

# COVID-19 Vaccination and the Fetal Cell Line Conundrum for Employee Religious Objections

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The Novavax COVID-19 vaccine recently received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) for individuals 18 and older, making Novavax the fourth COVID-19 vaccine to receive either authorization or full approval from the FDA.

This vaccine has been used in many other countries since November 2021 and is currently being used to mitigate the impacts of the SARS-CoV-2 virus in more than 40 countries globally.

The Novavax vaccine's introduction in the United States brings with it the question of whether and how the vaccine will impact religious exemptions. The use of fetal cell lines in some aspects of the development, manufacture, production, or testing of earlier authorized or approved COVID-19 vaccines has led many to seek and obtain religious exemptions from federal, state, and employer mandates.[1] However, Novavax materials state that “[n]o human fetal-derived cell lines or tissue, including HEK293 cells, are used in the development, manufacture or production of the Novavax COVID-19 vaccine candidate, NVX-CoV2373.”[2]

This *Insight* evaluates how the FDA's EUA for Novavax's COVID-19 vaccine may influence religious objector attitudes toward vaccination and clarifies disputed claims over whether fetal cell lines were used in the testing of the Novavax vaccine.

## Background: The Use of Immortalized Fetal Cell Lines

Briefly, several immortalized cell lines have been developed over time from donated embryonic tissue, some of which was derived from elective abortion procedures. Two of the most common

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immortalized cell lines are HEK293 and PER.C6. HEK293 cells were derived from embryonic kidney cells donated to researchers nearly half a century ago,[3] in 1973; PER.C6 cells were derived from embryonic retinal cells donated to researchers nearly four decades ago, in 1985.

After several decades of widespread research use, both HEK293 and PER.C6 cell lines are of distant embryonic origin and not at all representative of the primary tissue originally donated to researchers.[4] For these reasons, no vaccine developed using these tools contains any parts of primary embryonic tissue or human DNA, even if these cellular tools were used by some manufacturers in their development or manufacturing processes. It should be noted that these same cell lines have been used to test many popular medicines, such as acetaminophen, ibuprofen, and aspirin, and are used for treatment research in diseases such as Alzheimer's and hypertension.[5] Nevertheless, the distant association of the fetal cell lines with abortion gives pause to many religious objectors.

## Clarification for the Novavax Vaccine

The Novavax vaccine differs from the other COVID-19 vaccines in that HEK293 and PER.C6 cell lines were not used in any stage of its development, manufacturing, production, or testing. These differences should ameliorate the concerns around vaccination against COVID-19 commonly expressed by individuals seeking religious exemptions.

As indicated above, Novavax has stated outright that it has not used any of the immortalized fetal-cell lines at any stage—development, manufacturing, or testing. Nonetheless, some have raised religious objections to the Novavax[6] vaccine based on the use of these cell lines. Most notably, those questioning Novavax's claims regarding the use of fetal-derived cell lines highlight a single study (the "Study") [7] that they believe refers to the use of HEK293 cells in testing Novavax's COVID-19 vaccine. Novavax has stated that the Study, along with its reference to HEK293 cells, is "based on well-established scientific knowledge, did not include our vaccine protein, and is completely independent of Novavax COVID-19 vaccine development." [8]

Researchers in an article titled "COVID-19 Vaccination: Guidance for Ethical, Informed Consent in a National Context" have also suggested that Novavax "utilized aborted fetal cell lines during testing." [13] A reference for this assertion was not provided in the article. When contacted, the authors provided a study as their source. The study included Novavax's Senior Director of Vaccine Development and two other Novavax employees as authors, despite not being sponsored by Novavax. [14] The researchers used HEK293 cells to mimic the interactions between SARS-CoV-2 viruses and human cells and then tested whether antibodies from vaccinated monkeys were able to disrupt these interactions. [15] Crucially, as above, the SARS-CoV-2 spike protein expressed in these HEK293 cells is different from Novavax's vaccine product. This study, like the Study above,

does not appear to undermine Novavax's statement that no human fetal-derived cell lines or tissue, including HEK293 cells, were used in the development, manufacture, or production of the Novavax COVID-19 vaccine.

Novavax's EUA and supporting evidence should provide sufficient information for religious objectors to obtain the Novavax COVID-19 vaccine. Given the support for the assertion that human fetal-derived cell lines or tissue were not used in the development, manufacture, production, or testing of the Novavax COVID-19 vaccine, employers may see a reduction in the number of religious objections and requests for accommodation from vaccine mandates that they are receiving. However, we anticipate that some individuals who have objected to receiving the COVID-19 vaccine on religious grounds will continue to do so.<sup>[16]</sup> The evidence would also seem to present a sound factual basis for employers to question the need for such a religious accommodation.

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*This Insight was authored by **Richard H. Hughes IV** and **Arthur J. Fried**. For additional information about the issues discussed in this Insight, please contact one of the authors or the Epstein Becker Green **Health Care and Life Sciences** attorney who regularly handles your legal matters.*

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## ENDNOTES

[1] Priyanka Runwal, "Here are the facts about fetal cell lines and COVID-19 vaccines, Science: Coronavirus Coverage," *National Geographic* (November 29, 2021), available at <https://www.nationalgeographic.com/science/article/here-are-the-facts-about-fetal-cell-lines-and-covid-19-vaccines>.

[2] Alexander Tin, "FDA authorizes Novavax as new alternative to mRNA COVID-19 vaccines," *CBS* (July 13, 2022), available at <https://www.cbsnews.com/news/novavax-fda-authorizes-mrna-alternative-covid-19-vaccines/>.

[3] Runwal, *supra* note 1.

[4] ImmunizeBC, "Are human fetal cells used to make vaccines" (February 1, 2022), available at <https://immunizebc.ca/ask-us/questions/are-human-fetal-cells-used-make-vaccines-0>.

[5] Runwal, *supra* note 1.

[6] Australian Catholic Bishops Conference, "FAQs and Guidance for the Catholic community in Australia regarding a COVID-19 vaccine" (April 2021), *available at* [https://adelaide.catholic.org.au/\\_files/f/55450/FAQs%20and%20Guidance%20on%20COVID-19%20Vaccination.pdf](https://adelaide.catholic.org.au/_files/f/55450/FAQs%20and%20Guidance%20on%20COVID-19%20Vaccination.pdf).

[7] Bangaru et al., *Structural analysis of full-length SARS-CoV-2 spike protein from an advanced vaccine candidate*," 370 *Science* 1089 (2020), *available at* <https://www.science.org/doi/10.1126/science.abe1502>.

[8] Jack Jenkins, "Could Novavax win over some religious vaccine skeptics," *The Washington Post* (February 24, 2022), *available at* <https://www.washingtonpost.com/religion/2022/02/24/novavax-covid-vaccine-religious/>.

[9] Bangaru, *supra* note 7.

[10] *Id.*

[11] *Id.*

[12] Thomas F. Rogers et al., "Supplementary Materials for Isolation of potent SARS-CoV-2 neutralizing antibodies and protection from disease in a small animal model," *Science* (June 15, 2020), *available at* [https://www.science.org/action/downloadSupplement?doi=10.1126%2Fscience.abc7520&file=abc7520\\_rogers\\_sm.pdf](https://www.science.org/action/downloadSupplement?doi=10.1126%2Fscience.abc7520&file=abc7520_rogers_sm.pdf).

[13] Deirdre T. Little et al., "COVID-19 Vaccination: Guidance for Ethical, Informed Consent in a National Context," 36 *Issues L. & Med.* 127, 151 (2021), *available at* <https://heinonline.org/HOL/PDFsearchable?handle=hein.journals/ilmed36&collection=journals&section=14&id=&print=section&sectioncount=1&ext=.pdf&nocover=&display=0>.

[14] Matthew J. Gorman et al., "Fab and Fc contribute to maximal protection against SARS-CoV-2 following NVX-CoV2373 subunit vaccine with Matrix-M vaccination," 2 *Cell Reports Medicine* e3 (2021), *available at* <https://www.sciencedirect.com/science/article/pii/S2666379121002639>.

[15] *Id.*

[16] The benefits that potentially could come from the EUA of the Novavax COVID-19 vaccine is not a recommendation or endorsement by Epstein Becker Green of the Novavax vaccine over the Pfizer, Moderna, or Johnson & Johnson vaccine. Individuals should consult with medical providers regarding which vaccine option is right for them.