



Additional Comments by KEI on the PaxVax License, FR Doc. 2017–21986 Filed 10–11–17; as noted in Federal Register Vol. 82, No. 196, October 12, 2017.

KEI has a joint submission with MSF that describes our opposition to an exclusive license to PaxVax for the NIAID Zika vaccine patents, and which proposes safeguards in such a license, if the NIAID decides to use an exclusive license, despite our concerns.

This letter supplements the joint letter with KEI's deals with two sets of concerns. First, KEI wants to note that the appearance of potential conflicts of interest provides an additional compelling reason for more transparency. Second, KEI proposes additional limitations on the scope of exclusive rights.

1. The appearance of potential conflicts of interest provides additional reasons to be more transparent as regarding the proposed license.

There is at a minimum the appearance of a conflict of interest between interested parties at PaxVax and various parties within the federal government.

Ken Kelley, the founder, former CEO and Director on the Board of PaxVax from 2007-2015 has, since 2015, been working as,

“a White House Presidential Executive Fellow, and Senior Advisor to the Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Allergy and Infectious Disease Vaccine Research Center (NIAID/VRC), both within the U.S. Department of Health and Human Services. He is working on special projects within global biosecurity including the U.S. Government's response to the Zika Virus outbreak, aligning vaccine development efforts across agencies throughout the U.S. Government, and engaging with the new global vaccine development fund, the CEPI (Coalition for Epidemic Preparedness Innovations).”¹

In addition to the interests of Mr. Kelley, the grant of an exclusive license of this technology to PaxVax would likely also be in the interest of Cerberus Capital Management, which acquired

¹ <https://www.linkedin.com/in/kennethjkelley/>

majority interest in PaxVax in late 2015.² The co-founder and Chief Executive Officer of Cerberus Capital Management is Stephen Feinberg.³ Mr. Feinberg was a major contributor to Donald Trump's presidential campaign, giving an estimated \$2.2 million to groups backing his candidacy as well as hosting a fundraiser for the campaign, and is reportedly advising the Administration on matters concerning national security.⁴

The appearance of a potential conflict of interest creates a compelling need for transparency regarding the terms of and the rationale for an exclusive license for this publicly financed technology, and further supports the call made in our joint submission with MSF for a hearing on this proposed license.

2. Additional proposals to limit the scope of exclusive rights.

In addition to the four proposals in the joint MSF/KEI letter to limit the exclusive rights in a license to PaxVax, KEI provides the following suggestions.

1. The term of the exclusive licence to PaxVax should be no longer than 5 years, subject to successive three year extensions upon a finding that the PaxVax price is reasonable given the public sector role in funding the development of the vaccine, and that access to the vaccine is acceptable.
2. Assuming the vaccine candidate is already in a government funded phase 2 trial and PaxVax is solely funding the phase 3 trial, the exclusivity shall no longer be in effect if the vaccine generates more than \$500 million in sales globally, assuming this is at least more than three times the expected costs of phase 3 testing for the vaccine. If the NIH funds the phase 3 trial, a lower threshold will be appropriate, such as \$100 million.

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² <https://pitchbook.com/newsletter/cerberus-acquires-paxvax-majority-interest-for-105m>

³ <http://www.cerberuscapital.com/team/stephen-a-feinberg/>

⁴<https://www.bloomberg.com/news/articles/2017-04-03/billionaire-feinberg-might-keep-cerberus-stake-in-new-trump-role,> and
<https://www.nytimes.com/2017/02/15/us/politics/trump-intelligence-agencies-stephen-feinberg.html>.