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TO: USAMRMC FOIA Officer
CDR, USAMRMC
ATTN: MCMR-SG
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Fort Detrick, MD 21702-5000
USArmy.Detrick.MEDCOM-USAMRMC.List.FOIA-MRMC@mail.mil

DATE: December 13, 2016

RE: Freedom of Information Act Request, Records Related to Sanofi Zika Virus Vaccine Exclusive Patent License

Dear FOIA Officer:

Under the Freedom of Information Act (5 U.S.C. § 552) and relevant Department of the Army regulations (32 C.F.R. Part 518), Knowledge Ecology International (KEI) requests any and all records, from the period of January 1, 2016 to the present, related to agreements between Sanofi/Sanofi Pastuer and the United States Army to develop a vaccine for Zika virus, including, but not limited to:

- the Cooperative Research and Development Agreement (CRADA) between Sanofi/Sanofi Pasteur and the Walter Reed Army Institute of Research (WRAIR) for the development of a Zika purified inactivated virus (ZPIV) vaccine technology,[1] including, but not limited to:
    - the executed CRADA and any drafts,
    - any supporting documents,
    - memoranda,
    - correspondence between Sanofi/Sanofi Pasteur and WRAIR, and
    - internal communications at WRAIR and USAMRMC related to the CRADA;

[1] For additional information, see this press release: Sanofi, "Sanofi Pasteur Signs Research Agreement for Zika Vaccine," July 6, 2016, http://mediaroom.sanofi.com/sanofi-pasteur-signs-research-agreement-for-zika-vaccine/.

- the "Principles of Collaboration" between Sanofi/Sanofi Pasteur, WRAIR, and the Immuno-biological Technology Institute of the Oswaldo Cruz Foundation, known as Bio-Manguinhos/Fiocruz,[2] including, but not limited to:

    - the final Principles of Collaboration and any drafts,
    - any supporting documents,
    - memoranda,
    - correspondence between Sanofi/Sanofi Pasteur, WRAIR, and/or Bio-Manguinhos/Fiocruz, and
    - internal communications at WRAIR and USAMRMC related to the CRADA; and

- the intended grant of an exclusive license by USAMRMC to Sanofi/Sanofi Pasteur to develop U.S. government-owned pending patents on a Zika Virus vaccine as described in the Federal Register on December 9, 2016, at 81 Fed. Reg 89,087,[3] including, but not limited to:

    - copies of the patent applications described in the Federal Register Notice, that is, (1) pending United States Provisional Patent Application 62/343,315, entitled, "Zika Virus Vaccine and Methods of Production" filed May 31, 2016, and (2) pending United States Provisional Patent Application 62/370,260, entitled, "Zika Vaccine and Methods of Preparation" filed August 3, 2016, as well as other relevant intellectual property,
    - any supporting documents,
    - correspondence between Sanofi/Sanofi Pasteur and USAMRMC,
    - internal communications at USAMRMC related to the agreement,
    - memoranda, including evaluations related to compliance with the provisions of 35 U.S.C. § 209 and 37 C.F.R. Part 404,
    - a copy of the "Application for a License" filed by Sanofi/Sanofi Pasteur, as well as any other relevant applications filed with USAMRMC.

Request for Full Waiver of Fees

Knowledge Ecology International (KEI) requests a full waiver of fees under the Freedom of Information Act and under Army regulations [32 C.F.R. § 518.19(d)].

[2] For additional information, see this press release: Sanofi, "Sanofi Pasteur, Fiocruz, and WRAIR Agree to Collaborate on Zika Vaccine Research," October 27, 2016, http://mediaroom.sanofi.com/sanofi-pasteur-fiocruz-and-wrair-agree-tocollaborate-on-zika-vaccine-research/.

[3] Intent to Grant an Exclusive License of U.S. Government-Owned Patents, 81 Fed. Reg 89,087 (Dec. 9, 2016), https://www.federalregister.gov/documents/2016/12/09/2016-29514/intent-to-grant-an-exclusive-license-of-us-government-owned-patents.

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.

32 C.F.R. § 518.19(d)(2)(i): Activities should analyze whether the subject matter of the request involves issues that will significantly contribute to the public understanding of the operations or activities of DA or DoD.

The subject matter of the request involves issues that will significantly contribute to the public understanding of the operations or activities of the Department of the Army because they concern the administration of the Technology Transfer Office at USAMRMC; the operations of that office in determining whether and under what terms to enter into CRADAs or other agreements; and the government role in supporting private pharmaceutical industry research and development. In this particular case, the operations and activities relate to the grant of agreements and exclusive licenses to a French pharmaceutical company, Sanofi/Sanofi Pasteur, for patents and technologies related to vaccines for Zika Virus. In evaluating this factor, that is, whether the records relate to government operations or activities, "reasonable specificity" is "all that FOIA requires." *Judicial Watch v. Rossotti*, 326 F.3d 1309, 1313 (D.C. Cir. 2003).

The contribution to the public understanding will be significant because the records will shed light on the government grant of a monopoly on taxpayer-funded patents related to a Zika vaccine, as well as continued government support to subsidize research to commercialize those patents. Zika virus has been a matter of intense public interest, particularly given the public health and national security implications that the disease could have.

We note that, although some of the records — particularly submissions by Sanofi/Sanofi Pasteur that were submitted as part of the technology transfer process — "were originated by non-government organizations," they were not "sought for their intrinsic content, but rather for their "informative value" in that the central operation of the USAMRMC Technology Transfer Office is to evaluate such information and make a final determination as to whether to enter into an agreement with a private company.

32 C.F.R. § 518.19(d)(2)(ii): The informative value of the information to be disclosed requires a close analysis of the substantive contents of a record, or portion of the record, to determine whether disclosure is meaningful, and shall inform the public on the operations or activities of DA or DoD.

Disclosure of the requested records will be meaningful and inform the public on the operations and activities of the Department of the Army, as identified above because:

1. the requested records and information are not currently in the public domain. "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. the requested records will contain sufficient information to reconstruct a timeline of the license, CRADA, and other technology transfer processes at the USAMRMC/WRAIR, and reveal the evidence and standards used by the Army to enter into the agreements with Sanofi/Sanofi Pasteur.

32 C.F.R. § 518.19(d)(2)(iii): The contribution to an understanding of the subject by the general public is likely to result from disclosure that will inform, or have the potential to inform the public, rather than simply the individual requester or small segment of interested persons.

The contribution to the understanding of the subject by the general public is likely to result from disclosure that will inform, or have the potential to inform the public, because research and development into a vaccine for Zika virus is a matter of intense public interest, and the records will inform the public directly about how Army operations and activities related to technology transfer contribute to that research.

KEI has expertise in government technology transfer, intellectual property, pharmaceutical research and development, and global public health. For more, please see http://keionline.org.

Our research related to government research and license agreements on Zika virus is connected to our broader project to conduct oversight and advocate for the public interest in the government grant of patent licenses on pharmaceutical products, particularly in terms of price and access in the United States and developing countries. For more, see http://keionline.org/nih-licenses.

We plan to widely digest and disseminate the requested records to the public through our website, our listserves — which are widely followed by patients, advocates, doctors, and policymakers — and through social media.

KEI regularly publishes and analyzes records requested under the FOIA on its website, including recently:

- 18 October 2016, “Kite Pharma Uses CRADAs to Conduct Important Clinical Research on New Cancer Treatments,” http://keionline.org/node/2640
- 19 September 2016, “500+ Pages of Documents on NFL Attempts to Influence NIH Funding of Concussion Studies,” http://keionline.org/node/2630
- 16 September 2016, “NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs,” http://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:

- 22 June 2013, Kimberly Kindy, “Filmmakers’ group tries to reshape treaty that would benefit the blind,” Washington Post
- 24 June 2013, Paige McClanahan, ‘US film industry tries to weaken copyright treaty for blind people,” The Guardian
- 24 June 2013, Mike Masnick, “MPAA's Actions, Emails Show That They're Doing Everything Possible To Screw Over The Blind,” TechDirt
- 24 June 2013, Catherine Saez, “WIPO Negotiators Reach Breakthrough On ‘3-Step Test’ In Treaty For Blind,” IP-Watch

32 C.F.R. § 518.19(d)(2)(iv): Activities must differentiate the relative significance or impact of the disclosure against the current level of public knowledge, or understanding, which exists before the disclosure. In other words, will disclosure on a current subject of wide public interest be unique in contributing previously unknown facts, thereby enhancing public knowledge, or will it basically duplicate what is already known by the general public?

Disclosure of the requested records relate to a current subject of wide public interest — government operations and activities in research and development and response to Zika virus — and would be unique in contributing previously unknown facts regarding the relationship between USAMRMC and Sanofi Pasteur. While Sanofi has issued press releases related to its CRADA and Principles of Collaboration, there are no records or information in the public domain that contribute to the public’s understanding about how that relationship came about, what the government’s interests are in entering into agreements with Sanofi, and how the government justifies the use of taxpayer resources to support the research and development goals of Sanofi, a private pharmaceutical company headquartered in France.

We note that under this provision, “Activities shall not make value judgments as to whether the information is important enough to be made public,” but must rather judge objectively whether the disclosure would have “relative significance.” The legislative history of the FOIA shows that

information that is not yet in the public domain and would contribute to oversight of agency policy on public health would have relative significance compared to a lack of information. *McClellan*, 835 F.2d 1282, 1286.

32 C.F.R. § 518.19(d)(3) Disclosure of the information "is not primarily in the commercial interest of the requester."

As a 501(c)(3) non-profit organization, KEI plans to use the requested records to broadly educate the public on matters of public interest. KEI does not have any commercial interests in the records and is not acting on behalf of any other parties. KEI will not use the requested records to further its or others interests in business, trade, and profit, and are not in KEI's commercial interests.

Other

We note that under 5 U.S.C. § 552(a)(8)(A)(ii), that if you determine to withhold all records subject to this request, that you are obligated to: "(I) consider whether partial disclosure of information is possible whenever the agency determines that a full disclosure of a requested record is not possible; and (II) take reasonable steps necessary to segregate and release nonexempt information[.]"

We also 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, and the reasons that the statutory exemption or denial applies in this instance.

If possible, please conduct all correspondence by email and disclose all records via electronic copy. We look forward to your response within 20 days as required by statute.

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.

Sincerely Yours,

Zack Struver