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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON
EUGENE DIVISION

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| STATE OF OREGON, et al.,<br><br>Plaintiffs,<br>v.<br>ROBERT F. KENNEDY, JR., in his official capacity as the Secretary of the Department of Health and Human Services, et al.,<br><br>Defendants. | Case No. 6:25-cv-02409-MTK<br><br>PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO AMEND JUDGMENT |

## I. INTRODUCTION

Defendants' motion to amend the judgment attempts to relitigate the merits of this case after they had a full and fair opportunity to raise these issues in the summary judgment proceedings, including post-hearing briefing. The Court's ruling made clear that the Secretary of HHS lacks statutory authority to set standards of care that supersede professional standards recognized by the Plaintiff States. Despite ample opportunity, Defendants identified no statute conferring such authority upon the Secretary. And yet Defendants now seek to preserve a


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hypothetical exclusion authority that Defendants still fail to identify. Defendants' Motion should be denied.

Relying on that hypothetical and unidentified authority, Defendants ask this Court to confine its judgment to the framework contained in 42 U.S.C. § 1320a-7(b)(6)(B), 42 C.F.R. § 1001.2, and 42 C.F.R. § 1001.701. But this case has never been confined to those exclusion authorities. Instead, this litigation has focused on the Kennedy Declaration itself—which by its terms relies on "the authority vested in the HHS Secretary" to purportedly supersede other professionally recognized standards of care. Indeed, the Secretary declared broadly that medical professionals or entities providing transgender healthcare for youth are out of compliance with "these standards of healthcare." Fraas Decl. Ex. 27 (ECF No. 83). Accordingly, the scope of Plaintiffs' claims challenges the broad scope of the Kennedy Declaration's asserted authority. The scope of the relief Plaintiff States sought, and the Declaratory Judgment the Court entered, flow from those claims.

Defendants' belated protest that this case only put at issue a single "relevant exclusion framework" is unpersuasive, and inappropriate for a motion under Rule 59(e). Defendants now mischaracterize the Kennedy Declaration's scope and abandon the arguments they made in defending that document—namely, that the document had no binding effect on exclusion proceedings because it merely represented Secretary Kennedy's personal opinion. This Court should deny Defendants' motion on procedural and substantive grounds. First, Defendants raise novel arguments that are improper for a motion under Rule 59(e) because they could have raised these arguments earlier in the litigation. Second, the Secretary's claim to broad authority to set superseding standards of care was the central issue before the Court, and the Declaratory Judgment, declaring that no such authority exists, is appropriate in its scope.

## II. LEGAL STANDARD

Under Federal Rule of Civil Procedure 59(e), a party may file a "motion to alter or amend a judgment." "[A] Rule 59(e) motion is an extraordinary remedy, to be used sparingly in the interests of finality and conservation of judicial resources." *Kaufmann v. Kijakazi*, 32 F.4th 843,



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850 (9th Cir. 2022) (quotation marks omitted). "A district court may grant a Rule 59(e) motion if it is presented with newly discovered evidence, committed clear error, or if there is an intervening change in the controlling law.'" *Id.* Although "[d]istrict courts have considerable discretion in deciding Rule 59(e) motions," *id.*, those motions "may not be used to raise arguments or present evidence for the first time when they could reasonably have been raised earlier in the litigation." *Carroll v. Nakatani*, 342 F.3d 934, 945 (9th Cir. 2003); *see also Sec. Nat'l Ins. Co. v. Constr. Assocs. of Spokane, Inc.*, No. 2:20-cv-00167-SMJ, 2021 WL 784805, at *1 (E.D. Wash. Mar 1, 2021) ("Courts generally disfavor motions for reconsideration" and do not allow them to "be used to present new arguments or evidence that could have been raised earlier.") (citing *Fuller v. M.G. Jewelry*, 950 F.2d 1437, 1442 (9th Cir. 1991); *Knoa Enters., Inc. v. Estate of Bishop*, 229 F.3d 877, 890 (9th Cir. 2000)).

## III. ARGUMENT

### A. Defendants raise new arguments that are improper for a Rule 59(e) motion.

The Court should deny Defendants' motion because Defendants raise new legal arguments that they could have raised earlier in this litigation. A motion to amend "may not be used to raise arguments or present evidence for the first time when they could reasonably have been raised earlier in the litigation." *Marlyn Nutraceuticals, Inc. v. Mucos Pharma GmbH & Co.*, 571 F.3d 873, 880 (9th Cir. 2009). "A district court does not abuse its discretion when it disregards legal arguments made for the first time on a motion to amend." *Zimmerman v. City of Oakland*, 255 F.3d 734, 740 (2001).

In their briefing in this case, in lieu of arguing that the Secretary did in fact have authority to set superseding standards of care by which to exclude providers from participating in federal health care programs, Defendants repeatedly asserted that the Kennedy Declaration was *not exercising any statutory authority*. *See, e.g.*, Def's Resp. to Mot. for Summ. J. (ECF No. 74) at 12 ("The Declaration reflects only the Secretary's non-binding opinion, which does not establish the standard of care applicable to exclusion proceedings"); *id.* at 19 ("the Kennedy Declaration reflects only the Secretary's non-binding opinion" that "does not establish the standard of



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care."); *id.* at 30 ("the Court need not decide whether the Secretary possesses the authority to unilaterally declare that provision of a particular treatment is legally sufficient grounds for exclusion" because the Declaration "does not claim any authority to do so and does not in fact do so."). Defendants now request that the Court amend the Declaratory Judgment because it "lacks a nexus to the relevant exclusion framework at issue in this case and fails to provide for HHS's other grants of statutory authority to declare a treatment modality not safe and effective." Mot. to Amend J. at 2 (ECF No. 96). But in making this request, Defendants argue for the first time that the Secretary does in fact have authority to set superseding standards of care by which Defendants can exclude providers from participating in federal health care programs, and the Judgement will improperly abrogate such authority.

On the first point, Defendants attempt to narrow the scope of the Judgment by arguing that Plaintiffs had only challenged the Kennedy Declaration in the context of OIG exclusion proceedings, and that the Declaration "arose through the lens of that regulatory context and pertained only to standard-of-care exclusions." (ECF No. 96 at 5). But Defendants never raised that argument in their motion for summary judgment or motion to dismiss. Rather, Defendants insisted that "[t]he Secretary, just like anyone else, has the right to share his non-binding opinion on the safety and efficacy of certain pediatric and adolescent treatment modalities," and accordingly, "the Declaration communicates an evaluative judgment about the medical evidence; it does not, standing alone, prescribe conduct or determine legal consequences." (ECF No. 74 at 29); *see also* Mar. 19, 2026 Hr'g Tr. 28:5-11 (Defendants' Counsel: "That's in -- inapposite to action from the agency that has any type of binding force. This is [Secretary Kennedy's] opinion after reviewing the medical research that's cited within. And the opinion that he has formed is that certain types of treatments do not meet professionally recognized standards of care and they're not supported by the greater weight of the evidence."). This disclaimer of any legal effect is fundamentally at odds with Defendants' new argument that the Kennedy Declaration is an exercise of a specific exclusion authority.


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On the second point, Defendants raise a separate novel argument: that the Declaratory Judgment "encompasses circumstances where HHS may permissibly exercise specific grants of statutory authority." (ECF No. 96 at 5). But Defendants raised no such argument either in prior briefing or at oral argument, instead arguing that no statutory authorities were implicated by the Kennedy Declaration:

> The Court need not decide whether the Secretary possesses the authority to unilaterally declare that provision of a particular treatment is legally sufficient grounds for exclusion or otherwise exercise supervision or control over the practice of medicine, because the agency action Plaintiffs challenge here does not claim any authority to do so and does not in fact do so.

(ECF No. 74 at 30); *see also* Tr. 75:14-16 (Defendants' counsel: "Our position is that the Declaration is not citing some type of authority to regulate the practice of medicine, because that's not what it is doing.").

Even in their motion to amend the judgment, Defendants continue to dodge the question of whether there are any statutory grants of authority under which the Secretary could exclude providers from participation in federal health care programs by setting a superseding standard of care. Defendants' motion cites only Plaintiffs' own example of a Food and Drug Administration regulation regarding determinations about the safety and efficacy of drugs and medical devices—an example for which Defendants still do not identify an underlying statutory authority that would be implicated by the Declaratory Judgment, namely because this regulation does not grant FDA the authority to set a national standard of medical care. (ECF No. 96 at 6). Moreover, Defendants could have made that argument in the two briefs it filed before the hearing, at the hearing itself, or in the supplemental brief they filed afterward. They chose not to, instead arguing at every opportunity that the Kennedy Declaration exercised no statutory authority at all.

Neither of Defendants' new arguments for amending the Declaratory Judgment in this case were raised in Defendants' prior briefs or at the hearing. Rule 59(e) is not the vehicle by which to raise legal arguments for the first time. Defendants chose to take the position that the Kennedy Declaration was a non-binding statement merely expressing the Secretary's opinion; now that their litigation position has been rejected, they cannot seek to relitigate the case under



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an entirely new theory that the Kennedy Declaration was rooted in, and only in, the exclusion framework under 42 U.S.C. § 1320a-7. The Court can and should deny Defendants' Rule 59(e) motion on this basis alone.

**B. The Declaratory Judgment should not be amended.**

Even if Defendants' new arguments were properly before the Court, their motion should still be denied. Defendants advance two arguments to amend the Declaratory Judgment: (1) "the declaratory judgment is untethered from the relevant exclusion framework"; and (2) "the declaratory judgment inadvertently encompasses circumstances where HHS may permissibly exercise specific grants of statutory authority." (ECF No. 96 at 5). Both arguments fail.

**1. Legal Standard for Declaratory Judgment**

"A declaratory judgment offers a means by which rights and obligations may be adjudicated in cases brought by any interested party involving an actual controversy that has not reached a stage at which either party may seek a coercive remedy and in cases where a party who could sue for coercive relief has not yet done so." *Seattle Audubon Soc'y v. Moseley*, 80 F.3d 1401, 1405 (9th Cir. 1996) (internal quotations omitted). "[D]eclaratory relief is appropriate '(1) when the judgment will serve a useful purpose in clarifying and settling the legal relations in issue, and (2) when it will terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the proceeding.'" *Eureka Federal Sav. & Loan Ass'n v. American Cas. Co. of Reading, Pa.*, 873 F.2d 229, 231 (9th Cir. 1989) (quoting *Bilbrey by Bilbrey v. Brown*, 738 F.2d 1462, 1470 (9th Cir. 1984)). In the context of claims brought under the Administrative Procedure Act ("APA"), declaratory relief is appropriate where executive agencies fail "to offer substantial reassurance that they will not reprise their actions." *See Washington v. Dep't of Transp.*, No. 2:25-CV-00848-TL, 2026 WL 183584, *26 (W.D. Wash. Jan. 23, 2026) (citing recent APA cases where courts have granted declaratory judgment).

**2. In the circumstances of this case, the Declaratory Judgment should not be limited to a specific statutory authority.**

Contrary to Defendants' assertions, the Declaratory Judgment directly addresses the issues that the parties placed before the Court, which concerned the Secretary's authority to set



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superseding standards of care broadly, not just his authority to set standards for OIG exclusion proceedings under 42 U.S.C. § 1320a-7(b)(6)(B). At every turn of this litigation, the parties and the Court have considered the broad exercise of unauthorized executive power by the Secretary.

First, the Kennedy Declaration itself does not limit itself to any statutory authority. In its preamble, the Declaration states: "I, Robert F. Kennedy, Secretary of the U.S. Department of Health and Human Services (HHS), *pursuant to my authority and responsibilities under federal law*, and pursuant to 42 C.F.R. § 1001.2, hereby declare as follows." (emphasis supplied). Then, Section D titled "Legal Authority for this Declaration" states: "This declaration is issued pursuant to the authority vested in the HHS Secretary, and is informed by 42 C.F.R. § 1001.2." In addition to generic proclamations of unidentified authority, this reliance on 42 C.F.R. § 1001.2, which defines "professionally recognized standards of health care," only further underscores the Declaration's intended broad scope. The stated purpose of this regulation is to "specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in Medicare, Medicaid and all other Federal health care programs," and it applies to "the Office of Inspector General (OIG) in imposing and proposing exclusions, as well as to Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusion by the OIG (and, where applicable, in imposing exclusions proposed by the OIG)." 42 C.F.R. § 1001.1. Thus, the only codified authority that the Declaration invokes contemplates a broad application of standards of care, and does not even purport to be confined to the authorities under 42 U.S.C. § 1320a-7.

Second, in response to the Declaration's broad claim of authority, Plaintiffs' lawsuit challenged the Secretary's statutory authority to set standards of care that supersede professional standards recognized by the Plaintiff States. That challenge was not confined to 42 U.S.C.§ 1320a-7(b)(6)(B). In Plaintiffs' operative complaint, they alleged the Kennedy Declaration was an exercise of authority that Congress did not vest in the Secretary "to define the professionally established standard of care" (ECF No. 28 at ¶ 4). Plaintiffs specifically alleged that "[t]he Kennedy Declaration exceeds the Secretary's authority because it purports to set a


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national standard of care, but there is no statute that permits the Secretary of HHS to do so," and that, in fact, "[n]o statute allows the Secretary to unilaterally declare that a treatment modality is not safe and effective and thus grounds for exclusion from the program." (ECF No. 28 at ¶93). And Plaintiffs brought this issue squarely before the Court in their Motion for Summary Judgment, arguing again that "[n]o statute grants the Secretary of HHS authority to unilaterally declare that a treatment modality is not safe and effective or that providing their treatment is legally sufficient grounds for exclusion from the program." (ECF No. 32 at 14).

Plaintiffs also properly placed the scope of declaratory judgment before the Court. On summary judgment, Plaintiffs argued that "the Court should enter declaratory judgment to clarify that Defendants lack the authority to establish superseding standards of care to exclude providers from federal health care programs" because such relief was necessary to "alleviate the significant uncertainty caused by [Defendants'] conduct." Reply ISO Mot. for Summ. J. (ECF No. 77) at 31. Plaintiffs sought this declaratory relief because Defendants claimed that they maintain the authority to exclude providers from federal health care programs for provision of medically necessary transgender health care regardless of the Kennedy Declaration. *Id.*

And, until now, Defendants did not take the position that the Secretary relied on 42 U.S.C. § 1320a-7(b)(6)(B) or 42 C.F.R. § 1001.2 as authority for the Declaration. In Defendants' summary judgment briefing,[1] their argument was that "the Declaration [] does not exceed the Secretary's statutory authority because, contrary to Plaintiffs' allegations, the Declaration does not unilaterally declare that provision of a particular treatment is legally sufficient grounds for exclusion or otherwise exercise supervision or control over the practice of medicine." (ECF No. 74 at 12). Thus, neither Plaintiffs' nor Defendants' briefing indicated that the issue before the Court was limited to whether the Secretary had statutory authority to issue the Declaration under 42 U.S.C. § 1320a-7(b)(6)(B) or 42 C.F.R. § 1001.2. The Court did not commit "clear error" in failing to consider an argument that Defendants did not advance.

[1] Defendants submitted identical memoranda of law for their Response to Plaintiffs' Motion for Summary Judgment and their Motion to Dismiss, but Plaintiffs will refer simply to the Response for the purposes of this briefing. *See* ECF No. 73 at 2.



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Last, the Court's Opinion & Order correctly considered the scope of declaratory judgment to redress Defendants' unlawful actions. Declaratory judgments must be based upon the issues immediately before the Court. *See* *Ashwander v. Tennessee Valley Authority*, 297 U.S. 288, 325 (1936). "What separates a declaratory judgment from an advisory opinion is 'the settling of some dispute which affects the behavior of the defendant towards the plaintiff.'" *Rodriguez Vasquez v. Hermosillo*, 816 F.Supp.3d 1234, 1243 (W.D. Wash. January 14, 2026) (quoting *City & County of San Francisco v. Garland*, 42 F.4th 1078, 1087 (9th Cir. 2022)). The Court's Opinion & Order explains why the scope of the declaratory judgment is necessary to redress Defendants' actions toward the Plaintiffs:

> [A] declaratory judgment is appropriate here because such relief will serve a useful purpose in clarifying and settling the question of Defendants' authority to unilaterally establish a superseding standard of care for the provision of gender-affirming care to minors. It will also afford Plaintiffs relief from the uncertainty, insecurity, and controversy caused [by] the Kennedy Declaration's unprecedented overreach of authority, intrusion upon state sovereignty, and damage to Plaintiffs' provider networks and one of their most vulnerable populations: transgender minors.

Opinion & Order (ECF No. 93) at 42.

Thus, the Declaratory Judgment encompasses the appropriate scope of Defendants' authority because it directly addresses the broader question the parties placed before the Court. Plaintiffs argued that Defendants lack *any* authority to unilaterally establish standards of care that supersede professionally recognized standards for provision of gender-affirming care recognized in the Plaintiff States. The Court appropriately found for Plaintiffs, and Defendants' Motion should be denied.

**3. The Declaratory Judgment should not be amended based on hypothetical and unidentified statutory authority.**

Defendants' argument that the Declaratory Judgment inadvertently encompasses circumstances where HHS may permissibly exercise specific grants of statutory authority also fails—chiefly because Defendants cannot identify any such circumstances. In neither their briefing nor in their Motion to Amend Judgment have Defendants identified any alternative statutory authority upon which the Secretary may unilaterally establish superseding standards of



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care or exclude providers from participating in federal health care programs on that basis. On this point, the Court stated:

> Defendants have failed to invoke *any* statutory authority that authorizes the Kennedy Declaration, much less an "unmistakably clear" one that would be required to supplant states' authority to regulate medical conduct. Indeed, the Medicare statute specifically states that it *shall not* "be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. § 1395.

(ECF No. 93 at 37) (emphasis in original).

Defendants cannot credibly argue that the Declaratory Judgment infringes upon the Secretary's authority without identifying any instance of infringement. In their Motion, Defendants point only to Plaintiffs' own example that the FDA exercises some regulatory authority to declare a drug or medical device to not be safe or effective. (ECF No. 96 at 5). But Defendants do not articulate how the Declaratory Judgment unlawfully infringes upon that function of the FDA. Nor can they—determinations as to the safety and efficacy of particular drugs or devices pursuant to the applicable regulations do not "unilaterally establish standards of care that supersede professionally recognized standards of care for provision of gender-affirming care recognized in the Plaintiff States." Moreover, as every district court that has considered this question has found, investigation of medical providers for potential violation of FDCA in connection with provision of gender-affirming care is improper.[2] Thus, to the extent Defendants might wish to use prosecution under the FDCA as a basis to exclude providers from federal programs "based on their provision of gender-affirming care in a manner and quality consistent with the professionally recognized standards of care in the Plaintiff States," that would be the precise type of harm at issue in this case. This demonstrates that the Court correctly found the

[2] *See* *QueerDoc, PLLC v. U.S. Dep't of Just.*, 807 F. Supp. 3d 1295, 1303–04 (W.D. Wash. 2025); *In re Admin. Subpoena No. 25-1431-019,* 800 F. Supp. 3d 229, 239 (D. Mass. 2025); *In re Subpoena Duces Tecum No. 25-1431-016*, No. 2:25-mc-00041-JHC, 2025 WL 3562151, at *12–13 (W.D. Wash. Sept. 3, 2025); *In re Dep't of Just. Admin. Subpoena No. 25-1431-030,* No. 25-mc-00063-SKC-CYC, 2026 WL 33398, at *11 (D. Colo. Jan. 5, 2026); *In re Children's Nat'l Hosp.,* No. 1:25-cv-03780-JRR, 2026 WL 160792, at *8 (D. Md. Jan. 21, 2026); *In re Subpoena No. 25-1431-014,* 810 F. Supp. 3d 555, 580 (E.D. Pa. 2025); *In re 2025 UPMC Subpoena,* No. 2:25-MC-01069-CB, 2026 WL 570419 (W.D. Pa. Mar. 2, 2026); *In re Admin. Subpoena 25-1431-032,* No. 1:26-mc-0007-MSM-AEM, 2026 WL 1392565 (D. R. I. May 14, 2026).


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Declaratory Judgment and the resulting injunction, as written, are necessary to afford the Plaintiffs full relief. Accordingly, Defendants' Motion should be denied.

## IV. CONCLUSION

Defendants' Rule 59(e) motion improperly advances new legal arguments. Defendants also fail to articulate any legal error upon which the Court should amend the judgment. For these reasons, Defendants' Motion should be denied.

DATED: June 15, 2026

Respectfully submitted,

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