EXHIBIT 46

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, et al.,

Plaintiffs,

v.

Case No. 1:25-cv-10787-WGY

NATIONAL INSTITUES OF HEALTH, et al.,

Defendants.

SUPPLEMENTAL DECLARATION OF JEREMY M. BERG, PH.D.

I, Jeremy M. Berg, declare as follows:

- 1. I provide this supplemental declaration in support of Plaintiffs' Motion for Preliminary Injunction (ECF No. 37) and in response to Defendants' Opposition (ECF No. 66), including the Declaration of Jon Lorsch (ECF No. 66-1).
- 2. I am a former director of the National Institute of General Medical Sciences (NIGMS), one of the twenty-seven National Institutes of Health (NIH). I was Director of NIGMS from 2003-2011. To my knowledge, no terminations of any grants awarded by NIGMS occurred during my time as Director.
- 3. In his declaration (¶15), Jon Lorsch attaches and explains Exhibit A: a list of grants "related to health disparities in minority populations" which he represents NIH does not presently have any intent to terminate. However, searches of NIH Reporter revealed that MD013352 ("Impact of Navajo Nation Tax on Junk Food") ended in fiscal year 2021 and that MD018641 ("Understanding cancer and comorbidities among American Indian and Alaska Native people") was a two-year R21 award that ended on 4/30/25. In addition, two other awards (MD017106)

("Reducing Hypertension among African American Men: A Mobile Stress Management Intervention to Address Health Disparities") and MD018459 ("Elucidating the high and heterogeneous risk of gestational diabetes among Asian Americans: an integrative approach to metabolomics, lifestyles, and social determinants") have unusual records in NIH Reporter with Award Notice Dates of 5/4/25 and Budget End Dates and Project End Dates of 5/5/25. A Project End Date of 5/5/25 would normally indicate that these awards, made very recently, were no longer active. The Project End Dates for the remaining grants included in Exhibit A are as follows: MD015221, 6/30/26; MD019748, 5/31/29; MD018583, 12/31/27; MD014859, 11/30/25; MD018193, 6/30/27; MD014127, 12/31/25; MD015724, 4/30/26; MD012610, 7/31/25; MD016068, 2/28/27; MD015186, 1/31/26; MD015724, 4/30/26; MD014035, 1/31/26; MD013752, 1/31/26; MD014146, 4/30/26; MD013858, 1/31/26; MD016961, 3/31/26; MD014145, 4/30/26; MD016738, 4/30/26; MD019397, 4/30/26; MD015080, 5/31/26; MD019333, 12/31/25; MD019227, 1/31/26.

- 4. Lorsch notes (¶13) that 431 appeals of grant terminations have been received by NIH. This process is quite opaque, and at this point I have not been able to learn of any appeals that have been successful. In addition, although I have not been able to obtain specific information, colleagues have shared that some requests to appeal have been declined because the Notice of Funding Opportunities to which the applicant responded has been discontinued by the new administration so that there is no remedy for an appeal because there is no available funding opportunity for the specific grant that was terminated.
- 5. Lorsch states (¶16) that "any funds that are not re-obligated will return to the treasury at the end of the fiscal year consistent with standard practice." While this appears to suggest that returning appropriated funds to the treasury was a common occurrence, my

recollection is that, during my time as NIGMS Director, NIH fully obligated all appropriated funds, such that NIH had final balances of less than \$1000 out of an appropriation of nearly \$2 billion for each year's appropriated funds.

- 6. Lorsch states (¶22-26) that NIH has made good progress catching up with the delayed scientific review and advisory council meetings and claims that "NIH anticipates that it will have reviewed 100% of cycle III grant applications" (¶25). However, it is not clear whether 100% of applicants Lorsch refers to includes all applications that were submitted in response to Notices of Funding Opportunities that were active at the time of application submission that were subsequently "expired" i.e., there are some NOFOs that were active and had applications submitted and assigned out to specific peer reviewers but which were subsequently withdrawn by the new administration. It is not clear how many applications were connected to these withdrawn NOFOs and whether they are included in Lorsch's reporting. It is also not clear what the status is for applications that were submitted in response to active Notices of Funding Opportunities that have been subsequently "expired" with regard to advisory council review. It is possible that such applications may have completed scientific review at study section but then were withdrawn so that they were never made available for advisory council review.
- 7. In some cases, some applications, specifically F31 applications responding to F31-Diversity funding opportunities were repeatedly reassigned to different study sections and it is not clear if these applications were ever reviewed. My understanding is that for some of these F31-Diversity applications, reviewers asked NIH review staff if such applications could simply be assigned to the Parent funding announcement as the applications are identical except for a single page used to justify eligibility for the diversity program i.e., remove the one page diversity

¹ https://www.statnews.com/2025/02/07/trump-nih-scraps-prestigious-diversity-program/

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statement for F31-Diversity grants and allow these applications to continue under the standard F31 parent track. However, these reviewers were told that continuing to review the F31-Diversity applications was not possible as a matter of NIH policy.

- 8. Lorsch states (¶27) that "[f]rom the date of the temporary pause through May 12, 2025, NIH issued 11,362 non-competitive grants. NIH has also issued 1,971 new competitive grants in that same time frame." I was able to essentially reproduce those numbers through searches of the public database NIH Reporter (https://reporter.nih.gov/). To put Lorsch's 2025 numbers in context, I note that from January 28, 2024 through May 12, 2024, NIH issued 14,995 non-competitive grants and 5,557 competitive grants. In the last Presidential transition year (2021), NIH issued 15,691 non-competitive grants and 6,685 competitive grants from January 28 through May 12. Thus, compared to the last Presidential transition year, NIH has issued 72% as many non-competitive grants and 29% as many competitive grants over this same time period.
- 9. Lorsch states (¶31) that "the parent (NRSA) programs remain active". The parent Notices of Funding Opportunities for the F30², F31³ and F32⁴ all had their expiration dates moved up to May 8, 2025 and there were no Notice of Funding Opportunities for the F-series grants active at the time of his declaration as seen from a screen shot from May 13 from the page Lorsch cites in ¶32.

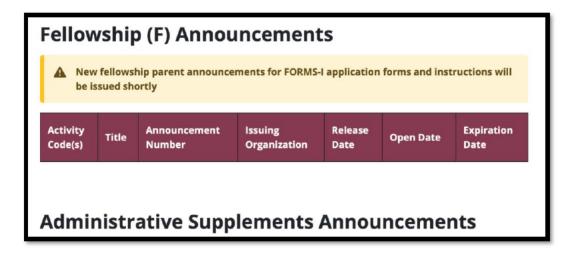
² https://grants.nih.gov/grants/guide/pa-files/PA-23-260.html

https://grants.nih.gov/grants/guide/pa-files/PA-23-272.html

⁴ https://grants.nih.gov/grants/guide/pa-files/PA-23-262.html



This page has now been updated with a comment that forms will be issued shortly.



However, no Notice of Funding Opportunity has yet appeared and NIH appears to be missing its own target dates. These delays are harmful as graduate students, both early in graduate school or later in graduate school and in the process of searching for postdoctoral fellowship opportunities, may be required to make career decisions based on the current uncertainty.

10. Also included and analyzed (¶34) in the Lorsch Declaration was Exhibit B with a list of 5,172 active NRSA grants.⁵ I have performed an analysis of the grants in Lorsch Decl.

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⁵ The list includes 148 entries from Harvard which, based on recent reports of wide-ranging grant terminations at Harvard University, may in fact have been terminated. *See* https://www.bostonglobe.com/2025/05/16/metro/harvard-trump-administration-grant-terminations/

Exhibit B and my analysis is attached to this declaration as **Exhibit A**. This analysis reveals that 25% of these awards are expected to end by 9/30/2025 with an additional 33% expected to end by 9/30/26. Furthermore, an additional 5% of the grants are at risk for being terminated in fiscal year 2026 as they were awarded in response to a NOFO with a substantial diversity focus and require a non-competitive renewal award for continuation in fiscal year 2027. Finally, it is noted that NIH is making new and competitive renewal awards at a rate that is only 18% of the average rate for the same period in the five previous fiscal years. Taken together, these observations suggests that the level of NRSA funding will drop dramatically if present policies are continued.

11. I have been tracking the amount of the NIH appropriation remaining to be committed and the time remaining in the fiscal year. A recent analysis is attached as **Exhibit B**. The conclusion from this analysis is that, in order to fully allocate the funds appropriated for this fiscal year, NIH must commit more than \$27 B appropriated funds from May 1st through September 30th. Such a pace is has essentially never occurred over any month period over the past decade (and likely ever).

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on this 19th day of May, 2025, in Gibsonia, PA.

Jeremy M. Berg, Ph.D. Former Director (2003-2011)

National Institute of General Medical Sciences

National Institutes of Health

EXHIBIT A

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Analysis of Lorsch Exhibit B

Jeremy M. Berg

5/19/2025

The pdf file supplied as Exhibit B in association with the Lorsch declaration was converted to an Excel file using Adobe Acrobat. This resulted in 5161 records. This is slightly less than the 5172 records claimed in the Lorsch declaration. It is not clear whether this small difference is related to the conversion to the Excel file or an error in the declaration, but the small difference is not material to the following analysis.

The distribution of Activity codes for these awards is as follows:

F30: 750
F31: 1919
F32: 674
FM1: 3
T32: 1597
T34: 78
T35: 60
T90: 23
TL1: 47
TL4: 10

These 5161 records correspond to 5087 distinct grants with 74 having multiple records in the pdf. These all or essentially all correspond to grants for which both the new, competitive renewal, on non-competitive renewal awards and a supplement to that award (identifiable by a grant number that begins with "3").

With these grant numbers available, we can search the NIH Reporter database to recover the full records for these grants including information about the Funding Opportunity used to obtain each award.

In doing this search, five grants (F31DE033887, F31AR082294, F31HL163924, TL4GM118986, F31AG077880) were not found doing a search for active grants. Subsequent searches revealed that the first four grants ended on 9/30/24, 5/31/24, 8/1/24, and 6/30/24. The remaining grant (F31AG077880) has a project end date of 5/24/25 but is not listed as an active grant.

The remaining 5082 grant numbers were found among active grants on May 17, 2025.

Searching the NIH Reporter database for Active grants with these grant numbers and Activity codes (F30, F31, F32, FM1, T32, T35, T36, T90, TL1, TL4) resulted in 5225 records. This is slightly higher than 5172, presumably due to capturing some additional awards with the same core grant number such as supplements. The sources of this difference could be identified with more analysis but, again, the difference will not be material for the present work.

Funding announcements focused on increasing diversity in the biomedical workforce

These awards were made in response to 83 Notices of Funding Opportunities (NOFOs). Of these NOFOs, 18 had a substantial focus on increasing the diversity of the biomedical workforce (hereafter "Diversity Opportunities")

Grant end dates

Among the 5225 grants, 1075 had Project End Dates on or prior to 9/30/25. Thus, 21% of these NRSA awards will end by the end of the current fiscal year. For the grants that were awarded in response to a Diversity Opportunity this percentage is slightly higher at 25%. The activity codes for these diversity grants are 144 F31, 3 T32, and 15 T34.

Of the 4149 grants that extend past the end of this fiscal year, the number of grants anticipated to end is fiscal year 2026 is 1706. Of these, 222 where awarded in response to Diversity Opportunities. The activity codes for these applications are 205 F31, 1 F32, 11 T32, and 5 T34.

Challenges to maintaining a robust NRSA portfolio

In order to maintain a reasonable level of NRSA awards, NIH will have to make a substantial number of new or competitive renewal awards. We can examine how NIH has been doing in this regard since the start of the current administration.

Between January 20, 2025 and May 10, 2025, NIH awarded 120 new or competitive renewal awards with an activity code F30, F31, F32, FM1, T32, T35, T90, TL1, or TL4.

For comparison, the number of these awards over the period from January 20 through May 10 for earlier years were:

2020: 709 2021: 686 2022: 627 2023: 703 2024: 590

Thus, the number of these awards in during this administration is 18% of the average over the prevous 5 years.

EXHIBIT B

Time Remaining for Award Making in Fiscal Year 2025

Jeremy Berg 5/4/2025

The Rate of NIH Grant Making and the Risk of not Investing the Entire NIH Appropriation in Fiscal Year 2025

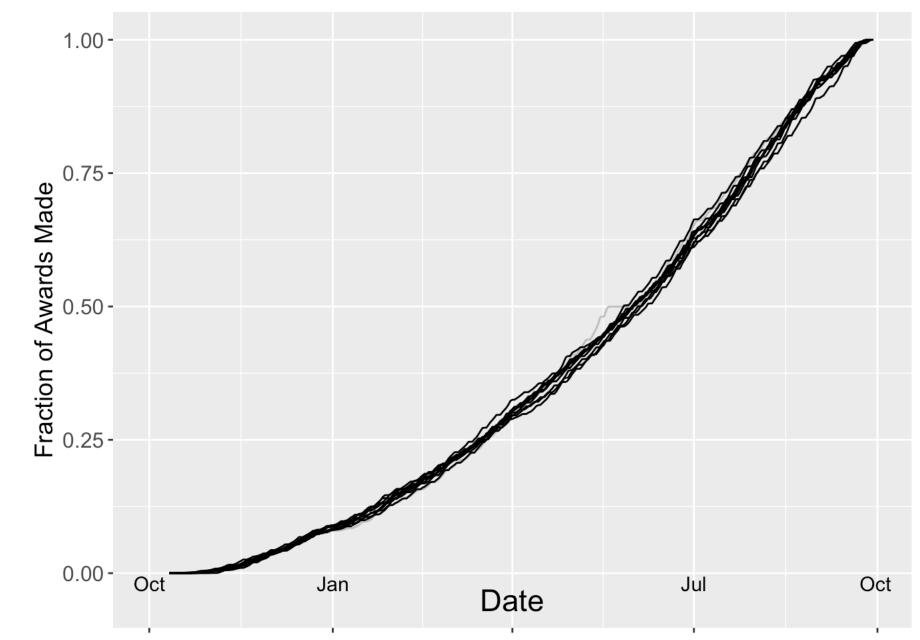
NIH has 27 institutes and centers, of which 24 have grant-making authority. In addition, some grants are funded through the NIH Office of the Director's Common Fund.

The rate does NIH award making

Data about NIH awards are available in the NIH Reporter database.

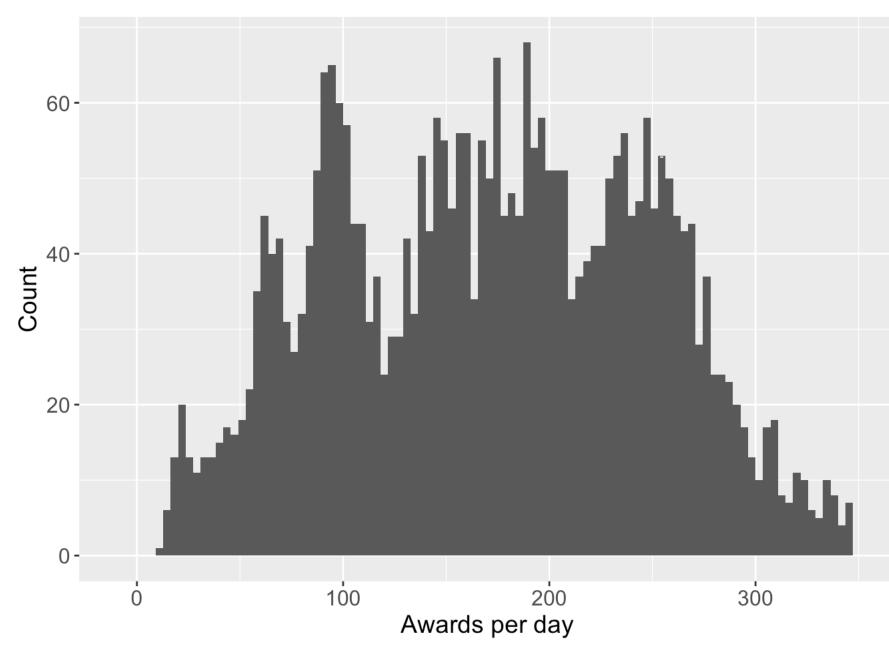
Data for fiscal years 2015-2024 reveal that the number of awards of all types (not including subawards) ranged from 50007 in fiscal year 2015 to 63483 in fiscal year 2024.

A plot of the fraction of awards over the course of these fiscal years is shown below:



The curves are very similar. They are not linear. The rate of making grant awards is relatively low at the beginning of each year and then increases before tapering off at the end of the year. This is due to several factors including the appropriations process (almost always delayed) and the timing of grant application submission opportunities, and the timing of advisory council meetings for grant approval (which occur three times per year).

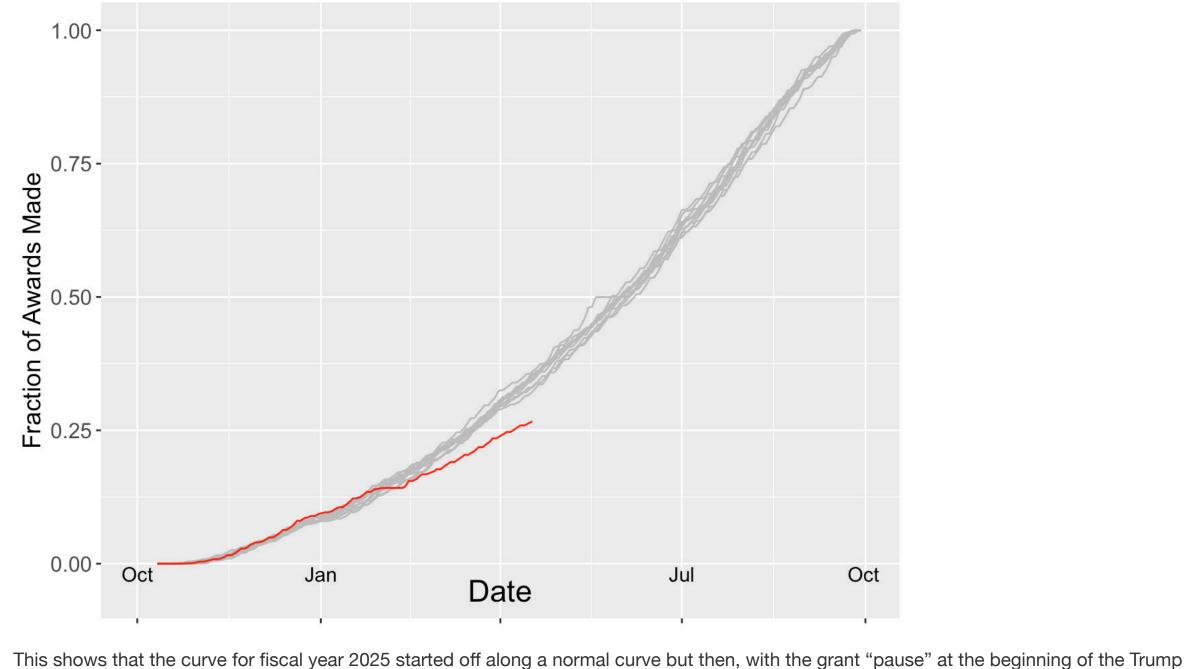
The daily number of grant awards ranges from 0 to 719. However, rather than just looking at daily rates, a more informative quantity is the rate over a more extended period of time. A histogram of the average daily rate over 30 day periods is shown below:



The median for the distribution is 174 with the 80%ile of 246, that is, 80% of all average daily rates are below this value.

Results for fiscal year 2025

The results for fiscal year to date can be added to the previous graph:



administration in early February 2025, the fiscal year 2025 diverged, lying below the other curves. It has remained there, due to a relatively low rate of award release.

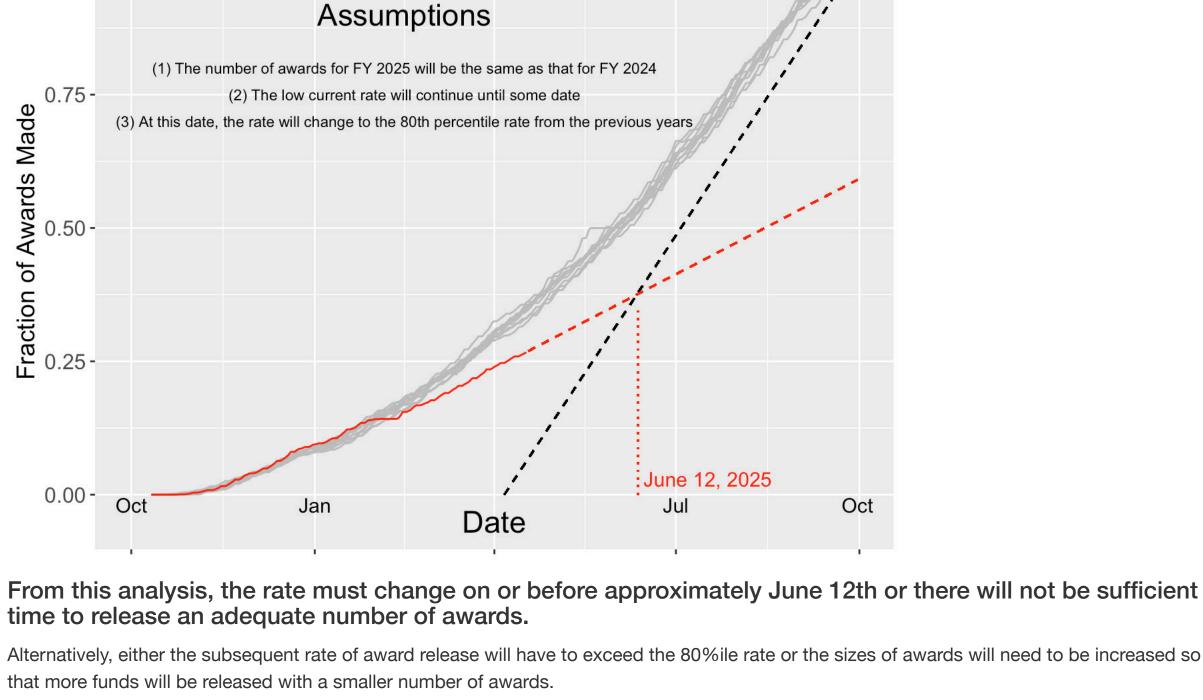
Does NIH have sufficient time to release its full appropriation in fiscal year 2025? We can address this important question but we need to make some assumptions.

One set of limiting assumptions are:

1. The number of awards for fiscal year 2025 will be the same as that for fiscal year 2024.

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- 2. The low current rate will continue until some date;
- 3. At this date, the rate will change to the 80th percentile rate from the previous years.
- The results from these assumptions are shown below:



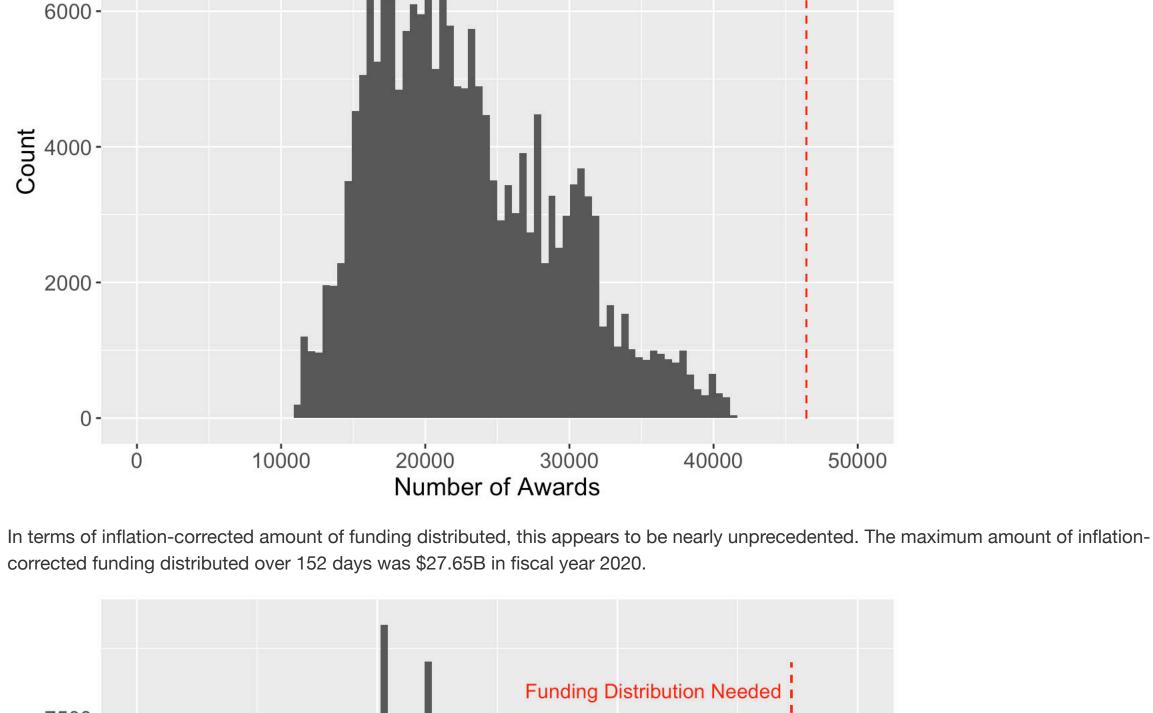
Sustained funding over five months

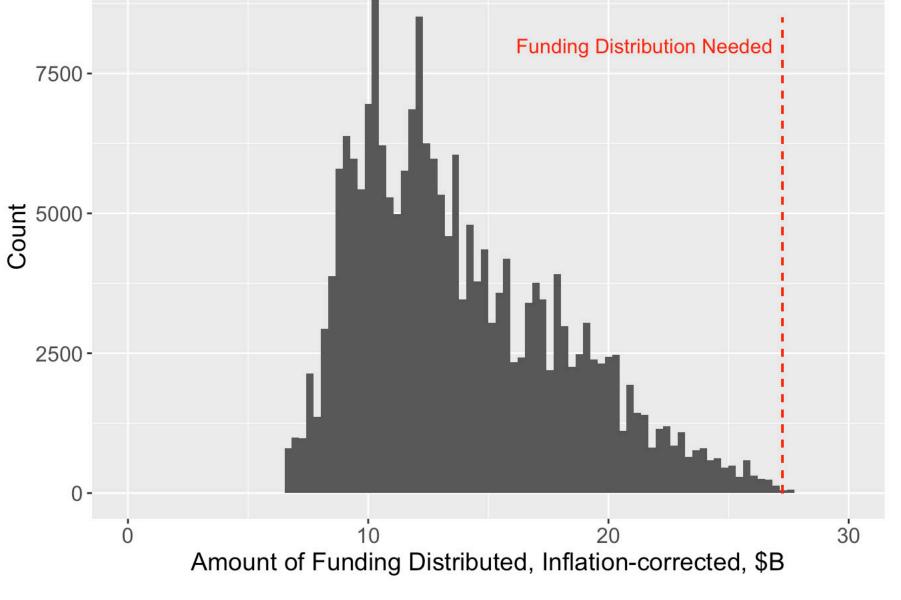
For the period from May 1st to September 30th, the number of awards that are needed to be made is 46444 and the amount of funding that needs to be distributed is \$27.25 B. This must occur over 152 days. Has this every occurred? This can examined by looking a fiscal years 2015 to 2024 over windows of 152 days. The amount of funding in each year was corrected for

inflation to 2025 dollars. The results are shown below.

Number of Awards Needed

For the number of awards, it appears that this number in unprecedented over this period of time.





This analysis suggests that it is even more imperative that the rate of fund distribution accelerate as soon as possible.