



Department of Health and Social Services

OFFICE OF THE COMMISSIONER

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February 1, 2022

The Honorable Lora Reinbold Alaska State Senate 1500 W. Benson Blvd Suite 210 Anchorage, AK 99503

Dear Senator Reinbold:

This letter – one of several that have been responsive to your public records requests – responds to questions and information you requested from the Department of Health & Social Services (DHSS) in a letter received on December 22, 2021, addressed to Dr. Anne Zink. Questions have been answered in the order in which you requested. For further information, please direct your public record request to the identified federal government agency.

1. Provide all available clinical evidence of the isolated COVID-19 virus and each known variant and the methods by which these variants have been identified and isolated.

Science and clinical evidence continue to evolve and a sample of the clinical evidence is available in the summary from DHSS on Variants and can be found online on the COVID-19 Cases Dashboard. It is under tab, "COVID-19 Variants,"

https://experience.arcgis.com/experience/af2efc8bffbf4cdc83c2d1a134354074/

2. Provide all available clinical evidence that masks have been successful in preventing the spread of COVID-19 including which masks have been the most effective at preventing the spread of COVID-19. In addition, provide the means by which this evidence was confirmed, along with all available information provided by the mask manufacturers concerning the use of masks for this purpose.

Science and clinical evidence continue to evolve. The Department of Health and Social Services has relied on the evidence provided by many resources and looked extensively at the primary data. A good summary of the data can be found at the Centers for Disease Control and Prevention.

a. Types of masks and respirators <u>https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html</u>

- b. Science Brief: Community Use of Masks to Control the Spread of SARS-CoV-2 https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/masking-science-sars-cov2.html
- 3. Provide all available clinical evidence that proves "social distancing" has been effective at stopping the spread of COVID-19 and the sources of clinical evidence.

Science and clinical evidence continue to evolve. Social distancing has shown to slow the transmission of airborne viruses. When a person becomes ill with an airborne virus, staying away from others is a basic public health response. That is true for coronaviruses such as the common cold, influenza, tuberculosis, and COVID-19; when those who are ill exercise a degree of distance, the opportunity for the transmission of the virus is mitigated. Here is one such study Quantifying the Effects of Social Distancing on the Spread of COVID-19

https://pubmed.ncbi.nlm.nih.gov/34071047/.

4. Provide all available clinical evidence that COVID-19 "vaccines" are in fact, true traditional vaccines that provide immunity, and no experimental mRNA gene therapy technology.

Science and clinical evidence continue to evolve. The two available classes of COVID-19 vaccines authorized in the United States are mRNA vaccines which include Pfizer and Moderna, and a one viral-vectored vaccine from J&J Janssen. None of the three vaccines are considered gene therapy because they do not alter or modify the expression of a gene or alter the biologic properties of living cells. Evidence can be reviewed at the following links:

https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/viralvector.html

5. Provide all available clinical evidence that COVID-19 "vaccines" are effective at preventing COVID-19 infection and which have been proven to be most effective.

Science and clinical evidence continue to evolve. Vaccines reduce the risk of COVID-19, including the risk of severe illness hospitalization and death among people who are up to date on their vaccines. In addition to data from clinical trials, real-world case evidence, including here in Alaska, show that COVID-19 vaccines help protect against COVID-19 infections. While COVID-19 vaccines have shown a decreased efficacy of preventing infection via delta or omicron variants, vaccine effectiveness against hospitalizations has remained relatively high over time, although it tends to be slightly lower for older adults and for people with weakened immune systems. This can be found at the following site:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/how-they-work.html

A monthly summary of Alaska data can be found here:

https://dhss.alaska.gov/dph/epi/id/siteassets/pages/HumanCoV/COVID_monthly_update.pdf

6. Provide all available clinical evidence that COVID-19 "vaccines" are effective at preventing the spread of COVID-19 and which vaccines have proven to be most effective at preventing the spread of COVID-19, along with all supporting clinical reports.

Senator Reinbold COVID letter response February 1, 2021

Science and clinical evidence continue to evolve. This link is to a science brief with many studies around vaccines and efficacy including prevention of COVID-19 spread, particularly with the ancestral strain and alpha variant.

https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html

The second link is a science brief on the Omicron variant. The department is still collecting efficacy data around vaccines and this current variant, but preliminary data shows that the COVID-19 vaccines may provide less protection against infection than prior variants, but still maintain a high efficacy of preventing severe illness, hospitalization and death.

https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/scientific-brief-omicron-variant.html

In keeping with the evolving science and recognizing the real-time data, DHSS has worked to remove messaging that COVID-19 vaccines prevent infection, as the primary benefit is the protection against severe illness, hospitalization and death.

7. Provide all available clinical evidence that COVID-19 "vaccines" have proven to be safe for human use, backed by clinical data concerning related illness, adverse events, and deaths, which have followed the use of the vaccines, and which vaccines have been the least safe, according to all available clinical evidence, including all related mammalian trials.

Science and clinical evidence continue to evolve. DHSS does not independently analyze vaccines; the FDA assumes authority over analyzing the efficacy and safety of vaccines as well as accepts federal responsibility. Here are links discussing vaccine safety and monitoring. These include descriptions on both active and passive systems used for adverse event surveillance.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safetysurveillance https://www.fda.gov/consumers/consumer-updates/learn-more-about-covid-19-vaccines-fda

8. Provide a detailed list of all ingredients in the COVID-19 "vaccines" currently in use, broken out by each vaccine manufacturer and each vaccine dose and batch, as produced by each manufacturer. Here are links to ingredients of each of the three vaccines authorized in the US.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Moderna.html https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html

9. Provide all available clinical evidence of known adverse events associated with each COVID-19 "vaccine" currently in use, separate by manufacturer, dose and batch, taking into account all available adverse event reporting systems, both within the USA and all foreign clinical COVID-19 event tracking and reporting systems.

Science and clinical evidence continue to evolve. Please see the following links for the requested clinical evidence.

https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safetysurveillance

https://www.fda.gov/consumers/consumer-updates/learn-more-about-covid-19-vaccines-fda https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

10. Provide all available evidence as it pertains to all current COVID-10 "vaccines" in use in the USA today, that each is in fact fully FDA approved for broad public use, and not just FDA authorized for emergency use only.

Currently, the only COVID-19 vaccine with full FDA approval is the Pfizer (Comirnaty) for ages 16 and older. The FDA granted full approval for Comirnaty on August 23, 2021. Pfizer COVID-19 vaccine is under Emergency Use Authorization for ages 5-16.

https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna

11. Provide all available clinical evidence that any "emergency" exists to justify "emergency use only" FDA status.

Science and clinical evidence continue to evolve. The link provided is on the Emergency Use Authorization (EUA) process as well as pertinent Public Health Acts. Under an EUA the FDA maintains its strict standards but makes decisions more quickly. An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. For an EUA to be issued for a vaccine, for which there is adequate manufacturing information to ensure quality and consistency, FDA must determine that the known and potential benefits outweigh the known and potential risks of the vaccine.

https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policyframework/emergency-use-authorization

12. Please provide that clinical information on which batches or lots of the COVID-19 "vaccine" carry which sequence of RNA or DNA.

A spike protein (also called S protein) is a protein on the surface of the SARS-CoV-2 virus that can recognize and bind to human cells. This binding interaction enables the virus to enter human cells and cause disease. Vaccines work, in part, by stimulating the production of antibodies that target the spike protein. Vaccines have utilized either mRNA or an adenovirus vector to direct human cells to produce the spike protein against which the body produces neutralizing antibodies.

Pfizer and Moderna use mRNA and J&J use DNA to encode the spike protein. (Please see links for question 4 as reference on how both mRNA and viral-vector vaccines work.) Please contact the manufacturer if you have specific questions around a specific vaccine lot.

13. Provide all clinical information and documentation on long-term effects to include side effects of all mRNA vaccinations for COVID-19.

Science and clinical evidence continue to evolve. Going back at least as far as the polio vaccine, which was widely released to the public in the 1960s, there has not been a vaccination with long-term side effects, side

Senator Reinbold COVID letter response February 1, 2021

effects that occur several months or years after injection. In every vaccine available, side effects, including rare but serious side effects, develop within six to eight weeks of injection.

The mRNA vaccine encodes only for the spike protein found on the surface of the virus. The spike protein is harmless by itself. Once the body creates that spike protein using the mRNA instructions, the body quickly breaks down those mRNA strands and they dissipate within a few hours or days after injection. The mRNA never enters the nucleus of any cell (where the DNA is located), it doesn't affect any genetic material in the body, and the mRNA strands are removed from the body through everyday cellular processes.

Similar to the mRNA vaccines, with the viral vectored vaccines the body receives genetic instructions for how to build the harmless spike protein of the SARS-CoV-2 virus, then it begins building an immune response and producing antibodies against COVID-19. Viral vector vaccines have been studied since the 1970s and recently were used to respond to Ebola outbreaks. Human clinical trials have tested the technology in vaccines against many viruses. There are robust reporting systems in place to continue monitoring these vaccines.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/reporting-systems.html

A good summary of vaccines, their safety and what we know can be found here: <u>https://www.nature.com/articles/s41577-020-00479-7</u>

Thank you for your patience as we compiled the answers to your questions.

Sincerely,

Adam Crum, Commissioner Department of Health & Social Services

Dr. Anne Zink, Chief Medical Officer Department of Health & Social Services

CC: The Honorable Mike Dunleavy, Governor Randy Ruaro, Chief of Staff, Office of the Governor Vasilios Gialopsos, Director, Governor's Legislative Office The Honorable Peter Micciche, Senate President