Senate Bill 2384
Human Services Committee
February 7th, 2023

Good morning, Chairwoman Lee and members of the Senate Human Services Committee. My name is Kylie Hall. I currently reside in north Fargo in District 45. I feel uniquely qualified to testify on this bill because I have a Master's Degree in Public Health, with an emphasis in the management of infectious diseases. I have spent the last 7.5 years working on vaccine-related projects at North Dakota State University in the Center for Immunization Research and Education, where I am the currently the Operations Director. I would like to make clear that my comments today are not on behalf of North Dakota State University.

Today I would like to spend my testimony discussing the history of mRNA vaccine technology, how mRNA vaccines work, and I would like to address some of the common mRNA vaccine concerns. This important vaccine technology has saved many lives over the last two years, and the technology will continue to be developed to prevent other diseases in the future. There are currently mRNA vaccines in the pipeline for RSV, influenza, Ebola, and many different cancers. It is vital that we have access to this vaccine technology in North Dakota.

History of mRNA vaccine technology:

Today's mRNA vaccine success comes from the decades of research that came before it. mRNA was first discovered in the early 1960s. In 1965, the first liposomes (fatty bubbles – composed of lipid molecules) were produced. Liposomes would eventually be used as a transport vehicle for the mRNA into cells. As far back as 1978, scientists had been using liposomes to transport mRNA into mouse and human cells to create proteins.

But there were many hurdles that scientists encountered along the way to creating mRNA vaccines. Scientists had to figure out how to manufacture genetic material in a laboratory. Production of mRNA and the vaccines was expensive, which made scientific developers hesitant to invest money in this area of research. Scientists also knew mRNA was a very unstable molecule and prone to degradation, so they had to find a way to get the mRNA to last long enough in the body to be "read". It also was known that you couldn't just insert mRNA into a cell; a transporter molecule would be needed. And even if we could get cells to take up the instructions and produce a protein, it needed to be done in a way that would produce an immune response.

From the 1980s through the late 2010s, there were many breakthroughs that eventually led to the creation of effective mRNA vaccines. These breakthroughs came in areas like how lipids work, how to use lipids to form a protective bubble around a medicine so that it can be delivered to cells safely and effectively, how to get the mRNA into cells safely and past the innate immune system, how the spike protein on a coronavirus works, and how to "lock" proteins in a certain configuration for immune system recognition. But even as scientific knowledge continued to evolve in the 1990s and 2000s, nearly every vaccine company working on mRNA opted to invest its resources elsewhere. mRNA was just too hard to work with. Some mRNA work was happening in the cancer space, which ultimately inspired some researchers to invest in the vaccine world. The work of these researchers laid the foundation for two of the mRNA vaccines were are using today.

<u>How mRNA vaccines work:</u>

Before I discuss how mRNA vaccines work, it is important to talk about what mRNA is. And to do that, I need to explain what DNA is, how our cells know how to build proteins, and the role mRNA plays.

What is DNA? DNA (or deoxyribonucleic acid) is the molecule inside cells that contains genetic information responsible for the development and function of an organism. We often think of DNA as a double stranded helix. DNA contains many short sections, called genes. Genes are the instruction manual for your body or for an organism - telling cells how to make proteins that will perform various functions. As humans, we have proteins that form our hair or nails, proteins that attack invading organisms like bacteria or viruses, and proteins that metabolize our food, as just a few examples.

You now know that DNA is the instruction manual, and proteins are the final product. But how do we get from one to the other? The answer is mRNA, and it happens in two phases, called transcription and translation.

During transcription, genes are “rewritten” onto a single-stranded piece of RNA (ribonucleic acid). We call this piece “messenger RNA”, or “mRNA” for short, because it is the molecule that carries genetic information needed to make a protein. The mRNA takes the information out of the nucleus of the cell (where the DNA is) and takes it out into the cell’s cytoplasm.

Once the mRNA is in the cytoplasm, a part of the cell called a ribosome “reads” the message and assembles the protein or a portion of a protein. The assembly stage is called translation. Our cells are constantly taking mRNA from the nucleus and making various proteins to help our bodies stay healthy.

Next, I’d like to talk about how mRNA vaccines work based on what I just told you about how cells make proteins. Scientists are able to determine the entire genome of viruses, including determining which parts of the viral genome code for specific viral proteins. Once we know which part of the genome we need an mRNA copy of, we can actually create the mRNA in the lab. Then that piece of mRNA is surrounded by a liposome (the fatty bubble) so it can be transported into a cell. Once it is in the cell’s cytoplasm, it acts like a regular piece of mRNA. It finds a ribosome, and the ribosome reads the message and assembles a protein or part of a protein. In the case of a viral mRNA vaccine, though, the protein assembled is a viral protein. When the cell presents that protein to the body, the body will recognize it as foreign and create an immune response against it.

In the case of COVID-19 vaccines, the mRNA vaccines code for the spike protein (sometimes called the “S-protein”), which is a protein found on the surface of the coronavirus. This protein helps the virus attach to cells. By giving human cells instructions for how to make this protein and ultimately creating an immune response to it, we hope that when the body sees the virus in the “wild”, the body will remember the protein and quickly activate its memory immune response.

Common mRNA vaccine concerns:

While mRNA vaccines have proven to be very safe, there are many concerns about the mRNA COVID-19 vaccines. I’ll address many of the concerns below.

1) Can mRNA vaccines cause COVID-19?

No. The vaccine does not contain a live virus, so it cannot cause disease.

2) Can mRNA vaccines change your DNA?

No. The mRNA from the vaccine enters the cytoplasm of the cell, but it cannot enter the cell’s nucleus, which is where DNA is located. If it cannot enter the nucleus, it cannot come in contact with DNA.

For mRNA vaccines to alter DNA, a series of impossible occurrences would have to happen. First, the mRNA would need the “secret door code” (called the “nuclear access signal”) to get through the nuclear membrane into the nucleus of a cell. The vaccine does not contain a nuclear access signal. If the mRNA got inside, the challenge you would now face is that RNA and DNA are different genetic “languages”. Going from RNA to DNA would require a reverse transcriptase. Finally, the new DNA molecule would require an integrase molecule to add itself into the host’s DNA. The vaccine contains neither the reverse transcriptase enzyme nor the integrase enzyme.

3) Do we know which ingredients are in the mRNA vaccines?

Yes. Vaccine ingredients are listed in the package inserts. There are four main types of vaccine ingredients in current mRNA vaccines: mRNA, fats (lipids), salts, and sugar.

Pfizer mRNA COVID-19 vaccine package insert: https://www.fda.gov/media/151707/download
Ingredients list: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

Moderna mRNA COVID-19 vaccine package insert:
https://www.fda.gov/media/155675/download
Ingredients list: Messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose.

4) How long does mRNA from the vaccine last in the body? How does the body know to stop making the protein after vaccination?

The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions, usually within a few days. mRNA is very fragile; that's one reason why mRNA vaccines must be so carefully preserved at very low temperatures.

5) How long do spike proteins last in the body?

The Infectious Disease Society of America (IDSA) estimates that the spike proteins that were generated by COVID-19 vaccines last up to a few weeks, like other proteins made by the body. The immune system quickly identifies, attacks and destroys the spike proteins because it recognizes them as not part of you.

Some have expressed concern that the spike protein or other parts of the mRNA vaccines build up in the body. There is no evidence that any mRNA or protein accumulates in any organ.

6) Does mRNA travel to other parts of the body other than just the injection site?

Vaccines mostly remain near the site of injection (the arm muscle) and local lymph nodes. This makes sense, and finding pieces of spike protein (from the vaccine) in the lymph nodes is completely normal, because lymph nodes act as the trash removal service for the body. That means the vaccine did its job (made spike proteins, which caused the creation of antibodies) and will be cleared from the body.

Here's a peer-reviewed study that shows where intramuscular vaccines (which the mRNA COVID-19 vaccines are) travel in macaques (a type of monkey). Another peer-reviewed study tested exactly where an mRNA vaccine went in mice. Most of the mRNA vaccine stayed in the injection site muscle – where you get the shot. A lot of mRNA vaccine was found in local lymph nodes, which peaked about eight hours after the shot was given. A much smaller amount of mRNA vaccine went to farther away lymph nodes.

7) Is the mRNA technology too new?

As previously stated in my testimony, work on mRNA vaccine technology had been going on for decades. The mRNA vaccine technology had never been approved by the FDA before. It's not because the past mRNA vaccines (for cancer, allergies, and SARS) have been deemed unsafe. It was because past mRNA vaccines weren't effective. mRNA breaks down very quickly, so it needs to be transported into the cell by something. Finding that something has been a challenge. For COVID-19, scientists found that fat bubbles worked great. Also, vaccine development for two viruses very close to SARS-CoV-2 (SARS and MERS) helped bring the mRNA vaccine development to its present-day use.

8) Can mRNA COVID-19 vaccines cause infertility?

There is no evidence to suggest that COVID-19 vaccines cause infertility. The American College of Obstetricians and Gynecologists (ACOG), the American Society for Reproductive Medicine (ASRM), and the Society for Maternal-Fetal Medicine (SMFM) have issued a joint statement to address this claim: "While fertility was not specifically studied in clinical trials of the vaccine, *no* *loss of fertility has been reported among trial participants or among the millions who have received the vaccines since they were authorized, and no signs of infertility appeared in animal studies.*"

In 2022, a study found that the administration of COVID-19 mRNA vaccines was not associated with adverse effect on stimulation or early pregnancy outcomes after IVF. You can read the press release here.

9) Should I be worried about mRNA from the vaccine?
The mRNA vaccine alone cannot cause disease; it can only provide your cells with a set of instructions for how to make a protein. With the vaccine, you are only exposed to the mRNA for the S-protein. If you are infected with SARS-CoV-2 (the virus that causes COVID-19), you will be exposed to all of the virus's mRNA at significantly higher levels than any vaccine.

Many North Dakotans have relied on this vaccine technology to protect them from COVID-19. Over half of North Dakotans have received their primary COVID-19 vaccine series, and more than 75% of adults 65 years of age and older have been vaccinated.

In the future, North Dakotans will continue to rely on this technology to protect them against COVID and potentially other infectious diseases and cancers.

Please vote "do not pass" on Senate Bill 2384.

Respectfully submitted,

Kylie Hall, MPH
Fargo, ND – District 45