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Making Publicly Funded Medical Technologies Accessible in Developing Countries

Ebola

U.S. Government Funded Leading Ebola Vaccine Candidate and Other Ebola Medicines

Ebola: Ebola is a rare and deadly disease caused by infection with one of the four Ebola virus strains that affects humans (with a fifth that causes disease in non-human primates).¹ Ebola was first discovered in the Democratic Republic of the Congo in 1976, and since outbreaks have occurred sporadically in Africa.² On average, Ebola is fatal for approximately half of those infected by the disease.³ As of November 29, the latest outbreak in West Africa (centered in Guinea, Liberia and Sierra Leone) has claimed nearly 7,000 lives, with more than 16,000 infected.⁴

Candidate Ebola Vaccines: At an urgent meeting in late September, the World Health Organization (WHO) discussed two candidate vaccines – cAd3-EBOV (cAd3), under development by GlaxoSmithKline (GSK) and the National Institute of Allergy and Infectious Diseases (NIAID), and rVSVΔG-EBOV-GP (rVSV), from NewLink Genetics and the Public Health Agency of Canada.⁵ Both of these candidate vaccines are undergoing Phase I clinical trials.⁶ On November 26, the National Institutes of Health (NIH) announced promising interim results from the Phase I trial of cAd3, in which the candidate vaccine “was well-tolerated and produced immune system responses in all 20 healthy adults who received it in a phase I clinical trial conducted by researchers from the National Institutes of Health.”⁷ Phase II trials are expected to be initiated early in 2015, with planning for large-scale vaccination to occur as soon as data on efficacy becomes available.⁸ On October 23, the WHO convened another high-level emergency meeting to discuss Ebola vaccines access and financing.⁹ The report from the October 23 meeting states that “...discussions of financing moved forward quickly: funding issues must not be allowed to drive the agenda; the funds will be found.”¹⁰

The U.S. government is one of the assignees on a key patent application covering cAd3 (along with the biotech company Okairo, which was purchased by GSK). As an assignee, and in accordance with 37 CFR 404.7, the “U.S. Government has an irrevocable, royalty-free right to practice and have the subject invention practiced on its behalf and on behalf of any foreign government or international organization

¹ About Ebola Virus Disease. (2014, October 3). Retrieved November 30, 2014, from <http://www.cdc.gov/vhf/ebola/about.html>

² *Ibid.*

³ Ebola virus disease. (2014, September). Retrieved November 30, 2014, from <http://www.who.int/mediacentre/factsheets/fs103/en/>

⁴ Johnson, C. (2014, November 29). Number of Ebola infections in west Africa passes 16,000. Retrieved November 30, 2014, from <http://www.theguardian.com/world/2014/nov/29/ebola-infections-west-africa-16000>

⁵ Experimental Ebola vaccines. (2014, October 1). Retrieved November 30, 2014, from <http://www.who.int/mediacentre/news/ebola/01-october-2014/en/>

⁶ Experimental Ebola vaccines. (2014, October 1). Retrieved November 30, 2014, from <http://www.who.int/mediacentre/news/ebola/01-october-2014/en/index1.html>

⁷ NIAID/GSK Experimental Ebola Vaccine Appears Safe, Prompts Immune Response. (2014, November 26). Retrieved November 30, 2014, from <http://www.niaid.nih.gov/news/newsreleases/2014/Pages/EbolaVaxResults.aspx>

⁸ Experimental Ebola vaccines. (2014, October 1). Retrieved November 30, 2014, from <http://www.who.int/mediacentre/news/ebola/01-october-2014/en/index4.html>

⁹ Summary report of a WHO High-level meeting on ebola vaccines access and financing. (2014, October 23). Retrieved November 30, 2014, from <http://www.who.int/mediacentre/news/ebola/23-october-2014/en/>

¹⁰ WHO High - level meeting on Ebola vaccines access and financing. (2014, October 23). Retrieved November 30, 2014, from http://apps.who.int/iris/bitstream/10665/137184/1/WHO_EVD_Meet_EMP_14.2_eng.pdf?ua=1

pursuant to any existing or future treaty or agreement with the United States.”^{11,12} While other barriers to access exist, including lack of infrastructure and the need to store the candidate vaccines at -80°C ¹³, the U.S. government can exercise its rights to help ensure cost does not become a barrier to widespread rollout of a successful vaccine or to the several treatments in development as well.

¹¹ 37 CFR 404.7 - Exclusive, co-exclusive and partially exclusive licenses. Available at: <http://www.law.cornell.edu/cfr/text/37/404.7>

¹² While this fact sheet focuses on the two most promising candidate vaccines, several other vaccines and medicines that may be candidates for Ebola vaccination and treatment are in earlier stages of research and development. Due to its investment in early stage research, the U.S. government also holds rights to patents on these medicines which it could license internationally.

¹³ *Ibid.* 6