

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

_____)	
STATE OF MISSOURI, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 4:21-cv-1329
)	
JOSEPH R. BIDEN, JR., <i>et al.</i> ,)	
)	
Defendants.)	
_____)	

**DEFENDANTS' REPLY IN SUPPORT OF
THEIR MOTION TO DISMISS THE FIRST AMENDED COMPLAINT**

INTRODUCTION

Plaintiff States filed suit and sought a preliminary injunction seeking to block the Secretary's vaccination rule. Their arguments reached the Supreme Court and were decisively rejected on the merits, effectively concluding the case. Of the four groups of state plaintiffs that originally sued to challenge the rule, two voluntarily dismissed their cases in light of the Supreme Court's ruling. A third group of states argued that its claims remained live, but a district court concluded that their claims were either precluded by the Supreme Court's ruling or without merit, and those states did not appeal that ruling. Plaintiffs here are the last litigants standing, trying to prolong arguments that have long since been rejected. In so doing, Plaintiffs invite the Court to effectively ignore the Supreme Court decision issued in this very case. *See, e.g.*, Opp'n at 11 (asserting that *Biden* has "little relevance as to the States' arbitrary-and-capricious claims"). The Court should decline the invitation. The Supreme Court either explicitly or implicitly rejected most claims in the First Amended Complaint, and what little remains clearly fails as a matter of law. This Court should accordingly dismiss the First Amended Complaint with prejudice and close this case.

ARGUMENT

I. Plaintiffs' Arbitrary and Capricious Claims Should be Dismissed

The Supreme Court rejected all of Plaintiffs' claims that were previously raised, but Plaintiffs argue that these claims survive, for different reasons. With respect to Plaintiffs' argument that the rule is arbitrary and capricious (Count I), the Supreme Court held explicitly that "the interim rule is not arbitrary and capricious." *Biden v. Missouri*, 142 S. Ct. 647, 653 (2022). Plaintiffs nonetheless make two arguments as to why this challenge can be revived post-*Biden*: (1) the Amended Complaint raises different arguments as to why the Rule is irrational, and (2) *Biden* is undeserving of "dispositive weight" because of the procedural posture in which it was issued. Opp'n at 11. Both points are meritless.

As to Plaintiffs' assertion that they are now providing "many, and different, reasons why the mandate is arbitrary and capricious," *id.*, they fail to explain how their arguments are substantively distinct from those presented to the Supreme Court, such that *Biden* is "not binding, or even on point, precedent on these issues." *Id.* at 2. To the contrary, many of Plaintiffs' allegations in the Amended Complaint in support of their arbitrary and capricious claims are virtually identical to those in the original Complaint. Compare, e.g., Compl. ¶¶ 174-83, 185-86, with Am. Compl. ¶¶ 262-73.

It is unclear whether Plaintiffs contend that these re-raised allegations in the Amended Complaint are somehow "different" from what was previously adjudicated, or whether other, unidentified allegations in their "ninety-one page, 389 paragraph, eleven count" Amended Complaint meet that definition. Opp'n at 1. In any event, neither this Court nor Defendants are "like pigs, hunting for truffles buried in briefs or Complaints," *Reinholdson v. Minnesota*, No. CIV.011650(RHK/JMM), 2002 WL 32658480, at *2 (D. Minn. Nov. 21, 2002) (alterations omitted), nor must Defendants or the Court "divine what [Plaintiffs are] trying to assert or [] cobble together claims" for them. *Schub v. Burleigh Morton Det. Ctr.*, No. 1:20-CV-142, 2022 WL 2293421, at *6 (D.N.D. Apr. 21, 2022). Plaintiffs fail to demonstrate that they have alleged sufficiently new arguments warranting continued litigation, when they decline to even identify what those arguments are and how they are different from the issues already decided by the Supreme Court.

In any event, Plaintiffs aver that their "more than twenty reasons why the mandate is arbitrary" collapse into a single "main point," namely that the Rule was "pre-determined," and the Secretary "had no evidence that the vaccine actually prevents the spread of COVID-19[.]" Opp'n at 2. But Plaintiffs made these arguments to the Supreme Court. See Resp. to Appl. for a Stay at 26-27, *Biden v. Missouri*, No. 21A240 (U.S. Dec. 30, 2021) (asserting that the Rule constituted a "pretextual change in position," and citing district court's finding that the Secretary "lack[ed] solid

evidence regarding transmissibility of COVID by the vaccinated”). And the Court in *Biden* nonetheless held that the Secretary had acted reasonably and had properly “examine[d] the relevant data[.]” *See* 142 S. Ct. at 653; *id.* at 654 (rejecting “additional flaws the District Courts found in the Secretary’s analysis, particularly concerning the nature of the data relied upon”). Plaintiffs thus fail to demonstrate that the “main point” of their amended arbitrary and capricious claim differs from what was presented to, and decided by, the Supreme Court.

Plaintiffs posit in the alternative that the Supreme Court’s decision does not constitute “law of the case” in this matter, but this argument is misguided. Plaintiffs first err in urging that “[r]eversals of a grant of a preliminary injunction do not establish the law of the case[.]” Opp’n at 11. The Eighth Circuit has explicitly rejected this argument. *See Howe v. Varity Corp.*, 36 F.3d 746, 752 (8th Cir. 1994) (holding that where the court of appeals had “reversed the District Court’s grant of a preliminary injunction” “[t]hat holding is the law of the case”). As the court of appeals explained, rulings in a preliminary injunction context “are sometimes tentative,” but in other instances an appellate court “may also determine whether the district court based its decision on an erroneous legal premise,” and thereby “reach the legal issues at the heart of the case[.]” *Id.* (citation omitted). In that circumstance, such “holdings [are] binding on the District Court on remand” and on the court of appeals as well. *Id.*; *see also J.M.O. v. United States*, No. 20-CV-577 (NEB/HB), 2021 WL 3856116, at *3 (D. Minn. Aug. 27, 2021) (applying law of the case doctrine, holding that the fact “that the Eighth Circuit’s decision came from a preliminary injunction context is of no moment,” given that both district and appellate rulings “were purely legal decisions”), *aff’d*, No. 21-3126, 2021 WL 7543778 (8th Cir. Dec. 1, 2021) (summary affirmance).

There can be no plausible dispute that the Supreme Court reached the legal issues at the heart of this case, including whether the Secretary had the statutory authority to issue the Rule, and whether the Rule was a reasonable exercise of that authority. *See, e.g., Biden*, 142 S. Ct. at 653

(explaining that the Rule “is a straightforward and predictable example of the ‘health and safety’ regulations that Congress has authorized the Secretary to impose”); *id.* (“[T]he interim rule is not arbitrary and capricious.”).

The Supreme Court was not tentative or otherwise limited in resolving the purely legal issues raised by Plaintiffs. *Id.*; *see also* at 653 (holding that “[g]iven the rulemaking record, it cannot be maintained” that the Secretary acted arbitrarily in issuing the Rule). As a consequence, there is no further “factual development,” Opp’n at 10-11, that could undermine *Biden*. For all these reasons, it is unsurprising that another district court held that *Biden* constituted the law of the case in a nearly identical action brought by sixteen states challenging the rule. *Louisiana v. Becerra*, No. CV 3:21-03970, 2022 WL 17408035, at *4-5 (W.D. La. Nov. 3, 2022) (holding that “law of the case principles extend to an interlocutory appeal of the granting of a preliminary injunction” and that “these issues have been resolved by a higher court and represent the law of the case, which is binding on this lower court”), *report and recommendation adopted*, No. CV 3:21-03970, 2022 WL 17405839 (W.D. La. Dec. 2, 2022). This Court should similarly hold that *Biden* is the law of this case and compels dismissal.

Moreover, whether *Biden* technically constitutes law of the case is ultimately irrelevant, because the decision constitutes precedent of the Supreme Court, controlling not just in this specific case, but in all lower courts. *Accord J.M.O.*, 2021 WL 3856116, at *3 (“[E]ven were the appellate decision not the law of the case, it remains a published decision of the Eighth Circuit that is binding on the Court.”). Plaintiffs suggest that *Biden* is not binding, however, citing to Justice Kavanaugh’s concurrence in *Merrill v. Milligan*, 142 S. Ct. 879 (2022) (mem.). But as Defendants previously explained, ECF No. 47 at 10, in *Merrill* the majority issued a stay of a lower court’s injunctive order *without an opinion* explaining its reasoning, and Justice Kavanaugh concurred to note that he did not view that order as a decision on the merits. 142 S. Ct. at 879 (Kavanaugh, J., concurring). The

Supreme Court may in some cases decide a stay application without finally deciding the merits of legal questions. But that is not what happened here. In this case, the Court squarely decided the merits of Plaintiffs' claims in an opinion issued after oral argument on the stay applications, and it did not qualify those holdings in any way. *See Biden*, 142 S. Ct. at 652-54.¹ That decision is binding on this Court, just as it is on any other lower court that would hear a similar challenge.

Numerous courts have properly followed *Biden* as binding precedent. *See, e.g., Griner v. Biden*, No. 2:22CV149 DAK-DBP, 2022 WL 7501065, at *10 (D. Utah Oct. 13, 2022) (holding that claim that “the Secretary lacked the authority to issue the Rule” was “foreclosed by the Supreme Court’s recent decision in *Biden*”); *Beckerich v. St. Elizabeth Med. Ctr.*, No. CV 21-105-DLB-EBA, 2022 WL 325453, at *4 (E.D. Ky. Feb. 2, 2022) (denying motion for sanctions against plaintiffs that sought to enjoin hospital vaccine requirement, due to their voluntary dismissal of the case and their “express recognition that the Supreme Court’s decision in *Biden* controls their case”); *Garlick v. Regents of the Univ. of Colo.*, No. 1:22-cv-00013-RMR-STV, 2022 WL 18533663, at *5 (D. Colo. Jan. 25, 2022) (holding that district court could not redress claimed harm from university vaccine policy because it “follows valid federal and state regulations that have been upheld by the Supreme Court[,]” citing *Biden* as authority). As a controlling decision addressing claims that are, at the very least, substantially similar to Plaintiffs’ arbitrary and capricious claims, and raised in the same suit challenging the very same agency action, *Biden* dictates dismissal of those claims.

II. Plaintiffs’ Notice-and-Comment and Consultation Claims Should be Dismissed

Plaintiffs next briefly assert that their claims asserting notice-and-comment and consultation

¹ The only other authorities Plaintiffs cite for this argument – *Stifel, Nicolaus & Co. v. Woolsey & Co.*, 81 F.3d 1540, 1544 (10th Cir. 1996) and *Nyffeler Construction, Inc. v. Secretary of Labor*, 760 F.3d 837, 841 (8th Cir. 2014) – concern whether law of the case principles apply to decisions by motions panels or administrative panels at the court of appeals and, accordingly, are inapposite.

violations also survive post-*Biden*, but—as with Plaintiffs’ arbitrary and capricious claims—these claims should be dismissed. The Supreme Court explicitly rejected Plaintiffs’ arguments that the rule was required to go through prior notice-and-comment rulemaking and that the Secretary was required to consult with state agencies in advance of promulgation. *See Biden*, 142 S. Ct. at 654 (holding that the Secretary’s “finding[s]” were sufficiently “specific” to “forgo notice and comment”); *id.* (“[T]he Secretary . . . was not required to ‘consult with appropriate state agencies,’ in advance of issuing the interim rule.”) (quoting 42 U.S.C. § 1395z).

Here Plaintiffs have re-raised similar allegations in their Amended Complaint as to notice and comment, and consultation, *compare* Compl. ¶¶ 206-228 *with* Am. Compl. ¶¶ 307-340, and argue only that the Supreme Court’s ruling does not “establish the law of the case” or even “provide on-point precedent” as to these claims. Opp’n at 12. But just as with Plaintiffs’ arbitrary and capricious arguments, the Supreme Court’s decision is binding with respect to these claims as well. *Accord Livingston Educ. Serv. Agency v. Becerra*, 35 F.4th 489, 491 (6th Cir. 2022) (explaining that the “Supreme Court recently . . . held that the Secretary of HHS was not required to use notice-and-comment rulemaking to issue a vaccine requirement for the staff of Medicare and Medicaid facilities”); *LifeNet, Inc. v. U.S. Dep’t of Health & Hum. Servs.*, ---F. Supp. 3d---, 2022 WL 2959715, at *9 n.6 (E.D. Tex. July 26, 2022) (noting that *Biden* “held that the agency had good cause to deviate from notice and comment because the rule was urgent and necessary to ‘significantly reduce COVID-19 infections, hospitalizations, and deaths’” (citing *Biden*, 142 S. Ct. at 654)).

Plaintiffs assert that “further development of the factual record may show that the Secretary improperly dispensed with notice and comment.” Opp’n at 12. Once again, this Court should decline to accept Plaintiffs’ invitation to ignore the Supreme Court’s decision. The Supreme Court found that the Secretary’s justification to forego pre-publication notice and comment was proper as a matter of law, and no “factual development” could plausibly undermine that legal conclusion.

As to the consultation requirement in 42 U.S.C. § 1395z, Plaintiffs appear to concede that the Supreme Court’s decision is on point and binding. Opp’n at 12 (“The *Biden* Court said that consultation was not necessary ‘in advance of issuing the interim rule,’ but could be done ‘during the deferred notice-and-comment period[.]’”). But Plaintiffs now argue that “there was no consultation, even during the deferred notice-and-comment period,” and aver that “the Government does not dispute” this point. *Id.* This argument does not cast doubt on the validity of the Rule, which Supreme Court has upheld. If Plaintiffs seek to challenge a later final agency action on this ground, they must await the issuance of that action. Moreover, in their Motion to Dismiss, Defendants cited the Declaration of Karen Tritz, ECF No. 47-1, filed here over a year ago, explaining that “CMS conducted a deferred notice and comment period, received feedback from state agencies during that time, and took additional steps to consult with relevant state agencies.” Mot. at 4 n.1, ECF No. 78.

1. Defendants accordingly complied with their obligations to consult with relevant state agencies, and Plaintiffs cannot show otherwise.

III. Plaintiffs’ Constitutional Claims Should be Dismissed

Next, Plaintiffs appear to concede that many of their constitutional claims in the Amended Complaint were previously put before the Supreme Court and rejected. But Plaintiffs nonetheless argue that because these contentions were “raised in *Louisiana v. Becerra*,” Opp’n at 13, the Supreme Court’s decision on these issues is law of the case only in that matter. In fact, *Missouri* and *Louisiana* were not consolidated solely for oral argument but for decision as well. *See Louisiana*, 2022 WL 17408035, at *2 (“The Supreme Court consolidated the two cases[.]”). Indeed, *Biden* constituted a single decision resolving the arguments advanced in both cases and did not distinguish between any holdings applicable in one suit but not the other. 142 S. Ct. at 652 (recounting how “[t]he Government filed applications asking us to stay both District Courts’ preliminary injunctions,”

which were granted in the decision).² *Biden* thus constitutes both law of the case, and just as importantly, precedent directly on point.

In fact, multiple courts have correctly recognized that the Supreme Court “effectively rejected” the constitutional claims that had been raised, namely claims under the Spending Clause (Count VII), the Tenth Amendment (Count IX) and the Non-Delegation Doctrine (Count X). *See Livingston Educ. Serv. Agency v. Becerra*, 589 F. Supp. 3d 697, 713 (E.D. Mich. 2022) (explaining that *Biden* rejected arguments under the “Spending Clause,” of an “intru[sion] on the states’ police powers,” “the Tenth Amendment,” and “the Separation of Powers Doctrine”), *denying injunction pending appeal*, 35 F.4th 489 (6th Cir. 2022); *Griner*, 2022 WL 7501065, at *11 (agreeing that the Court “effectively dispos[ed] of the Tenth Amendment claim as well”); *Louisiana*, 2022 WL 17408035, at *5 (“[T]he Supreme Court also implicitly or tacitly rejected the constitutional claims as well”). Accordingly, Plaintiffs may not prevail on constitutional claims already disposed of by the Supreme Court.

Moreover, Plaintiffs’ arguments as to their constitutional claims are meritless. On the Spending Clause and Tenth Amendment claims, Plaintiffs assert that a “condition on spending” must “bear[] some relationship to the purpose of the federal spending.” Opp’n at 14 (citation omitted). But the Court in *Biden* held that the Rule “fits neatly” into the statute that permits the Secretary to “impose conditions on the receipt of Medicaid and Medicare funds” that the Secretary “finds necessary in the interest of the health and safety of individuals who are furnished services.” 142 S. Ct. at 652 (quoting 42 U.S.C. § 1395x(e)(9)). Indeed, the Court explained that “healthcare facilities that wish to participate in Medicare and Medicaid have always been obligated to satisfy a

² Plaintiffs cite *Washington v. Countrywide Home Loans, Inc.*, 747 F.3d 955, 958 (8th Cir. 2014), but that decision has no relevance here. In that case, the Eighth Circuit explained that a Missouri state court decision did not constitute law of the case for the federal litigation at issue, initiated years later. *Id.*

host of conditions that address the safe and effective provision of healthcare, not simply sound accounting.” *Id.*; *see also id.* at 653 (“[R]espondents do not contest the validity of this longstanding litany of health-related participation conditions[.]”). Plaintiffs thus cannot plausibly contend that the Rule somehow “reaches beyond the spending program” of Medicare and Medicaid, such that it compels the adoption of a particular viewpoint or is otherwise overbroad. Opp’n at 14.

Plaintiffs’ arguments as to non-delegation are similarly misguided. As Plaintiffs’ own cited case law makes clear, the non-delegation doctrine poses only a “low threshold” for agency actions to clear: an authorizing statute need only contain “an intelligible principle” to which an agency should “conform.” *Bhatti v. Fed. Hous. Fin. Agency*, 15 F.4th 848, 854 (8th Cir. 2021) (citation omitted); *see also United States v. Fernandez*, 710 F.3d 847, 849 (8th Cir. 2013) (“[W]ith the exception of two cases in 1935 . . . the Supreme Court has uniformly rejected every nondelegation challenge it has considered.”) (internal citations omitted). Here, Plaintiffs cannot show that 42 U.S.C. § 1395x(e)(9), for instance, violates any non-delegation principles, given the Supreme Court’s conclusion that the Rule “fits neatly” within the bounds of the statutory language. *Biden*, 142 S. Ct. at 652. Indeed, the law directs the Secretary to implement measures that he “finds necessary in the interest of the health and safety of individuals who are furnished services.” *Id.* (quoting 42 U.S.C. § 1395x(e)(9)). Such a clear directive plainly constitutes an “intelligible principle” sufficient to guide agency discretion. *Cf. United States v. Kuehl*, 706 F.3d 917, 920 (8th Cir. 2013) (explaining that even “broad policy statements . . . [are] sufficient to provide an intelligible principle for delegation”); *Nat’l Broad. Co. v. United States*, 319 U.S. 190, 215 (1943) (upholding a delegation of legislative authority based on the general policy to regulate according to “public interest, convenience, or necessity”) (citation omitted). While Plaintiffs hypothesize about potential statutory applications over any provider activities that “could have a downstream effect on patient health,” Opp’n at 15, the Rule is limited to controlling the spread of COVID-19 by facilities participating in federal health care programs, and

“addressing infection problems in Medicare and Medicaid facilities is what [the Secretary] does.”

Biden, 142 S. Ct. at 652.

Finally, as to their anti-commandeering claim, Plaintiffs fault the Government for not explicitly addressing an allegation that the “mandate commandeers the States’ surveyors.” Opp’n at 16. But beyond gesturing at the allegation, and noting that “*Louisiana v. Becerra*, 2022 WL 17408035, at *6 (W.D. La. Nov. 3, 2022), discusses this theory,” *id.*, Plaintiffs fail to explain how some unspecified guidance to state surveyors constitutes commandeering. Moreover, the *Louisiana* decision did not merely “discuss[] this theory,” Opp’n at 16, but rejected the notion that an anti-commandeering claim could be based on the Rule’s impact on state surveyors. 2022 WL 17408035, at *6 (“The State Governments have not shown that these circumstances suffice to state a plausible claim for relief for violation of the anti-commandeering principle.”). This Court should conclude the same.

Plaintiffs next concede that “[e]ven-handed, direct regulation may not violate the anti-commandeering prohibition.” Opp’n at 16. While they urge that there is some exception to this principle “in the spending context,” *id.*, Plaintiffs cite to no case supporting this novel proposition. And for good reason, for where a “law applie[s] equally to state and private actors” it does not “regulate the States’ sovereign authority to ‘regulate their own citizens.’” *Murphy v. Nat’l Collegiate Athletic Ass’n*, 138 S. Ct. 1461, 1479 (2018) (citation omitted). Accordingly, where the Secretary imposes funding conditions that apply equally to state and private actors, no anti-commandeering problem exists. See *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1152 (D.N.D. 2021) (rejecting anti-commandeering claim and holding that “North Dakota offers healthcare services alongside private entities, meaning the state must accept the universally applicable regulations that follow”); *Louisiana*, 2022 WL 17408035, at *6 (similar).

In their final swing, Plaintiffs collapse their anti-commandeering claim with their claim under

the Spending Clause, arguing that conditions on funding required by the Rule serve to “micromanage . . . State providers.” Opp’n at 17. But, as even Plaintiffs’ cited case law makes plain, the Government may properly “condition the receipt of [federal] funds on the States’ complying with restrictions on the use of those funds, because that is the means by which Congress ensures that the funds are spent according to its view of the ‘general Welfare.’” *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 580 (2012) (opinion of Roberts, C.J.); *South Dakota v. Dole*, 483 U.S. 203, 210 (1987) (“[A] perceived Tenth Amendment limitation on congressional regulation of state affairs did not concomitantly limit the range of conditions legitimately placed on federal grants”). Thus, even if any constitutional arguments survive the Supreme Court’s decision in this case, Plaintiffs fail to show that such claims are cognizable.

IV. Plaintiffs’ “Change in Core Circumstances Claim” Should be Dismissed

In their Motion to Dismiss, Defendants pointed out that Plaintiffs’ Count XI did not identify *any* cause of action permitting a claim of “changes in core circumstances,” necessitating dismissal. Mot. at 9 (citation omitted). Plaintiffs provide only a one-sentence response, that the “change in core circumstances claim seeks relief consistent with the APA and equity based on significant factual and legal developments postdating publication of the mandate.” Opp’n at 17. Plaintiffs thus tacitly admit that they identified no cause of action in the First Amended Complaint supporting this claim, and similarly cannot point to any qualifying cause of action in their brief. *Accord Lee v. Kansas City Mo. Sch. Dist.*, No. 07-0487-CV-W-FJG, 2008 WL 539276, at *3 (W.D. Mo. Feb. 26, 2008) (dismissing case in part because “plaintiff did not allege under which basis this Court has jurisdiction in which to hear plaintiff’s allegations”). Litigants may not properly bring legal claims on the theory that they are similar to, or “consistent with,” actual, recognized causes of action. Nor can Plaintiffs sue the Federal Government on a vague invocation of “equity.” *See also Davis v. Nationwide Mut. Fire Ins.*, No. 4:10CV101, 2010 WL 11463176, at *1 (E.D. Va. Oct. 6, 2010)

(“[T]he Court needs to be certain about which causes of action Plaintiff intended to assert and aware of the facts supporting such claims.”). Plaintiffs’ basic failure to identify any cause of action supporting Count XI supports dismissal of this claim.

Moreover, the only support Plaintiffs cite for their amorphous “changed circumstances claim,” are decades-old, out-of-circuit decisions, including a footnote in a 1986 district court case. Opp’n at 17-18. Putting aside that the instant circumstances are distinguishable from even those cases, *see* Mot. at 10-11, binding caselaw precludes such a nebulous argument here. For example, *Auer v. Robbins*, 519 U.S. 452 (1997), makes clear that Plaintiffs may not challenge the validity of the rule based on later-arising facts. The plaintiffs in *Auer* asserted that new developments had rendered a regulation arbitrary and capricious. The Supreme Court rejected this claim, holding that “there is no basis for the court to set aside the agency’s action prior to any application for relief addressed to the agency itself” through a petition for a new rulemaking under 5 U.S.C. § 553(e). *Id.* at 459.

Plaintiffs also cite authority for the proposition that in unusual circumstances the administrative record may be supplemented, Opp’n at 19-20, indicating that they improperly seek to raise their “changed circumstances” claim under the APA. But potential supplementation of the administrative record once a plaintiff has validly alleged a cognizable APA claim (which has not occurred here) is a far cry from Plaintiffs’ request for this Court to “analy[ze] . . . subsequent changes affecting the [Rule],” *id.* at 19, and invalidate the Rule on account of the Court’s own weighing of post hoc scientific evidence. Such a de novo trial of an agency decision is not authorized under the APA, whether pursuant to a claim of “changed circumstances,” or any other avenue. *See South Dakota v. U.S. Dep’t of Interior*, 423 F.3d 790, 802–03 (8th Cir. 2005) (holding that the Court is “confined to the administrative record in deciding an appeal under the APA” to “preclude[] the reviewing court from conducting a de novo trial and substituting its opinion for that of the agency.”) (citations omitted). Binding authority of the Court of Appeals could hardly be

clearer: “This court’s task is to make sure the [agency] considered the information available at the time it made its decision; if the agency’s decision was proper at the time it was made, our inquiry is at an end.” *Newton Cnty. Wildlife Ass’n v. Rogers*, 141 F.3d 803, 808 (8th Cir. 1998) (citation omitted). Simply put, this Court should not exceed the clear boundaries for administrative review set by the Eighth Circuit.

As Defendants previously explained, the proper avenue to raise changed circumstances in regard to the Rule is by submitting to the agency a petition to amend the Rule. Plaintiffs have already pursued this course, submitting a petition requesting that Defendants “repeal” the Rule. Am. Compl. ¶ 149. That petition is still under consideration at the agency. Once the agency makes a determination as to that petition, the APA provides for judicial review of the agency’s determination. *See* 5 U.S.C. §§ 555(e); 706(2). Plaintiffs do not address these points. Accordingly, there is no dispute that the proper mechanism by which to address “changed circumstances” is to seek judicial review of an agency’s determination on a petition to amend the Rule, which is not before the Court. Count XI should accordingly be dismissed.

V. Plaintiffs’ Remaining Claims, Counts II and VI, Should be Dismissed

Plaintiffs’ remaining arguments are meritless. Plaintiffs assert that Counts II (the Secretary lacked statutory authority to issue the Rule) and VI (the Rule required a regulatory impact analysis) should not be dismissed, “even in light of *Biden v. Missouri*.” Opp’n at 20. Yet as Plaintiffs seem to recognize, the Supreme Court resolved both of these claims as a matter of law. *See Biden*, 142 S. Ct. at 652 (holding that the Rule “falls within the authorities that Congress has conferred upon” the Secretary); *id.* at 654 (holding that the Secretary “need not prepare a regulatory impact analysis discussing a rule’s effect on small rural hospitals when he acts through an interim final rule”).

Rather than follow the explicit decision of the Supreme Court, Plaintiffs insist that these claims remain live because “neither the Supreme Court nor the Eighth Circuit has directed this

Court to dismiss those counts.” Opp’n at 20. But regardless of the precise mandate provided, the holdings of the Supreme Court in this matter are clear and controlling, both as law of the case and binding precedent. *Accord Griner*, 2022 WL 7501065, at *10 (holding that claim that “the Secretary lacked the authority to issue the Rule” was “foreclosed by the Supreme Court’s recent decision in *Biden*”).

There is accordingly no justification for Plaintiffs’ purported “good-faith basis for concluding that the law is not settled.” Opp’n at 21. It is hard to imagine how the law in this case could be *more* settled, over and above a Supreme Court opinion issued in this very matter, rejecting Plaintiffs’ statutory and regulatory claims. Nor can Plaintiffs’ rejected claims be kept “live” in order to “allow” Plaintiffs to engage in unspecified “discovery.” *Id.* These counts were definitively rejected by the Supreme Court and may not be further pursued to allow a fishing expedition, or for any other purpose. Plaintiffs’ Amended Complaint should be dismissed in full, and the case should be closed.

CONCLUSION

For the foregoing reasons, the First Amended Complaint should be dismissed.

Dated: March 31, 2023

Respectfully submitted,

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