An Ethics Assessment of COVID-19 Vaccine Programs

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Vaccine List Table updated last June 19, 2020

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The recent global concern for a devastating disease impact by COVID-19, the disease caused by the newly identified SARS-CoV-2 (CoV-19) coronavirus, has prompted a rapid intensification of efforts to develop an effective vaccine to limit the spread of the virus and to reduce COVID-19 illness and deaths. A study from the Coalition of Epidemic Preparedness Innovation (CEPI) identified 115 COVID-19 vaccines in development. At least 78 of these vaccine development initiatives were confirmed to be actively under way. However, many of these active projects are still only at the laboratory investigation stage (1), with many different biological strategies being investigated (2,3).

As shown in Table 1, there are a number of COVID-19 vaccine programs that are now in registered clinical trials or in early pre-clinical stages of development. Five of these identified efforts use genetically engineered adenoviruses for production of CoV-19 products that are thought likely to make effective vaccines. Engineered adenoviruses are established manufacturing vectors for gene therapies and viral vaccine development. The safety of these genetically modified viruses is due to their inability to reproduce themselves in the absence of artificially supplied factors that promote their self-multiplication. They are described as replication-deficient (RD) viruses. In order to manufacture RD adenoviruses or, in the case of vaccine production, their CoV-19 viral products, their viral genomes are introduced into cultured human cells genetically engineered to make their missing required replication factors (4,5). Several commonly used human cell lines developed for this function were established from cells taken from electively aborted human fetuses (4).

The use of cells from electively aborted fetuses for vaccine production makes these five COVID-19 vaccine programs potentially controversial and could reduce willingness of some to use the vaccine. While some may see no ethical problem, for many a straight line can be drawn from the ending of a human life in an abortion to a vaccine or drug created using cells derived from the harvesting of the fetal tissue. Even if the cells have been propagated for years in the laboratory far removed from the abortion, that connection line remains. Thus, use of such cells for vaccine production raises problems of conscience for anyone who might be offered that vaccine and is aware of its lineage. Moreover, the possibility of conscientious objection by those to whom a vaccine is offered creates ethical demands on the policymakers, healthcare officials, scientists, vaccine creators and funders, whether or not they themselves have an ethical concern, because of the question of access to the vaccine by the entire citizenry in good conscience. (6) This is especially true if alternative production methods and vaccines are possible for which there is no ethical question.

In June 2019, the U.S. Department of Health and Human Services (HHS) announced that it would no longer provide intramural funding for government research that requires new

acquisition of tissues harvested from victims of ongoing elective abortion, would empanel an ethics review board to review all new or renewal extramural research applications proposing use of fetal tissue, and would provide funding to optimize and develop alternative research models that do not rely on human fetal tissue from elective abortions (7). Funding of new research using abortion-derived cells established prior to the new HHS rule (i.e., HEK293, Per.C6) was allowed to continue.

A rapidly-growing number of COVID-19 vaccine programs, 17 so far identified in Table 1, underscore the many alternative strategies available and useful for COVID-19 vaccine development that pose no controversy. In total, the U.S. government has invested just over a half billion dollars to support three of these vaccine programs (8). Although RD adenovirus strategies are not among the current ethically uncontroversial vaccine programs, good ethics do not preclude the use of adenoviruses to develop COVID-19 vaccines. Human cell lines engineered for RD adenovirus production that were ethically uncontroversial, established from amniocentesis cells have been available for more than a decade (4,5).

Adherence to the highest ethical standards in science and medicine serves all humanity, because it values the dignity of every human life and respects the consciences of all, without exploitation of any group.

Ethical Assessment of SARS-CoV-2 (CoV-19) Vaccine Candidates –
Updated 19 June 2020

Unethical CoV-19 Vaccine Programs				
Sponsor(s)	**Country**	**Strategy**	**Clinical Trial Status**	**Public Funding**
CanSino Biologics, Inc. Institute of Biotech., Acad. Military Med. Sciences	China	Adenovirus vaccine "Ad5-nCoV"[2] HEK293 cells	NCT04313127 NCT04341389	
University of Oxford Astrazeneca	USA UK	Adenovirus vaccine "AZD1222" "ChAdOX1nCoV-19" HEK293 cells	NCT04324606 NCT04400838	HHS-BARDA[3] $1.2 billion[4]
Janssen Res. & Devel., Inc. Johnson & Johnson	USA	Adenovirus vaccine "Ad26" PER.C6 cells	NLF[5]	HHS-BARDA $456,237,081[4]
Univ. of Pittsburgh	USA	Adenovirus expressed recombinant proteins "PittCoVacc" HEK293 cells	Pre-clinical	
Altimmune	USA	Adenovirus vaccine "AdCOVID" (RD-Ad5) PER.C6 cells	NLF	
Ethically Uncontroversial CoV-19 Vaccine Programs				
Shenzhen Geno-immune Medical Institute	China	Lentivirus minigenes + Adult human APC[6] cells	NCT04299724	

Shenzhen Geno-immune Medical Institute	China	Lentivirus minigenes + Adult human CD/T[7] cells "LV-SMENP-DC"	NCT04276896	
Symvivo Corporation	Canada	Oral bacterium *B. longum,* "bacTRL-spike"	NCT04334980	
Moderna, Inc. with National Institutes of Health	USA	RNA vaccine "mRNA-1273"	NCT04283461 NCT04405076	HHS-BARDA $430,298,520[4]
Inovio Pharmaceuticals	USA	DNA vaccine "INO-4800"	NCT04336410	
Inovio Pharmaceuticals Korea Natl. Inst. of Health	So. Korea	DNA vaccine "INO-4800"		CEPI[8] $6,900,000[9]
Protein Sciences-Sanofi Co.	USA	Protein vaccine Baculovirus expression	Pre-clinical	HHS-BARDA $30,775,336[4]
John Paul II Medical Research Institute	USA	Recombinant Protein Perinatal human cells[10]	NLF	
John Paul II Medical Research Institute	USA	Live attenuated virus Perinatal human cells	NLF	
Sanofi & Translate Bio	USA	RNA vaccine	Pre-clinical	
Sinovac Biotech Co., Ltd.	China	Inactivated CoV-19 "PiCoVacc" Vero monkey cells	NCT04352608 NCT04383574	
Pfizer and BioNTech	USA Germany	RNA vaccine "BNT-162a1,b1,b2,c2"	NCT04368728 NCT04380701	
Novavax	USA	Protein vaccine "NVX-CoV2373" Sf9 insect cells	NCT04368988	
Sorrento	USA	CoV-19 spike protein Expressed on K562 cells		
Arcturus Therapeutics	USA	RNA vaccine	Pre-clinical	
CureVac	Germany	RNA vaccine	Pre-clinical	CEPI $34 million[11]
Merck/IAVI	USA	Replication-competent recombinant vesicular stomatitis virus (VSVΔG) Vero monkey cells	Pre-clinical	HHS-BARDA $38,033,5704[4]

Table 1 legend

[1] National Institutes of Health, National Library of Science NCT number for clinical trials listed on U.S. clinicaltrials.gov

[2] Manufactured by CanSino Biologics, Inc.

[3] HHS-BARDA, U.S. Health and Human Services-Biomedical Advanced Research and Development Authority

[4] BARDA's rapidly-expanding COVID-19 medical countermeasure portfolio. 2020. https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx.

[5] NLF, no registration listing found

[6] APC, antigen-presenting cells

[7] DC/T, dendritic cells and T cells

[8] CEPI, Coalition of Epidemic Preparedness Innovations

[9] Weil, D. 2020. Inovio gets $6.9M in funding for South Korea coronavirus vaccine trial. *The Street*. https://www.thestreet.com/investing/inovio-funding-coronavirus-vaccine-trial

[10] Donor-consented human umbilical cord and placental cells

[11] Christodoulou, M. 2020. CEPI awards US $34million contract to CureVac to advance The RNA Printer™—a mRNA vaccine platform that can rapidly combat multiple diseases. *CEPI News*. https://cepi.net/news_cepi/cepi-awards-contract-to-curevac-to-advance-the-rna-printer-a-mrna-vaccine-platform-that-can-rapidly-combat-multiple-diseases/

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