4 August 2020

The Hon Scott Morrison MP
Prime Minister
Parliament House
CANBERRA ACT 2600

Dear Prime Minister,

Re: Medical and Moral Concerns Regarding the Development of COVID-19 Vaccines

The Australian Catholic Medical Association is a national body created to provide support and a voice for Catholic doctors. We write to express our concern to you about two issues pertaining to the development of COVID-19 vaccines:

1. Opposition in principle to the development of vaccines utilizing aborted fetal cell lines; and
2. The need for the community to have confidence in the process of 'fast-tracked' vaccine development.

The purpose of this letter is to inform you of our concerns regarding these issues, which are supported by a number of key individuals and groups whose names appear at the end of the letter, and to make recommendations to you that we believe will best address our concerns.

There are many persons and families across many faith traditions who would not access vaccines developed with the use of aborted fetal cell lines. This will be problematic if the vaccine becomes mandatory. If there is no ethically derived COVID-19 vaccine, we expect there will be a portion of the community who will have concerns that may lead to reduced population coverage at a time when coverage is critical.

To be clear, we do not oppose the development of a vaccine, but believe that the issue of vaccine selection and choice is important both medically and morally. It is something which the government of a tolerant and diverse society should support and address now, so as to ensure that good decisions are made, and that there is sensible public discussion.

Vaccines utilizing aborted fetal cell lines

The present viral pandemic caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) has stimulated a surge in vaccine research to curb the COVID 19 toll on human life and on the health systems of the world.

For a vaccine to be effective in a given community a level of population coverage must be reached. The speed of pandemic spread and the haste to find a safe and effective vaccine that is acceptable to as many persons as possible has understandably led to fast tracking of the usual vaccine development processes. The World Health Organization's 'Landscape Document' presents potential vaccine candidate research.[1] What is apparent from these WHO documents is that of over 120 vaccine candidates in development, just over 20 have progressed to clinical trials. Out of those, eight vaccines including four frontrunners use aborted fetal cell lines.

As noted above, within our Australian community, many people may find a vaccine derived from aborted fetuses to be morally unacceptable. Certainly, the Catholic Church holds that the use of fetal cell lines gives rise to various ethical problems with regard to cooperation in evil and with regard to scandal, and the Church imposes a duty on Catholics to make known their disagreement and to ask that their healthcare system make other types of vaccines available.

Unfortunately, it is those vaccines which utilize fetal cell lines which have progressed to reach Phase 2 and Phase 2b/3 stages of clinical trial. The details of the four leading candidate vaccines using aborted fetal cell lines are set out below:

i. AstraZenica/Oxford University, using a non-replicating viral vector; and derived aborted girl's kidney cell line HEK-293. [ChAdOx1 with Astra Zeneca AZD 1222; Patent US 20150044766 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5516308/].

ii. CanSino Biological Inc./Beijing Institute of Biotechnology, vaccine candidate Ad5-nCoV using a non-replicating viral vector; derived from same baby girl's cell line HEK-293 previously developed [http://www.jshealth.com/jgzn/zzjg/ymlcpjs/ymlcpjs_gzdt/201612/W020161214426550507006.pdf. P 25. (Based on Ebola Vaccine platform).

iii. Moderna/NIAID, using mRNA and fetal cell line HEK- 293. [U.S. Patent Number 9149506: http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=2&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=62&f=G&l=50&co1=AND&d=PTXT&s1=moderna&OS=moderna&RS=moderna]

iv. Inovio Pharmaceuticals, using DNA and fetal cell line HEK-293. [Patent number 10548971 http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrch-num.htm&r=1&f=G&l=50&s1=10,548,971.PN.&OS=PN/10,548,971&RS=PN/10,548,971].

Potential vaccines being progressed by President Trump's Administration are derived from the kidney of a female fetus aborted in 1972, and the retina of an 18-week male fetus aborted in 1985 and converted to a cell line in 1995.

Whilst fetal cell lines are perceived to have advantages in growing viral vector vaccines because they are not contaminated by significant viruses and bacteria, many pharmaceutical companies with vaccine candidates in the pipeline do not use aborted fetal cells. Ethically acceptable vaccine candidates are being researched and trialed by Sanofi Pasteur, GlaxoSmithKline, Novavax, and Sinovac (ethically grown in monkey kidney cells), the latter two being among those which have progressed to the clinical trial stage.

It is these vaccine candidates which should be supported as they are *prima facie* acceptable to the faithful and those who respect human life from conception.

Vaccine developmental and reproductive safety

Notwithstanding that safe effective vaccines against COVID -19 are a clear and pressing need, pre-clinical vaccine studies must continue to observe normal research standards. These include adhering to toxicology guidelines[2] which require histological examination of animal organs including gonads; and appropriate fertility, fecundity and embryological observation.

This rigor and scrutiny in pre-clinical and clinical trials is particularly important since the COVID-19 candidate vaccine method of using DNA and mRNA is new, and no such vaccine methods have previously been approved for use. Of concern is that the fast tracking of vaccine development increases the chance of mistakes. Should these guidelines by bypassed or truncated, it could potentially undermine public vaccine confidence and reduce community uptake.

The recent scandal in the *Lancet* demonstrates that mistakes can be made. Despite peer review, editorial oversight and WHO acceptance, the *Lancet* had to retract a published study of a COVID-19 drug which was later shown to have used poor and secretive methodology, false data, incorrect statistical analysis, incorrect dosaging, the absence of an ethics review, a failure to adjust for confounders, and the use of confidence intervals inconsistent with the data.

Whilst this is a separate issue to that of opposition to a vaccine utilizing fetal cell lines, it is consistent with our call that there be transparency in the development of a vaccine that we may all be asked/required to receive. The community has a right to information about this important issue, notwithstanding that time is of the essence.

Recommendations

As seven billion persons worldwide may seek vaccination, manufacturing and production logistics support vaccine production by multiple companies.

Our three recommendations are as follows:

1. That in the spirit of respecting the diversity of beliefs of faith groups, the government acknowledge that a portion of the community opposes a COVID-19 vaccine that uses aborted fetal cell lines and that this is not an irrational concern. It is a genuine concern for many people, most especially for Catholics.
2. That in acknowledging this concern, the government use its powers to ensure that there be at least one vaccine available to the public that does not use fetal cell lines so as to ensure maximum community acceptance and coverage. Such vaccines include:
    a. The more developed, ethically formulated ‘Sinovac’ inactivated vaccine entering phase three clinical trials (NCT04456595);
    b. Novavax glucoprotein nanoparticle vaccine currently in phase one/two trials (NCT04368988); and
    c. The Sanofi Pasteur/GSK S Protein vaccine currently in pre-clinical trials.

3. That the government ensure that the selection and availability of COVID-19 vaccines demonstrate transparency in safety research and adhere to existing toxicology guidelines, and that you make this information available to the public.

We understand there are a number of community organizations that will be collecting signatures from people supporting the views contained within this letter.

Conclusion

The common good requires respect for the concerns for all members of our society, including people who respect life from the moment of conception. Thank you for taking the time to read this letter and hear our concerns. We would be pleased to meet with you at your convenience to discuss any of these issues further and we look forward to your early response.

Yours faithfully,

Dr Eamonn Mathieson, President, Australian Catholic Medical Association

This letter is endorsed by:

Mrs Kate Mathai, National President, Catholic Women's League Australia Incorporated
Mr Paul Hanrahan, Executive Director, Family Life International Australia
Professor Gerald Fogarty, Patron, Solidarity for Healthcare

References:

1. WHO Landscape Document. 2020; https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines.
2. Guidance for Industry: Considerations for Developmental Toxicity Studies for Prevention and Therapeutic Vaccines for Infectious Disease Indications. Center for Biologics Evaluation and Research February 2006.
3. Mehra MR, Desai SS, Ruschitzka F, Patel AN. RETRACTED: Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis. *Lancet (London, England).* 2020.

Cc. The Hon Greg Hunt MP

Minister for Health

cc. The Hon Mark Coulton MP

Minister for Regional Health, Regional Communications and Local Government

cc. Professor Paul Kelly

Acting Chief Medical Officer

Department of Health