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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES, *et al.,*	Case No. 26-cv-10510
Plaintiffs,	DEFENDANTS' SUPPLEMENTAL BRIEFING IN RESPONSE TO THE COURT'S NOV. 6 ORDER
v.	
NATIONAL INSTITUTES OF HEALTH, *et al.,*	
Defendants.	

The National Institutes of Health ("NIH") is entrusted with nearly $48 billion of taxpayers' money, most of which is used to fund critical scientific breakthroughs, improve Americans' health, and save lives. Budget, Nat'l Insts. of Health, https://beta.nih.gov/about-us/budget. As a steward of the public fisc, and in line with its mission, the NIH must make maximal use of its limited funds, ensuring each dollar is used in the most scientifically sound way possible. Accordingly, the NIH has prioritized research that relies on solution-oriented approaches and measurable datasets through a series of policy statements, which Plaintiffs now challenge as arbitrary and capricious.[1] But Plaintiffs' arguments fail because the policies are reasonable and reasonably explained.

I. Policies are not arbitrary and capricious when they are reasonable and reasonably explained.

Section 706(2)(A) of the APA authorizes courts to "set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "The touchstone of arbitrary and capricious review under the APA is reasoned decisionmaking." *All. for the Wild Rockies v. Petrick*, 68 F.4th 475, 493 (9th Cir. 2023) (citation modified). Agency action can "survive arbitrary or capricious review where it has articulated a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id.* (citation modified). "Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016). At a minimum, an agency that "changes its existing position" must "'display awareness that it is changing position' and 'show that there are good reasons for the new policy.'" *Id.* (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). An agency

[1] Defendants maintain that this Court need not consider whether the challenged policy statements are arbitrary and capricious because they are not final agency action. *See* Defs. Opp'n to Mot. for Prelim. Inj. at 16-18 ("PI Opp'n"), ECF No. 84. Rather, the operative agency action Plaintiffs challenge are the individual grant determinations themselves. *Id.*

need not convince a court that its new policy is better than its old one, rather so long as the agency "*believes*" the policy to be better and "there are good reasons for it," it will be upheld. *FCC*, 556 U.S. at 516. An agency undertaking a "policy change" must also provide "a reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy[.]" *Id.* at 222 (quoting *Fox Television Stations*, 556 U.S. at 515-16).

II. The challenged policies are reasonable and reasonably explained.

In its current operative guidance, "Advancing NIH's Mission Through a Unified Strategy," dated July 2, 2026, NIH prioritized funding research "that goes beyond measuring health disparities outcomes to focus on solution-oriented approaches" and deprioritized research based on "beliefs that promote differential treatment or unnecessary classification of people based on race or ethnicity," "poorly defined concepts," or "unfalsifiable theories."[2] Nat'l Insts. of Health, U.S. Dep't of Health & Hum. Servs., *Advancing NIH's Mission Through a Unified Strategy* (July 2, 2026), https://perma.cc/3WDE-NSJT. Specifically, "NIH is sharpening its focus on chronic health issues that affect Americans, including chronic childhood diseases and nutrition." *Id.* at 2. NIH also deprioritized supporting research that relies on "[o]verly broad assumptions" and that presents those assumption as "established background facts[,]" including "attributing, without evidentiary basis, worse health outcomes in a particular population to poorly measured or unproven factors like systemic racism."[3] *Id.* at 4. NIH does not prohibit consideration of race,

[2] Earlier guidance, which Plaintiffs identify in their Complaint, ¶¶ 116-18, used terms such as "DEI" as a stand-in for "artificial and non-scientific categories." "amorphous . . . objectives," and other methods that are "antithetical to the scientific inquiry," which is largely consistent with current operative guidance that seeks to maximize scientific merit in grant determinations.

[3] For example, research that assumes certain treatments are better over others, such as puberty suppression, hormone therapy, or surgical intervention to treat gender dysphoria, gender identity disorder, or gender incongruence in minors, would be less promising than a broader approach that identifies whether those treatments have had a negative affect and how to best address the needs of these minors so that they may live long, healthy lives. *See* Off. of the Dir., Nat'l Insts. of Health, U.S. Dep't of Health & Hum. Servs., NIH Priorities and Internal Review of Intramural and Extramural Programs 3 (Aug. 15, 2025), https://perma.cc/CA7M-8CWW.

gender, sexual orientation, and other characteristics. For example, such factors may be properly considered where genetically inherited disorders are more likely to affect certain groups. *Id.*

Plaintiffs assert these are vague standards.[4] Even if a document setting out funding priorities could be considered actionably "vague," this document is not. The entirety of the NIH's priority statement provided the contours of this science-focused policy. For example, the statement detailed the importance of replicability in research, *id.* at 2, as well as research that focuses on innovative evidence-based interventions and treatments, *id.* at 4, and certain research areas and methods that are of particular national import such as "Artificial Intelligence," nutrition, autism, alternative testing models, and HIV/AIDS research, *id.* at 3, 5. This approach is eminently reasonable: it makes sense to prioritize research that produces measurable, replicable results with empirical methods over more interpretive results with unmeasurable and unproven factors. It is also nothing new that "NIH will support scientifically rigorous research." Nat'l Insts. of Health, NIH Priorities and Internal Review of Intramural and Extramural Programs, *supra* note 3. NIH has long said the "[k]ey to the successful application of that knowledge toward health outcomes is scientific rigor in conducting biomedical research." Nat'l Insts. of Health, U.S. Dep't of Health & Hum. Servs., NOT-OD-15-103 "Enhancing Reproducibility through Rigor and Transparency." (June 9, 2015) (defining "Scientific rigor" as "the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results" and requiring applicants to describe how they will achieve robust and unbiased results in their experiments, which must be designed to avoid bias and be reproducible

[4] Plaintiffs cite to *Washington v. U.S. Dep't of Educ.*, 167 F.4th 1241, 1247 (9th Cir. 2026), arguing that NIH's prior decisions not to fund "vaccine hesitancy" or "climate change" research violated the APA because there was no public announcement that these areas of research would not be funded. PI Mot. at 26. But in *Washington*, the Court found individual grant terminations were arbitrary and capricious because they "failed to explain what was wrong with each grantee's project," *Washington*, 167 F.4th at 1247, which Plaintiffs do not allege here, *see* PI Mot. at 26.

under well-controlled and reported experimental conditions.). NIH's priority statement is consistent with these longstanding principles.

The process used for the review, termination, denial, or renegotiation of any grant is also reasonable, and utilizes a multi-stage, individualized, substantive review of proposed and ongoing research. While NIH uses computational text analysis tools to initially review existing grants and grant applications for certain terms, all identified grants then proceed through multiple layers of additional review, including individualized manual review prior to any termination, denial, or renegotiation, as Plaintiffs acknowledge. *See* Compl. ¶¶ 141, 153-54. Indeed, NIH's staff guidance requires case-by-case review of each application or grant that is flagged due to the inclusion of certain terms, with staff identifying specific areas of nonalignment and linking their determinations to the relevant agency priority. *See* Nat'l Insts. of Health, U.S. Dep't of Health & Hum. Servs., Staff Guidance –Award Assessment for Alignment with Agency Priorities - March 2025 (Mar. 4, 2025), https://perma.cc/J7BX-3FPG. Certain terms are often paired with types of research that lack empirical measurements and rely on unproven, theoretical factors. Other terms are not standardized and lack clear meaning, such as "DEI." And in any event, if such terms are not indicative of deprioritized research, manual review of the grants would identify as much. These terms serve as a tool to identify grants and applications that potentially do not align with current agency priorities. As every grant or grant application receives manual and multi-layer review to determine whether it complies with the challenged policies and current agency priorities, NIH is not relying on these terms in a way that Congress did not intend. Rather, NIH's review of grants centers around factors related to scientific merit and the mission of the NIH, such as measurability, replicability, objectivity, and the likelihood of meaningful results. *See* 42 U.S.C. § 284(b)(3); 42 C.F.R. § 52.5; Nat'l Insts. of Health, *Advancing NIH's Mission Through a Unified Strategy*, *supra*

at 2. Indeed, Congress instructed NIH to consider these factors for each potential grant, which the challenged policies prioritize. *Id*. To the extent that terms are revised in grants, it is in favor of more precise language or less divisive language to "improve public trust," which has been a stated goal of the challenged policies. Nat'l Insts. of Health, *Advancing NIH's Mission Through a Unified Strategy* at 1*, supra* at 2.

These policies are facially neutral and applied to every grant neutrally. Plaintiffs argue Defendants are using the policies to "jeopardize funding of research that could be expected to uncover negative health impacts of favored policies" or "the positive health impacts of disfavored policy," Compl. ¶ 159; Mot. for Prelim. Inj. at 9, 25, but research on a purportedly "favored" or "disfavored" policy could generate negative or positive results, and Plaintiffs' assertion that certain research "could be expected" to return a predetermined result that advocates for a particular government policy precisely demonstrates why it was deprioritized and is of less scientific value.

NIH reasonably explained these policy changes as well. NIH explained it is entrusted with a substantial sum of taxpayer dollars, and it is incumbent upon the agency as a steward of the public fisc to both safeguard and make maximal use of the limited funds it is allocated. "Funding research containing such poorly defined concepts and unfalsifiable theories would divert resources away from projects that advance the health and longevity of all Americans, including minority populations." Nat'l Insts. of Health, *Advancing NIH's Mission Through a Unified Strategy* at 1, 4, *supra* at 2. Additionally, the NIH explained it had historically invested substantially in health disparities research without tangible improvements in health outcomes for the populations that research purported to benefit. *Id.* at 4. This rationale easily clears the APA's requirement for a "reasoned explanation." *See Encino Motorcars, LLC*, 579 U.S. at 221. Accordingly, the challenged policies are reasonable and reasonably explained.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 10, 2026, I electronically filed this document with the Court by using the CM/ECF system, and that this document was distributed via the Court's CM/ECF system.

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