FROM: Knowledge Ecology International
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TO: FOIA Officer
Freedom of Information Office, NIH
Building 31, Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892-2107

DATE: June 29, 2018

Re: Freedom of Information Act Request Regarding NIH technology described in 83 FR 30448

Dear FOIA Officer:

Under the Freedom of Information Act (5 U.S.C. § 552), Knowledge Ecology International (KEI) requests documents related to the technology to be licensed by the National Institutes of Health (NIH), outlined in the Federal Register notice 83 FR 30448.

KEI is asking that the request be given expedited processing, as the data is necessary in forming the response to the following Federal Register request for comments, which was published June 28, 2018 and has a deadline for submissions of July 13, 2018. The notice number and full title are below:

> 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer.

1. KEI requests documents that show the enrollment and costs of clinical trials, for
    a. mesothelin expressing cancers, and
    b. NIH-funded and/or -administered trials involving chimeric antigen receptor (CAR) -modified T cells.

To be clear, we want to know the budget or actual spending for specific trials. If the enrollment is in the ClinicialTrials.Gov database, then all we need is the budget/spending data.

This includes, for example, the budget and/or actual spending on the following trials identified by ClinicalTrials.Gov as pertaining to mesothelin that were funded by the NIH.

Table 1: NCT Numbers for trials pertaining to mesothelin funded by the NIH.

1. NCT03126630
2. NCT02798536
3. NCT03436732
4. NCT02810418
5. NCT01413451
6. NCT02839681
7. NCT01583686
8. NCT03455556
9. NCT01950572
10. NCT00066651
11. NCT00006981

In addition, the trials below that pertain to CAR T.

Table 2: NCT Numbers for trials pertaining to chimeric antigen receptor (CAR) -modified T cells.

1. NCT02659943
2. NCT03241940
3. NCT01087294
4. NCT02107963
5. NCT03049449
6. NCT03448393
7. NCT02830724
8. NCT03277729
9. NCT03502577
10. NCT02706392
11. NCT02203825
12. NCT03103971
13. NCT02663297
14. NCT00924326
15. NCT01454596
16. NCT01865617
17. NCT03283631
18. NCT01475058
19. NCT02159495
20. NCT02315612
21. NCT02146924
22. NCT03338972
23. NCT03226704
24. NCT02706405
25. NCT01460901

26. NCT01953900
27. NCT01318317
28. NCT02208362
29. NCT01822652
30. NCT01593696

KEI is willing to narrow the scope of the request to a subset of these trials, if that makes it feasible for the NIH to provide a quicker response, that would allow us to comment on the proposed license within the 15 day period.

2. Documents related to the NIH analysis to determine whether a term of exclusivity less than the life of a patent would be appropriate and sufficient under 35 U.S.C. § 209.

3. The NIH request for antitrust advice from the Attorney General, under 40 U.S.C. § 559.

Request for Full Waiver of Fees

KEI requests a full waiver of fees under the Freedom of Information Act and under DHHS regulations (45 C.F.R. § 5.54).

KEI is a 501(c)(3) non-profit organization that promotes the public interest in ensuring equitable access to affordable medicines.

Congress enacted the current FOIA fee waiver provisions to protect the interests of non-profit public interest groups, such as KEI, that seek to disseminate information that is in the public interest:

> "The waiver provision was added to FOIA 'in an attempt to prevent government agencies from using high fees to discourage certain types of requesters and requests,' in a clear reference to requests from journalists, scholars and, most importantly for our purposes, nonprofit public interest groups." *Better Gov't Ass'n v. Department of State , 780 F.2d 86, 94* (D.C. Cir. 1986) (citations omitted).

Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not in the commercial interest of the requester.

1. § 5.54(b)(1): "Disclosure of the requested information would shed light on the operations or activities of the government."

Disclosure of the requested records would shed light on the operations and activities of the federal government with regards to setting policy and practice regarding the price of prescription

drugs, particularly in cases related to the use of march-in rights under the Bayh-Dole Act, federal policy related to the grant of exclusive licenses on patented inventions, and federal policy related to pricing under CRADAs.

In evaluating this factor, "reasonable specificity" is "all that FOIA requires." *Judicial Watch v. Rossotti , 326 F.3d 1309, 1313* (D.C. Cir. 2003).

2. § 5.54(b)(2): Disclosure of the requested information would be likely to contribute significantly to public understanding of those operations or activities. This factor is satisfied because the following criteria are met.

2.i. § 5.54(b)(2)(i): Disclosure of the requested records must be meaningfully informative about government operations or activities.

Disclosure of the requested records would be meaningfully informative about government operations and activities because it would reveal information that is not yet in the public domain about how the NIH approaches engagement with pharmaceutical companies and sets terms on research products developed using taxpayer funding.

Information concerning prospective exclusive licenses is not publicly available.

"Legislative history suggests that information has more of this potential [to contribute to public understanding] to the degree that the information is new and supports public oversight of agency operations, including the effect of agency policy on public health." *McClellan Ecological Seepage Situation v. Carlucci , 835 F.2d 1282, 1286* (9th. Cir. 1987) (citations omitted).

2.i. § 5.54(b)(2)(ii): The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester.

The subject of the request is government operations and activities related to the price of prescription drugs in the United States, including the creation of policy and the use of existing statutory mechanisms to lower drug prices.

There is a broad audience of persons interested in the subject, including, inter alia, advocates for affordable access to medicines; doctors, nurses, and other medical providers; patients and caretakers; policy experts; and people who purchase insurance or other forms of medical care. Disclosure would contribute to the understanding of that broad audience of persons because it would provide context for the policies, positions, and decisions of the National Institutes of Health related to access to medicines and drug pricing.

KEI is an NGO that works on drug pricing and access to medicines, and has expertise in public health, drug pricing, and access to medicines.

KEI has the ability and intention to effectively convey the information contained in the requested records to the public. KEI operates a website (https://keionline.org) which hosts an extensive archive that is regularly consulted by advocates, academics, and the press. KEI will review the requested records and produce a clear and concise analysis of those records. KEI will use social media and listservs to distribute that analysis to the broad audience of persons interested in the subject of the request.

KEI regularly publishes and analyzes records requested under the FOIA on its website, including recently on various government operations and activities at parts of DHHS:

- 28 February 2017, "CDC FOIA shows US, WHO opposed request to discuss UNSG's High-Level Panel on Access to Medicines Report at EB," https://keionline.org/node/2727
- 18 October 2016, "Kite Pharma Uses CRADAs to Conduct Important Clinical Research on New Cancer Treatments," https://keionline.org/node/2640
- 19 September 2016, "500+ Pages of Documents on NFL Attempts to Influence NIH Funding of Concussion Studies," https://keionline.org/node/2630
- 16 September 2016, "NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs," https://keionline.org/node/2629

Additionally, KEI works closely with journalists to provide analysis for documents requested by KEI under the FOIA. KEI does not merely distribute documents to journalists, but provides in-depth analysis that later becomes the basis for stories:

- 3 March 2017, Vidya Krishnan, "U.S. nixed India's plea on reforms in medicine," The Hindu,http://www.thehindu.com/news/national/us-nixed-indias-plea-on-reforms-in-medicine/article17403526.ece
- 31 December 2016, Dan Vergano, "If Taxpayers Invent A Drug, Should The Government Just Give It Away?," Buzzfeed News, https://www.buzzfeed.com/danvergano/nih-drug-giveaway
- 20 December 2016, "Front page New York Times story explores Kite Pharma's profitable relationship with NIH regarding expensive cancer drug," https://keionline.org/node/2703

3. § 5.54(b)(3): The disclosure must not be primarily in the commercial interest of the requester.

Knowledge Ecology International is a non-profit 501(c)(3) organization that does not have any commercial, trade, or profit interest in disclosure of the requested records.

Other

We request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, the reasons that the statutory exemption or denial applies in this instance, and the interests that would be foreseeably harmed by disclosure of the record.

We look forward to your acknowledgement of this request within 10 working days and your final determination within 20 working days. 5 U.S.C. § 552(a)(6)(A)(i). Please inform us of any unusual circumstances that would require you to extend the 20-day statutory time limit, “setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched.” 5 U.S.C. § 552(a)(6)(B)(i).

If possible, please conduct all correspondence by email and disclose all records via electronic copy. Please contact me if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver. Thank you in advance for your assistance.

Sincerely,

James Love
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Claire Cassedy
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