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Making Publicly Funded Medical Technologies Accessible in Developing Countries

Human Papillomavirus (Cervical Cancer)

U.S. Government Funding of Critical Anti-Cancer Vaccine

Merck's human papillomavirus (HPV) vaccine, marketed as Gardasil and Silgard, represented a significant breakthrough for public health when first approved by the FDA in 2006. The vaccine's efficacy in preventing HPV infections offers its greatest benefits to developing countries, where it nevertheless remains least accessible. HPV, which is estimated to cause approximately 70 percent of cervical cancer cases, disproportionately impacts the global poor, most of whom live in low- and middle-income countries. Among developing countries, HPV prevalence is highest in sub-Saharan Africa.¹ Approximately 90 percent of the more than 600,000 annual cases of cervical cancer occur in women from low- or middle-income countries.² Nearly half of these cases result in death, many of which could have been avoided with access to technology that is easily available in the developed world. Cervical cancers respond well to treatment *if* detected at an early stage; however, this remains contingent on having access to treatment once diagnosed.

For those who remain free of HPV infection, most can avoid future infection with access to quality HPV vaccines. In 2013, GAVI negotiated a price of \$4.50 per dose for a range of least-developed countries.³ Yet even with GAVI's price rebate, \$9 for the full regimen of three doses translates to a prohibitively expensive outlay to scale up treatment in many of the world's poorest countries. Médecins Sans Frontières estimated that the vaccine could be produced at a cost as low as one dollar per dose.

Beyond traditional cost barriers, there are also potential logistical and cultural barriers to diffusion of the vaccine in the developing world. The vaccine must be administered two times over a six-month period⁴. Nevertheless, cost remains a bottleneck to implementation on a broad scale.

As knowledge expands of how viruses can ultimately lead to cancer, the HPV vaccine can be seen as an early pioneer in the category of anti-cancer vaccination. Key discoveries behind the vaccine took place on university campuses, with much of that research publicly funded. Two of Gardasil's patents (one pending, and one

¹ Forman, D. et al. Global burden of human papillomavirus and related diseases. *Vaccine*. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/23199955>

² Cohen, Susan. "A Long and Winding Road: Getting the HPV Vaccine to Women in the Developing World." *Guttmacher Policy Review*. Summer 2007. Volume 10, Number 3. Available from: <https://www.guttmacher.org/pubs/gpr/10/3/gpr100315.html>

³ McNeil, Donald. "Cancer Vaccines Get a Price Cut in Poor Countries." May, 9 2013. Available from: <http://www.nytimes.com/2013/05/10/health/prices-cut-for-hpv-cervical-cancer-vaccines-for-neediest.html>

⁴ Comprehensive Cervical Cancer Control -- A guide to essential practice, Second edition. (2014, December 3). Retrieved December 5, 2014, from apps.who.int/iris/bitstream/10665/144785/1/9789241548953_eng.pdf

granted) disclose rights held by the government due to public investment which led to the development of the patented invention. Furthermore, the patents disclose the government grants which triggered the government holding certain rights over the patents. Under P50 CA098252, the National Cancer Institute and Eunice Kennedy Shriver National Institute of Child Health & Human Development contributed more than \$12 million^{5,6} towards Johns Hopkins University's Specialized Program of Research Excellence in Cervical Cancer. Under this program, the inventor cited on the patent application, Richard Roden, led a project on development of a pan-oncogenic HPV preventive vaccine. Furthermore, three grants listed on a patent covering Gardasil amount to an additional \$9 million^{7,8} in government support of the drug's development from the National Institutes of Health. Government licensing of its rights would be an important step towards expanding access to the vaccine.

⁵ See http://projectreporter.nih.gov/project_info_details.cfm?aid=6947598&icde=22619782&ddparam=&ddvalue=&ddsub=&cr=2&csb=FY&cs=ASC, http://projectreporter.nih.gov/project_info_details.cfm?aid=6805771&icde=22619782&ddparam=&ddvalue=&ddsub=&cr=3&csb=FY&cs=ASC, http://projectreporter.nih.gov/project_info_details.cfm?aid=6948599&icde=22619782&ddparam=&ddvalue=&ddsub=&cr=4&csb=FY&cs=ASC, http://projectreporter.nih.gov/project_info_details.cfm?aid=7127657&icde=22619782&ddparam=&ddvalue=&ddsub=&cr=5&csb=FY&cs=ASC, http://projectreporter.nih.gov/project_info_details.cfm?aid=7281293&icde=22619782&ddparam=&ddvalue=&ddsub=&cr=6&csb=FY&cs=ASC, and http://projectreporter.nih.gov/project_info_details.cfm?aid=6559508&icde=22619782

⁶ While grants listed on the patent application cover a greater time span than relevant for any research leading to the patent, this amount was calculated based only on funding disclosed through the year the patent application was filed.

⁷ See http://projectreporter.nih.gov/project_info_details.cfm?aid=2297064&icde=22620143&ddparam=&ddvalue=&ddsub=&cr=1&csb=FY&cs=ASC, http://projectreporter.nih.gov/project_info_details.cfm?aid=2297066&icde=22620143&ddparam=&ddvalue=&ddsub=&cr=2&csb=FY&cs=ASC, http://projectreporter.nih.gov/project_info_details.cfm?aid=2297065&icde=22620143&ddparam=&ddvalue=&ddsub=&cr=3&csb=FY&cs=ASC, http://projectreporter.nih.gov/project_info_details.cfm?aid=2297067&icde=22620143&ddparam=&ddvalue=&ddsub=&cr=4&csb=FY&cs=ASC, http://projectreporter.nih.gov/project_info_details.cfm?aid=2295768&icde=22620200&ddparam=&ddvalue=&ddsub=&cr=1&csb=FY&cs=ASC, http://projectreporter.nih.gov/project_info_details.cfm?aid=3101265&icde=22620221&ddparam=&ddvalue=&ddsub=&cr=1&csb=FY&cs=ASC, http://projectreporter.nih.gov/project_info_details.cfm?aid=3101266&icde=22620221&ddparam=&ddvalue=&ddsub=&cr=2&csb=FY&cs=ASC, http://projectreporter.nih.gov/project_info_details.cfm?aid=3101272&icde=22620221&ddparam=&ddvalue=&ddsub=&cr=3&csb=FY&cs=ASC, http://projectreporter.nih.gov/project_info_details.cfm?aid=2085953&icde=22620221&ddparam=&ddvalue=&ddsub=&cr=4&csb=FY&cs=ASC

⁸ While grants listed on this patent cover a greater time span than relevant for any research leading to the patent, this amount was calculated based only on funding disclosed through the year the application on this patent was filed. Furthermore, the online database of the National Institutes of Health did not have complete funding information for some of the relevant time frame, so this figure is lower than the actual amount of government funding.