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To:
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Appeal to the Department of Defense Decision to Grant an Exclusive License for U.S. Government-Owned Patents on Zika Vaccine Candidate

May 19, 2017

Doctors Without Borders/Médecins Sans Frontières (MSF) would like to submit an appeal to the decision of the Department of Defense (DoD) to grant an *exclusive, royalty-bearing, revocable license to Sanofi Pasteur to pending United States Provisional Patent Application 62/ 343,315, entitled, “Zika Virus Vaccine and Methods of Production” filed May 31, 2016 and an exclusive, royalty-bearing, revocable license to pending United States Provisional Patent Application 62/370,260, entitled, “Zika Vaccine and Methods of Preparation” filed August 3, 2016.*

MSF specifically meets the requirements of 37 CFR 404.11(c) and Appendix B of Army regulation 70-57 as **MSF filed a timely written objection and will be damaged by the decision.** This appeal refers to the letter from DoD from April 21 2017¹ responding to our original submission from January 23 2017². The original Notice appeared in 81 FR 89087 on Friday, December 9, 2016.

MSF objects to the granting of an exclusive patent license on a U.S. government-funded invention to a single pharmaceutical company as well as to the lack of conditions to ensure the vaccine will be appropriately developed and made available and affordable to all patients and medical providers who administer vaccines in the U.S. and globally.

MSF urges the U.S. government to consider the negative impact this decision will have on the development, affordability and availability of a Zika vaccine urgently needed to protect people from the Zika virus. We ask the U.S. government to consider instead granting an open non-exclusive patent license with appropriate and publicly available terms and conditions to help ensure that further development of this vaccine will prioritize all health needs and guarantee sustainable and affordable access by MSF and other vaccine providers worldwide.

The need for an open and public-health driven approach to research and development (R&D) is even more important given that this medical technology has been fully funded and is owned by the U.S. government. The licensing of this technology should ensure a full public return on the public investment that the U.S. government made on this biomedical innovation. The vaccine was initially developed by government scientists at the Walter Reed Army Institute of Research and has received significant funding and resources from the U.S. government, including more than \$40 million in BARDA grant funding that was given to Sanofi.³

MSF is an international medical humanitarian organization and vaccine provider working in nearly 70 countries. We need biomedical innovations that improve medical outcomes and are accessible and affordable, including for prevention and treatment of global health emergencies. We hope to be able to use the Zika vaccine in our medical operations in the future. However, MSF, Ministries of Health and patients will only benefit from this publicly-funded resource if the resulting vaccine is effective, safe, available, affordable and suitably adapted to the settings where most people affected by the Zika virus live. Through our work, MSF witnesses the everyday impact on people's lives when they have limited or no access to medicines, diagnostics and vaccines due to the lack of investment in essential, suitably-adapted and affordable medical tools in the places and for the people populations that need them most.

The high price of vaccines is already a key medical and operational challenge for MSF and many governments. By 2014, the price to fully vaccinate a child in the poorest countries of the world had risen to become 68 times more expensive⁴ than it was in 2001, and the price in other countries is even higher. Many countries, especially those considered middle-income economies, are often unable to afford new high-priced vaccines that prevent countless deaths from vaccine-preventable diseases such as childhood pneumonia. The lack of competition in the manufacturing and distribution of newer vaccines is a key barrier to access given high prices and shortages.

At a time when the high price of life-saving medical tools, including hepatitis drugs, biologics and vaccines, is becoming a barrier to effective medical care worldwide and medicines are being rationed because of high prices in the U.S. and around the world, it is very concerning to see the U.S. government considering locking in a development deal that will limit innovation and will not safeguard affordable access to the resulting vaccine. Instead of creating new exclusivities for pharmaceutical companies by giving away exclusive rights on publicly funded innovation, the U.S. government should pursue R&D strategies that promote the open and collaborative creation of new products and ensure affordable access to resulting products.

MSF recognizes the need to reward innovation and finance R&D. This can be done in a different way that benefits more people⁵ and makes sure U.S. taxpayers aren't paying twice – first by paying a significant percentage of the R&D costs and second by paying high prices for medical products. Opening up the creation of new medical tools to various developers and demanding the right terms and conditions ensures the vaccine development and manufacturing process is public health-driven and beneficial for all in need, especially for essential medical tools like vaccines needed for emergencies and epidemics.

We would like the United States government to reconsider the arguments and the data we provided in our January 2017 submission. A vaccine that is not appropriately developed or that is not sufficiently affordable and available to patients in need is a missed opportunity and a poor use of limited government resources.

¹ DOD response from April 2017 is available here:

https://www.doctorswithoutborders.org/sites/usa/files/dod_zika_license_letter_response.pdf

² MSF January 2017 submission to DOD objecting to the grant of an exclusive license is available here:

https://www.doctorswithoutborders.org/sites/usa/files/msf_comments_to_fr_notice_re_zika_vaccine_candidate_licensing.pdf

³ Pellerin C. Army Researchers, Sanofi Pasteur to Co-Develop Zika Virus Vaccine. Department of Defense. 7 July 2016. Available from:

<https://www.defense.gov/News/Article/Article/830751/army-researchers-sanofi-pasteur-to-co-develop-zika-virus-vaccine>, and Sagonowsky E.

Sanofi grabs \$43M in U.S. government funds to advance Zika vaccine into Phase I. FiercePharma. 26 September 2016. Available from:

<http://www.fiercepharma.com/vaccines/sanofi-grabs-43m-u-s-government-funds-for-zika-vaccine-r-d>

⁴ MSF. The Right Shot: Bringing down barriers to affordable and adapted vaccines, 2nd ed. January 2015. Available from:

<https://www.msfaaccess.org/our-work/vaccines/article/2345>

⁵ For an example of a non-exclusive patent licensing approach by the US government, see NIH Rotavirus Vaccine technology transfer strategy:

<https://www.ott.nih.gov/sites/default/files/documents/pdfs/casestudy13.pdf>