



**Doctors Without Borders/Médecins Sans Frontières and Knowledge Ecology
International Comments to the National Institutes Notice of Prospective Grant of Exclusive Patent
License: DNA-Based Vaccine for Prevention of Zika Virus Infection**

November 13, 2017

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Introduction

Doctors Without Borders/Médecins Sans Frontières (MSF) and Knowledge Ecology International (KEI) provide the following comments regarding the Notice from the National Institutes of Health (NIH) regarding the Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection.¹

We object to the grant of an exclusive patent license and urge the United States government to consider the negative impact an exclusive agreement will have on the development, affordability and availability of a Zika vaccine, which is needed for people affected by the Zika virus in the United States and worldwide.

Our objections cover the following points.

1. There is a lack of transparency regarding the proposed technology to be licensed, and the extent the public sector has already and will going forward subsidize the development of one or more vaccines covered by the license.
2. The NIH has not demonstrated an appropriate justification for the grant of an exclusive license, under the standards set out in 35 USC 209.
3. If the NIH does go ahead with an exclusive license, the license should at a minimum include provisions to safeguard affordable access, and limit the scope of the exclusive rights to that reasonably necessary to induce the necessary investment to bring the inventions into practical application, as defined in 35 USC 201(f).

Based upon the objections described herein, and the lack of sufficient information provided in the Federal Register notice, we request that the NIH consider a non-exclusive license or provide additional information relevant to evaluating this proposed licensing agreement and provide opportunities to consider the proposed license based on this information through a hearing or subsequent comment period.

Overview

MSF is an international medical humanitarian organization working in nearly 70 countries. Every year, MSF vaccinates tens of thousands of children, delivering about 5.3 million doses of vaccines and immunological products in 2015 alone. 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 use an effective Zika vaccine in our medical operations in the future. MSF, Ministries of Health and people around the world will only be able to benefit from the U.S. government investment if the resulting vaccine is effective, safe, available, affordable and suitably adapted to the resource-limited settings where most people affected by Zika virus live. Through our work, MSF witnesses the everyday impact of having limited or no access to medicines, diagnostics and vaccines, due to the lack of innovation on essential, suitably adapted and affordable medical tools in the contexts and populations where they are most needed.

¹ Federal Register. Department of Health and Human Services, National Institutes of Health. Notice of Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection. Vol 82, No 186, 12 October 2017. Available from: <https://www.federalregister.gov/documents/2017/10/12/2017-21986/prospective-grant-of-exclusive-patent-license-dna-based-vaccine-for-prevention-of-zika-virus#addresses>

Knowledge Ecology International (KEI) is a not for profit non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. KEI is focused on social justice, particularly for the most vulnerable populations, including low-income persons and marginalized groups. KEI is particularly concerned about the pricing and affordability of drug, vaccines and other medical technologies, and the management of government owned patents and other knowledge based assets derived from public sector funded research and development.

Our organizations recognize the need to reward innovation and finance research and development (R&D). We thank the U.S. government for its funding and leadership in Zika vaccine research and welcome the investment of US government resources in research on Zika vaccine candidates. We also encourage the NIH to grant licenses to entities that can help bring effective vaccines to market in a timely way. Our concerns are on the terms of such licenses, given the public interest in affordability and access to products and services based upon inventions owned by the NIH and the public health need for affordable, effective and appropriately developed Zika vaccines.

Under the Bayh-Dole Act, there are restrictions on the use of exclusive licensing of patents owned by the federal government, including those set out in 35 USC 209. These restrictions are designed to limit the grant of monopolies on federally owned patents to only those cases where an exclusive license is necessary to induce investments in the development of a product. The Bayh-Dole Act also requires agencies to limit the scope of such rights when exclusive licenses are used, to minimize the harm to competition.

In this case, the National Institute of Allergy and Infectious Diseases (NIAID) seeks to give PaxVax an exclusive license on inventions which have not been disclosed, but which we believe are related to more than one Zika DNA vaccine candidate. We believe at least one of the DNA vaccine candidates has already entered phase 2 testing, at taxpayer expense. If the vaccine is successful, we anticipate that PaxVax will received several benefits unrelated to patent rights.

The benefits that PaxVax will receive outside of the patent rights include:

1. Tax credits under the orphan drug tax credit, currently equal to 50 percent of the costs of conducting trials (net of any subsidy from the NIH).
2. Seven years of exclusive rights under the Orphan Drug Act.
3. 12 years of exclusive rights on test data, which may or may not extend to the NIAID funded trials on the vaccines, depending upon the content of the licensing and other contractual agreements with the NIAID.
4. A priority review voucher (most recently sold for \$150 million 2017Q3).
5. A period of years during which no other company can realistically register a biosimilar vaccine, regardless of the patent status.

We believe this collective set of subsidies and exclusive rights associated with regulatory test data and orphan disease status make the use of an exclusive license, particularly one that would extend the monopoly until the year 2037 or later, unnecessary and illegal under 35 USC 209.

We are also concerned about the affordability of and access to the vaccine, in the United States, and worldwide. These concerns exist even under non-exclusive license to the patents, if PaxVax is able to obtain exclusive rights to test data and/or orphan drug exclusivity.

PaxVax has a history of marketing vaccines to travelers and tourists, and may not be willing or able to scale access in countries where the need is the greatest.

A vaccine that is not appropriately developed or a vaccine without appropriate measures to ensure access is a missed opportunity to make maximal use of limited US government resources. The next step in the Zika vaccine development process, including its licensing and technology transfer strategy, needs to ensure that U.S. government funding and leadership in vaccine R&D results in a vaccine that is effective and accessible for all patients in need in the U.S. and globally, including the most neglected. As the latest Ebola outbreak in West Africa should constantly remind us, diseases have no borders in a globalized world. Without a global research and access strategy for the Zika vaccine, the disease cannot be prevented in the most at-risk populations.

We object to the granting of this exclusive license for development of Zika vaccine candidates for the following reasons:

1. There is insufficient information provided regarding the technology to satisfy requirements under the Bayh Dole Act and Regulations

We believe that the Federal Register notice of October 12, 2017 fails to meet the requirements of 35 U.S.C. 209(e) and 37 CFR 404.7 in failing to provide sufficient detail regarding the technology to permit meaningful and substantive comment by the public.

35 U.S.C. 209(e) requires that “No exclusive or partially exclusive license may be granted under section 207(a)(2) unless public notice of the intention to grant an exclusive or partially exclusive license on a federally owned invention has been provided in an appropriate manner at least 15 days before the license is granted, and the Federal agency has considered all comments received before the end of the comment period in response to that public notice.” 37 CFR 404.7 requires that the notice identify the technology and prospective licensee.

The Federal Register notice in this instance does not provide sufficient information regarding the technology to even answer basic questions regarding which type of Zika vaccine this particular technology is. The notice provides a Department of Health and Human Services (HHS) reference number and a provisional patent application number for “Zika virus vaccines,” and describes certain characteristics of the vaccine in question, including that it is a DNA-based candidate referred to in a Federal Register Notice published on December 12, 2016.

That Federal Register Notice of December 12, 2016 in fact refers to two separate vaccine candidates: (1) VRC-ZKADNA085-00-VP (referred to as VRC5288); and (2) VRC-ZKADNA090-00-VP (referred to as VRC5283). VRC5288 has been in clinical trials²; likewise, VRC5283 has also been in clinical trial.³

² <https://clinicaltrials.gov/ct2/show/NCT02840487>.

³ <https://clinicaltrials.gov/ct2/show/NCT02996461> and <https://clinicaltrials.gov/ct2/show/NCT03110770>.

It is impossible to know which of these two are the candidate referred to in the Federal Register notice of October 12, 2017. Moreover, NIH has failed to respond to two separate emails requesting clarification on this matter. An email on October 25, 2017 from Kim Treanor of Knowledge Ecology International to Dr. Petrik of NIH, who is described in the Federal Register notice as the contact for all inquiries related to the contemplated exclusive license, and asked a series of questions to help clarify basic facts about this invention; having received no response, Ms. Treanor sent a follow-up email on November 7, 2017, asking once again for responses to her prior questions, explicitly adding a question as to whether the subject invention of the proposed exclusive license was VRC-ZKADNA090-00-VP.⁴ KEI also tried to reach out to Dr. Petrik via phone. To date, KEI has not received any response to any of these queries.

Without clarity as to what the invention is that HHS proposes to license, and without access to the patent application, the public does not have access to basic facts that are critical to providing meaningful comment.

We ask the NIH to publish an explanation of why an exclusive license has been deemed to be “reasonable and necessary” and if so, if the restrictions on the scope of exclusivity are limited to that “reasonably necessary” and includes appropriate safeguards. The NIH should at a minimum provide the following information to the public:

1. The intellectual property that the NIH intends to license to PaxVax, including (1) United States Provisional Patent Application 62/396,613, including in particular the patent claims that will be licensed.
2. Whether any other potential vaccine developers expressed interest in this license
3. The estimated spending to date by the NIH or any other public US institution in the development of this vaccine candidate
4. The estimated spending to date by PaxVax in the development of this vaccine candidate
5. The estimated costs to further develop this vaccine candidate through market approval
6. Identification of any clinical trials using the patented inventions, including the trial name, ClinicalTrials.gov identification number, the number of patients enrolled, and the trial phase.

2. There is considerable evidence that the grant of exclusivity is not a reasonable and necessary incentive to promote innovation and further development of a Zika vaccine.

Based on our analysis of available information, granting an exclusive license to patents on a potential Zika vaccine to PaxVax is contrary to the provisions of 35 U.S.C. 209(a)(1). According to U.S. law, the United States government may grant an exclusive or partially exclusive license “only if” the exclusivity is “a reasonable and necessary incentive to call forth the investment capital needed to bring the invention to practical application; or otherwise promote the invention’s utilization by the public.” In other words, the U.S. government cannot grant exclusive licenses in cases where the exclusive rights are not reasonable and necessary for the practical application and utilization of the invention.

⁴ Emails on file with Knowledge Ecology International.

Before an exclusive license is granted, PaxVax or any other potential recipient of an exclusive license and the National Institutes of Health have the burden of proving that these exclusive rights are necessary.

Pharmaceutical companies often assert that exclusivity is necessary to recoup investments and risk associated with the research and development process, as well the opportunity cost to work on a given technology. However, we argue that this exclusivity is unnecessary to promote innovation and the further development of these vaccine candidates given:

- a. The funding and resources that the U.S. government has already dedicated to the vaccine candidates have significantly reduced the need for investment and lowered the risks to the company. This is particularly true for the vaccine candidate C-ZKADNA090-00-VP (Zika virus wildtype DNA vaccine), which is now in phase 2 testing, funded by NIAID⁵, if this is one of the technologies to be licensed. (We have asked NIAID to at least confirm this is one of the candidates to be licensed, but have not received a response, and discuss this in further detail below).
- b. PaxVax and any other vaccine developer that further develops this vaccine candidate are eligible to receive additional funding from the federal government. (We have asked the NIH about future funding prospects, but have not received a response).
- c. Any investments by PaxVax in the clinical trials for the vaccine are eligible for an orphan drug tax credit. Under current law, the value of the credit would be equal to 50 percent of the cost of qualifying trials.⁶ We believe the credit would be available even for trials conducted outside of the United States.
- d. The company that registers the vaccine will be eligible to receive a Food and Drug Administration (FDA) Priority Review Voucher (PRV) for neglected diseases, without any product access conditions attached.⁷ Since August 2015, the known prices for traded PRVs have ranged from \$125 to \$350 million. We note, for example, that PaxVax reportedly sold a PRV they were awarded for a cholera vaccine approval for \$200 million,⁸ and that there was a reported sale of a PRV for \$150 million sales in 2017 Q3.⁹
- e. The Zika vaccine candidate is likely to benefit from the seven years of marketing exclusivities attached to an orphan drug designation, which is available for any vaccine that is used to treat fewer than 200,000 persons annually in the United States. If the U.S. market is larger than 200,000, there is even less reason to grant an exclusive license, given other barriers to competition and the larger size of the U.S. market.

⁵ <https://clinicaltrials.gov/ct2/show/NCT03110770>

⁶ There may be modifications to the credit in the current tax reform legislation.

⁷ Brock W, Cohen R, Cone J, McKenna L. The Zika loopholes. Politico. 25 March 2016. Available from:

<http://www.politico.com/agenda/story/2016/03/the-right-way-to-encourage-companies-to-develop-a-treatment-for-zika-000079>

⁸ BioPharma Dive. GSK uses priority voucher to file HIV combo. 2 June 2017. Available from: <https://www.biopharmadive.com/news/gsk-uses-priority-voucher-to-file-hiv-combo/444131/>

⁹ Alexander Gaffney, RAC, Michael Mezher, Zachary Brennan, Regulatory Explainer: Everything You Need to Know About FDA's Priority Review Vouchers, October 2, 2017. Available from: <http://www.raps.org/Regulatory-Focus/News/2015/07/02/21722/Regulatory-Explainer-Everything-You-Need-to-Know-About-FDA%E2%80%99s-Priority-Review-Vouchers/>

- f. As vaccines are included among the definition for biologic products under 42 U.S.C. 262(i), PaxVax would also benefit from twelve years of exclusive rights to market the vaccine under 42 U.S.C. 262(k)(7)(A), barring competitors from gaining market approval through reliance upon evidence that a vaccine is safe and effective. The 12 years of exclusive rights in test data are, wholly apart from any patent protection that may or may not exist, a significant barrier for entry by a biosimilar product, and would require a follow on biosimilar product to replicate costly, time consuming and potentially unethical clinical trials.¹⁰
- g. PaxVax and other vaccine developers may also receive other resources provided by other countries. For example, the funds and resources that will be made available to accelerate vaccine development for emerging infectious diseases with the recently launched Coalition for Epidemic Preparedness Innovations (CEPI) that multiple governments, philanthropies like the Bill & Melinda Gates Foundation and the Wellcome Trust, and MSF are members of.

3. The grant of patent exclusivity can hinder innovation for Zika vaccines and doesn't allow research strategies that promote collaboration and focus on neglected medical needs.

- a. While the NIAID has not provided the public with any details of the patent claims for the proposed license, patents can be a threat to the timely development of and access to affordable versions of newer vaccines.¹¹ We are concerned that an exclusive license will allow PaxVax to block other companies from developing DNA vaccines that would be less expensive, more effective, or both.
- b. The grant of exclusivity does not ensure that the Zika vaccine development process will target the populations most in need. PaxVax will be allowed to pursue research strategies to maximize use of the vaccine candidate in profitable markets, like the U.S. or the travelers market, limiting or excluding clinical development of competing research agendas that should include a broader and diverse geographical scope to ensure any resulting vaccine is effective and useful in the full range of populations who may need this vaccine.¹²
- c. The grant of exclusivity does not ensure that a vaccine will be developed or that it will adhere to a timely development process. The example of promising results of clinical trials of rVSV Ebola vaccine that MSF supported shows the importance of government funding and leadership for vaccine development. It also shows how the Canadian government's exclusive licensing was unnecessary and tragically delayed urgently needed innovation. It was thanks to initial studies at a Canadian government laboratory that the VSV-EBOV vaccine was confirmed as potentially effective against Ebola. Despite the fact that the government licensed this vaccine to a U.S. company, NewLink, four years before the West African Ebola outbreak, the project stalled and the vaccine was not made available to people at risk for more than five years. If at least phase 1 clinical trials had been conducted prior to the most recent outbreak, the vaccine could have been deployed

¹⁰ See, e.g.: Emerging Health Care Issues: Follow-on Biologic Drug Competition, Federal Trade Commission Report, June 2009.

¹¹ MSF. A Fair Shot for Vaccine Affordability. September 2017. Available from: <https://www.msfaccess.org/vaccine-ip-report>.

¹² Adams P, Nutt C. A Zika Vaccine, but for Whom? New York Times. 28 December 2016. Available from:

https://www.nytimes.com/2016/12/28/opinion/a-zika-vaccine-but-for-whom.html?_r=0

during the emergency and potentially helped save lives. This wasted opportunity and failure to advance the vaccine's development nevertheless netted NewLink more than \$63.5M profit when they sold the rights to pharmaceutical company Merck during the most critical phase of the outbreak. A non-exclusive license could have allowed the Canadian government, either prior to or during the outbreak, to take more decisive action to encourage or require the timely testing and development of the vaccine.

4. An exclusive license can be a barrier to ensuring a Zika vaccine will be available and affordable to all who need it.

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 was 68 times more expensive than it was in 2001.¹³ The price in other countries is even higher. Many countries, especially countries 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.

Before granting a license on U.S. government-owned rights, the U.S. government should ensure that the license will ensure that the “benefits” of the invention will be “available to the public on reasonable terms,” a requirement of 35 U.S.C. § 201(f). Granting an exclusive license to a vaccine manufacturer will not only fail to ensure any resulting vaccine is available on reasonable terms, but can also become a significant barrier to the future availability and affordability of the vaccine.

As the vaccine development has been publicly financed by the U.S. government, the price of any resulting vaccine should be closely aligned with production costs. Yet, an exclusive license to PaxVax will allow the company to charge high prices based on what their targeted markets will bear regardless of actual costs. Based on our experience, leaving these decisions exclusively to a pharmaceutical company may not lead to appropriate public health outcomes.

We hope PaxVax commits to and implements an appropriate access and manufacturing strategy, but also note that PaxVax does not have an established record in making vaccines available in disease-endemic countries. PaxVax currently has two approved vaccine products, both for disease primarily affecting people in developing countries. One is Vaxchora, a vaccine for cholera that earned PaxVax a US FDA priority review voucher (PRV) for neglected diseases, despite the fact that “the effectiveness of Vaxchora has not been established in persons living in cholera affected areas.”¹⁴

An exclusive license will also be barrier to competition in the manufacturing and supply of the technology, as it will allow PaxVax to exclude other manufacturers from producing and selling the technology.

Promoting competition is the best tool to ensure affordability as well as ensuring sufficient manufacturing and supply of any resulting vaccine. MSF and patients have repeatedly experienced the consequences of

¹³ MSF. The Right Shot: Bringing down barriers to affordable and adapted vaccines, 2nd ed. January 2015. Available from: <https://www.msfaccess.org/our-work/vaccines/article/2345>

¹⁴ FDA. FDA approves vaccine to prevent cholera for travelers. 10 June 2016. Available from: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm506305.htm>.

what happens when a single supplier discontinues manufacturing of an effective and needed product for conditions affecting neglected populations.¹⁵

A better way to promote U.S. government funded innovation: open non-exclusive licenses with terms and safeguards for patient-driven innovation and future affordable access

An exclusive license fails to address the need for an innovation strategy that put the needs of all patients and vaccine providers at the center of the biomedical innovation system.

We recommend that the U.S. government consider an open licensing and technology transfer strategy to allow PaxVax and a variety of vaccine developers and researchers to test and further develop this vaccine, promoting a variety of scientific, research, development, business and delivery approaches.

The licensing of this technology should include safeguards to ensure that the development will be patient-driven and that any resulting vaccine will be safe, effective, appropriately available and affordable to all people in need. We also recommend that the U.S. government make the terms and conditions of the license publicly available to allow for appropriate review, accountability and implementation of the safeguards created.

An open, non-exclusive license not only ensures that multiple companies can move towards developing the product, but can ensure that if one company fails to meet milestones or advance development, the patent holder (the US government) can move on to others and without having to go through the onerous and possibility litigious process of terminating a license, granting a march-in request or testing the boundaries of allowing third parties to produce a vaccine under the federal government's royalty free right in the license.

A non-exclusive license allows several vaccine developers to pursue different research, regulatory and development strategies of the vaccine candidate, and also can reduce the negative health impact of research stalled or delayed by a single researcher strategy. For example, in the case of the rVSV Ebola vaccine highlighted above, had the Canadian government granted an open license, governments and medical service providers such as MSF – and, most importantly, patients in need – would not have been dependent on the development timeline of only one company.

An open license allows several companies and vaccine researchers to test the effectiveness and safety of the technology in a variety of settings, including pursuing research strategies that target the needs of neglected populations due to expectation of limited profitability and/or knowledge gaps on Zika epidemiology in Africa.

An open license allows several companies to manufacture a resulting vaccine and reduces the public health liability created by a single manufacturer that decides to stop manufacturing or is not able to meet the global demand of a successfully developed Zika vaccine.

¹⁵ See for example, MSF. Snakebite: How Sanofi slithered its way out of the neglected antivenom market. July 2015. Available from: https://www.msfaccess.org/sites/default/files/NTDs_Brief_FavAfrique_ENG_2015.pdf

An open license may facilitate the emergence of competition in the manufacturing and supply of Zika vaccines, which is ultimately the best tool to promote affordability.

The NIH has extensive experience in engaging in open licenses. Many of the licenses the NIH grants are non-exclusive; in FY 2015, of 275 license agreements executed, 262 were non-exclusive.¹⁶ In FY 2016, the NIH issued 279 licenses, and 235 were non-exclusive.¹⁷ This includes vaccine product development. Consider for example the example of a non-exclusive licensing approach applied for the success development and manufacturing of a rotavirus vaccine.¹⁸ Another example that of a dengue vaccine developed by NIAID and licensed non-exclusively to at least seven licensees, “enhancing the commercialization” of the product in multiple regions including high-income and developing countries.¹⁹

If an exclusive license is granted, we recommend the following limitations on the scope of rights, safeguards on pricing and affordability, and other terms to advance the public interest.

If, despite our opposition, the NIH intends to grant an exclusive license to PaxVax or any other manufacturer, the terms of the license should at a minimum include conditions to ensure affordable access to any resulting vaccine for all who need it.

In particular, we ask the NIH to include, at a minimum, the following safeguards on pricing and affordability:

1. PaxVax must agree to disclose the steps it will take to enable the timely registration and availability of the vaccine at an affordable price in the United States and in every county with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC)/ World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.
2. PaxVax must agree to make the vaccine available to the public in the U.S. at publicly disclosed prices no higher than the median price charged in the seven countries with the largest GDP which have per capita incomes of at least half that of the U.S.
3. The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the vaccine from competitive suppliers, including

¹⁶ NIH. Combine NIH-wide annual reporting on technology transfer activities FY 2015. Available from: <https://www.ott.nih.gov/sites/default/files/documents/pdfs/AR2015.pdf>

¹⁷ Annual Report, FY 2016, NIH Technology, Transfer Activities. Available from: <https://www.ott.nih.gov/sites/default/files/documents/pdfs/AR2016.pdf>

¹⁸ NIH. Rotavirus Vaccine: NIH Office of Technology Transfer. Available from: <https://www.ott.nih.gov/sites/default/files/documents/pdfs/casestudy13.pdf>

¹⁹ NIH. NIH Technology Transfer Activities Annual Report FY 2016. Available from: <https://www.ott.nih.gov/sites/default/files/documents/pdfs/AR2016.pdf>

technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the vaccine.

4. PaxVax must provide annual public reports on the R&D costs incurred, the manufacturing costs of the vaccine, the number of units sold in every country, as well as the status of any patents on the vaccine and all country registrations. Note, such reports are not constrained by the limits on public disclosure for plans referred to in 35 U.S.C. 209(f).

KEI is proposing additional conditions on pricing in a separate letter that are specific as regards limitations on exclusivity.

Conclusion

At a time when the high prices of life-saving medical tools, including hepatitis drugs, biologics and vaccines have become a major 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 concerning to see the U.S. government considering a license that will lock in a monopoly on an important NIH invented and developed vaccine to one company, until 2037, without any safeguards regarding 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 open and collaborative innovation and ensure affordable access to resulting products.

The Bayh-Dole Act has restrictions on the grant of exclusive licenses in order to protect the public from harm caused by the unnecessary grant to monopolies. Among those restrictions are a requirement for a finding that an exclusive license is a necessary measure to secure development of a vaccine, and that rights have been limited to only that reasonable necessary to accomplish that goal, consistent also with an obligation to ensure that the invention is “available to the public on reasonable terms.”

MSF and KEI have provided ample evidence that an exclusive license is not necessary in this case, particularly as regards the vaccine candidate that is currently in phase 2 testing. When an exclusive license on a federally owned invention is not reasonably necessary, it is not allowed under the Bayh-Dole Act. The NIH has failed to provide sufficient information and rationale to address these concerns.

We ask that the NIH instead consider a non-exclusive license. We have also asked that if an exclusive license is indeed used, that the license include limitations on the scope of the rights granted, and specific, clear and actionable safeguards as regards the pricing of and access to the vaccine.

If the NIH intends of pursue an exclusive license, they should first release necessary and relevant information relevant to evaluating the license, then provide a new comment period, and hold a public hearing on the proposed license.

For follow up, please contact Jennifer Reid at MSF (Jennifer.Reid@newyork.msf.org), or James Love (James.Love@KEIonline.org) or Andrew Goldman (Andrew.Goldman@KEIonline.org) at KEI.

Doctors Without Borders/Médecins Sans Frontières

Knowledge Ecology International