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An Ethics Assessment of COVID-19 Vaccine Programs

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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).

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 16 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 (3,4). Several commonly used human cell lines developed for this function were established from cells taken from electively aborted human fetuses (3).

The use of cells from electively aborted fetuses for vaccine production makes these five COVID-19 vaccine programs unethical, because they exploit the innocent human beings who were aborted. 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. (5) 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 (6). Funding of new research using abortion-derived cells established prior to the new HHS rule (i.e., HEK293, Per.C6) was allowed to continue.

Ten of the 16 COVID-19 vaccine programs identified in Table 1 underscore the many alternative strategies available and useful for COVID-19 vaccine development that pose no ethics trespasses. In total, the U.S. government has invested another nearly half billion dollars to support two of these vaccine programs (Table 1, B4, B7). For an 11th vaccine program, at this time, it is indeterminate whether cells

derived from electively aborted human fetuses are used (Table 1, C). Although RD adenovirus strategies are not among the current ethical 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 established from amniocentesis cells have been available for more than a decade (3,4).

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.

Table 1. Active SARS-CoV-2 (CoV-19) Vaccine Clinical Trials

Sponsor(s)	Country	Strategy	Clinical Trial Status[1]	Public Funding
A. Unethical CoV-19 vaccine programs				
1. CanSino Biologics, Inc.	China	Adenovirus vaccine "AdV5-nCoV" [HEK293 cells][3]	NCT04313127	N.A.[2]
2. Institute of Biotech. Acad. Military Med. Sciences	China	Adenovirus vaccine "AdV5-nCoV" [HEK293 cells][3,4]	NCT04341389	N.A.
3. University of Oxford	UK	Adenovirus vaccine "ChAdOX1nCoV-19" In HEK293 cells	NCT04324606	N.A.
4. Janssen Res. & Devel., Inc.	USA	Adenovirus vaccine "Ad26" in Per.C6 cells	NLF[5]	HHS-BARDA[6] $456,237,081[7]
5. Univ. of Pittsburgh	USA	Adenovirus expressed Recombinant proteins In HEK293 cells	Pre-clinical	N.A.
B. Ethical alternative CoV-19 vaccine programs				
1. Shenzhen Geno-immune Medical Institute	China	Lentivirus minigenes + Adult human APC[8] cells	NCT04299724	N.A.
2. Shenzhen Geno-immune Medical Institute	China	Lentivirus minigenes + Adult human DC/T[9] cells	NCT04276896	N.A.
3. Symvivo Corporation	Canada	Oral bacterium *B. longum*, "bacTRL-spike"	NCT04334980	N.A.
4. National Institutes of Health NIAID with Moderna, Inc.	USA	RNA vaccine "mRNA-1273"	NCT04283461	HHS-BARDA $430,298,520[7]
5. Inovio Pharmaceuticals	USA	DNA vaccine "INO-4800"	NCT04336410	N.A.
6. Inovio Pharmaceuticals Korea Natl. Inst. Health	So. Korea	DNA vaccine "INO-4800"	NLF	CEPI[10] $6,900,000[11]

7. Protein Sciences – Sanofi Co.	USA	Protein vaccine Baculovirus expression	NLF	HHS-BARDA $30,775,336[7]
8. John Paul II Medical Res. Inst.	USA	Recombinant protein Perinatal human cells[12]	NLF	N.A.
9. John Paul II Medical Res. Inst.	USA	Live attenuated virus Perinatal human cells	NLF	N.A.
10. Sanofi & Translate Bio	USA	RNA vaccine	Pre-clinical	N.A.
C. Indeterminate ethical status				
Sinovac Biotech Co., Ltd.	China	Inactivated CoV-19 Production Cell Source?	NCT04352608	N.A.

Table 1 legend
1, National Institutes of Health, National Library of Science NCT number for clinical trials listed on U.S. clinicaltrials.gov
2, N.A., not applicable
3, Replication defective (RD) adenovirus vaccines are generally produced in one of several human cell lines derived from the cells of electively aborted human fetuses (*e.g.*, HEK293 and PER.C6; ref. 2). The specific line utilized was not discernible from identified public reports. Based on cells used for earlier RD adenovirus vaccines developed, HEK293 cells are the most likely line used.
4, Manufactured by CanSino Biologics, Inc.
5, NLF, no registration listing found
6, HHS-BARDA, U.S. Health and Human Services-Biomedical Advanced Research and Development Authority
7, Ref. 7
8, APC, antigen-presenting cells
9, DC/T, dendritic cells and T cells
10, CEPI, Coalition of Epidemic Preparedness Innovations
11, Ref. 8
12, Donor-consented human umbilical cord and placental cells

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