controversy from the one that existed when suit was filed." *Am. Freedom Def. Initiative*, 815 F.3d at 109 (cleaned up).

Plaintiffs' opposition fails to engage with this mootness standard. Again, they focus their argument on the district court orders that preliminarily restrain the agency from enforcing several provisions of the 2024 Rule. Pls.' Mem. at 9-13. But any attempt by Plaintiffs to seek prospective relief against HHS in light of these orders presents an entirely different case than the one filed in 2020. "These new attacks on [HHS's] conduct are 'qualitatively different' from those contained in [Plaintiffs'] complaint and reflect the formation of a sufficiently different controversy for mootness purposes." *Am. Freedom Def. Initiative*, 815 F.3d at 109 (quoting *Lamar*, 356 F.3d at 378 n.16).

II. Plaintiffs' Opposition Ignores the Adversariness Element of Mootness Doctrine and Any Relief Would Be Advisory in Nature.

Plaintiffs' argument that a live controversy remains between the parties to this lawsuit "because courts have . . . issued orders" that restrain HHS from enforcing provisions of the 2024 Rule, Pls.' Mem. at 13, ignores Article III's adversariness requirement. That requirement demands "a substantial controversy, between parties having adverse legal interests[.]" *Golden v. Zwickler*, 394 U.S. 103, 108 (1969) (citation omitted). But this standard is not met because the preliminary orders invoked by Plaintiffs were issued over HHS's objections and in contravention of HHS's view of the law. Plaintiffs, moreover, do not dispute that HHS's 2024 Rule is consistent with Plaintiffs' view of the law too. For example, insofar as Plaintiffs claim that Section 1557's prohibition on discrimination on the basis of sex includes discrimination on the basis of gender identity, ECF No. 109 at 39, HHS agrees, meaning there is no live controversy. The 2024 Rule provides, at 45 C.F.R. § 92.101(a)(2)(iv), that discrimination on the basis of sex includes discrimination on the basis of gender identity. As another example, the parties agree on the scope of covered entities governed by Section 1557. *Compare* ECF No. 109 at 28-36, *with* 45 C.F.R. § 92.2(a) (2024). Orders issued by district courts in other cases that preliminarily restrain HHS from taking enforcement action against covered entities consistent with the views of the parties

here that discrimination on the basis of sex includes discrimination on the basis of gender identity do not create a substantial controversy between the parties in this suit. Any injury to Plaintiffs no longer stems from HHS's voluntary conduct, but rather the decisions issued by those district courts. *Iron Arrow Honor Soc'y v. Heckler*, 464 U.S. 67, 72 (1983) (case moot when injury no longer turned on defendant's conduct but rather the "acts of a third-party non-defendant").

Plaintiffs' arguments also ignore the Court's related duty under Article III to avoid issuing an advisory opinion. Plaintiffs argue that continuing with this litigation would not lead to an advisory opinion because "Defendants have not conceded that [unspecified] parts of the 2020 Rule [were] invalid." Pls.' Mem. at 13. But in considering whether any opinion issued by the Court would be advisory, the issue is not whether there remains a spirited abstract dispute about whether HHS violated the Administrative Procedure Act ("APA") when it promulgated the 2020 Rule. Rather, if the Court's judgment, as a practical matter, "would accomplish nothing" to change a defendant's conduct, it "amount[s] to exactly the type of advisory opinion Article III prohibits." *Larsen v. U.S. Navy*, 525 F.3d 1, 4 (D.C. Cir. 2008). "[A] request for a declaratory judgment as to a past violation cannot itself establish a case or controversy to avoid mootness." *Exxon Mobil Corp. v. Healey*, 28 F.4th 383, 394-95 (2d Cir. 2022). As the Supreme Court has explained:

> In all civil litigation, the judicial decree is not the end but the means. At the end of the rainbow lies not a judgment, but some action (or cessation of action) by the defendant that the judgment produces—the payment of damages, or some specific performance, or the termination of some conduct. Redress is sought *through* the court, but from the defendant. This is no less true of the declaratory judgment suit than of any other action. The real value of the judicial pronouncement—what makes it a proper judicial resolution of a 'case or controversy' rather than an advisory opinion—is in the settling of some dispute *which affects the behavior of the defendant toward the plaintiff*.

Rhodes v. Stewart, 488 U.S. 1, 3-4 (1988) (quoting *Hewitt v. Helms*, 482 U.S. 755, 761 (1987)).

Plaintiffs' opposition focuses on the claimed availability of "declaratory and injunctive relief as to the 2020 Rule." Pls.' Mem. at 12 (emphasis omitted). But Plaintiffs do not explain how any relief would affect HHS's conduct toward them or anyone else. For example, Plaintiffs could not expect HHS to respond to a declaratory judgment, an injunction, or a vacatur order with

respect to the 2020 Rule by conducting a new rulemaking. HHS already did that—on May 6, 2024, HHS promulgated the 2024 Rule, which Plaintiffs do not dispute is consistent with their view of the law.

Nor is relief available to guide a hypothetical future rulemaking. Even when an agency announces its intent to propose new regulations—which HHS has not done here—courts are clear that "[i]t would be entirely inappropriate for [a] court to . . . issue an advisory opinion to guide the Secretary's rulemaking." *Alaska v. USDA*, 17 F.4th 1224, 1228 (D.C. Cir. 2021) (quoting *Nat'l Wildlife Fed'n v. Hodel*, 839 F.2d 694, 742 (D.C. Cir. 1998)).

Nor have Plaintiffs explained how their proposed relief would affect HHS's enforcement of Section 1557 at all. Consider if this Court entered a judgment against HHS in favor of Plaintiff New York declaring that HHS's promulgation of the 2020 Rule violated the APA. If New York thereafter refers a complaint to HHS's Office for Civil Rights alleging that a health care provider has violated Section 1557 by subjecting an individual to discrimination on the basis of gender identity, HHS would not be permitted to take enforcement action against that provider without violating district court orders in other cases. For example, HHS is presently preliminarily enjoined "nationwide from enforcing, relying on, implementing, or otherwise acting pursuant to the [2024 Rule] to the extent that the [2024 Rule] provides that 'sex' discrimination encompasses gender identity [discrimination]." Preliminary Injunction at 2, *Tennessee v. Becerra*, No. 1:24-cv-00161-LG-BWR (S.D. Miss. July 3, 2024). "[T]hose who are subject to the commands of an injunctive order must obey those commands, notwithstanding eminently reasonable and proper objections to the order, until it is modified or reversed." *Pasadena City Bd. of Educ. v. Spangler*, 427 U.S. 424, 439-40 (1976). Plaintiff's proposed relief would not affect any of that. It "would be essentially advisory in nature." *Georgia v. Wheeler*, No. 2:15-cv-00079, 2020 WL 6948800, at *3 (S.D. Ga. Jan 3, 2020). And insofar as Plaintiffs are seeking an order that would force HHS to implement the law and process complaints in a manner that would violate other courts' orders, that would be the very "collateral attack" on other courts' injunctive orders that is unavailable and that Plaintiffs

disclaim to be seeking from this Court. Pls.' Mem. at 13 (citation omitted); *Celotex Corp. v. Edwards*, 514 U.S. 300, 313 (1995); *Miller v. Benson*, 68 F.3d 163, 165 (7th Cir. 1995).

III. This Case is Moot Because the 2024 Rule is "On the Books."

"When a plaintiff's complaint is focused on a particular statute, regulation, or rule and seeks only prospective relief, the case becomes moot when the government repeals, revises, or replaces the challenged law and thereby removes the complained-of defect." *Ozinga v. Price*, 855 F.3d 730, 734 (7th Cir. 2017). By promulgating the 2024 Rule, HHS has done just that. In seeking to undermine that basic principle, Plaintiffs frame the relevant debate as whether the 2020 Rule or the 2024 Rule is "on the books." Pls.' Mem. at 12 (citation omitted). Undoubtedly, the entirety of the 2024 Rule, which superseded the 2020 Rule, is on the books. "Like an enacted statute, which becomes 'valid law' once enacted even if not yet 'effective,' . . . a duly prescribed rule is law even if it sets a future effective date." *Humane Soc'y of the U.S. v. USDA*, 41 F.4th 564, 571 (D.C. Cir. 2022) (quoting *United States v. Brundage*, 903 F.2d 837, 843 (D.C. Cir. 1990)). Because "the law that is the basis for the complaint has been replaced by a new law during the case's pendency," this case is moot. *ACP*, 2024 WL 3206579, at *2. HHS has "'deal[t] with the problem afresh' by taking *new* agency action." *See Biden v. Texas*, 597 U.S. 785, 808 (2022) (quoting *Dep't of Homeland Sec. v. Regents of Univ. of Cal.*, 591 U.S. 1, 21 (2020)).

Plaintiffs' opposition fails to rebut this "well-settled principle of law." *Akiachak Native Cmty.*, 827 F.3d at 113. Although they point out that district court orders preliminarily restrain HHS from enforcing certain provisions of the 2024 Rule that "govern the definition of sex-based discrimination and implement related requirements to prevent discrimination on the basis of gender identity," Pls.' Mem. at 10, they do not identify any corresponding provisions from 45 C.F.R Part 92 that were on the books between 2020 and Spring 2024 that HHS is enforcing in place of those provisions. In any event, the fact that HHS may not enforce certain provisions of the 2024 Rule pursuant to various courts' preliminary orders does not mean that the 2024 Rule itself did not "wipe[] the slate clean on Section 1557." *ACP*, 2024 WL 3206579, at *1. Any harm

is thus a result of other courts' orders and not some unidentified provision that HHS had previously purportedly promulgated in 2020. *Cf. Am. Freedom Def. Initiative*, 815 F.3d at 110.

Plaintiffs cite no authority to support their theory that other court orders preliminarily restraining enforcement of a superseding rule render a lawsuit challenging the original rule still live. They rely on only one case—*National Association of Manufacturers v. Department of Defense* ("*NAM*"), 583 U.S. 109 (2018)—finding that a challenge to an agency rule was not mooted by further agency action. Pls.' Mem. at 9-10, 12-13. But the further agency action at issue in *NAM* was a proposed rule. *NAM*, 583 U.S. at 120 n.5. The 2024 Rule is not a proposed rule.

Moreover, *NAM* does not otherwise advance Plaintiffs' argument. *NAM* involved a challenge to a 2015 Environmental Protection Agency ("EPA") Rule defining the statutory term "waters of the United States." Final Rule, *Clean Water Rule: Definition of "Waters of the United States*," 80 Fed. Reg. 37,054 (June 29, 2015) ("2015 WOTUS Rule"). At the time the Supreme Court decided *NAM*, EPA had not been enforcing the 2015 WOTUS Rule because the Sixth Circuit stayed its enforcement nationwide and a federal district court had enjoined the Rule's enforcement in thirteen states. Proposed Rule, *Definition of "Waters of the United States"—Addition of an Applicability Date to 2015 Clean Water Rule*, 82 Fed. Reg. 55,542, 55,543 (Nov. 22, 2017). In 2017, EPA issued two proposed rules. One proposed rescinding and replacing the 2015 WOTUS Rule. Proposed Rule, *Definition of "Waters of the United States"—Recodification of Pre-Existing Rules*, 82 Fed. Reg. 34,899 (July 27, 2017). The other proposed to change the effective date of the 2015 WOTUS Rule, pushing it back several years. 82 Fed. Reg. at 55,542-43. In *NAM*, the Supreme Court implicitly suggested that challenges to the 2015 WOTUS Rule would likely be mooted if EPA finalized the proposal to rescind and replace the challenged 2015 WOTUS Rule. *See* 583 U.S. at 120 n.5. On the other hand, the Court opined that challenges to the 2015 WOTUS Rule would remain live if EPA finalized the proposed rule that "simply delays the WOTUS Rule's effective date" because the 2015 WOTUS Rule itself would remain "on the books." *Id*.

Here, HHS has not merely delayed the effective date of the 2020 Rule that Plaintiffs challenge; it has finalized the 2024 Rule to rescind and replace the 2020 Rule. And Plaintiffs do

not dispute that the 2024 Rule is consistent with their view of the law and addresses their concerns with the 2020 Rule. Under *NAM*, Plaintiffs' challenge to the 2020 Rule is thus moot; it is sufficient that HHS has issued a new rule to rescind and replace the rule that Plaintiffs challenge. Indeed, in *ACP*, after the 2024 Rule was promulgated but before its effective date, the Sixth Circuit concluded that the 2024 Rule rendered moot those plaintiffs' challenge to HHS's Notification of Interpretation. *ACP*, 2024 WL 3206579, at *1-2. Thus, Plaintiffs' challenge here to the 2020 Rule is similarly moot. *See id*.

IV. Plaintiffs Mistake the Relevant Burdens of Proof that Apply in the Context of Mootness Arising from Superseding APA Notice and Comment Rulemaking.

Plaintiffs claim that a defendant "bears the formidable burden of showing that it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur." Pls.' Mem. at 9 (quoting *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 190 (2000)). That burden, however, arises in the context of the "voluntary cessation" doctrine. *Friends of the Earth,* 528 U.S. at 189. And this doctrine "does not apply" when the ceased conduct "was not abandoned as a strategic litigation ploy." *E.I. Dupont de Nemours & Co. v. Invista B.V.*, 473 F.3d 44, 47 (2d. Cir. 2006). The Second Circuit has rejected the "characterization" of an agency's newly promulgated "regulation as a last-minute attempt to evade federal court jurisdiction." *Harrison & Burrowes Bridge Contractors, Inc. v. Cuomo*, 981 F.2d 50, 59 (2d Cir. 1992).[3]

What HHS has accomplished by completing new rulemaking "is more accurately characterized as the provision of appropriate relief . . . than as the 'cessation of illegal conduct.'" *Nat. Res. Def. Council v. U.S. Nuclear Regul. Comm'n*, 680 F.2d 810, 814 n.8 (D.C. Cir. 1982);

[3] Plaintiffs do not argue that HHS's promulgation of the 2024 Rule was a strategic ploy to avoid this litigation, nor could they. HHS issued the 2024 Rule "to better align the Section 1557 regulation with the statutory text of 42 U.S.C. 18116, to reflect recent developments in civil rights case law, to address unnecessary confusion in compliance and enforcement resulting from the 2020 Rule, and to better address issues of discrimination that contribute to negative health interactions and outcomes," not for the purpose of mooting this case or any others. Proposed Rule, *Nondiscrimination in Health Programs and Activities*, 87 Fed. Reg. 47,824, 47,829 (Aug. 4, 2022).

see also Alaska, 17 F.4th at 1227-30 (voluntary cessation exception inapplicable in cases involving rules promulgated by notice and comment rulemaking); *Miller*, 68 F.3d at 165 (legislative enactment "gave plaintiffs what they sought, and this case is therefore moot"); *ACP*, 2024 WL 3206579, at *2 ("Because HHS promulgated the 2024 rule through a multiyear notice-and-comment process, we see little basis for applying the voluntary-cessation doctrine to preserve the justiciability of this case."). Indeed, Plaintiffs' assertion that HHS's promulgation of a rule consistent with their view of the law is not what they were seeking in this case, Pls.' Mem. at 12, is inconsistent with the parties' prior contention that this "dispute is better addressed in the context of HHS's reconsideration of the 2020 Rule than before this Court," Joint Mot. for a Stay of Proceedings & to Hold the Parties' Mots. in Abeyance at 5, ECF No. 145.

In this context, rescinding and replacing a rule by publishing a new notice-and-comment rule in the Federal Register is enough, standing alone, to satisfy the Government's burden to show that a challenge to the original rule is moot. *See Alaska*, 17 F.4th at 1227-30; *ACP*, 2024 WL 3206579, at *2. At most, the burden then shifts to Plaintiffs to show "evidence of bad faith," *M.W. ex rel. Hope W. v. U.S. Dep't of Army*, No. 16-CV-04051-LHK, 2017 WL 10456732, at *6 (N.D. Cal. Dec. 15, 2017) (citation omitted), *aff'd on appeal sub nom. Am. Diabetes Ass'n v. U.S. Dep't of Army*, 938 F.3d 1147 (9th Cir. 2019)—that the new rule was promulgated only "to secure a dismissal" and with an intent to return to the old policy "when the judge is out of the picture," *see Bos. Bit Labs v. Baker*, 11 F.4th 3, 10 (1st Cir. 2021) (citation omitted). *See also Alaska*, 17 F.4th at 1229 n.5. Plaintiffs come nowhere close to satisfying that burden, as they do not question that HHS promulgated the 2024 Rule in good faith.

Even if promulgation of the 2024 Rule were deemed "voluntary cessation," the case would still be moot. "Courts will find a case moot after voluntary cessation of challenged conduct where '(1) it can be said with assurance that there is no reasonable expectation that the alleged violation will recur and (2) interim relief or events have completely and irrevocably eradicated the effects of the alleged violation.'" *New York v. Raimondo*, No. 1:19-cv-09380-MKV, 2021 WL 1339397, at *2 (S.D.N.Y. Apr. 9, 2021) (citation omitted). Those standards are met where, as here, an

agency has "completely revised its regulations though proper procedures," *id*. at *3 (citation omitted), and thus has "officially abandoned" the challenged rule, *see Rivers v. Doar*, 638 F. Supp. 2d 333, 338 (E.D.N.Y. 2009). "As the Second Circuit has explained, 'deference to the [government's] decision to amend is the rule, not the exception.'" *Raimondo*, 2021 WL 1339397, at *3 (citation omitted).

As to the first prong, "[a] defendant satisfies its burden where it shows that the possibility of recurrence is merely 'speculative.'" *Dark Storm Indus. LLC v. Hochul*, No. 20-2725-cv, 2021 WL 4538640, at *1 (2d Cir. Oct. 5, 2021) (quoting *Lillbask ex rel. Mauclaire v. State of Conn. Dep't of Educ.*, 397 F.3d 77, 88 (2d. Cir. 2005)). And the notion that HHS will engage in new rulemaking to reflect policies in the 2020 Rule is speculative. *See Alaska*, 17 F.4th at 1229 ("[T]o determine whether the [challenged rule] will be reapplied . . . would require us to speculate about future actions by policymakers"); *Rivers*, 638 F. Supp. 2d at 338. Moreover, even if HHS were to change course and propose new rulemaking, "[t]he content of any future regulation [would be] currently unknowable." *See Alaska*, 17 F.4th at 1229. And again, courts have held that "[i]t would be entirely inappropriate for th[e] court to . . . issue an advisory opinion to guide the Secretary's rulemaking." *Id*. at 1228 (quoting *Hodel*, 839 F.2d at 742); *see also id*. at 1229 n.5. In any event, promulgation of a new rule reflecting the policies embodied in the 2020 Rule would give rise to a new challenge to a different rule based on a new administrative record; it would not resurrect a challenge to the 2020 Rule. *See Lujan v. Nat'l Wildlife Fed'n*., 497 U.S. 871, 891 (1990) ("Under the terms of the APA, [a plaintiff] must direct its attack against some particular 'agency action' that causes it harm."); *The Fund for Animals v. Norton*, 390 F. Supp. 2d 12, 15 (D.D.C. 2005) ("[A] new 'final agency action' resulting from an entirely new rule making process" is "based upon a different administrative record[.]").

As to the second prong, Plaintiffs have not identified any ongoing effects from the 2020 Rule. They do not point to any specific provision of the rule that remains in force and injures them. *See Am. Freedom Def. Initiative*, 815 F.3d at 110; *supra* at 7-8. And, in any event, any ongoing harm would be a consequence of other courts' orders that prevent HHS from enforcing

certain provisions of 45 C.F.R Part 92 that are now on the books, not any action of HHS. *See Iron Arrow Honor Soc'y*, 464 U.S. at 72.

CONCLUSION

HHS has promulgated a rule that supersedes all of the provisions of the 2020 Rule that Plaintiffs challenge in this case. Accordingly, Plaintiffs' challenge to the 2020 Rule is moot, and this case should be dismissed without prejudice.[4]

Dated: November 5, 2024

Respectfully submitted,

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[4] Plaintiffs have not invoked the mootness exception for controversies capable of repetition, yet evading review. Because Plaintiffs bear the burden of demonstrating that this exception applies, *Video Tutorial Servs., Inc. v. MCI Telecomm. Corp.*, 79 F.3d 3, 6 (2d Cir. 1996), they have forfeited any reliance on it. And the Court should decline Plaintiffs' demand, which is supported by no argument, to "reinstate a stay of these proceedings pending resolution of the litigations challenging the 2024 Rule." ECF No. 191 at 14. *See Raimondo*, 2021 WL 1339397, at *3 (declining similar stay request because there is no justification for a court retaining jurisdiction over a civil case when there is no real controversy before it).