UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUETTS, *et al.* Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, Defendants.	Case No. 25-CV-10338
ASSOCIATION OF AMERICAN MEDICAL COLLEGES, *et al.* Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, Defendants.	Case No. 25-CV-10340
ASSOCIATION OF AMERICAN UNIVERSITIES, *et al.*, Plaintiffs, v. DEPARTMENT OF HEALTH & HUMAN SERVICES, *et al.*, Defendants.	Case No. 25-CV-10346

MEMORANDUM AND ORDER
ON MOTION FOR PRELIMINARY INJUNCTION

ANGEL KELLEY, D.J.

These three cases came before the Court on an emergency basis on Monday, February 10, 2025.The National Institutes of Health ("NIH") issued a Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates (NOT-OD-25-068) ("Rate Change Notice") on Friday night, February 7, 2025, slashing and capping previously negotiated indirect cost rates on all existing and future grant awards for biomedical research, with an effective date of February 10. This Notice impacts thousands of existing grants, totaling billions of dollars across all 50 states—a unilateral change over a weekend, without regard for on-going research and clinical trials. The imminent risk of halting life-saving clinical trials, disrupting the development of innovative medical research and treatment, and shuttering of research facilities, without regard for current patient care, warranted the issuance of a nationwide temporary restraining order to maintain the status quo, until the matter could be fully addressed before the Court.

Following full briefing and oral argument by the parties, as well as review of accepted amicus briefs, the Court **GRANTS** a nationwide preliminary injunction.

I. BACKGROUND

Plaintiffs in action 25-CV-10338 are 22 attorneys general, who filed suit on behalf of their states, Massachusetts, Michigan, Illinois, Arizona, California, Connecticut, Colorado, Delaware, Hawaii, Maine, Maryland, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Rhode Island, Vermont, Washington, and Wisconsin ("Plaintiff States"). Plaintiffs in action 25-CV-10340 are five medical associations, including the Association of American Medical Colleges, the American Association of Colleges of Pharmacy, the Association for Schools and Programs of Public Health, the Conference of Boston Teaching

Hospitals, Inc., and the Greater New York Hospital Association ("AAMC"). Plaintiffs in action 25-CV-10346 are 17 associations and universities, including the Association of American Universities, the American Council on Education, the Association of Public and Land-grant Universities, Brandeis University, Brown University, the Regents of the University of California, Carnegie Mellon University, The University of Chicago, Cornell University, The George Washington University, John Hopkins University, Massachusetts Institute of Technology, the Trustees of the University of Pennsylvania, University of Rochester, the Trustees of Tufts College, and the California Institute of Technology ("AAU"). The Defendants[1] in each action are the National Institutes of Health and the Department of Health and Human Services ("HHS").

The National Institutes of Health is a federal agency created to support innovative medical research strategies to enhance health, lengthen life, and reduce illness and disability. This case concerns NIH's co-sharing method of funding biomedical and public health research. NIH is the primary source of federal funding for health research projects in the United States through grant awards. In fiscal year 2023, NIH grants totaled over $35 billion—giving out nearly 60,000 competitive grants to more than 300,000 researchers. The grants primarily go to public and private colleges and universities, and other non-governmental research institutions.

Congress has established a regulatory framework for how these grants are awarded, consisting of three primary actions. First, it has authorized NIH to "make grants-in-aid to universities" for research support. 42 U.S.C. § 241(a)(3). Second, it has instructed the Office of Management and Budget ("OMB") to issue general guidance on such grants. See 31 U.S.C. § 503(a), (b)(2)(C). Third, Congress passed an appropriations rider that prohibits HHS and, by

[1] The acting directors for each agency are also named as defendants in their official capacities.

extension, NIH from spending appropriated funds "to develop or implement a modified approach to" the reimbursement of "indirect costs" and "deviations from negotiated rates." Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, 132 Stat. 348, § 226.

A. Grant Award Process

Under the structure of these Acts, NIH has set the regulations that govern the grant awarding process. As a general overview, the process begins with a notice from NIH that funding is available for a specific topic. Research institutions then submit applications for a grant on this specific topic. These applications are formally reviewed—including peer review by others working in the same field. If the application is approved, NIH will issue a Notice of Award ("NOA"), which is a legally binding decision indicating that funds can be withdrawn. This drawdown, or receipt of funds, is very rarely done as one lump sum withdrawal. Typically, the grantee will use a cost-based accounting system where they are reimbursed for their actual and documented costs connected to their research grant over the life of the grant.

The regulations proscribe two different categories of costs: direct costs and indirect costs. 45 C.F.R. § 75.412. Direct costs are costs that are attributed to one specific research project. For example: materials and supplies used in the research project, or a stipend for a graduate student working only on that one project. Indirect costs are research costs that cannot be attributed to one specific project but are incurred for common or joint objectives. 45 C.F.R. § 75.2. Indirect costs include expenses such as, building construction and maintenance, utilities, laboratory equipment maintenance, and faculty and staff employed across multiple research projects. Indirect costs are also referred to as facilities and administration ("F&A") costs. 45 C.F.R. § 75.414(a). All drawdowns for reimbursement of indirect expenses paid are subject to federal audit.

B. The Rate Change Notice

The acting director of the National Institutes of Health issued a Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates (NOT-OD-25-068) on Friday night, February 7, 2025. This Rate Change Notice relates to the administration of indirect costs. Before this Notice, each institution had negotiated its indirect cost rate ("ICR") with the appropriate federal agency, also known as the cognizant agency. Once negotiated, that rate became binding on every federal agency interacting with the institution. The ICR represents a percentage of the total grant—not a dollar amount. For example, if an organization has negotiated an ICR of 30%, and the grant award is $100,000, the total grant amount for the receiving institution is $130,000 ($100,000 (direct costs), plus $30,000 (indirect costs, or 30% of $100,000)). These negotiated rates are formalized in a Negotiated Indirect Cost Rate Agreement ("NICRA"). The varying rates of indirect costs are established so that each research institution can plan accordingly and facilitate the preparation of their budgets to fulfill their specific research needs. 45 C.F.R. pt. 75, appx. III § C(4).

After the ICR is agreed upon and the actual costs are incurred, federal agencies are authorized to conduct audits to ensure that the negotiated ICR conforms with actual costs and address any amounts questioned during the audit. 2 C.F.R. pt. 200, appx. III § C.11(2)(d). Funds are recouped and the ICR must be adjusted if the audit indicates that the institution recovered any unallowable costs. 2 C.F.R. § 200.411(a), (b).

Per federal regulations, the NICRA is binding on every federal agency throughout the life of the grant. 45 C.F.R. pt. 75, appx. III § C(7). There are limited exceptions through which the previously negotiated rate can be adjusted and only in particular circumstances, as their fixed nature is essential for institutions as they budget and plan for their research in the long term. As

an initial matter, a different-than-negotiated rate can only be used for a single federal award or a class of awards, defined as a "group of Federal awards either awarded under a specific program or group of programs or to a specific type of non-Federal entity or group of non-federal entities to which specific provisions or exceptions may apply." 45 C.F.R. §§ 75.2, 75.414(c)(1). The first circumstance under which an ICR can be adjusted is when "required by Federal statute or regulation." § 75.414(c)(1). The second circumstance, relevant to the cases before the Court, is when "approved by a Federal awarding agency head or delegate based on documented justification," as later described in Section (c)(3). Id. Turning to Section (c)(3), "[t]he HHS awarding agency must implement, and make publicly available, the policies, procedures and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates." 45 C.F.R. § 75.414(c)(3).

The February 7 Rate Change Notice eliminates the individually negotiated rates to impose a flat rate of 15% across all grants. This usurps all currently existing NICRAs, impacting both all existing grants and all new grants going forward.

C. Prior Attempts to Limit Indirect Cost Rates Governing NIH Grants

Prior presidential administrations have made changes or attempted to make changes to the determination of F&A costs. The Clinton Administration limited indirect costs collectable by NIH grant recipients to 26% of modified total direct costs via the administrative rulemaking process. See Final Revision to Circular A-21, 56 Fed. Reg. 50224, 50228 (Oct. 3, 1991) (codified at 2 C.F.R. pt. 200, appx. III § C(8)(a)). A later budget proposal from the Clinton Administration related to the cutting of F&A funding was rejected out of hand by Congress. See H. Rep. 103-553 at 67 (1994); Genevieve J. Knezo, Cong. Rsch. Serv., Indirect Costs for R&D at Higher Education Institutions 32 (1994). The Obama Administration had some discussion

regarding a cap on all indirect costs, but later changed course after nearly universal institutional opposition.

In 2017, the first Trump Administration released a budget proposal that would have slashed the indirect cost rate to a uniform, across-the-board rate of 10%. In direct response, Congress passed the previously mentioned appropriations rider to prevent this change, deeply concerned for the resulting harm to the nation's research capability. Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 226, 132 Stat. 348. This rider has remained the law from its passage through the present day. Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224, 138 Stat. 460, 677; see also Dept. of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245, § 224, 132 Stat. 2981, 3094 (2018); Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 224, 133 Stat. 2534, 2582 (2019); Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, § 224, 134 Stat. 1182, 1594 (2020); Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, § 224, 136 Stat. 49, 470-71; Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 224, 136 Stat. 4459, 4883-84 (2022).

II. PROCEDURAL HISTORY

The Rate Change Notice was signed on the evening of February 7, 2025—and was set to go into effect on the following business day, February 10, 2025. On February 10, the three Plaintiff groups filed their cases seeking injunctive and declaratory relief, each alleging that the Rate Change Notice ignores existing regulations, is in excess of statutory authority, and violates the Administrative Procedure Act ("APA") because it is arbitrary and capricious, the Administration failed to follow proper procedure, and the Notice is impermissibly retroactive.

Each Plaintiff group requested an *ex parte* temporary restraining order ("TRO"), two of which were granted, and the third was denied as moot after the Court issued a nationwide injunction in the second action, AAMC, 25-CV-13460. Defendants subsequently filed reports confirming that they would not implement the Rate Change Notice until further notice from the Court. The Court then directed Defendants to submit a consolidated opposition to Plaintiffs' motions, and the Plaintiff groups to submit a consolidated reply brief.

On the eleventh day of the temporary restraining orders, February 21, 2025, the Court extended the temporary orders for good cause, pursuant to Fed. R. Civ. P. 65(b)(2), to resolve the fully briefed and argued motions for preliminary injunction, which both parties acknowledge is ripe for this Court.

III. SUBJECT MATTER JURISDICTION

As a threshold matter, the Court addresses Defendants' contention that this Court lacks subject matter jurisdiction to hear these cases. District courts are courts of limited jurisdiction and can only exercise jurisdiction when authorized by the Constitution or a federal statute. See, e.g., Exxon Mobil Corp. v. Allapattah Servs., Inc., 545 U.S. 546, 552 (2005). If a district court finds that it lacks subject matter jurisdiction, it shall transfer the case at issue to the appropriate district "if it is in the interest of justice." 28 U.S.C. § 1631. Thus, before moving onto the merits, the Court first addresses whether it can properly exercise jurisdiction.

Defendants contend that Plaintiffs' claims lie exclusively in the United States Court of Federal Claims, pursuant to the Tucker Act, 28 U.S.C. § 1491. Plaintiffs do not agree that the Tucker Act divests this Court of jurisdiction. For the reasons stated below, the Court rejects Defendants' characterization of Plaintiffs' claims as mere breach of contract claims meant for the Court of Federal Claims. The Court retains subject matter jurisdiction to hear these cases under

5 U.S.C. § 702. See Taydus v. Cisneros, 902 F. Supp. 278, 284 (D. Mass. 1995) (holding that the district court retains jurisdiction per the APA waiver of sovereign immunity).

A. The Tucker Act

The Tucker Act: (1) "confers jurisdiction upon the Court of Federal Claims over the specified categories of actions brought against the United States," and (2) "waives the Government's sovereign immunity for those actions."[2] Fisher v. United States, 402 F.3d 1167, 1172 (Fed. Cir. 2005). The Tucker Act vests jurisdiction in the United States Court of Federal Claims with respect to "any claim against the United States founded either upon the Constitution, or any Act of Congress or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort." 28 U.S.C. § 1491(a)(1). In suits seeking more than $10,000 in damages, the Court of Federal Claims' jurisdiction is exclusive of the federal district courts. See, e.g., Burgos v. Milton, 709 F.2d 1, 3 (1st Cir. 1983).[3] Thus, plaintiffs wishing to file "a suit against the United States involving a contract" where the "relief [sought is] over $10,000" must do so in the Court of Federal Claims. Vill. W. Assocs. v. R.I. Hous. & Mortg. Fin. Corp., 618 F. Supp. 134, 138 (D.R.I. 2009), judgment entered, 641 F. Supp. 2d 135 (D.R.I. 2009).

Generally, claims brought in the Court of Federal Claims "must be for monetary relief; [they] cannot be for equitable relief, except in very limited circumstances[.]" Gonzales &

[2] The Tucker Act's waiver of sovereign immunity does not "create[] a substantive right enforceable against the Government by a claim for money damages." United States v. White Mountain Apache Tribe, 537 U.S. 465, 472 (2003). Rather, plaintiffs invoking the Tucker Act's waiver of sovereign immunity must point to "a statute" that "can fairly be interpreted as mandating compensation by the Federal Government for the damage[s] sustained." Id. (quoting United States v. Mitchell, 463 U.S. 206, 217 (1983)).

[3] For suits against the United States with claims for less than $10,000, the Court of Federal Claims and Federal District Courts have concurrent jurisdiction under 28 U.S.C. § 1346(a)(2), also known as the "Little Tucker Act."

Gonzales Bonds & Ins. Agency, Inc. v. Dep't of Homeland Sec., 490 F.3d 940, 943 (Fed. Cir. 2007). Such "limited circumstances" are found in cases in which the equitable relief requested is "an incident of and collateral to" monetary relief. James v. Caldera, 159 F.3d 573, 580 (Fed. Cir. 1998) (quoting 28 U.S.C. § 1491(a)(2) (1994)).

B. The Administrative Procedure Act

The Administrative Procedure Act entitles "a person suffering legal wrong because of any agency action" to seek "judicial review thereof." 5 U.S.C. § 702. Congress amended § 702 in 1976 to "broaden the avenues for judicial review of agency action by eliminating the defense of sovereign immunity" in suits "seeking relief other than money damages . . . ." Bowen v. Massachusetts, 487 U.S. 879, 891-92 (1988); see Act of Oct. 21, 1976, Pub. L. No. 94-574, 90 Stat. 2721. By clarifying that § 702's waiver of sovereign immunity applied "only to actions 'seeking relief other than money damages' and where 'there is no other adequate remedy in a court,'" Congress "sought to pull together the 'patchwork' of various statutory waivers of federal sovereign immunity" into one coherent scheme. Gregory C. Sisk, The Jurisdiction of the Court of Federal Claims and Forum Shopping in Money Claims Against the Federal Government, 88 Ind. L.J. 83, 90 (2013) (quoting 5 U.S.C. §§ 702, 704). Congress intended "the [1976 APA amendments] to complement[] . . . the Tucker Act[.]" Id. at 90 n.59 (citing H.R. Rep. No. 94-1656, at 11 (1976)).

C. Rights and Remedies Test

The "jurisdictional boundary" between the Tucker Act and Administrative Procedure Act is well-traversed by litigants seeking relief against the federal government. Suburban Mortg. Assocs., Inc. v. U.S. Dep't of Hous. & Urb. Dev., 480 F.3d 1116, 1117 (Fed. Cir. 2007). Still, the boundary's precise contours remain elusive. See, e.g., Id. at 1124 (listing cases treading the

jurisdictional line); Bublitz v. Brownlee, 309 F. Supp. 2d 1, 6 (D.D.C. 2004) (noting "[t]he bright-line rule" between monetary and equitable relief in the Tucker Act–APA context "turns out to be rather dim . . . ."). Plaintiffs often attempt to "avoid Tucker Act jurisdiction by 'converting complaints which "at their essence" seek money damages from the government into complaints requesting injunctive relief or declaratory actions.'" Martin v. Donley, 886 F. Supp. 2d 1, 8 (D.D.C. 2012) (quoting Kidwell v. Dep't of Army, Bd. for Correction of Mil. Recs., 56 F.3d 279, 284 (D.C. Cir. 1995)).

The Supreme Court has made clear that "[n]ot every claim invoking the Constitution, a federal statute, or a regulation is cognizable under the Tucker Act." United States v. Mitchell, 463 U.S. 206, 216 (1983). Indeed, not every "failure to perform an obligation" by the federal government "creates a right to monetary relief." United States v. Bormes, 568 U.S. 6, 16 (2012). When traversing the Tucker Act–APA jurisdictional boundary, courts "must look beyond the form of the pleadings to the substance of the claim[,]" Suburban Mortg., 480 F.3d at 1124, to determine whether "the essence of [an] action is in contract . . . ." Am. Sci. & Eng'g, Inc. v. Califano, 571 F.2d 58, 63 (1st Cir. 1978). The "essence" of an action encompasses two distinct aspects—the "source of the rights upon which the plaintiff bases its claim" and "the type of relief sought (or appropriate)." Piñeiro v. United States, No. 08-CV-2402, 2010 WL 11545698, at *5 (D.P.R. Jan. 26, 2010) (quoting Megapulse, Inc. v. Lewis, 672 F.2d 959, 968 (D.C. Cir. 1982)); see also R.I. Hous. & Mortg. Fin. Corp., 618 F. Supp. 2d at 138.

While the First Circuit has not formally adopted the "rights and remedies" test that is used by several other circuits,[4] courts in this Circuit have adopted the test to determine if the

[4] See, e.g., Cohen v. Postal Holdings, LLC, 873 F.3d 394, 403 (2nd Cir. 2017); RMI Titanium Co. v. Westinghouse Elec. Corp., 78 F.3d 1125, 1136 (6th Cir. 1996); Evers v. Astrue, 536 F.3d 651, 657-658 (7th Cir. 2008); United Aeronautical Corp. v. U.S. Air Force, 80 F.4th 1017, 1026

"essence" of an action is truly contractual in nature. See R.I. Hous. & Mortg. Fin. Corp., 618 F. Supp. 2d at 138; Piñeiro, 2010 WL 11545698, at *5. This Court adopts the Megapulse framework and discusses each element in turn.

1. Source of Right

The Defendants contend that Plaintiffs' source of rights stems from the legally binding Notice of Awards that are provided to selected grant recipients stating that funds may be requested. Defendants contend that, generally, grants are treated as contracts when all the necessary attributes are present and that "[a]ll elements [of a contract] are present in the Notices of Award," and the Court should look no further if this "contract" exists. States [Dkt. 73, at 8]. Plaintiffs, however, argue that their claims are not based on the contract. Rather, according to the Plaintiffs, their claims are rooted in "the Constitution, federal statutes, and federal regulations, not contract terms." States [Dkt. 81, at 3]. Plaintiffs explicitly ask this Court to interpret and enforce the federal regulations, not the grants in which the regulations are incorporated.

After examining the three Complaints in their entirety, the Court finds that the gravamen of Plaintiffs' Complaints does not turn on terms of a contract between the parties; it turns on federal statute and regulations put in place by Congress and NIH. See, e.g., K-Mar Indus., Inc. v. U.S. Dep't of Def., 752 F. Supp. 2d 1207, 1214 (W.D. Okla. 2010) ("The source of the rights alleged in this action is not contractual, it is the procedures put in place by the defendants."). While it is true that the Notice of Award operates as a contract, the claims in this case turn on how the regulations govern the provision of these awards. This is further underscored by the

(9th Cir. 2023); McKay v. United States, 516 F.3d 848, 851 (10th Cir. 2008); Begner v. United States, 428 F.3d 998, 1002 (11th Cir. 2005); cf. United States v. J&E Salvage Co., 55 F.3d 985, 988 (4th Cir. 1995) (applying Megapulse to a dispute arising under the Contract Disputes Act).

Rate Change Notice's impact not just on current grants, but future ones as well. It follows that the source in which Plaintiffs aim to vindicate their rights is not in contracts that are yet to exist (future grants) but is actually in the regulation that facilitates such grants.

Plaintiffs' contractual relationships with NIH do not automatically "convert a claim asserting rights based on federal regulations into one which is, 'at its essence,' a contract claim." Normandy Apartments, Ltd. v. U.S. Dep't of Hous. & Urb. Dev., 554 F.3d 1290, 1299 (10th Cir. 2009). This is especially the case since "[c]ontract issues may arise in various types of cases where the action itself is not founded on a contract." Megapulse, 672 F.2d at 968 (listing examples of tort theories that could require a court to dispose of contractual issues incidentally). This is not a request for "monetary relief" that is "dressed in equitable and declaratory garb." R.I. Hous. & Mortg. Fin. Corp., 618 F. Supp. 2d at 138 (D.R.I.). Plaintiffs are not seeking judicial review of a contract. In fact, Plaintiffs have not requested the Court to examine any contract or grant agreement created between the parties. Rather, they have asked this Court to review and interpret the governing federal statute and regulations. Accordingly, Plaintiffs have sufficiently established that the source of their rights is not rooted in any contract between them and the Defendants.

2. Relief Sought

This Court now turns to the type of relief sought by Plaintiffs. Defendants contend that Plaintiffs "seek monetary relief greater than $10,000 for NOA's reduction of the indirect cost rate to 15%." States [Dkt. 73, at 10]. Plaintiffs, on the other hand, contend that they are not seeking a money judgment at all. Instead, they only "seek declaratory and injunctive relief returning the parties to the pre-existing status quo by requiring the government to respect negotiated rates for indirect costs," States [Dkt. 81, at 5], with existing contracts establishing

ICR's for the next several years, underscoring the nature of the ongoing relationship between the Plaintiffs, other third-parties, and NIH. See, e.g., AAU [Dkt. 2-12, Declaration of Dr. David F. Kotz, of Dartmouth College] ("Direct negotiations and detailed audits with the federal government in 2022 resulted in the setting of a predetermined rate that Dartmouth had expected in good faith would be applicable through 2029."); Id. [Dkt. 2-20, Declaration of Anshuman Razdan, of the University of Oregon] ("UO's current negotiated rate for organized research is 49% (up from 47.5%), last negotiated August 2023 and valid through June 30, 2027."). None of Plaintiffs' Complaints refer to compensatory damages.[5]

It is now axiomatic that there is a "distinction between an action at law for damages," which provides monetary compensation, and "an equitable action for specific relief," which might nonetheless require monetary relief. Bowen, 487 U.S. at 893; see Great-West Life & Annuity Ins. Co. v. Knudson, 534 U.S. 204, 213 (2002) ("[W]hether [restitution] is legal or equitable depends on 'the basis for [the plaintiff's] claim' and the nature of the underlying remedies sought." (quoting Reich v. Continental Casualty Co., 33 F.3d 754, 756 (7th Cir. 1994) (Posner, J.))). Simply because "a judicial remedy may require one party to pay money to another" does not necessarily "characterize the relief as 'money damages.'" Bowen, 487 U.S. at 893. A hallmark of such equitable actions is the existence of prospective relief in ongoing relationships. Compare Bowen, 487 U.S. at 905 (holding the district court had jurisdiction because declaratory or injunctive relief was appropriate to clarify petitioner state's ongoing obligations under the Medicaid plan), with Me. Cmty. Health Options v. United States, 590 U.S. 296, 298 (2020) (holding that petitioners properly relied on the Tucker Act to sue for damages in

[5] All three Complaints request declaratory judgment and injunctive relief. The Complaint by AAU also requests vacatur of the Rate Change Notice.

the Court of Federal Claims because plaintiffs were strictly concerned with "specific sums already calculated, past due, and designed to compensate for completed labors"). Plaintiffs do not bring claims for past pecuniary harms. Rather, like the petitioners in Bowen, their claims are to preserve their ongoing and prospective agreements with NIH. The various harms identified by Plaintiffs properly correspond to the sought equitable relief. Plaintiffs indicate that the Rate Change Notice would result in the loss of jobs, the suspension of research, including clinical trials and infrastructure projects, and a reduction of teaching staff who are committed to cultivating medical students. See, e.g., States [Dkt. 6-34, Declaration of Dr. Greg Hirth, of Brown University] ("At a 15% indirect cost rate, many of Brown's current research projects and clinical trials will be forced to cease abruptly."); AAU [Dkt. 2-12, Declaration of Dr. David F. Kotz, of Dartmouth College] ("The world's best scientists will not move to (or stay at) universities where they are not able to conduct world-class research."); AAU [Dkt. 2-28, Declaration of Ishwar K. Puri, of the University of Southern California] (discussing the likely cutting of 73 staff members while also adding "slowdowns or halts in research by USC and other American universities will allow competitor nations that are maintaining their investments in research to surpass the United States on this front, threatening both our Nation's national security and its economic dominance."). Ultimately, it is these harms (among many others) for which Plaintiffs are pleading relief. It would be legal error to construe Plaintiffs' harms as couched pleas for monetary relief for which they never ask.

Plaintiffs' primary purpose in bringing their claims is to seek equitable, not monetary, relief. Since this Court finds that the proper source of Plaintiffs' rights is federal statute and regulations and because the relief sought is injunctive in nature, this Court determines that the "essence" of the action is not contractual in nature. R.I. Hous. & Mortg. Fin. Corp., 618 F. Supp.

2d at 138. Thus, Plaintiffs' claims cannot properly be brought under the Tucker Act in the Federal Claims Court and this Court retains jurisdiction.

IV. PRELIMINARY INJUNCTION LEGAL STANDARD

Courts apply the same standard in assessing motions for temporary restraining order— as the Plaintiffs originally requested—and motions for preliminary injunction, which follow full briefing and the opportunity to be heard by the Court. See Fed. R. Civ. P. 65; Wash. Tr. Advisors, Inc. v. Arnold, 646 F. Supp. 3d 210, 217 (D. Mass. 2022). Following the briefing and oral argument in this matter, the parties agree the request for a preliminary injunction, as opposed to a temporary restraining order, is ripe.

The "extraordinary and drastic" remedy of a preliminary injunction requires a showing of four elements: (1) substantial likelihood of success on the merits; (2) a high likelihood of irreparable harm if injunctive relief is not granted; (3) a balance of equities tips in the movant's favor; and (4) the injunctive relief is in the public interest. See Voice of the Arab World, Inc. v. MDTV Med. News Now, Inc., 645 F.3d 26, 32 (1st Cir. 2011) (citing Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 20 (2008)). The last two factors "merge when the Government is the party opposing the preliminary injunction." Nken v. Holder, 556 U.S. 418, 435 (2009). The most important of the four elements is the likelihood of success on the merits—which is considered the "sine qua non" of the inquiry. Ryan v. U.S. Immigr. & Customs Enf't, 974 F.3d 9, 18 (1st Cir. 2020) (quoting New Comm Wireless Servs., Inc. v. SprintCom, Inc., 287 F.3d 1, 9 (1st Cir. 2002)).

The evaluating court need not conclusively determine the merits of the movant's claim but should evaluate the likelihood or not that the movant will prevail on the merits. Id. (citing Ross-Simons of Warwick, Inc. v. Baccarat, Inc. (Ross-Simons I), 102 F.3d 12, 16 (1st Cir.

1996)). The court may accept as true well-pleaded allegations in the complaint and uncontroverted affidavits. Rohm & Haas Elec. Materials, LLC v. Elec. Circuits, 759 F. Supp. 2d 110, 114 n.2 (D. Mass. 2010) (quoting Elrod v. Burns, 427 U.S. 347, 350 n.1 (1976)). The court may also rely upon otherwise inadmissible evidence in deciding a motion for preliminary injunction. Howe v. U.S. Bank Nat'l Ass'n as Tr. for RMAC Tr. Series 2016-CTT, 440 F. Supp. 3d 99, 102 (D. Mass. 2020) (citing Asseo v. Pan Am. Grain Co., Inc., 805 F.2d 23, 26 (1st Cir. 1986)).

A. Likelihood of Success on the Merits

Turning to the likelihood of success on the merits, this Court considers three main categories as presented by the various Plaintiffs. First, Plaintiffs claim the February 7 Rate Change Notice violates the plain language of the regulations regarding the administration of indirect, or F&A, costs. See AAMC [Dkt. 1, at 16]. Second, Plaintiffs argue that absent compliance with said regulation, the Rate Change Notice is contrary to law. See [id. at 18]. Finally, Plaintiffs argue that the Rate Change Notice failed to follow administrative procedure, as required by the Administrative Procedure Act, including that the action was arbitrary and capricious, that it failed to abide by notice-and-comment requirements, and that it is impermissibly retroactive. See [id. at 19]. The Court addresses each claim in turn.

Before turning to these claims, the Court recognizes that the Plaintiffs made several other claims, including constitutional arguments, but it is cognizant of the doctrine of constitutional avoidance, which declares that "federal courts are not to reach constitutional issues where alternative grounds for resolution are available." Marasco & Nesselbush, LLP v. Collins, 6 F.4th 150, 178 (1st Cir. 2021) (quoting Vaquería Tres Monjitas, Inc. v. Pagan, 748 F.3d 21, 26 (1st Cir. 2014)). Although not resolving the merits of the instant cases, alternative grounds exist here

such that discussion of "the constitutional questions would be inconsistent with our obligation to avoid doing so where a non-constitutional disposition is possible." Id. at 179.

1. 45 C.F.R. § 75.414

45 C.F.R. § 75.414, the regulation that explains the provision of, and potential deviation from, indirect (F&A) costs, operates within a larger regulatory structure. This structure includes: (1) Appendix III to Part 75—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs); and, (2) Appendix IV to Part 75—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Nonprofit Organizations. The appendices expound upon the identification, negotiation, and administration of indirect costs, which also operate alongside policy statements provided by HHS and NIH in the effectuation of grants generally and indirect costs more specifically. See, e.g., States [Dkt. 82-1, NIH Grants Policy Statement].

These regulations and policies provide for a system in which the cognizant agency for indirect costs, or "the Federal agency responsible for reviewing, negotiating, and approving cost allocation plans or indirect cost proposals . . . on behalf of all Federal agencies," undertakes a lengthy negotiation process to establish a long-term ICR, memorialized in NICRAs, that complies with this strict regulatory framework. 45 C.F.R. §§ 75.2, 75.414; 45 C.F.R. pt. 75, appx. III; 45 C.F.R. pt. 75, appx. IV; States [Dkt. 82-1, NIH Grants Policy Statement]; see also AAU [Dkt. 2-12, Declaration of Dr. David F. Kotz, of Dartmouth College] ("Direct negotiations and detailed audits with the federal government in 2022 resulted in the setting of a predetermined rate that Dartmouth had expected in good faith would be applicable through 2029."); AAU [Dkt. 2-20, Declaration of Anshuman Razdan, of the University of Oregon] ("UO's current negotiated rate for organized research is 49% (up from 47.5%), last negotiated August 2023 and valid

through June 30, 2027."); States [Dkt. 6-41, Declaration of Dorota Grejner-Brzezinska, of the University of Wisconsin-Madison] ("The sense of whiplash is particularly acute, given that UW-Madison had finalized its most recent NICRA with DHHS less than three weeks prior.").

With this understanding of the larger regulatory structure, 45 C.F.R. § 75.414(c) prescribes the process by which HHS, and by extension NIH, can "deviate" from NICRAs in seemingly limited circumstances. According to the regulation:

> An HHS awarding agency may use a rate different from the negotiated rate for a class of Federal awards or a single Federal award only when required by Federal statute or regulation, or when approved by a Federal awarding agency head or delegate based on documented justification as described in paragraph (c)(3) of this section.

45 C.F.R. § 75.414(c)(1). Turning to paragraph (c)(3),

> The HHS awarding agency must implement, and make publicly available, the policies, procedures and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates.

Id. § 75.414(c)(3).

According to Defendants, "[i]n issuing the Supplemental Guidance, NIH acted under authority expressly granted in 45 C.F.R. § 75.414(c)." States [Dkt. 73, at 11]. Defendants argue that the three-page Rate Change Notice provides a "documented justification," 45 C.F.R. § 75.414(c)(1), for "us[ing] a rate different from the negotiated rate for a class of Federal awards or a single Federal award," Id., by "implement[ing] and mak[ing] publicly available[] the policies, procedures and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates." Id. § 75.414(c)(3). This Rate Change Notice, which at best provides a summary explanation of the government's policy to cut all ICRs to a standard 15% rate for *all* existing and future Federal grants, fails to fulfill the above regulatory mandates for several reasons.

First, the Rate Change Notice ignores the separate requirements of § 75.414(c)(3), which dictates that the Agency must provide a "documented justification" by making publicly available the "policies, procedures and general decision making criteria" that the Agency will use to then seek and justify deviations from negotiated rates. The Rate Change Notice purports to announce a single, uniform policy for all current and future grants, but fails to offer the procedures and decision making criteria it "will follow to seek and justify" the deviations from the negotiated rates. Defendants have failed to provide or point to any announced procedure or decision making criteria. At base, NIH failed to provide any requisite *documented justification*, which certainly was available to it through audits and other materials.

Even if the Rate Change Notice represented sufficient explanation of policy, procedures, and decision making criteria—of which it includes none—NIH did not comply with the step-by-step process mandated by the language of the regulation. The plain language is instructive, making clear NIH "must"—present tense—make available the policies, procedures, and decision making criteria that the Agency "will follow"—future tense—to seek and justify the deviation. The Federal Register notice discussing § 75.414 specifically recognizes this sequential process, stating:

> Language in paragraph (c) provides for the consistent application of negotiated indirect cost rates, and articulates the conditions under which a Federal awarding agency may use a different rate. These conditions include approval of the Federal awarding agency head (as delegated per standard delegations of authority) based on documented justification, the public availability of established policies for determinations to use other than negotiated rates, the inclusion of notice of such a decision in the announcement of funding opportunity, as well as in any pre-announcement outreach, and notification to OMB of the decision.

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 78 Fed. Reg. 78,590, 78,600 (Dec. 26, 2013). The three-page Rate Change Notice purported, but failed, to do all of these required steps in one fell swoop.

Second, by creating such a uniform policy, NIH molds the language of the regulation to fit its policy goals, rendering the text as written meaningless. As provided for in the regulation, the Agency may seek to deviate from the NICRA for "a *class of Federal awards* or a single Federal award." 45 C.F.R. § 75.414(c)(1) (emphasis added). A class of federal awards is defined as, "a group of Federal awards either awarded under a specific program or group of programs or to a specific type of non-Federal entity or group of non-Federal entities to which specific provisions or exceptions may apply." Id. § 75.2. Defendants argue that there is no limit to the size of the class, States [Dkt. 73, at 12], but fails to mention the definition of that term-of-art provided for in the regulation itself. If a "class of Federal awards" actually means *all* Federal awards, the definition provided for in § 75.2, and the inclusion of "a class of Federal awards" in § 75.414(c)(1), would be rendered entirely superfluous and meaningless. Pulsifer v. United States, 601 U.S. 124, 125 (2024) ("When a statutory construction 'render[s] an entire subparagraph meaningless,' this Court has noted, the canon against surplusage applies with special force." (quoting National Ass'n of Mfrs. v. Dep't of Def., 583 U.S. 109, 128 (2018)).

Even the dictionary definition of class—a "group, set, or kind sharing common attributes" —underscores that the plain meaning of the text refers to a subset, as opposed to all, federal awards. Class, The Merriam-Webster Dictionary (2025). In ignoring the plain meaning, Defendants are asking the Court to re-mold the text to meet the Administration's policy goals. See Fourstar v. Garden City Grp., Inc., 875 F.3d 1147, 1152 (D.C. Cir. 2017) (Kavanaugh, J.) ("It is not a judge's job to add to or otherwise re-mold statutory text to try to meet a statute's perceived policy objectives. Instead, we must apply the statute as written.").

In light of the above, the Rate Change Notice directly conflicts with the plain language of 45 C.F.R. § 75.414(c), disregarding an existing regulation and regulatory structure. FCC v. Fox

Television Stations, Inc., 556 U.S. 502, 515 (2009) ("An agency may not . . . simply disregard rules that are still on the books."); Nat'l Env't Dev. Ass'n's Clean Air Project v. EPA, 752 F.3d 999, 1009 (D.C. Cir. 2014) ("It is axiomatic . . . that an agency is bound by its own regulations." (internal quotation marks and citation omitted)). As a result, the Plaintiffs are likely to succeed in claiming the Rate Change Notice conflicts with existing regulation.

2. Section 224 Rider

If one is looking for further assurances that the Rate Change Notice violates 45 C.F.R. § 75.414(c), it was reiterated through the adoption of the § 224 Rider in 2018. The rider has been re-adopted by Congress in each year since. In 2017, the first Trump Administration released a budget proposal that would have slashed the indirect cost rate to a uniform, across-the-board rate of 10%. It stated, "[t]he Budget includes an indirect cost rate for NIH grants that will be capped at 10 percent of total research. This approach would be applied to all types of grants with a rate higher than 10 percent currently and will achieve significant savings in 2018. It would also bring NIH's reimbursement rate for indirect costs more in line with the reimbursement rate used by private foundations, such as the Gates Foundation, for biomedical research conducted at U.S. universities." Office of Management & Budget, Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2018, at 43 (2017).

Following its introduction, the House Subcommittee Labor, Health and Human Services, and Education of the Committee on Appropriations held a two-hour long hearing discussing concerns, on a bipartisan basis, relating to the cap of indirect costs. Hearing on the Role of Facilities and Administrative Costs in Supporting NIH-Funded Research Before the Subcomm. on Labor, Health and Human Services, Education, and Related Agencies of the H. Comm. on Appropriations, 115th Cong. (2017), available at:

https://www.youtube.com/watch?v=R3Eb7CjsjRE. Instead of solely declining to adopt the Administration's budget recommendation, Congress, again on a bipartisan basis, adopted the previously mentioned appropriations rider to prevent such a change through regulatory action. Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 226, 132 Stat. 348. This rider has remained the law from its passage through the present day. Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224, 138 Stat. 460, 677; see also Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245, § 224, 132 Stat. 2981, 3094 (2018); Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 224, 133 Stat. 2534, 2582 (2019); Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, § 224, 134 Stat. 1182, 1594 (2020); Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, § 224, 136 Stat. 49, 470-71 (2021); Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 224, 136 Stat. 4459, 4883-84 (2022). When enacting the rider, both the House and Senate Appropriations Committees specifically addressed the need for the rider in direct response to the Administration's proposal in their respective reports.

> According to the House Appropriations Committee,
>
> > While the Committee appreciates the Secretary's efforts to find efficiencies in NIH research spending, the Administration's proposal to drastically reduce and cap reimbursement of facilities and administrative (F&A) costs to research institutions is misguided and would have a devastating impact on biomedical research across the country. To ensure that NIH can continue supporting both direct and F&A costs as is their current practice, the bill includes a new general provision directing NIH to continue reimbursing institutions for F&A costs according to the rules and procedures described in 45 CFR 75 (with the exception of existing waivers for training grants). This provision also prohibits funds in this Act from being used to implement any further caps on F&A cost reimbursements.

H.R. Rep. No. 115-244, at 50 (2017). The Senate Appropriations Committee shared the same sentiment in adopting the rider:

> Central to the Administration's proposal to reduce Federal investments in biomedical research is its proposal to cap the F&A costs of grants, so-called "indirect costs," at 10 percent. The F&A cost of a grant is intended to cover the indirect costs of biomedical research, ranging from administration and facilities to the cost of equipment shared across multiple researchers. For example, at research facilities focused on making the next breakthrough in cancer treatment, indirect costs supply the air handlers that provide the precise conditions needed to generate therapeutic T cells for immunotherapy trials, complex data systems to analyze and protect patients' genomic data, and support for the next generation of scientific leaders. The methodology for negotiating indirect costs has been in place since 1965, and rates have remained largely stable across NIH grantees for decades. The Administration's proposal would radically change the nature of the Federal Government's relationship with the research community, abandoning the Government's long-established responsibility for underwriting much of the Nation's research infrastructure, and jeopardizing biomedical research nationwide. The Committee has not seen any details of the proposal that might explain how it could be accomplished without throwing research programs across the country into disarray. To avoid this possibility, the Committee has included bill language to prohibit HHS from developing or implementing a modified approach to funding F&A costs.

S. Rep. No. 115-150, at 109 (2017). Both committees across both chambers of Congress were clear. Not only would they not adopt the budget proposal as written, but they wanted to ensure any future, similar proposals would be contrary to law, not just regulation. Congress' rebuke of the first Trump Administration's proposal to slash and cap was patently clear.

Turning to the language of the rider itself, Congress provided:

> In making Federal financial assistance, the provisions relating to indirect costs in part 75 of title 45, Code of Federal Regulations, including with respect to the approval of deviations from negotiated rates, shall continue to apply to the National Institutes of Health to the same extent and in the same manner as such provisions were applied in the third quarter of fiscal year 2017. None of the funds appropriated in this or prior Acts or otherwise made available to the Department of Health and Human Services or to any department or agency may be used to develop or implement a modified approach to such provisions, or to intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter.

Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224, 138 Stat. 460, 677. This rider contains three, overlapping provisions meant to restrict NIH's ability to enact an across-the-board rate reduction.

Taking each in turn, Congress first mandated, "with respect to the approval of deviations from negotiated rates, [45 C.F.R. § 75] shall continue to apply to the National Institutes of Health to the same extent and in the same manner as such provisions were applied in the third quarter of fiscal year 2017." As described above, the Rate Change Notice failed to comply with 45 C.F.R. § 75.414(c). If looking for further confirmation, Congress intended the rider to prevent the Administration from implementing the proposed 10% cap, or any similar cap, as violative of the provisions of 45 C.F.R. § 75. Otherwise, passing such a statute would be meaningless and ineffective in addressing congressional concerns regarding the Administration's efforts to cap ICRs. Congress does not pass meaningless statutes. See, e.g., Plaut v. Spendthrift Farm, Inc., 514 U.S. 211, 216 (1995); Rumsfeld v. FAIR, 547 U.S. 47, 57 (2006). The Trump Administration previously unequivocally agreed, including in its 2019 budget proposal:

> For the past two years, NIH has been prohibited by law from reducing grantee administrative costs and shifting these resources to support direct research on high impact areas, such as cancer, Alzheimer's disease, and heart disease. The Congress imposed this prohibition, which limits NIH's ability to maximize its support of direct biomedical research. The Budget proposes to eliminate the current prohibition, which would give NIH the flexibility to support more direct research while encouraging research institutions to improve the efficiency of operations

Office of Management & Budget, Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2020, at 43 (2019). Congress, the first Trump Administration, and this Court agree: A universal cap to ICRs is contrary to the first provision of the appropriations rider.

Turning to the second provision, "[n]one of the funds appropriated . . . may be used to develop or implement a modified approach to such provisions." Again, Congressional intent

makes clear that an across-the-board ICR cap was considered a modified approach to the existing regulations. At base, a single ICR capped at 15% is certainly a different approach than negotiating ICRs institution by institution with deviations allowed in limited, justified circumstances. As such, the Rate Change Notice is also contrary to the second provision of the appropriations rider.

Turning to the third provision of the rider, "[n]one of the funds appropriated . . . may be used . . . to intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter." The Plaintiffs and Defendants put forth two interpretations of this provision. Plaintiffs claim the "fiscal effects" focus on the institution. As a result, "the 'fiscal effect' of [the Rate Change Notice]—which yields across-the-board 15% indirect cost rate, compared with the near 30% historical average—plainly goes beyond 'the proportional effect of such approvals' in the third quarter of Fiscal Year 2017." AAU [Dkt 16, at 18]. Should the fiscal effect refer to the institution, this Court agrees the Rate Change Notice plainly violates the provision.

The Defendants argue the "fiscal effect" refers to the government, and "because the [Rate Change Notice] does not seek to save the government money; rather, it takes the appropriations to NIH as a given and allocates the grants made with that money so that more of the money is spent on the direct costs[,] . . . the [Rate Change Notice] does not increase the 'fiscal effects.'" States [Dkt. 73, at 17]. Should the fiscal effect refer to the government, the Court disagrees with Defendants claim that the action does not "expand the fiscal effects" for two reasons.

First, as Plaintiffs argue, "[t]he rider focuses on [] 'the fiscal effect of the approval of such deviations from negotiated rates.' . . . Nothing in the rider suggests that the Executive may try to make up for that forbidden effect [of cutting ICRs across the board] through separate

grants." States [Dkt 81, at 10]. This is supported by the history of the 2017 proposed rate cut. Contrary to Defendants' assertion, the 2017 proposal did not only focus on savings. It also claimed that a cut to F&A (indirect) costs was necessary so "available funding can be better targeted toward supporting the highest priority research on diseases that affect human health . . . ." Office of Management & Budget, Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2018, at 43 (2017). In essence, the administration made the same claim that "available funding" would be redirected to direct costs. Again, Congress passed the rider to prevent any similar efforts following the 2017 proposal and any alternative interpretation would again render the rider meaningless and superfluous. Again, Congress does not pass meaningless statutes. See, e.g., Plaut, 514 U.S. at 216; FAIR, 547 U.S. at 57.

Second, Defendants argue, both in their briefing and at the February 21, 2025 motion hearing, this "fiscal effect" is different from the 2017 "fiscal effect" because in 2017, the focus was "saving," as opposed to the reallocation of indirect costs to direct costs. States [Dkt. 73, at 17]. This is unconvincing for two reasons. First, as described above, the Administration's 2017 proposal similarly claimed the "available funds" would be repurposed for direct costs. Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2018, at 43 (2017). This view is reinforced by the 2019 budget proposal, which stated that because of the rider, the "NIH has been prohibited by law from reducing grantee administrative costs and *shifting these resources to support direct research* on high impact areas, such as cancer, Alzheimer's disease, and heart disease . . . . The Budget proposes to eliminate the current prohibition, which would give NIH the flexibility *to support more direct research* while encouraging research institutions to improve the efficiency of operations." Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2020, at 43 (2019). This explanation echoes in the same reasoning as the current

proposed cap, particularly considering the Rate Change Notice offers no explanation as to how the newly available funding will be re-allocated to direct costs. Second, this Court is unconvinced the 15% ICR is unrelated to saving. NIH issued the Rate Change Notice on the evening of February 7, 2025. By 6:19 P.M., NIH had tweeted, "This change will save more than $4B a year effective immediately." States [Dkt. 6-5]. Considering the current explanation nearly mirrors that of the 2017 and 2019 budget proposals, the Court sees little reason to credit the Defendants' post-hoc explanation.

Considering the above, whether the fiscal effect is at the institution level or the government level is of little consequence because the Rate Change Notice violates the third provision of the appropriations rider under either interpretation.

Based on the plain language of the rider, reinforced by legislative history and acknowledged by the first Trump Administration, the Rate Change Notice is in direct contravention of Section 224. Again, the Plaintiffs are likely to succeed on the merits of their claim that the Rate Change Notice as issued is contrary to law.

3. The Administrative Procedure Act

While contrary to both statute and regulation, the Court must also consider the Rate Change Notice in light of the Administrative Procedure Act's substantive and procedural requirements. Generally speaking, the Federal government, absent its express consent, is immune from suit, also known as sovereign immunity. With that said, "[t]he APA 'sets forth the procedures by which federal agencies are accountable to the public and their actions subject to review by the courts.'" Dep't of Homeland Sec. v. Regents of the Univ. of California, 591 U.S. 1, 16 (2020) (quoting Franklin v. Massachusetts, 505 U.S. 788, 796 (1992)). More specifically, and relevant to the claims in the current matter, the APA provides that a "reviewing court

shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be: [1] arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; [2] in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; [or, 3] without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C), (D).

Before proceeding to judicial review, the court must ensure the agency action is considered "final" and thus ripe for review. See 5 U.S.C. § 704. "As a general matter, two conditions must be satisfied for agency action to be 'final': First, the action must mark the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" Bennett v. Spear, 520 U.S. 154, 177-78 (1997) (first quoting Chicago & Southern Air Lines, Inc. v. Waterman S.S. Corp., 333 U.S. 103, 113 (1948); and then quoting Port of Bos. Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic, 400 U.S. 62, 71 (1970)). Uncontested by either party, it appears clear that the Rate Change Notice is a "final" agency action ripe for judicial review. The Rate Change Notice, capping ICRs at 15%, is neither tentative nor interlocutory in nature. The Notice itself states that "[f]or any new grant issued, and for all existing grants to IHEs . . . , award recipients are subject to a 15 percent indirect cost rate . . . . This policy shall be applied to all current grants for go forward expenses from February 10, 2025 forward as well as for all new grants issued." Additionally, it is clear the action is one by which "rights or obligations" are determined—namely, the ICR applied to each grant recipient, which will determine the amount of indirect costs reimbursed to each institution.

As the Rate Change Notice is a final agency action, the Court turns to three of the claims put forth by plaintiffs and contemplated by the APA: (1) that the Rate Change Notice, as put

forth, is arbitrary and capricious; (2) that the Agency failed to comply with procedure required by law, specifically notice-and-comment rulemaking; and, (3) the Rate Change Notice is impermissibly retroactive.

a. Arbitrary & Capricious

It has long been recognized that "[t]he agency's action . . . may be set aside if found to be 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 41 (1983) (quoting 5 U.S.C. § 706(2)(A)); see also Regents, 519 U.S. at 16 (noting that the APA "requires agencies to engage in 'reasoned decisionmaking'" (quoting Michigan v. EPA, 576 U.S. 743, 750 (2015))). With that said, "[t]he scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." State Farm, 463 U.S. at 43; see also Regents, 591 U.S. at 16; Fox Television Stations, 556 U.S. 502, 513-14 (2009).

Although the scope of review is narrow, "the court must undertake 'a thorough, probing, in-depth review' and a 'searching and careful' inquiry into the record." Penobscot Air Servs., Ltd. v. FAA, 164 F.3d 713, 720 (1st Cir. 1999) (quoting Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 415-16 (1971)). "Only by 'carefully reviewing the record and satisfying [itself] that the agency has made a reasoned decision' can the court 'ensure that agency decisions are founded on a reasoned evaluation of the relevant factors.'" Id. (quoting Marsh v. Or. Nat. Res. Council, 490 U.S. 360, 378 (1989) (alteration in original)). To put a finer point on the issue, "[w]hile this is a highly deferential standard of review, it is not a rubber stamp." Penobscot, 164 F.3d at 720 (quoting Dubois v. U.S. Dep't of Agric., 102 F.3d 1237, 1285 (1st Cir. 1996)); see also Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc., 419 U.S. 281, 285 (1974).

There are several considerations that courts have found important when determining if an agency action is arbitrary and capricious, within the bounds of the standard described above. An agency has acted arbitrarily and capriciously if it has

> relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

State Farm, 463 U.S. at 43; see Penobscot, 164 F.3d at 719 (holding that courts must "determine whether the agency has examined the pertinent evidence, considered the relevant factors, and 'articulate[d] a satisfactory explanation for its action including a "rational connection between the facts found and the choice made"'") (quoting State Farm, 463 U.S. at 43); Associated Fisheries of Me., Inc. v. Daley, 127 F.3d 104, 109 (1st Cir. 1997).

Plaintiffs argue the Rate Change Notice is arbitrary in capricious for several reasons, including: (1) NIH failed to provide adequate reasoning, disregarding prior fact finding that supported the existing system of negotiation and failing to consider the relevant factors, and (2) NIH did not appropriately consider grant recipients' reliance interests. The Court will take each argument in turn.

1. Inadequate Reasoning

Agencies must provide sufficient reasoning to justify their rulemaking. "[A] 'fundamental requirement of administrative law is that an agency set forth its reasons for decision; an agency's failure to do so constitutes arbitrary and capricious agency action.'" Amerijet Int'l, Inc. v. Pistole, 753 F.3d 1343, 1350 (D.C. Cir. 2014) (quoting Tourus Records, Inc. v. Drug Enf't Admin., 259 F.3d 731, 737 (D.C. Cir. 2001)). As described above, agencies must provide reasons that both exhibit sufficient consideration of the relevant factors and

pertinent aspects of the problem and demonstrate a rational connection between the facts and choice that was made. See Regents, 591 U.S. at 16.

Defendants argue the Rate Change Notice supplies three independent reasons justifying the cap of ICRs at 15%, despite a header that solely claims that the rate notice "Provide[es] Indirect Cost Rates that Comport with Market Rates." First, in a single line, NIH claims, "[i]t is . . . vital to ensure that as many funds as possible go towards direct scientific research costs rather than administrative overhead." No additional explanation is provided. Second, again in a single line, NIH insists that "[i]ndirect costs are, by their very nature, 'not readily assignable to the cost objectives specifically benefitted' and are therefore difficult for NIH to oversee." Beyond the fact that the "not readily assignable" language refers to the ways in which indirect costs support more than one project, in contrast to the direct costs of a single grant award, see 75 C.F.R. § 75.2, no other explanation is provided in the Notice. Third, NIH purports to bring indirect costs in line with a random collection of private organizations. The Rate Change Notice offers no explanation as to why those organizations were selected, fails to consider both how private organizations calculate direct and indirect costs differently than the federal government (including many indirect costs in their direct costs calculation) and that private foundations are more likely to fund different types of research with lower F&A costs than the government, and finally, ignores private organizations' reliance on complementary federal funding.

These "explanations" are insufficient, and thus the Rate Change Notice is arbitrary and capricious, for two reasons. First, the explanations are conclusory. "[T]o this end, conclusory statements will not do; an 'agency's statement must be one of *reasoning*.'" Amerijet, 753 F.3d at 1350 (quoting Butte Cnty., Cal. v. Hogen, 613 F.3d 190, 194 (D.C. Cir. 2010)) (emphasis in original). As described above, NIH failed to provide any reasoning, rationale, or justification at

all. It claims that more funds will go to direct research but fails to address how the money will actually be directed to cover direct costs and how that research will be conducted absent the necessary indirect cost reimbursements provided by the federal government. This is particularly true considering the number of universities and associations that have made clear that research will have to be cut, as other funding sources will not be able to make up the shortfall. See, e.g., States [Dkt. 6-34, Declaration of Dr. Greg Hirth, of Brown University, at ¶ 24] ("Any further increases in the gap between Brown's current cost of research and federally sponsored funding cannot be recouped from other revenue sources."); AAU [Dkt. 2-1, Declaration of Barbara R. Snyder, of the Association of American Universities, at ¶ 17] ("AAU member universities' existing endowments cannot simply be redirected to pick up these losses. The vast majority of endowed funds often are restricted by the terms on which the funds were donated to the AAU member university and cannot legally be used to cover research infrastructure costs. Moreover, an AAU member university may only draw down the portion of the endowment that is unrestricted at a rate that complies with applicable law."); AAU [Dkt. 2-3, Declaration of Mark Becker, of the Association of Public & Land-grant Universities, at ¶ 14] ("Nor can APLU member institutions' endowments be simply redirected to make up for these losses . . . . Endowments are also complex assets with many legal requirements stipulating how they can be used. And not all universities have large endowments, or any endowment at all—in fact, of the public institutions that have endowments, nearly half are valued at less than $50 million."); AAU [Dkt. 2-8, Declaration of Theresa S. Mayer, of Carnegie Mellon University, at ¶ 18] ("CMU cannot cover the funding gap itself that would result from the reduction of the indirect cost rate. While CMU maintains an endowment, it is neither feasible nor sustainable for CMU funds or other revenue sources to offset shortfalls in indirect cost recovery[.]"); AAU [Dkt. 2-11,

Declaration of Robert A. Harrington, M.D., of Cornell University, at ¶ 17] ("Cornell's existing endowment cannot simply be redirected to pick up these losses. The vast majority of endowed funds are restricted by the terms on which the funds were donated to the University and cannot legally be used to cover research infrastructure costs. Moreover, Cornell may only draw down the portion of the endowment that is unrestricted at a rate that complies with New York State law.").

NIH then claims indirect costs are difficult to oversee but fails to explain the inadequacy of the existing audit system or how the auditing system differs from the tracing of direct costs. See 45 C.F.R. § 75.500 et seq. Defendants argument that Plaintiffs' "extensive citations to audit and calculation requirements for indirect costs confirm NIH's position" fails to address why the audit system is deficient. States [Dkt. 73, at 21]. Instead, the citations point to a fairly comprehensive regulatory regime that NIH seems to ignore in the Rate Change Notice altogether. See, e.g., 45 C.F.R. § 75.504 (frequence of audits); § 75.507(a) (noting availability of "program-specific audit guide[s]" maintained by HHS); § 75.508(a)-(d) (describing responsibilities of IHEs in preparing their audits). Finally, NIH asserts the Rate Change Notice will bring the ICRs in line with private foundations, providing no explanation for this choice in light of the fact that private organizations, like the Gates Foundation, are "more expansive than NIH in defining direct costs, meaning some overhead payments are wrapped in with the grant." Jocelyn Kaiser, NIH Plan to Reduce Overhead Payments Draws Fire, Science (June 2, 2017), https://www.science.org/content/article/nih-plan-reduce-overhead-payments-draws-fire; States [Dkt 81, at 17 n.14]; see also generally States [Dkt 82-2]. Instead, NIH simply makes a conclusory claim that "[m]ost private foundations that fund research provide substantially lower indirect costs than the federal government, and universities regularly accept grants from these

foundations." The Notice does not contemplate if bringing the federal government in line with private foundations is actually a good thing. NIH's conclusory statements hardly rise to the level of "reasoned decisionmaking" required by the APA. Regents, 591 U.S. at 16 (quoting Michigan, 576 U.S. at 750). It is this Court's obligation to hold NIH "accountable to the public." Franklin v. Massachusetts, 505 U.S. 788, 796 (1992). The failure to provide any type of *reasoning* renders the Rate Change Notice arbitrary and capricious.

Second, NIH's proffered "reasons" fail to grapple with the relevant factors or pertinent aspects of the problem and fails to demonstrate a rational connection between the facts and choice that was made. In cutting indirect costs without identifying a countervailing funding stream for such costs of research, the only reasonable outcome will be the discontinuing of research supported by the slashed F&A rates, including ongoing clinical trials. See, e.g., AAU [Dkt 2-5, Declaration of Greg Hirth, of Brown University, at ¶ 15] ("At a 15% indirect cost rate, many of Brown's current research projects and clinical trials will be forced to cease abruptly."); Id. [Dkt. 2-6, Declaration of Theresa A. Maldonado, of the University of California, at ¶ 15] ("[Indirect costs] not only support the infrastructure and buildings that house pioneering research teams, but also the personnel who assure the safety of adults and children enrolling in clinical trials for cancer and chronic disease, the ethics teams that assure those trials are done safely, and the data and privacy teams that protect research subjects' personal data."); Id. [Dkt. 2-15, Declaration of Laurent Heller, of Johns Hopkins University, at ¶¶ 5-6 ("NIH's reimbursement of its portion of indirect costs is essential for supporting . . . critical research" such as "clinical trials . . . focusing on innovative treatments for pediatric and young adult craniopharyngioma (a rare type of brain tumor)."]; Id. [Dkt. 2-18, Declaration of Arthur Lupia, of the University of Michigan, at ¶¶ 7-8 ("[T]here are currently 425 NIH-funded interventional clinical trials

underway and not yet completed at the University of Michigan . . . . The loss of [indirect cost coverage] will immediately impact the University of Michigan's ability to . . . pay expenses associated with these [clinical trials]."). The Rate Change Notice seems to have ignored the need for indirect funds in the administration of *any and all* research. In essence, by cutting indirect funds, NIH is cutting research. There also seems to be a limited rational connection between the facts, particularly the nature of private funding opportunities and their differences from federal funding grants, as well as the limitation on university endowments, and the decision to cut ICRs to bring them in line with private organizations.

This failure to grapple with relevant factors and facts is even more egregious in light of the drastic change from the existing ICR negotiation process. Although a change in policy does not result in a heightened standard of review, if an agency's "new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests" an agency's failure to consider such factors "would be arbitrary or capricious . . . ." Fox Television Stations, 566 U.S. at 515. "In such cases it is not that further justification is demanded by the mere fact of policy change; but that a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." Encino Motorcars, LLC v. Navarro, 579 U.S. 211, 222 (2016) (quoting Fox Television Stations, 556 U.S. at 515-16) (internal quotation marks omitted). Thus, "when an agency rescinds a prior policy[,] its reasoned analysis must consider the 'alternative[s]' that are 'within the ambit of the existing [policy].'" Regents, 591 U.S. at 30 (quoting State Farm, 463 U.S. at 51).

As described above, the NIH Rate Change Notice failed to provide even the most basic level of "reasoning," let alone recognize or justify the disregarded facts that underlay its existing

policy. NIH's existing ICR negotiation process contemplates the need for an individualized analysis at the institution level, as well as the dramatically different needs of those varying institutions. The Rate Change Notice failed to acknowledge those circumstances, nor provides any justification for that disregard.

As the reasons in the Rate Change Notice are both conclusory and fail to grapple with the necessary factors, facts, and pertinent aspects of the problem demanded by this change from the existing ICR negotiation process, the Plaintiffs are likely to succeed in their claims that the Rate Change Notice is arbitrary and capricious.

2. Substantial Reliance Interests

The justifications provided by the Rate Change Notice fails in an additional respect. Even if the reasons provided had been more thorough and sufficient, the Notice fails in its entirety to recognize or consider the substantial reliance interests at issue. Courts have long recognized that "[w]hen an agency changes course . . . it must 'be cognizant that longstanding policies may have "engendered serious reliance interests that must be taken into account."'" Regents, 591 U.S. at 30 (quoting Encino Motorcars, 579 U.S. at 222). "It would be arbitrary and capricious to ignore such matters." Regents, 591 U.S. at 1913 (quoting Fox Television Stations, 556 U.S. at 515); see also Perez v. Mortg. Bankers Ass'n, 575 U.S. 92, 106 (2015) ("[T]he APA requires an agency to provide more substantial justification when . . . its prior policy has engendered serious reliance interests that must be taken into account. It would be arbitrary and capricious to ignore such matters."); Smiley v. Citibank (South Dakota), N. A., 517 U.S. 735, 742 (1996) ("Sudden and unexplained change[s to prior policies] . . . may be 'arbitrary, capricious [or] an abuse of discretion.'" (quoting 5 U.S.C. § 706(2)(A)).

As a result, "because [NIH] was not writing on a blank slate, it was required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." Regents, 591 U.S. at 33 (internal quotation marks omitted). The reliance interests at play are many and acknowledged by all parties. Non-governmental organization have relied on the Federal provision of indirect costs for decades. E.g., AAU [Dkt. 2-7, Declaration of David A. Tirrell, of the California Institute of Technology, at ¶ 14]; Id. [Dkt. 2-8, Declaration of Theresa S. Mayer, of Carnegie Mellon University, at ¶ 15]; Id. [Dkt. 2-13, Declaration of David Paul Norton, of the University of Florida, at ¶ 15]; Id. [Dkt. 2-20, Declaration of Anshuman Razdan, of the University of Oregon, at ¶ 17]; Id. [Dkt. 2-21, Declaration of Elizabeth Duggins Peloso, of the University of Pennsylvania, at ¶ 18]; Id. [Dkt. 2-28, Declaration of Ishwar K. Puri, of the University of Southern California, at ¶ 15]; Id. [Dkt. 2-29, Declaration of C. Cybele Raver, of Vanderbilt University, at ¶ 14].

Indirect costs are taken into consideration when universities and associations formulate their overall operating budgets and consider improvements to research infrastructure. E.g., Id. [Dkt. 2-3, Declaration of Mark Becker, of the Association of Public & Land-grant Universities, at ¶ 11] ("For each NIH award, APLU member institutions necessarily rely on both the direct cost and indirect cost allocations in formulating their overall operating budgets for any given year. These allocations are used to plan for annual staffing needs, infrastructure support (e.g., IT networks, regulatory compliance, and grant management support), facility building and renovation, and equipment purchases to support a broad range of overlapping research activities."); Id. [Dkt. 2-6, Declaration of Theresa A. Maldonado, of the University of California, ¶ 17] ("UC campuses receive and expend hundreds of millions of dollars annually in multiyear awards for their projects, centers, and institutes, and can proceed with establishing budget

estimates for planning purposes in reliance on the facilities and administrative cost recovery rates periodically negotiated between individual campuses and the federal government (the Department of Health and Human Services) that set rates for three to five years."); Id. [Dkt. 2-12, Declaration of Dr. David F. Kotz, of Dartmouth College, at ¶ 9] ("Dartmouth spent $17 million of its own funds for the repair and renovation of research facilities in fiscal years 2022 and 2023, and anticipates spending another $14 million in institutional funds to maintain these existing facilities in fiscal years 2024 and 2025. These investments, to which Dartmouth has already committed, have been made specifically in reliance on our ability to recover a portion of these expenses through the negotiated indirect costs rate with federal agencies like the NIH."). Beyond the institutions, the reliance interests are plenty, ranging from the researchers who chose to conduct research at certain institutions with the understanding that they would be supported, to the students who will no longer be admitted to these institutions, to the local communities that will suffer from the loss of community-based programming. See, e.g., States [Dkt. 6-11, Declaration of Donald M. Elliman, Jr., of Colorado Anschutz Medical Campus, at ¶ 10] ("The drastic cuts to NIH F&A will bring the Institute's research and community-based programs to a virtual standstill due to the loss of shared administrative staff and the specialized computing infrastructure essential for the Institute's efforts."); AAU [Dkt. 2-7, Declaration of David A. Tirrell, of the California Institute of Technology] ("Caltech is currently making decisions regarding admission of graduate students who conduct much of our NIH-supported research. The number of graduate students – who are the future of biomedical research – who can be admitted will have to be reduced substantially. The impact on the future of research will be immediate and unrecoverable. [] Offers to new postdoctoral scholars also will be reduced, with similar impact on the quality of the research environment and on the future of biomedical research.").

In short, the Notice fails to consider the impact the Rate Change Notice would have on public health, which is the purpose of the entire regulatory regime. The Notice fails to contemplate the budgets of these institutions, formulated months and years before this Notice's sudden implementation. It fails to contemplate the risk to human life as research and clinical trials are suspended in response to the shortfall. It fails to contemplate the life, careers, and advancement that will be lost as these budgets are indiscriminately slashed. Although reticent to consider together, the Rate Change Notice fails to reflect on the health of those whose hopes rely on clinical trials and the financial investment that will be lost as research is disrupted. It fails to consider that public health will suffer.

As an initial matter, Defendants claim that Plaintiffs' reliance interests "relate[] only to existing grants, because Plaintiffs can have no legally protectible reliance interests in grants that they have not yet been awarded." States [Dkt. 73, at 23] (citing Lemon Bay Cove, LLC v. United States, 160 Fed. Cl. 593, 613 (2022) ("A property owner who acquires land with knowledge of a regulatory restraint could be said to have no reliance interest or to have assumed the risk of any economic loss.")). However, Defendants misunderstand the nature of the reliance interests. ICRs, memorialized in NICRAs, are negotiated for a period of several years, irrespective of any specific grant. Cf. 45 C.F.R. pt. 75, appx. III § C.1 et seq. (establishing procedures for the "[d]etermination and [a]pplication of [i]ndirect (F&A) [c]ost [r]ates"). At the very least, these reliance interests exist for the length of the NICRA, which institutions negotiated with the cognizant agency for the purpose of consistency until the conclusion of the agreement. See, e.g., AAU [Dkt. 2-12, Declaration of Dr. David F. Kotz, of Dartmouth College, at ¶ 10] ("Direct negotiations and detailed audits with the federal government in 2022 resulted in the setting of a predetermined rate that Dartmouth had expected in good faith would be

applicable through 2029."); Id. [Dkt. 2-20, Declaration of Anshuman Razdan, of the University of Oregon, at ¶ 12] ("UO's current negotiated rate for organized research is 49% (up from 47.5%), last negotiated August 2023 and valid through June 30, 2027."). As a result, the reliance interests concern both existing and future grants—at least those grants awarded within the timeframe contemplated by each institution's NICRA.

Nonetheless, Defendants claim to have addressed these substantial and long-standing reliance interests despite the Rate Change Notice, read generously, offering only a fleeting reference to reliance interests:

> Although cognizant that grant recipients, particularly "new or inexperienced organizations," use grant funds to cover indirect costs like overhead . . . , NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Indirect costs are, by their very nature, "not readily assignable to the cost objectives specifically benefitted" and are therefore difficult for NIH to oversee. . . . Yet the average indirect cost rate reported by NIH has averaged between 27% and 28% over time. And many organizations are much higher—charging indirect rates of over 50% and in some cases over 60%.

This explanation is plainly insufficient because it is conclusory and fails to address some, or any, of the reliance interests discussed above. "[S]ummary discussion may suffice in other circumstances, but here—in particular because of decades of industry reliance on [NIH]'s prior policy—the explanation fell short of the agency's duty to explain why it deemed it necessary to overrule its previous position." Encino Motorcars, 579 U.S. at 222. As stated in Encino Motorcars, and equally applicable here, "[i]n light of the serious reliance interests at stake, . . . conclusory statements do not suffice to explain [the agency] decision." 579 U.S. at 224 (citing Fox Television Stations, 556 U.S. at 515–16).

In both its opposition to the Temporary Restraining Order and at the motion hearing, Defendants attempted to supplement NIH's consideration of Plaintiffs' tremendous reliance

interests with additional arguments. In its opposition, Defendants stated, "NIH did note that 'grant recipients use grant funds to cover indirect costs.' It simply concluded that the other interests justifying the Supplemental Guidance outweighed that interest." States [Dkt. 73, at 23] (citation omitted). Defendants added, "NIH likewise considered that grantees often accept grants with lower indirect cost rates, demonstrating that those rates are generally acceptable to the grantees and would not unduly upset their reliance interests." [Id. at 24]. However convincing or unconvincing these arguments may be, the fact of the matter is that they did not appear in the Rate Change Notice. Defendants attempted to further supplement these claims at oral argument. After reciting the above quoted language from the Rate Change Notice, counsel for Defendants added, "[the Rate Change Notice] goes on to explain the various rationales that it thinks trump those reliance interests. So it was considered. And the idea that it's not . . . that's a policy disagreement . . . . [S]o they were considered here. And you can see the reasons that NIH put forward for not adhering to them."

The Court is prohibited from considering these additions to the brief explanation provided in the Rate Change Notice. "It is a 'foundational principle of administrative law' that judicial review of agency action is limited to 'the grounds that the agency invoked when it took the action.'" Regents, 591 U.S. at 20 (quoting Michigan, 576 U.S. at 758); see also State Farm, 463 U.S. at 50 (stating that it has long been recognized that an agency action may only be upheld "on the basis articulated by the agency itself"); Sec. & Exch. Comm'n v. Chenery Corp., 332 U.S. 194, 196 (1947) ("[It is] a simple but fundamental rule of administrative law . . . that a reviewing court . . . must judge the propriety of [an agency's] action solely by the grounds invoked by the agency."). Especially in light of Defendants' arguments in their papers and at the motion hearing, "[t]he functional reasons for requiring contemporaneous explanations apply with

equal force regardless whether post hoc justifications are raised in court by those appearing on behalf of the agency or by agency officials themselves." Regents, 591 U.S. at 23; see also Am. Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 539 (1981) ("[T]he post hoc rationalizations of the agency . . . cannot serve as a sufficient predicate for agency action."); Volpe, 401 U.S. at 419 (rejecting "litigation affidavits" from agency officials as "merely 'post hoc' rationalizations" (citation omitted)). Thus, with no additional explanation on top of what amounts to one sentence in the Rate Change Notice, NIH plainly failed to sufficiently consider the substantial reliance interests at stake. Of note, even had the Court considered these additional statements both in the opposition and at oral argument, NIH still failed to appropriately consider the substantial and long-standing reliance interests.

In summary, a "[s]udden and unexplained change . . . , or change that does not take account of legitimate reliance on prior interpretation may be 'arbitrary, capricious [or] an abuse of discretion.'" Smiley, 517 U.S. at 742 (1996) (quoting 5 U.S.C. § 706(2)(A)) (citing State Farm, 463 U.S. at 46-57; United States v. Pa. Indus. Chem. Corp., 411 U.S. 655, 670-75 (1973); NLRB v. Bell Aerospace Co., 416 U.S. 267, 295 (1974)). The Rate Change Notice was issued, without warning, on the evening of Friday, February 7, 2025. It was set to take effect on Monday, February 10, 2025. It would be difficult to mandate a more sudden change. The three-page Notice failed to provide basic reasoning for its decision, as described above, and failed to address the substantial reliance interests. Although empowered to make impactful policy decisions, "a new administration may not . . . ignore statutory standards in carrying out its regulatory functions." State Farm, 463 U.S. at 59 n.* (Rehnquist, J., concurring in part and dissenting in part). The Defendants have ignored those statutory standards here and the Plaintiffs are likely to succeed in their claim that the Rate Change Notice is arbitrary and capricious.

b. Failure to Follow Notice and Comment Procedures

According to the APA, before a federal agency adopts a rule a "[g]eneral notice of proposed rule making shall be published in the Federal Register." 5 U.S.C. § 553(b). After providing notice, "the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." Id. at § 553(c). Taken together this process is known as notice-and-comment rulemaking and "[f]ailure to abide by these requirements renders a rule procedurally invalid." N.H. Hosp. Ass'n v. Azar, 887 F.3d 62, 70 (1st Cir. 2018) (citing Warder v. Shalala, 149 F.3d 73, 75 (1st Cir. 1998); Hoctor v. U.S. Dep't of Agric., 82 F.3d 165, 167 (7th Cir. 1996) (stating that, unless an exception applies, a "rule promulgated by an agency that is subject to the [APA] is invalid unless the agency" follows notice-and-comment procedures)).

Generally speaking, "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" are exempted from notice-and-comment rulemaking. 5 U.S.C. § 553(b)(A). Interpretive rules are those "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." Perez, 575 U.S. at 97 (quoting Shalala v. Guernsey Mem'l Hosp., 514 U.S. 87, 99 (1995)). Conversely, so-called "legislative" or "substantive" rules are subject to the process described above, absent some other exception. N.H. Hosp. Ass'n, 887 F.3d at 70. Legislative rules are those that "create[] rights, assign[] duties, or impose[] obligations, the basic tenor of which is not already outlined in the law itself." La Casa Del Convaleciente v. Sullivan, 965 F.2d 1175, 1178 (1st Cir. 1992) (citation omitted). A legislative rule "'has the force of law,' while an interpretive rule is 'merely a clarification or explanation of an existing statute or rule' and is 'issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers.'" Id.

(quoting Guardian Fed. Sav. & Loan Ass'n v. FSLIC, 589 F.2d 658, 664-65 (D.C. Cir. 1978); United States Department of Justice, Attorney General's Manual on the Administrative Procedures Act 30 n.3 (1947)).

1. Waiver of the Grant Exception

Before examining the boundary between interpretive and legislative rules, Defendants raise an alternative argument: The Rate Change Notice is exempt from notice-and-comment rulemaking because an alternative exception applies. The APA provides that notice-and-comment rulemaking applies "except to the extent that there is involved . . . a matter relating to agency management or personnel or to public property, loans, *grants*, benefits, or contracts." § 553(a)(2) (emphasis added). Although seemingly on point, the application of the exception is not nearly that straightforward. In 1971, the Secretary of the Department of Health, Education, and Wealth ("HEW"), the predecessor agency of HHS, voluntarily waived the grant exception found in § 553(a)(2). The Secretary's statement reads as follows:

> The APA exempts from [notice-and-comment rulemaking] matters relating to public property, loans, grants, benefits, or contracts. . . . The public benefit from such participation should outweigh any administrative inconvenience or delay which may result from use of the APA procedures in the five exempt categories. Effective Immediately, all agencies and offices of the Department which issue rules and regulations relating to public property, loans, grants, benefits, or contracts are directed to utilize the public participation procedures of the APA, 5 U.S.C. 553. Although the APA permits exceptions from these procedures when an agency for good cause finds that such procedures would be impracticable, unnecessary or contrary to the public interest, such exceptions should be used sparingly, as for example in emergenc[i]es and in instances where public participation would be useless or wasteful because proposed amendments to regulations cover minor technical matters.

Public Participation in Rule Making: Statement of Policy, 36 Fed. Reg. 2,532 (Feb. 5, 1971).

2. Binding Nature of the Grant Exception Waiver

In their papers and at oral argument, Defendants state that despite the Secretary's explicit statement otherwise, the grant exception in the APA continues to apply, and thus the Rate Change Notice is entirely exempt from notice-and-comment rulemaking. Defendants argue,

> [w]hile the Secretary [of] the Department of Health and Human Services predecessor department voluntarily agreed to follow notice and comment rulemaking, he did so 'as a matter of policy'—not in a binding regulation. See 36 Fed. Reg. 2,532 (Feb. 5, 1971). There is thus no binding requirement of notice-and-comment rulemaking here—and, in any event, no matter what the executive branch says as a matter of policy discretion, the Court should not extend the APA's notice-and-comment requirements to a context, i.e., grant making, that Congress expressly dictated they should not reach.

States, [Dkt. 73, at 19-20]. At oral argument, Defendants added that post-Loper Bright, courts "should not let an agency extend a statute to a context that Congress plainly didn't want it to go."

As an initial matter, Loper Bright is inapplicable to the matter at hand. In that case, the Supreme Court held that under the APA, courts need not defer to agency interpretation of ambiguous statutes. See generally Loper Bright Enters. v. Raimondo, 603 U.S. 369 (2024). That is not relevant here, where the head of HHS issued a policy statement that was not an interpretation of an ambiguous statute. The statute was clear. Instead, by adding a notice-and-comment requirement for exempted actions, the agency head was simply adding procedures on top of the minimum laid out by Congress.

Second, the Supreme Court has long held that agency heads are well within their function, contrary to Defendants' statements otherwise, to impose additional procedural and substantive requirements beyond those required by Congress. Serv. v. Dulles, 354 U.S. 363, 388 (1957) ("While it is of course true . . . the Secretary was not obligated to impose upon himself these more rigorous substantive and procedural standards, neither was he prohibited from doing so, . . . and having done so he could not . . . proceed without regard to them."). While an agency

cannot go below the floor set by Congress, it can certainly go above it. Once such procedural requirements have been put in place agencies must follow them, even when the internal procedures exceed the process otherwise required. See Morton v. Ruiz, 415 U.S. 199, 235 (1974) (citing Dulles, 354 U.S. at 388; Vitarelli v. Seaton, 359 U.S. 535, 539-40 (1959)) ("Where the rights of individuals are affected, it is incumbent upon agencies to follow their own procedures. This is so even where the internal procedures are possibly more rigorous than otherwise would be required."); cf. Rotinsulu v. Mukasey, 515 F.3d 68, 72 (1st Cir. 2008) ("An agency has an obligation to abide by its own regulations. The failure to follow an applicable regulation may be a sufficient ground for vacation of an agency's decision, resulting in a remand." (citing Accardi v. Shaughnessy, 347 U.S. 260, 265-67 (1954); Picca v. Mukasey, 512 F.3d 75, 79-80 (2d Cir. 2008); Nelson v. INS, 232 F.3d 258, 262 (1st Cir. 2000))).

Courts across the country have not only found such self-imposed requirements binding on the agency by which they were issued: Courts have found HHS, and thus NIH, bound by *this* self-imposed waiver of the grant exception. Clarian Health W., LLC v. Hargan, 878 F.3d 346, 356-57 (D.C. Cir. 2017) ("The Government recognizes that, in 1971, the Secretary voluntarily waived the § 553(a)(2) exception and subjected itself to the statute's procedural requirements . . . . Yet, it appears to contest the assertion that this waiver binds the agency . . . . The Government provides no basis for this argument, however, and it fails to address this court's and the Supreme Court's cases treating this or other such waivers as binding." (citing Samaritan Health Serv. v. Bowen, 811 F.2d 1524, 1529 & n.14 (D.C. Cir. 1987); Humana of S.C., Inc. v. Califano, 590 F.2d 1070, 1084 (D.C. Cir. 1978); Rodway v. U.S. Dep't of Agric., 514 F.2d 809, 814 (D.C. Cir. 1975) ("[T]he regulation fully bound the Secretary to comply thereafter with the procedural demands of the APA."); Dulles, 354 U.S. at 388));

Buschmann v. Schweiker, 676 F.2d 352, 356 n.4 (9th Cir. 1982) ("The Administrative Procedures Act is applicable to rulemaking by the Secretary of Health and Human Services. Although 5 U.S.C. § 553(a)(2) would have exempted the rulemaking procedure now in dispute, the then Secretary of Health, Education and Welfare, in a policy statement dated January 28, 1971, (36 F.R. 2532), required all agencies and offices in his department to utilize the public participation procedures of § 553. The Secretary does not contest his legal obligation to comply with § 553 procedures."); Nat'l Welfare Rts. Org. v. Mathews, 533 F.2d 637, 646 (D.C. Cir. 1976) ("In addition to these substantive standards a regulation must be promulgated in accord with procedural requirements of the Administrative Procedure Act . . . and any further rules imposed by the department itself." (citing Rodway, 514 F.2d at 814; 36 Fed. Reg. 2532 (1971)); Herron v. Heckler, 576 F. Supp. 218, 229-30 (N.D. Cal. 1983) ("The APA contains a provision that ordinarily would exempt the Secretary from its rule-making procedures . . . . Notwithstanding this statutory exemption, the Secretary elected to abide by the provisions of the APA . . . . The Secretary asserts that her obligations under the APA remain discretionary, because 'statements of policy,' unlike rules or regulations, do not create binding legal obligations . . . . This Court perceives no reason to depart from [] authority. [T]he Court finds that the Secretary was bound by the provisions of the APA when she promulgated the claims manual limitations at issue."); Herron, 576 F. Supp. at 229 n.12 ("Defendants mistakenly rely solely on the January 1971 directive's label— 'statement of policy'—to argue that it carries no binding legal effect."); Lewis v. Weinberger, 415 F. Supp. 652, 661 (D.N.M. 1976) ("HEW, the agency of which the IHS [(Indian Health Service)] is a part, has placed itself under the procedural requirements of section 553 in all its rulemaking relating to 'public property, loans, grants, benefits or contracts.' 36 Fed. Reg. 2536 (Feb. 5, 1971). Thus, the IHS was bound to

comply with A.P.A. rulemaking procedures in this case despite the otherwise applicable exemption found at subsection (a)(2) of section 553." (citing Morton, 415 U.S. at 235 (1973); Rodway, 514 F.2d 809; Florida v. Weinberger, 401 F. Supp. 760 (D.D.C. 1975))).

Defendants cite to a single case that seems to state the opposite: "'[A]lthough it appears that no notice of proposed rule making was given when these regulations were issued, the requirement of notice in the Administrative Procedure Act, 5 U.S.C. § 553(b), is inapplicable when regulations concern matters relating to grants, as do the instant ones.' . . . Since the rule challenged by the plaintiffs falls within the 'grant' exception, it is not necessary for the purpose of procedural review to determine whether the rule is legislative or interpretative." Opelika Nursing Home, Inc. v. Richardson, 356 F. Supp. 1338, 1342 (M.D. Ala. 1973) (quoting Rodriguez v. Swank, 318 F. Supp. 289, 295 (N.D. Ill.1970)). Although the Court assumes it was not purposely misleading, the case cited by the Defendants is entirely inapplicable. The original Opelika Nursing Home case was decided on January 29, 1971. Opelika Nursing Home, Inc. v. Richardson, 323 F. Supp. 1206 (M.D. Ala. 1971), rev'd, 448 F.2d 658 (5th Cir. 1971). It concerned regulations from 1970, *before* the Secretary put the new procedural requirements in place on February 5, 1971. 36 Fed. Reg. 2,532. In short, the 1970 agency action at issue in the case cited by the Defendants was certainly not subject to the Secretary's February 1971 announcement. Conversely, seemingly every case that addressed the question *after* the policy was issued came to the opposite conclusion.

In light of the weight of precedent, the waiver of the grant exception is binding and cannot be summarily disregarded. Fox Television Stations, 556 U.S. at 515 ("An agency may not, for example, depart from a prior policy sub silentio."). The only remaining question is

whether the Rate Change Notice is the type of legislative rule that is subject to notice-and-comment rulemaking.

3. Legislative Rule

As described above, legislative rules are those that "create[] rights, assign[] duties, or impose[] obligations, the basic tenor of which is not already outlined in the law itself." N.H. Hosp. Ass'n, 887 F.3d at 70 (quoting La Casa Del Convaleciente, 965 F.2d at 1178). At its most basic level, the Rate Change Notice does just that. As opposed to honoring existing NICRAs and negotiating ICRs on a case-by-case basis as contemplated by the existing regulation, the Rate Change Notice provides that "there will be a standard indirect rate of 15% across all NIH grants for indirect costs in lieu of a separately negotiated rate for indirect costs in every grant." This is a two-fold overhaul of the existing regulatory regime.

First, courts consider if "the rule is 'inconsistent with another rule having the force of law,' or otherwise 'alter[s] or enlarg[es] obligations imposed by a preexisting regulation.'" N.H. Hosp. Ass'n, 887 F.3d at 73 (quoting Warder, 149 F.3d at 75; Aviators for Safe & Fairer Regulation, Inc. v. FAA, 221 F.3d 222, 226-27 (1st Cir. 2000)) (alterations in original). There is no question the Rate Change Notice is both inconsistent with an existing rule and alters existing obligations: The institutions currently dedicated to the good work of improving the lives and health of Americans do so in reliance on their negotiated indirect cost rates. Despite being dressed up as a simple deviation, which the Court addressed above, this Rate Change Notice imposes entirely different obligations, slashing ICRs that resulted from a lengthy negotiation process prescribed by the current regulation. Thus, this Rate Change Notice is inconsistent with a current rule having the force of law. In so doing, it alters the agency's and the institutions' obligations.

Second, courts "consider the manner in which the . . . action[] fit[s] within the statutory and regulatory scheme." N.H. Hosp. Ass'n, 887 F.3d at 73 (citing Warder, 149 F.3d at 81). As the Association of American Universities state, the Rate Change Notice is "manifest not only with respect to the rate itself, but also with respect to the reticulated process by which the rates were previously set on an individualized basis, which is not compatible with a single, across-the-board rate." AAU [Dkt. 16, at 37]. For decades, institutions have relied on the negotiation process, as laid out by the regulations. With the Rate Change Notice, this negotiation process would no longer exist. Such a change does not simply, "advise the public of the agency's construction of the statutes and rules which it administers," which would bring it within the gambit of an interpretive rule. Perez, 575 U.S. at 97. It changes the entire field of play, as legislative rules often do.

HHS and other agencies have recognized the need for notice-and-comment rulemaking in similar circumstances. For example, HHS submitted to notice and comment when it intended to restrict indirect costs for foreign organizations and foreign public entities, Health and Human Services Grants Regulation, 81 Fed. Reg. 45270 (proposed July 13, 2016) (to be codified at 45 C.F.R. pt. 75), while the Office of Management and Budget submitted to notice and comment when it planned to "establish a consistent policy for adjustment of indirect cost rates based on a proposal(s) subsequently found to have contained unallowable costs," Proposed Revisions to Circular A-21, 56 Fed. Reg. 29530 (proposed June 27, 1991). In both cases, the agencies recognized that rules even less substantive than the Rate Change Notice at issue were legislative, and thus subject to notice-and-comment. The Rate Change Notice does not simply restrict indirect costs for a subset of organizations, as did the rule submitted in 2016. It also does not simply adjust the policy for unallowable costs. It restricts indirect costs for every institution

accepting a grant from NIH and changes the process by which those indirect costs are determined on a wholesale basis. If notice-and-comment rulemaking was appropriate for the former proposed rules, it is certainly appropriate for the proposed Rate Change Notice.

On a final note, Defendants make an additional argument that because the Rate Change Notice purports to comply with an existing regulation, 45 C.F.R. § 75.414(c), which has already gone through notice-and-comment rulemaking, no additional notice-and-comment safeguards are required. States [Dkt. 73, at 22]. This plainly cannot be true. First, as described above, the Rate Change Notice is inapposite with § 75.414. Second, because the Rate Change Notice is a legislative rule, any existing regulation cannot excuse NIH from compliance with the APA's notice-and-comment rulemaking requirements. Simply claiming a legislative rule complies with some other regulation does not excuse compliance with administrative law altogether.

As the Rate Change Notice is a legislative rule and no exception is applicable, NIH was required to submit the Rate Change Notice to notice-and-comment rulemaking. Failure to comply with these requirements renders the rule procedurally invalid. Thus, the Plaintiffs are, again, likely to succeed on the merits of their claim.

c. Impermissibly Retroactive

In considering whether retroactive application of an agency regulation is permissible, the court conducts a two-step inquiry. First, it must determine if the enabling statute endorses retroactive rulemaking. Landgraf v. USI Film Prods., 511 U.S. 244, 280 (1994). If it does, the inquiry is complete. If it does not, the court must continue to the second step—determining if the regulation truly operates retroactively. Id. If it does, the regulation is impermissibly retroactive.

Turning to the first step, "[i]t is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress . . . .

Retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result." Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) (citing Greene v. United States, 376 U.S. 149, 160 (1964); Claridge Apartments Co. v. Commissioner, 323 U.S. 141, 164 (1944); Miller v. United States, 294 U.S. 435, 439 (1935); United States v. Magnolia Petroleum Co., 276 U.S. 160, 162-63 (1928)); see also Brimstone R. & Canal Co. v. United States, 276 U.S. 104, 122 (1928) ("The power to require readjustments for the past is drastic . . . . [I]t ought not to be extended so as to permit unreasonably harsh action without very plain words."). Thus, as a threshold matter, the Court must determine if the authority delegated by Congress explicitly empowers HHS, and therefore NIH, to issue retroactive regulations. The express language of the enabling statute does not appear—at least explicitly—to give NIH any such power. See 42 U.S.C. § 241.

Thereafter, the question for the Court becomes whether the Rate Change Notice does, in fact, operate retroactively. If so, the Rate Change has an impermissible retroactive effect. As an initial matter, both Plaintiffs and Defendants focus their arguments on the Rate Change Notice's application to existing grants, thus so too will the Court. AAU [Dkt. 16, at 32]; States [Dkt. 73, at 25]; States [Dkt. 81, at 15].

Defendants argue that this case is unlike prior cases that found legislative action to be impermissibly retroactive, as in those cases, "an agency attempted to claw back money that already had been paid out." States [Dkt. 73, at 25]. Defendants argue, instead, that the Rate Change Notice only applies to existing grants' "go forward expenses," and that, therefore, the Rate Change Notice is not retroactive. However, the Supreme Court has specifically rejected this view. "[T]he ban on retrospective legislation embrace[s] 'all statutes, which, though

operating only from their passage, affect vested rights and past transactions . . . . Upon principle . . . every statute, which takes away or impairs vested rights acquired under existing laws, or creates a new obligation, imposes a new duty, or attaches a new disability, in respect to transactions or considerations already past, must be deemed retrospective.'" Landgraf, 511 U.S. at 268-69 (quoting Soc'y for Propagation of the Gospel v. Wheeler, 22 F. Cas. 756 (No. 13,156) (CCNH 1814)). Thus, the Supreme Court held in Landgraf that a regulation has retroactive effect when "it would impair rights a party possessed when he acted, increase a party's liability for past conduct, or impose new duties with respect to transactions already completed." Id. at 280. Important to the matter before the Court, "[t]he largest category of cases in which we have applied the presumption against statutory retroactivity has involved new provisions affecting *contractual or property rights*, matters in which predictability and stability are of prime importance." Id. at 271 (emphasis added).

Although not a contract, the Notice of Award and NICRA are both legally binding and have many of the key hallmarks of a contract. When receiving a grant from NIH, institutions are subject to a Notice of Award, which integrates the previously settled-upon NICRA. In adopting the Rate Change Notice, even as to "go-forward" expenses, the ICR cap would impair the rights the institution possessed when accepting the Notice of Award—specifically, the negotiated ICR at the time of the NOA. The Rate Change Notice imposes a new, lower rate, displacing the institutions' right to the previously negotiated—and legally binding—ICR. Additionally, the institutions will now be liable for more expenses with respect to the Notices of Award already executed, imposing new duties for transactions already completed. As a result, there is little

question the Rate Change Notice is retroactive as to its application to existing grants.[6] Thus, again, Plaintiffs are likely to succeed on the merits as to the retroactive application of the Rate Change Notice on existing grants.

4. Other Claims

Plaintiffs make a series of additional statutory and constitutional claims, including violations of the Public Health Service Act and the Appropriations Clause. Without commenting on the substance, the Court finds its unnecessary to address those claims at this stage of the litigation, as the likelihood of success on the merits on each claim addressed above is independently sufficient to support the issuance of a preliminary injunction. Specifically as to the constitutional claim(s), the Court "find[s] it unnecessary and, indeed, inappropriate . . . to reach these claims. Under the doctrine of constitutional avoidance, 'federal courts are not to reach constitutional issues where alternative grounds for resolution are available.'" Marasco & Nesselbush, 6 F.4th at 178 (quoting Vaquería Tres Monjitas, Inc. v. Pagan, 748 F.3d 21, 26 (1st Cir. 2014)) (citing Nw. Austin Mun. Util. Dist. No. One v. Holder, 557 U.S. 193, 205 (stating that the court ordinarily "will not decide a constitutional question if there is some other ground upon which to dispose of the case")). As in Marasco & Nesselbush, the Court finds discussion of the merits of the above claims "adequately addresses [Plaintiffs'] remedial requests and that,

[6] This Court finds the retroactivity concerns as to new grants that are otherwise still subject to an existing NICRA to be a closer question. While the Rate Change Notice does not appear to impose new duties with respect to transactions already completed, as no institution is forced to undertake new or additional research, the NICRA itself is still its own contractual relationship. The Rate Change Notice could thus foreseeably impair rights protected by institutions' NICRAs. Because all parties limit the retroactivity discussion to existing grants, and success on the merits is likely for both existing and new grants on several other grounds, the Court finds it unnecessary to rule on the issue of retroactivity as it applies to future grants, particularly without additional briefing.

hence, resolving the constitutional questions would be inconsistent with our obligation to avoid doing so where a non-constitutional disposition is possible." 6 F.4th at 179.

B. IRREPARABLE HARM

The second element that Plaintiffs must show to justify a preliminary injunction is that they are "likely to suffer irreparable harm in the absence of preliminary relief." Voice of the Arab World, 645 F.3d at 32 (quoting Winter v. Nat. Res. Def. Council, Inc., 555 U.S. at 20); see also Winter, 555 U.S. at 22 ("Our frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction." (first citing Los Angeles v. Lyons, 461 U.S. 95, 103 (1983); then Granny Goose Foods, Inc. v. Teamsters, 415 U.S. 423, 441 (1974)); and then O'Shea v. Littleton, 414 U.S. 488, 502 (1974)). Importantly, "[d]istrict courts have broad discretion to evaluate the irreparability of alleged harm and to make determinations regarding the propriety of injunctive relief." K-Mart Corp. v. Oriental Plaza, Inc., 875 F.2d 907, 915 (1st Cir. 1989) (quoting Wagner v. Taylor, 836 F.2d 566, 575-76 (D.C. Cir.1987)).

1. Standard

"Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with [the Supreme Court's] characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." Winter, 555 U.S. at 22 (citing Mazurek v. Armstrong, 520 U.S. 968, 972 (1997) (per curiam)). The burden falls directly on the moving party to demonstrate the likely irreparable harm. See Fed. R. Civ. P. 65(a); Narragansett Indian Tribe v. Guilbert, 934 F.2d 4, 6 (1st Cir.1991) ("[I]rreparable harm is not assumed; it must be demonstrated."); Ross-Simons I, 102 F.3d at 18 ("[T]he burden of demonstrating that a denial of interim injunctive relief would cause

irreparable harm [rests] squarely upon the movant."). Although "[t]he burden is substantial . . . it is possible to overstate its dimensions." Ross-Simons I, 102 F.3d at 18. Additionally, when, as here, "the likelihood of success on the merits is great, a movant can show somewhat less in the way of irreparable harm and still garner preliminary injunctive relief." Vaqeria Tres Monjitas, Inc. v. Irizarry, 587 F.3d 464, 485 (1st Cir. 2009) (quoting E.E.O.C. v. Astra U.S.A., Inc., 94 F.3d 738, 743-44 (1st Cir. 1996)); Ross-Simons I, 102 F.3d at 19 ("[A]n attempt to show irreparable harm cannot be evaluated in a vacuum; the predicted harm and the likelihood of success on the merits must be juxtaposed and weighed in tandem."); Gately v. Massachusetts, 2 F.3d 1221, 1232 (1st Cir. 1993) (noting a "general principle" of equity "that irreparable harm is subject to a sliding scale analysis").

In determining if the harm is irreparable, "[i]t is settled beyond peradventure that irreparable harm can consist of 'a substantial injury that is not accurately measurable or adequately compensable by money damages.'" Ross-Simons of Warwick, Inc. v. Baccarat, Inc. (Ross-Simons II), 217 F.3d 8, 13 (1st Cir. 2000) (quoting Ross-Simons I, 102 F.3d at 19); see also e.g., Weinberger v. Romero-Barcelo, 456 U.S. 305, 312 (1982) ("The Court has repeatedly held that the basis for injunctive relief in the federal courts has always been irreparable injury and the inadequacy of legal remedies."); K-Mart Corp., 875 F.2d at 915 (noting "injuries to real estate interests" along with "harm to goodwill" are types of irreparable harm that "frequently come within the ken of the chancellor"); Danielson v. Local 275, Laborers Int'l Union, 479 F.2d 1033, 1037 (2d Cir. 1973) ("Irreparable injury is suffered where monetary damages are difficult to ascertain or are inadequate.").

As made clear by the declarations in support of a preliminary injunction against the implementation of the Rate Change Notice, the risk of harm to research institutions and beyond is immediate, devastating, and irreparable.

2. Imminent, Dangerous, and Irreparable Harms

Although the harms resulting from the Rate Change Notice are many, not all harms are irreparable. With that said, Plaintiffs identify several irreparable harms in their declarations. First, the suspension of ongoing clinical trials and the resulting threats to patients' lives represents a dire risk of a quintessentially irreparable nature. Second, the threats to non-human, yet still essential, research subjects similarly rings in irreparability. Finally, the potential loss of human capital and talent to virtually every Plaintiff poses yet another harm incapable of run-of-the-mill legal relief. Because each of these harms, discussed in detail below, cannot be adequately remedied once inflicted the Court finds Plaintiffs have met their burden of demonstrating irreparable harm.

The first, and most pressing, irreparable harm is the suspension of ongoing research and risk to patients' lives. Institutions across the country described the immediate suspension of research, and more specifically, clinical trials, should the Court fail to grant a preliminary injunction in this case. E.g., States [Dkt. 6-34, Declaration of Dr. Greg Hirth, of Brown University] ("There is no simpler way to put it: At a 15% indirect cost rate, many of Brown's current research projects and clinical trials will be forced to cease abruptly. . . . Even a temporary interruption of work would threaten clinical trials that supply lifesaving medicine and risk derailing years of careful progress and efforts directed towards major health challenges."); States [Dkt. 6-36, Declaration of Bharat Ramratnam, M.D., of Lifespan Corporation d/b/a Brown University Health] ("Additionally, [the Rate Change Notice] will hinder the purchase of supplies

for clinical trials from national and local vendors. As [a] result, this will lead to the premature closure of clinical trials leading to layoffs in nursing staff. The overall impact will be the greatest on patient care with potentially life-saving treatments withdrawn from individuals who have failed all other treatments." (emphasis removed)); States [Dkt. 82-8, Declaration of Dr. Penny Gordon-Larsen, PhD, of the University of North Carolina at Chapel Hill] ("In the event the Supplemental Guidance is implemented, UNC also anticipates, and is planning for, paused or canceled clinical trials due to an inability to maintain the facilities and regulatory support necessary for proper trial execution. This would directly impact patient care in North Carolina."); AAU [Dkt. 2-13, Declaration of David P. Norton, of the University of Florida in Gainesville] ("The NIH's proposal to cut indirect cost rates to 15% would end or seriously jeopardize[:] . . . the University of Florida['s] . . . cancer research[] . . . , clinical research aimed at providing better outcomes for persons stricken with [Parkinson's] disease . . . , [and] cutting edge genetics research [into the cause and treatment of ALS]."); AAU [Dkt. 2-21, Declaration of Elizabeth Duggins Peloso, of the University of Pennsylvania] ("A 15 percent cap on F&A costs would disrupt numerous ongoing clinical trials in cancer treatment, immunotherapy and bone marrow transplant therapy with enrolled patients, including those who have already started but not yet completed treatment."); AAU [Dkt. 2-28, Declaration of Ishwar K. Puri, of the University of Southern California] ("USC anticipates the following immediate consequences of cutting the indirect cost rate to 15%: [1] Stopping/curbing clinical trials[; 2] Closing critical [biomedical] research programs[; and, 3] Cancell[ation of] Research Symposia . . . [on] Alzheimer's disease, diabetes . . . , prostate cancer, addiction, and many other issues."). The lives that will certainly be lost from a pause in these trials cannot be replaced. That is not an opinion of the Court—that

is the belief put forth by dozens of declarants who represent universities, research institutions, and associations whose very goals are to protect the sanctity of human life and science.

Even a temporary halt in clinical trials would be catastrophic, as "clinical trials must generally be continuous to be effective, due to concerns for both patient care and trial validity." States [Dkt. 6-34, Declaration of Dr. Greg Hirth, of Brown University]. Because clinical "trials take years to set up, create, and perform[,]" a freeze in F&A costs would make it "difficult, if not impossible, to restart" ongoing clinical trials. [Id.] And even if trials were to resume, "the lack of continuity [would] compromise[] the scientific results . . . ." [Id.]; see also, e.g., States [Dkt. 6-40, Declaration of Leslie Anne Brunelli, of Washington State University] ("[T]he Sharma lab has already developed nanotherapeutics and is actively testing them on prostate cancer cells and organoids. This is time-sensitive work, and any disruption would result in immediate and potentially irreplaceable data loss on these active tests, which would delay and could ultimately eliminate the viability of the treatment they are researching."). Existing NIH-funded clinical trials represent not only significant capital investments in research equipment and animal specimens, but also an incalculable commitment to patients, who by the very nature of their condition have nowhere else to turn. Human safety and scientific integrity are immeasurably compromised by NIH's slash-and-cap approach. The Court is hard pressed to think of a loss more irreparable than the loss of a life, let alone the thousands of people who are counting on clinical trials as their last hope. There is no question, "there can be no do over and no redress." League of Women Voters of U.S. v. Newby, 838 F.3d 1, 9 (D.C. Cir. 2016) (quoting League of Women Voters of N.C. v. North Carolina, 769 F.3d 224, 247 (4th Cir. 2014)); see also States [Dkt. 6-7, Declaration of Ken A. Dill, Ph.D., of the State University of New York] ("It is not an

exaggeration to say that the true cost of the NIH's decision may be that thousands of American lives are needlessly degraded or sacrificed.").

The Court not only considers the harm to research, and by extension, to human life; the lives of animals that are essential to research in advance of human trials are also put at risk by the indirect rate cut. For example, at Washington State University,

> [w]ithout funds for animal care through the Office of the Campus Veterinarian, combined with the loss of indirect[costs] for the research projects themselves within CVM, research animal colonies will have to be severely reduced or eliminated. The loss of life would be massive: in 2023, WSU accounted for use of 90,000 animals of which 50% were fish and 39% were mice. The remaining 11% include amphibians, reptiles, birds and other mammals. The results would be horrific. . . . WSU cares for valuable *gene-edited strains of cattle, rodents and fish which are irreplaceable*, and elimination of animal colonies will take potentially years to replace even the ones that are capable of replacement. Even if some funding could be later restored, *the massive loss of animal life cannot be easily replaced, and some projects are unlikely to restart*. Moreover, the loss of the animal population would require layoffs of professional animal care and veterinary staff that are nearly impossible to replace, given the current disparity in opportunities in veterinary medicine that are available in the private sector.

States [Dkt. 6-40, Declaration of Leslie Anne Brunelli, of Washington State University] (emphasis added). At the University of Washington, which operates one of only seven National Primate Research Centers, "[t]he cut in IDC rates will cripple [the Research Center]'s life-saving research," as it is "required to shut down facilities, directly impacting the 170 individuals employed by the Center. In addition, with other NPRCs impacted, there will be animals that cannot be sold or relocated to other research facilities. There is limited sanctuary space available, and the UW would not be able to cover the high costs associated with lifetime sanctuary care, so these animals would have to be euthanized." States [Dkt. 6-39, Declaration of Mari Ostendorf, of the University of Washington]. As a result, the Center's "pioneering biomedical advances that benefit human health . . . will be crippled from loss of NIH funding." Id. Several other institutions also identified the need to euthanize animals, including those that are currently key to

on-going research, as an immediate consequence. See, e.g., AAU [Dkt. 2-21, Declaration of Elizabeth Duggins Peloso, of the University of Pennsylvania] ("F&A costs are crucial in clinical trials with live subjects. In one of the studies mentioned [], where researchers are developing therapies for HIV, autoimmune disease, and cancer, researchers utilize F&A funds to support 16,000 mice, which includes the cost of 5,333 cages, 11 mice caretakers, 4 cage wash technicians, 3 veterinary technicians, 1 veterinarian, cage equipment costs, feed, bedding, enrichment, water bottles for all animals, and regulatory and facility support."); id. [Dkt. 2-28, Declaration of Ishwar K. Puri, of the University of Southern California] ("NIH's proposal to cut indirect cost rates to 15% would seriously jeopardize" "Aging and Alzheimer's disease research . . . [conducted with] genetically engineered mice . . . .").

For essentially all of the Plaintiff institutions, there are myriad other immediate consequences that will make it harder to fulfill their purpose. "[O]bstacles [that] unquestionably make it more difficult for the [plaintiff] to accomplish [its] primary mission . . . provide injury for purposes . . . [of] irreparable harm." Newby, 838 F.3d at 9 (citing Nat'l Treasury Emps. Union v. United States, 101 F.3d 1423, 1430 (D.C. Cir. 1996)). These consequences include the degradation of vital infrastructure, the loss of imperative staff necessary for research to be conducted, the loss of human capital resulting from leading scientists choosing to work elsewhere and universities admitting fewer students, and finally, the uncertainty around the ability to sustain future grant applications, resulting in the loss of direct research. See, e.g., States [Dkt. 6-11, Declaration of Donald M. Elliman, Jr., of Colorado Anschutz Medical Campus] ("The drastic cuts to NIH F&A will bring the Institute's research and community-based programs to a virtual standstill due to the loss of shared administrative staff and the specialized computing infrastructure essential for the Institute's efforts."); States [Dkt. 6-15, Declaration of

Dr. Tony Allen, of Delaware State University] ("[T]he loss of these funds will necessitate laying-off three or more research support personnel, and reductions in or elimination of stipends for institutionally-supported doctoral students in DSU's neuroscience PhD program, the only such program offered at an Historically-Black university."); States [Dkt. 6-19, Declaration of Denise Barton, of the University of Massachusetts] ("Loss of IDC will curtail the ability of UMass Chan Medical School to provide and keep necessary equipment in good shape. Malfunctioning equipment can produce faulty data and loss of equipment would bring research relying on that equipment to a halt, which could erase several years of progress on a project or grant."); States [Dkt. 6-24, Declaration of Douglas A. Gage, Ph.D., of Michigan State University] ("MSU next anticipates to draw funds on or around Friday, February 14, 2025. At that time, the reduced IDC rate will reduce reimbursement for actual expenditures incurred, and MSU must begin to reduce staffing and identify other reductions, which will be detrimental to attaining committed research goals."); States [Dkt. 6-41, Declaration of Dorota Grejner-Brzezinska, of the University of Wisconsin-Madison] ("NIH's eleventh-hour change in available funding forces researchers and university administrators to reconsider whether to submit grant applications, many of which they have been fine-tuning for months, given uncertainty about whether the institution can afford to sustain these projects at a 15% IDC rate. The sense of whiplash is particularly acute, given that UW-Madison had finalized its most recent NICRA with DHHS less than three weeks prior."); States [Dkt. 82-8, Declaration of Dr. Penny Gordon-Larsen, PhD, of the University of North Carolina at Chapel Hill] ("[T]he loss of these funds will immediately impact UNC's ability to cover expenses associated with, among other items: facilities operations and maintenance, facilities debt service and rent, research equipment purchases, federally-mandated regulatory compliance and grant administration functions, research-specific IT services, and research-

specific student support."); AAU [Dkt. 2-7, Declaration of David A. Tirrell, of the California Institute of Technology] ("This reduction will have deeply damaging effects on Caltech's ability to conduct research from day one. For example: . . . [1] The number of graduate students – who are the future of biomedical research – who can be admitted will have to be reduced substantially. The impact on the future of research will be immediate and unrecoverable. [2] Offers to new postdoctoral scholars also will be reduced, with similar impact on the quality of the research environment and on the future of biomedical research. [3] Support for our shared biomedical research facilities will have to be reduced immediately. The viability of these facilities will be compromised."); [id.] ("Caltech is in the process of submitting 11 applications for NIH research support. The uncertainty regarding NIH indirect cost policy makes it impossible to complete submission of these applications, which are intended to support research related to nicotine addiction, congenital birth defects, aging, neuromodulation, Parkinson's disease, and biomedical measurement technologies."); AAU [Dkt. 2-12, Declaration of David F. Kotz, of Dartmouth College] ("Such cuts would certainly result in a hiring freeze on faculty, postdoctoral associates, and graduate students, directly impacting our ability to conduct advanced research in the public interest and train the next generation of research scientists. . . . The world's best scientists will not move to (or stay at) universities where they are not able to conduct world-class research. The reality of this shortfall and the cuts it would necessitate would reduce the amount available for new faculty "start-up" packages, which are required for junior investigators to set up their laboratories and jump start their own new research programs."); AAU [Dkt. 2-13, Declaration of David Paul Norton, of the University of Florida] ("The University of Florida Research Integrity, Security & Compliance (RISC) unit . . . would have to reduce staffing within RISC by an estimated 5 individuals, which would immediately

impact its ability to ensure university compliance with federal regulations. The University of Florida's Division of Sponsored Programs (DSP) . . . would have to reduce staffing within DSP by an estimated 18 individuals, thus crippling [] its ability to submit proposals, negotiate awards, and setting up subcontracts such as to be consistent with the funding agency's accountability requirements. The University of Florida's Research Division of Contracts & Grants . . . would have to reduce staffing within Contracts & Grants by an estimated 22 individuals, thus crippling the University of Florida's ability to meet its obligations to manage federally-funded grants, including grants from the NIH, so as to meet the funding agency's accountability requirements."); AAU [Dkt. 2-28, Declaration of Ishwar K. Puri, of the University of Southern California] (discussing the likely cutting of 73 staff members).

These harms are particularly irreparable, as the losses are compounding. Most institutions draw funds multiple times per month. Each time there is a draw, the immediate cap on ICRs is felt anew, exacerbating the harms identified more and more over time. See, e.g., States [Dkt. 6-13, Declaration of Dr. Pamir Alpay, of the University of Connecticut] ("UConn and UCH anticipate this will reduce its draw to recover these costs by about $673,000 per week."); States [Dkt. 6-32, Declaration of Peter Barr-Gillespie, Ph.D., of Oregon Health and Science University] ("OHSU's next anticipated draw of funds is on or around February 10, 2025. At that time, the reduction in the IDC rate will result in the loss of $1.6M per week in reimbursement that supports the salaries, facility costs, and research infrastructure that allows OHSU to conduct research."); AAU [Dkt. 2-31, Declaration of Dorota Grejner-Brzezinska, of the University of Wisconsin-Madison] ("UW-Madison typically draws down funds for NIH-funded projects twice per month and next anticipates drawing funds on or around February 17, 2025. At that time, if allowed to be implemented, the reduced IDC rate will result in UW-

Madison experiencing a $3.9 million loss in IDC recovery for this upcoming draw."). Additionally, despite NIH's claims, institutions' endowments, which vary from institution to institution, will be unable to make up the shortfall—a majority of the funds in endowments are legally bound for specific purposes based on the gift. See, e.g., States [Dkt. 6-34, Declaration of Dr. Greg Hirth, of Brown University] ("Brown's endowment, which provides an essential source of support for the University's financial aid, faculty salaries, and academic and co-curricular programs, consists of over 3,800 unique funds that are legal contracts given as charitable gifts by alumni, parents, students, and friends of the University."); AAU [Dkt. 2-8, Declaration of Theresa S. Mayer, of Carnegie Mellon University] ("While CMU maintains an endowment, it is neither feasible nor sustainable for CMU funds or other revenue sources to offset shortfalls in indirect cost recovery. . . ."); [id.] (noting 83.3% "of CMU's endowment . . . is restricted to specific donor-designated purposes . . . ."); AAU [Dkt. 2-11, Declaration of Robert A. Harrington, M.D., of Cornell University] ("Cornell's existing endowment cannot simply be redirected to pick up these losses."). Further, even the funds that are unrestricted are generally subject to a managed annual payout, often further restricted by applicable state laws. See, e.g., AAU [Dkt. 2-1, Declaration of Barbara R. Snyder, of the Association of American Universities] ("The vast majority of endowed funds often are restricted by the terms on which the funds were donated to the AAU member university and cannot legally be used to cover research infrastructure costs."); AAU [Dkt. 2-8, Declaration of Theresa S. Mayer, of Carnegie Mellon University] ("Even the portion of the endowment that is unrestricted is subject to a carefully managed annual payout, typically around 5%, to ensure long-term financial stability for the institution."); AAU [Dkt. 2-11, Declaration of Robert A. Harrington, M.D., of Cornell

University] ("Cornell may only draw down the portion of the endowment that is unrestricted at a rate that complies with New York State law.").

As most universities are non-profit institutions, almost all revenue is re-invested in an effort to advance the universities' mission and enhance student life, leaving little option to redirect funds. See, e.g., AAU [Dkt. 2-8, Declaration of Theresa S. Mayer, of Carnegie Mellon University] ("As a non-profit institution, CMU reinvests nearly all of its revenue into mission-critical activities, leaving little margin to absorb unexpected funding gaps . . . . CMU does not generate significant surpluses that could be redirected without impacting core academic priorities such as educational programs and financial aid support for students."). These harms, and many more, do not only impact the Plaintiff states and institutions, but the communities and people they serve. See generally States [Dkt. 91, Amicus Brief by Cities, Counties, and Mayors, at 4-12] (discussing harms in local communities including staffing cuts for some localities' largest employer, slowing job creation and economic growth, and increasing disparities in health outcomes for rural and urban communities). The ripples are profound and have the potential to reverberate around the world.

Finally, "[b]y its very nature injury to goodwill and reputation is not easily measured or fully compensable in damages. Accordingly, this kind of harm is often held to be irreparable." Ross-Simons I, 102 F.3d at 20. This reputational harm will operate on an institutional, local, and national basis. For example, clinical trial patients have "placed their trust in [the] U[niversity of] W[ashington] for what is in many cases their last option at lifesaving care" and the "scaling back in their level of care[,]" an inevitable result of capping indirect costs at 15%, "would be a devastating breach of trust." States [Dkt. 6-39, Declaration of Mari Ostendorf, of the University of Washington]. "The damage to these patients' lives and their relationship with their care team

at UW would be nearly impossible to rectify." [Id.]. No dollar amount can be placed on patient trust. On an institutional level, "any limit on [UW's] ability to start new trials will delay lifesaving treatments that rely on decades of research and development." [Id.]. More broadly, the United States leads the world in the health sciences. The cut proposed immediately hinders the medical research industries, which will jeopardize the United States' standing as a global leader in discovery, innovation, and technological advancement. The cut undermines the universities' and institutions' ability to drive medical breakthrough that benefits public health and contributes to national advancement in science. Once that is lost, it can almost certainly never be regained. No dollar amount can be placed on the value of the United States remaining the world leader in research and medical advancement.

As Plaintiffs have demonstrated their collective harm "is not accurately measurable or adequately compensable by money damages, irreparable harm is a natural sequel." Ross-Simons I, 102 F.3d at 19. Even though, as established above, the likelihood of success on the merits is great, which would allow "a movant [to] show somewhat less in the way of irreparable harm and still garner preliminary injunctive relief," the allowance is unnecessary. Astra U.S.A., 94 F.3d at 743-44 (1st Cir. 1996). It is impossible to accurately measure or compensate humans who lose their lives from a pause in research. It is impossible to measure the value of lost research animals—representing years of study central to medical breakthrough—that will be euthanized. It is impossible to measure the value of discovery from scientists who choose to leave, or of the potential students who now never become scientists at all. Even for those harms than can be measured in dollars and cents, the losses are compounding and will result in even greater disruption to ongoing research and clinical trials. As a result, failure to grant a preliminary injunction would certainly result in irreparable harm.

C. BALANCE OF EQUITIES AND PUBLIC INTEREST

Finally, the Court must balance the parties' relative hardships and consider the public interest. These factors merge because government parties oppose the preliminary injunction. Nken, 556 U.S. at 435.

Courts have consistently held there is a strong public interest in health and safety. See World Gym, Inc. v. Baker, 474 F. Supp. 3d 426, 434 (D. Mass. 2020) (noting a "great" public interest in public health); see also Grand River Enters. Six Nations, Ltd. v. Pryor, 425 F.3d 158, 169 (2d Cir. 2005) (writing that public health is a "significant public interest"); Jones v. Wolf, 467 F. Supp. 3d 74, 94 (W.D.N.Y. 2020) (confirming there is a public interest in "public health and safety"). The Plaintiffs' hardship absent a preliminary injunction, as described above, is substantial and ranges from the halting of research and clinical trials, resulting in the loss of life for those of whom are relying on clinical trials as their last hope, to a negative impact on patient health and outcomes, the death of animals that represent years of research, the degradation of infrastructure, the loss of staff who are central to patient care and research activities, brain drain in the healthcare industry, and the delay and potential suspension of future grant applications as institutions are unable to support additional research projects. Thus, in light of these hardships, a preliminary injunction would preserve public health, and by extension, serve the public interest. Additionally, there is "substantial public interest 'in having governmental agencies abide by the federal laws.'" Newby, 838 F.3d at 12 (D.C. Cir. 2016) (quoting Washington v. Reno, 35 F.3d 1093, 1103 (6th Cir. 1994)). As described above, it is likely Plaintiffs will succeed on the merits, rendering the Notice unlawful. Therefore, the preliminary injunction would serve the public interest as NIH is forced to abide by existing law and regulations.

Conversely, Defendants do not specifically address the hardship or public interest factors and thus waive arguments as to their balancing. Doe v. Trump, No. 25-CV-10135-LTS, 2025 WL 485070, at *14 (D. Mass. Feb. 13, 2025); see also United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990). Despite this waiver, the Court will consider the three government interests asserted in the Rate Change Notice: First, NIH seeks to maximize funding toward "direct scientific research costs rather than administrative overhead"; second, "indirect costs are . . . difficult for NIH to oversee"; and third, NIH hopes to make indirect costs "reflect . . . the private sector indirect cost rates." Despite these interests, the scales remain tipped in Plaintiffs' favor because the government "cannot suffer harm from an injunction that merely ends an unlawful practice." Rodriguez v. Robbins, 715 F.3d 1127, 1145 (9th Cir. 2013); see also R.I.L-R v. Johnson, 80 F. Supp. 3d 164, 191 (D.D.C. 2015) (finding that the government "cannot suffer harm from an injunction that merely ends an unlawful practice"). Further, there is no public interest in upholding unlawful agency action. Newby, 838 F.3d at 12.

Nonetheless, even if promulgation of the Rate Change Notice is ultimately vindicated, the temporary halting of the rate change cannot create hardship if it does not frustrate Defendants' policy choices. Defendants indicate they seek to maximize direct funding but neither the Rate Change Notice nor their filings demonstrate how that is accomplished under the proposed regulation. Instead, Plaintiffs' declarations show repeatedly that the overall volume of research will necessarily decrease. Defendants also state an oversight goal but fail to explain how the Rate Change Notice increases or simplifies grant supervision beyond the accountability already required by Appendix III § (C)(11)(c)-(d) to 45 C.F.R. § 75. Finally, as described above, NIH failed to explain how bringing ICRs in line with private institutions, which not only serve different roles in supporting institutions that conduct research but also follow entirely different

procedures in defining direct versus indirect costs, would serve the public interest. In fact, it only seems to diminish institutions' ability to support both existing and potential research.

Because Plaintiffs are likely to prevail in their argument that the Rate Change Notice is counter to statute and regulation, an injunction supports the public interest in having agencies abide by federal law. Further, an injunction also pauses cuts in grant funding that would adversely and immediately affect public health. Thus, the public interest factors weigh in favor of a preliminary injunction.

V. SCOPE OF INJUNCTION

Having concluded that Plaintiffs have met their burden under the preliminary injunction standard, the Court must craft the appropriate relief. The AAMC and AAU Plaintiffs urge the Court to preliminarily enjoin the Defendants from taking any steps to further implement the Rate Change Notice in its entirety for all grant recipients, while Plaintiff States seek preliminary injunctive relief for the 22 named Plaintiff States. AAMC and AAU assert there are compelling reasons to enjoin the implementation of Rate Change Notice, namely the breadth of the impact on the victims in these suits, but also similarly situated states, associations, universities, and research institutions. The Plaintiffs represent an excess of 1,400 medical institutions across all 50 states and territories, including Puerto Rico and the District of Columbia. NIH issues nearly 60,000 grants, involving 300,000 researchers at 2,500 universities, medical schools, and research institutions.

While federal district courts have issued nationwide or "universal" injunctions and they have been acknowledged by the circuit courts, the Supreme Court has not directly addressed the issue despite concerns expressed by some justices over their use. See Trump v. Hawaii, 585 U.S. 667, 713 (2018) (Thomas, J., concurring) (expressing skepticism of the use of such authority by

the district courts.); Dep't. of Homeland Sec. v. New York, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring). With that said, there are appropriate circumstances during which nationwide injunctions are not only appropriate, but necessary. Florida. v. Dep't of Health & Hum. Servs., 19 F.4th 1271, 1281-82 (11th Cir. 2021). Such appropriate circumstances include the need "to protect similarly situated nonparties, [] to avoid the 'chaos and confusion' of a patchwork of injunctions, . . . [or] where the plaintiffs are dispersed throughout the United States." Id. (citing Chicago v. Barr, 961 F.3d 882, 916-17 (7th Cir. 2020)). To this end, in drafting equitable relief, courts must consider "what is necessary, what is fair, and what is workable." North Carolina v. Covington, 581 U.S. 486, 488 (2017) (quoting New York v. Cathedral Acad., 434 U.S. 125, 129 (1977)).

As to the similarly situated nonparties, the need here is particularly acute. The Rate Change Notice was signed on Friday, February 7, 2025 and was set to go into effect on the following business day, Monday, February 10, 2025. Plaintiffs here were moving with great speed to file this suit, as the change was announced after business hours on a Friday and its implementation was set for that following Monday, resulting in immediate harm. As discussed at oral argument, there are certainly other similarly situated nonparties who likely would have joined the suits had there been time ahead of the Rate Change Notice's implementation. These nonparties should not be forced to suffer the harm just because there was not enough time and resources for them to join the suit because of the agency's rush to implement the Rate Change Notice. "[N]ationwide injunctions provide a mechanism for courts to protect all those who could be harmed by a federal policy when only a few have the ability to quickly bring their case before a court." Amanda Frost, In Defense of Nationwide Injunctions, 93 N.Y.U. L. Rev. 1065, 1094-95 (2018) ("Nationwide injunctions are at times the only way to prevent irreparable injury to

individuals who cannot easily or quickly join in litigation."). Further, this Court agrees with Plaintiffs that "[c]ourts should also avoid issuing an injunction that 'lop[s] a state off' thereby 'entirely undercut[ting] that injunction's effectiveness.'" States [Dkt 81, at 26] (quoting DraftKings Inc. v. Hermalyn, 118 F.4th 416, 424 (1st Cir. 2024)) (modifications in original).

Turning to the "chaos and confusion" of a patchwork of injunctions, the concern is certainly present in this case. Should an injunction be limited to the named Plaintiffs, institutions both within and outside the scope of the injunction will need to operate with concern for the future sustainability of their research. The Massachusetts Institute of Technology ("MIT") provides an enlightening example:

> As a direct result of real and threatened federal cost-cutting in fundamental research and potential increased levies on universities, including this attempted reduction in F&A cost reimbursement rate, MIT is being forced to take immediate and contemporaneous action to reduce its financial exposure. The Institute is implementing operating budget reductions and curtailing its capital investments. At the Institute level, MIT is deferring capital projects, notably including research infrastructure and space renewals, lab equipment installations, ventilation air capacity improvements, and energy efficiency upgrades. MIT also expects to implement a partial hiring freeze across the Institute this week. In addition, this week MIT is issuing central budgets to its internal units that mandate cuts from current resource levels.

AAU [Dkt. 2-17, Declaration of Ian A. Waitz, of the Massachusetts Institute of Technology]. Absent a nationwide injunction, institutions across the country will be forced to operate with the same uncertainty, resulting in the types of irreparable harm that a preliminary injunction is meant to prevent. In the face of this uncertainty, institutions would almost certainly file many additional lawsuits. The potential patchwork of injunctions would cause administrability problems, not only for the institutions relying on consistency to prevent the harm discussed above but also for NIH as it attempts to comply with varying injunctions across the country.

As to the third point, Plaintiff States, institutions, associations, and association members are plainly dispersed across the country. There are 22 states, university declarations from 32 states, and association membership in all 50 states. There is no doubt the Plaintiffs are dispersed across the country, which weighs in favor of a nationwide injunction.

In addition to the considerations discussed above, the nature of the action itself supports a nationwide injunction. The normal remedy for a successful APA challenge is vacatur of the rule and its applicability to all who would have been subject to it. Victim Rts. L. Ctr. v. Cardona, 20-CV-11104-WGY, 2021 WL 3516475, at *1 (D. Mass. Aug. 10, 2021) (citing 5 U.S.C. § 706(2)(A) ("The reviewing court shall hold unlawful and set aside agency action . . . found to be . . . arbitrary [and] capricious . . . ."); William Baude et. al., The Federal Courts and the Federal System 1354 (8th ed. 2025) (describing how "the Administrative Procedure Act's provision for the vacatur of federal agency action may confer" a power analogous to universal injunction "by statute"); see also Gailius v. INS, 147 F.3d 34, 47 (1st Cir.1998) (finding that vacation and remand is appropriate when an agency has failed to give adequate explanation for its conclusions); Nw. Env't Advocs. v. EPA, 537 F.3d 1006, 1026 (9th Cir. 2008) ("We affirm the district court's decision to vacate the regulation and to remand for further proceedings as a valid exercise of its remedial powers."); Lovely v. FEC, 307 F. Supp. 2d 294, 301 (D. Mass. 2004) ("[V]acation is a proper remedy when an agency fails to explain its reasoning adequately." (quoting Harrington v. Chao, 280 F.3d 50, 60 (1st Cir. 2002) (internal quotation marks omitted)). It would be anathema to reasonable jurisprudence that only the named Plaintiffs should be protected from the irreparable harms of an unlawful regulation. Thus, "when a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed." Nat'l Min. Ass'n

v. U.S. Army Corps of Eng'rs, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (quotation marks and citation omitted); see also Griffin v. HM Fla.-ORL, LLC, 144 S. Ct. 1, 2 n.1 (2023) (explaining that "[u]nlike judicial review of statutes, in which courts enter judgments and decrees only against litigants, the APA . . . go[es] further by empowering the judiciary to act directly against the challenged agency action. This statutory power to 'set aside' agency action is more than a mere non-enforcement remedy. . . . In these situations, the courts do hold the power to 'strike down' an agency's work, and the disapproved agency action is treated as though it had never happened." (quoting Jonathan F. Mitchell, The Writ-of-Erasure Fallacy, 104 Va. L. Rev. 933, 1012-13 (2018))). Thus, particularly in light of the likelihood of success on the merits as to the unlawfulness of the Rate Change Notice and the APA claims, the nature of these suits counsel in favor of a nationwide injunction.

On a final note, there is a noteworthy factor of judicial economy and efficiency that likewise favors a universal solution to the current dilemma. Plaintiffs' challenge to the lawfulness of NIH's action and the unique nature of the broad impact of the Rate Change Notice warrants a broad response until final judgment or appellate review, whichever occurs first, resolves the question of the lawfulness of NIH's actions. Considering the irreparable harm likely to befall similarly situated nonparties, the chaos that would result both for institutions and NIH from a patchwork of injunctions, the diffuse nature of the Plaintiffs, and the nature of the suit, a nationwide preliminary injunction is the appropriate and reasonable remedy.

VI. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Preliminary Injunction is **GRANTED**.

The Defendants and their officers, employees, servants, agents, appointees, and successors are hereby enjoined from taking any steps to implement, apply, or enforce the

Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Costs Rates (NOT-OD-25-068), issued by the Office of the Director of the National Institutes of Health on February 7, 2025, above referred to as the Rate Change Notice, in any form with respect to institutions nationwide until further order issued by this Court.

SO ORDERED.

Dated: March 5, 2025

/s/ Angel Kelley
Hon. Angel Kelley
United States District Judge