UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

KNOWLEDGE ECOLOGY INTERNATIONAL 1621 Connecticut Ave NW Suite 500 Washington, DC 20009 *Plaintiff*, v. NATIONAL INSTITUTES OF HEALTH 9000 Rockville Pike Bethesda, MD 20892 *Defendant.*	Case No. 8:20-cv-2927

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

Knowledge Ecology International (KEI) brings this action under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, for injunctive, declaratory, and other appropriate relief, seeking the expedited release of records improperly withheld from KEI by the National Institutes of Health (NIH) with respect to five FOIA requests, all of which pertain to the NIH's role in the development of products that diagnose, treat, or prevent COVID-19. As grounds therefore, Plaintiff alleges as follows:

INTRODUCTION

1. Since the onset of the COVID-19 pandemic, the United States federal government has devoted an unprecedented amount of U.S. taxpayers' dollars and other resources toward the development and commercialization of diagnostics, therapeutics, and vaccines to detect, treat, and

prevent the transmission of the novel coronavirus (collectively, "COVID-19 medical products") on an accelerated timeline.

2. From March to September 2020, KEI submitted to the NIH the five FOIA requests at issue in this action, all of which relate to the role of the NIH in the development of COVID-19 medical products.

3. KEI requested expedited processing for the requests, on the grounds that the records sought are urgently needed to inform the public of the extent to which the NIH has supported the development of COVID-19 medical products, the nature of the government's rights in any intellectual property arising from the funding agreements, and the extent to which there exist any conflicts of interest regarding the NIH's partnerships with the private sector.

4. In one instance, the NIH granted expedited processing but stated, more than five months later, that it had not yet begun to process the request. In all other instances, the NIH either did not address the request for expedited processing or denied the request, in violation of the FOIA.

JURISDICTION AND VENUE

1. Jurisdiction over this action is conferred by 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

2. Venue is properly vested in this Court under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. §1391(e).

3. Plaintiff has constructively exhausted all administrative remedies and is entitled to judicial review over this matter, as Defendant has failed to provide responsive records or issue a final response to the requests at issue within the deadline established by the FOIA.

PARTIES

4. KEI is a nonprofit organization that works on issues pertaining to access to affordable medicines, access to knowledge and related intellectual property concerns. As part of its mission, KEI researches and publishes reports tracing the role of the federal government in the research and development of publicly-funded biomedical inventions, and advocates for greater transparency over federally-funded innovation. KEI submitted the five FOIA requests at issue.

5. The NIH is a component of the Department of Health and Human Services, and is an agency of the U.S. government within the meaning of 5 U.S.C. § 552(f). The NIH has possession, custody, and control over the records sought. It is headquartered in Bethesda, Maryland.

STATEMENT OF FACTS

Request No. 53786—The NIH's Contributions to Remdesivir

6. Remdesivir is an investigational antiviral drug that was granted Emergency Use Authorization by the United States Food and Drug Administration for the treatment of severe COVID-19.

7. Access to remdesivir has been limited by shortages, leading to rationing.[1]

8. On March 20, 2020, KEI published a report detailing the role of U.S. scientists and U.S. taxpayers' dollars in contributing to the refinement and preclinical and clinical development of remdesivir.[2] The paper lists several scientific articles that report the results of

[1] *See* Kate Gibson, *Remdesivir shortages force doctors to make "heart wrenching" choices*, CBS NEWS (July 16, 2020), https://www.cbsnews.com/news/limited-supply-of-covid-19-drug-doctors-face-hard-decisions/.
[2] Kathryn Ardizzone, *Role of the Federal Government in the Development of Remdesivir*, KEI Briefing Note 2020:1, KNOWLEDGE ECOLOGY INT'L (March 20, 2020), https://www.keionline.org/wp-content/uploads/KEI-Briefing-Note-2020_1GS-5734-Remdesivir.pdf.

preclinical and clinical research on remdesivir, as well as the funding sources acknowledged in each of the scientific papers.[3]

9. Many of the funding sources that were listed in the KEI report as supporting remdesivir research are grants awarded by the National Institute of Allergy and Infectious Diseases (NIAID), an institute of the NIH.

10. NIAID grants funded preclinical research that helped justify the use of remdesivir as a treatment for COVID-19. For example, the NIAID grant R01 AI132178, titled "Broad-Spectrum Antiviral GS-5734 to Treat MERS-COV and Related Emerging COV", funded research demonstrating that GS-5734 can inhibit replication of coronaviruses.[4] GS-5734 is the former name of remdesivir.

11. NIAID is listed, at ClinicalTrials.gov, as sponsor of the following clinical trials of remdesivir, or GS-5734:

a. NCT04280705, "Adaptive COVID-19 Treatment Trial (ACTT)";

b. NCT04401579, "Adaptive COVID-19 Treatment Trial 2 (ACTT-2)";

c. NCT04492475, "Adaptive COVID-19 Treatment Trial 3 (ACTT-3)";

d. NCT03719586, "Investigational Therapeutics for the Treatment of People With Ebola Virus Disease";

e. NCT04501978, "ACTIV-3: Therapeutics for Inpatients With COVID-19 (TICO)"; and

f. NCT02818582, "GS-5734 to Assess the Antiviral Activity, Longer-Term Clearance of Ebola Virus, and Safety in Male Ebola Survivors With Evidence of Ebola Virus Persistence in Semen".

[3] *Id.*

[4] *See* https://pubmed.ncbi.nlm.nih.gov/28659436/.

12. It is impossible to use publicly-available sources to determine precisely how much money U.S. taxpayers have spent, and are currently spending, to develop remdesivir.

13. The NIH does not provide an estimate of how much taxpayer funding the agency has allocated toward the development of remdesivir, nor does it disclose the cost of each NIAID-sponsored clinical trial of remdesivir.

14. KEI sought to gain a better understanding of the role of federal funding in contributing to the development of remdesivir. After exhausting publicly-available sources, KEI turned to the Freedom of Information Act.

15. On March 20, 2020, KEI submitted a FOIA request to NIAID seeking "[a]ll records related to the National Institute of Allergy and Infectious Diseases (NIAID)'s role in the preclinical and clinical research on remdesivir[.]"

16. The request further specifies that the scope of the request includes, but is not limited to:

> (1) All records (such as progress reports, grant applications, grant awards, etc.) related to the following grants: U19 AI109761, R01 AI108197, R01 AI132178, U19 AI109680, and 5T32AI089554; and
> (2) All records related to the costs or budget (including documents that state any component of the total cost or budget) of clinical trials NCT02818582, NCT03719586, and NCT04280705.

17. The request outlines why KEI is entitled to expedited processing.

18. The NIH acknowledged the request and assigned it Case No. 53786.

19. On March 26, 2020, the NIH FOIA Office sent KEI a letter stating that the NIH was granting KEI's request for expedited processing. The March 26, 2020 letter states as follows:

> You have demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. You demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity.

20. On September 10, 2020, after hearing nothing from the NIH regarding the request, KEI sent an email to the NIH FOIA Office asking it to "please let [KEI] know what the timeline [for a response] is [.]"

21. The NIH FOIA Office responded by email dated September 16, 2020. The email states as follows:

> The request is in our Expedited Processing queue and we anticipate processing will begin in about 2 weeks. Please note that COVID-related requests typically involve other federal stakeholders, and their review will add to our response time.

22. More than five and a half months after granting expedited processing, the NIH had not begun to process the request.

23. Agencies are required to process FOIA requests granted expedited processing "as soon as practicable." 5 U.S.C. § 552(a)(6)(E)(iii).

24. "[A] *prima facie* showing of agency delay exists when an agency fails to process an expedited FOIA request within the time limit applicable to standard FOIA requests." *Elec. Privacy Info. Ctr. v. Dep't of Justice*, 416 F. Supp. 2d 30, 39 (D.D.C. 2006).

25. More than five and a half months have passed since KEI submitted FOIA Request No. 53786.

26. The NIH's unlawful delay has diminished the useful tool of the FOIA and impeded KEI's efforts to research, analyze, and inform the public regarding NIAID's role in contributing to preclinical and clinical research on remdesivir.

27. Since the request was submitted, patient activist groups, academics, and journalists, including CNN's senior medical reporter, have asked KEI about the U.S. government's total financial contribution to remdesivir.

28. KEI has declined to provide an estimate, given the limitations to the publicly-available information about remdesivir's government funding.

29. The responsive records will help clarify the nature of NIAID's financial contributions to the preclinical and clinical research on remdesivir.

30. As of the date of this Complaint, the NIH has not provided responsive records, a final determination for the request, or an anticipated timeframe for a final response.

31. KEI has constructively exhausted all administrative remedies with regard to its FOIA request assigned Case No. 53786.

FOIA Request No. 54105—The ACTIV Public-Private Partnership

32. On April 17, 2020, the NIH announced the launch of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership, in which the NIH is engaging with the Foundation for the National Institutes of Health (FNIH), other federal agencies, and pharmaceutical companies to coordinate the research and development of COVID-19 treatments and vaccines.

33. On April 17, 2020, KEI submitted a FOIA request for "all records relating to the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership[.]"

34. The request states that KEI is entitled to a full waiver of fees associated with processing and responding to the request, as KEI's analysis of the responsive records will contribute to the public's understanding of ACTIV and KEI does not have a commercial interest in the records sought.

35. The request outlines why KEI is entitled to expedited processing:

a. KEI is primarily engaged in disseminating information.

b. There is a strong public interest in the terms of the partnership and agreements with the partners, as those terms inform what rights the government has in place as legal safeguards to ensure that resulting medical technologies are available on an affordable and equitable basis.

c. The records are urgently needed because COVID-19 is a public health emergency, and the United States government is responding by attempting to ensure that any diagnostic, vaccine, or treatment authorized by the FDA for the detection, prevention, or treatment of COVID-19 is distributed as quickly as possible, making time of the essence in understanding more about ACTIV, the terms of the agreement, and extent to which it has been backed by taxpayer support.

36. The NIH acknowledged the request and assigned it Case No. 54105.

37. By email dated May 15, 2020, the NIH FOIA office stated that "this request is too broad to process", and that "[i]n order for a proper search to be conducted", KEI needed to "provide more detail."

38. On July 13, 2020, KEI sent the NIH FOIA office an email offering to bifurcate the request into two parts:

a. "Any and all contracts establishing the ACTIV partnership, including copies of agreements related to the ACTIV partnership between the NIH and [a list of industry partners]"; and

b. "Correspondence between the NIH and the FNIH, and any correspondence between the NIH and [the same list of industry partners.]"

39. On July 29, 2020, the NIH sent KEI a letter denying the request in full.

40. The letter states that the NIH was denying KEI's request because:

> [E]stablishing funding, data, contracts, agreements, etc. is [sic] currently being worked out and will be available once decisions are finalized. Therefore, for the time being, records on this topic are protected pursuant to FOIA Exemption 5. You are welcome to refile the request once some of the records may become releasable in a few months' time.

41. The July 29, 2020 later states that the FOIA Request No. 54105 is "dated July 26, 2019", when the NIH accepted the scope of the request as clarified on July 13, 2020.

42. On July 29, 2020, when the NIH denied KEI's requested records on the grounds all the responsive records were pre-decisional and therefore protected by Exemption 5, there existed responsive records that are not pre-decisional. As part of ACTIV, the NIH had already executed grants and other contracts, including Other Transaction Agreement No. 1OT2OD03019501, titled "Establish a Public Private Partnership for COVID19 Research," which was awarded to the FNIH on May 2, 2020.

43. Emails with the FNIH and industry partners discussing the partnership, the second component of the bifurcated request, are not inter- or intra-agency memoranda.

44. On September 1, 2020, KEI submitted an administrative appeal to the NIH outlining why the NIH had wrongly withheld responsive records not protected by Exemption 5.

45. On September 8, 2020, the NIH acknowledged the appeal.

46. As of the date of this Complaint, more than 20 working days after the appeal was submitted, the NIH has not provided responsive records, a final determination on the appeal, a timeframe for responsive records, or a determination regarding KEI's requests for a full waiver of fees and expedited processing.

47. KEI has constructively exhausted all administrative remedies with regard to Request No. 54015.

FOIA Request No. 54858—RADx Initiative

48. The NIH's Rapid Acceleration of Diagnostics (RADx) program, launched in April of 2020, is an initiative designed to accelerate the development and commercialization of COVID-19 diagnostics.

49. On July 31, 2020, the NIH announced that the agency had awarded contracts to seven companies for the development of COVID-19 diagnostics as part of RADx.

50. On July 31, 2020, KEI submitted a FOIA request to the NIH for "seven contracts that are part of the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx) initiative to address challenges related to testing for COVID-19."

51. The request outlines why KEI is entitled to expedited processing:

a. KEI is primarily engaged in disseminating information, and has used and is using its analysis of COVID-19 research and development contracts obtained under the FOIA to disseminate information about government activities to the public, resulting in members of the United States Senate questioning the heads of the NIH and Biomedical Advanced Research and Development Authority (BARDA) about the records obtained and analyzed by KEI.

b. The records are needed urgently because the death toll is mounting everyday and there is a race to develop COVID-19 tests; as such, once an accurate diagnostic is developed, the government will want to ensure that it is distributed as quickly as possible, and time is thus of the essence to learn the cost of developing RADx's diagnostics and the U.S. government's rights in the technologies.

52. The NIH acknowledged the request and assigned it Case No. 54858.

53. By letter dated August 14, 2020, the NIH notified KEI that it was denying KEI's request for expedited processing, stating only that KEI had not demonstrated a "compelling need".

54. As of the date of this Complaint, the NIH has not provided responsive records, a final determination for this request, or a timeframe for a response.

55. KEI has constructively exhausted all administrative remedies with regard to FOIA Request No. 54858.

FOIA Request No. 55015—EIDD-2801 Grants and Contracts

56. EIDD-2801 is an antiviral drug currently being investigated in clinical trials as a potential treatment for COVID-19.

57. EIDD-2801 has been described as being similar to remdesivir, in terms of its chemical composition, but also as having a potential advantage over remdesivir, because EIDD-2801 is delivered orally, in pill form, and remdesivir is administered intravenously.[5]

58. EIDD-2801 was invented by Emory University and developed by Emory and other university scientists, backed by NIH grants and contracts.

59. For example, an Emory University press release about EIDD-2801 states that its development:

> has been funded in part with federal funds from the National Institute of Allergy and Infectious Diseases (NIAID), under contract numbers HHSN272201500008C and 75N93019C00058, and from the Defense Threat Reduction Agency (DTRA), under contract numbers HDTRA1-13-C-0072 and HDTRA1-15-C-0075.

[5] Joe Palca, *Promising Drug on the Horizon for COVID-19*, NPR (Apr. 6, 2020), https://www.npr.org/sections/coronavirus-live-updates/2020/04/06/828322576/promising-drug-on-the-horizon-for-covid-19.

60. On August 24, 2020, KEI submitted a FOIA request to the NIH seeking "seeking copies of all agreements by the NIH that supported research and development related to EIDD-2801." The request states that the scope of the request includes, but is not limited to, several NIH grants and contracts identified by number.

61. The request outlines why KEI was entitled to expedited processing:

a. KEI is primarily engaged in disseminating information to the public.

b. There is an urgent need to inform the public about the government's role in funding the development of a drug being investigated for the treatment of COVID-19, as well as the government's rights in the intellectual property related to the drug—two factors informed by the funding agreements—given the race to develop and distribute COVID-19 effective treatments as quickly as possible and the widespread demand for such a treatment.

62. The NIH acknowledged the request and assigned it Case No. 55015.

63. By letter dated September 11, 2020, the NIH informed KEI that it was denying KEI's request for expedited processing, stating only that KEI had not demonstrated a "compelling need".

64. As of the date of this Complaint, the NIH has not provided responsive records, a final determination for this request, or a timeframe for a response.

65. KEI has constructively exhausted all administrative remedies with regard to FOIA Request No. 55015.

FOIA Request No. 55060—ACTIV Conflict of Interest Disclosures

66. On September 3, 2020, KEI submitted a FOIA request to the NIH seeking "all records relating to any conflict of interest disclosures submitted by members of the Accelerating

COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, the private-public partnership announced by the National Institutes of Health (NIH) and the Foundation for the NIH (FNIH)."

67. The request outlines why KEI is entitled to expedited processing:

a. KEI is primarily engaged in the dissemination of information.

b. There is a strong public interest in the conflict of interest disclosures, which are critical for the public to assess, considering the importance of eradicating the COVID-19 pandemic, and the fact that the ACTIV partnership engages representatives of private companies that could stand to profit from potential vaccines or treatments for COVID-19.

c. The records are urgently needed because the COVID-19 crisis is rapidly unfolding and the U.S. government is working to develop and distribute an effective vaccine or treatment as quickly as possible, making it important to obtain the responsive records on an expedited basis.

68. The NIH acknowledged the request and assigned it Case No. 55060.

69. By letter dated September 18, 2020, the NIH notified KEI that it was denying KEI's request for expedited processing, stating only that KEI had not demonstrated a "compelling need".

70. As of the date of this Complaint, the NIH has not provided responsive records, a final determination for this request, or a timeframe for a response.

71. KEI has constructively exhausted all administrative remedies with regard to FOIA Request No. 55060.

COUNT I

72. KEI realleges the foregoing paragraphs as if stated herein.

73. KEI properly submitted Request No. 53786 seeking records within the custody and control of the NIH and expedited processing of the request.

74. KEI has a statutory right under the FOIA to the responsive records and expedited processing of the request.

75. The NIH recognized KEI's right to expedited processing of the request.

76. The NIH failed to provide responsive records.

77. The NIH failed to process the request on an expedited basis.

78. There is no legal basis for the NIH's failure to disclose the responsive records and its failure to process this request on an expedited basis.

COUNT II

79. KEI realleges the foregoing paragraphs as if stated herein.

80. KEI properly submitted Request No. 54105 seeking records within the custody and control of the NIH, a full waiver of fees, and expedited processing of the request.

81. KEI has a statutory right under the FOIA to the responsive records, a full waiver of fees, and expedited processing of the request.

82. The NIH failed to provide responsive records.

83. The NIH did not address KEI's request for a full waiver of fees.

84. The NIH failed to process the request on an expedited basis.

85. There is no legal basis for the NIH's failure to disclose the responsive records, its failure to provide a full waiver of fees, and its failure to process this request on an expedited basis.

COUNT III

86. KEI realleges the foregoing paragraphs as if stated herein.

87. KEI properly submitted Request No. 54858 seeking records within the custody and control of the NIH and expedited processing of the request.

88. KEI has a statutory right under the FOIA to the responsive records and expedited processing of the request.

89. The NIH failed to provide responsive records.

90. The NIH failed to process the request on an expedited basis.

91. There is no legal basis for the NIH's failure to disclose the responsive records and its failure to process this request on an expedited basis.

COUNT IV

92. KEI realleges the foregoing paragraphs as if stated herein.

93. KEI properly submitted Request No. 55015 seeking records within the custody and control of the NIH and expedited processing of the request.

94. KEI has a statutory right under the FOIA to the responsive records and expedited processing of the request.

95. The NIH failed to provide responsive records.

96. The NIH failed to process the request on an expedited basis.

97. There is no legal basis for the NIH's failure to disclose the responsive records and its failure to process this request on an expedited basis.

COUNT V

98. KEI realleges the foregoing paragraphs as if stated herein.

99. KEI realleges the foregoing paragraphs as if stated herein.

100. KEI properly submitted Request No. 55060 seeking records within the custody and control of the NIH and expedited processing of the request.

101. KEI has a statutory right under the FOIA to the responsive records and expedited processing of the request.

102. The NIH failed to provide responsive records.

103. The NIH failed to process the request on an expedited basis.

104. There is no legal basis for the NIH's failure to disclose the responsive records and its failure to process this request on an expedited basis.

REQUESTED RELIEF

WHEREFORE, Plaintiff respectfully request that the Court:

A. Declare that the NIH's failure to provide KEI with timely and full responses to KEI's FOIA requests described above, including its failure to make a timely determination and produce all records requested, is in violation of the FOIA;

B. Order the NIH to produce, within 20 days of the Court's order and at no cost, all non-exempt responsive records and *Vaughn* indexes of any responsive records withheld under a claim of exemption;

C. Enjoin the NIH from continuing to withhold responsive records;

D. Award KEI its reasonable costs, litigation expenses, and attorneys' fees incurred in prosecuting this civil action under the FOIA, 5 U.S.C. § 552(a)(4)(E); and

E. Grant such other relief as the Court deems just and proper.

Dated: October 9, 2020

/s/ *Kathryn Ardizzone*
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