NATIONAL CITIZENS INQUIRY

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EVIDENCE

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Wayne Lenhardt
Good afternoon. Our next presenter is Deanna McLeod. She's been on a couple of times before as an expert. Deanna, if you could give us your full name again and spell it for us and do the oath again, please.

Deanna McLeod
My name is Deanna McLeod, that's D-E-A-N-N-A, McLeod M-C-L-E-O-D.

Wayne Lenhardt
And do you promise that the evidence you give today is the truth, the whole truth, and nothing but the truth.

Deanna McLeod
Yes, I do.

Wayne Lenhardt
Thank you. I think I'm just going to let you launch into your presentation [Presentation exhibit number unavailable], but I gather that this time you're going to be talking about some of the Pfizer data, the six-month reports and the two-month reports, and then you're going to do some analysis for us.

Deanna McLeod
That's right.

Wayne Lenhardt
Okay, take it away.

Deanna McLeod
Thank you very much for having me today. My name is Deanna McLeod and I am the principal and founder of a medical research firm called Kaleidoscope Strategic. I've worked for about a decade in industry in many roles in medical marketing and sales. I have a background in immunology and cognitive psychology. And I founded my firm in 2000 because of what I came to perceive as undue industry influence on recommendations related to cancer therapy, and I wanted to create an opportunity for clinicians to basically make guidelines free of industry influence. And so my team and I have spent probably about 23 years now analyzing clinical data, especially relating to industry bias. And how they might, I guess, bias the information in their favour, which tends to include emphasis of benefits of a drug and minimizing safety issues.

Today what I'd like to do is I'd like to walk you through the cornerstone phase III trial used to support the use of the COVID-19 mRNA products that have been promoted by Pfizer as vaccines.

What I'd like to do is begin with the concept of Do No Harm, which is the Hippocratic Oath. It's the foundation of what we do: in the sense of medicine, meaning things that promote health, the very, very minimum needs to be that it's safe. We don't want to be doing additional harm when we're promoting a drug or recommending a drug for the general public. And that comes in direct conflict with industry's primary goal, which is to make profit. And so we're in a good place when we can balance the opportunity for innovation and profit against the— To ensure that they're also safe.

What I'm going to do today is I'm going to walk you through the phase III trial and the multiple stages of reporting that went on there. And I want to talk to you about how they manipulated the data to emphasize benefits and minimize safety issues in order to profit handsomely off of a world that was looking for a solution to the COVID-19 crisis.

So many of you may or may not be familiar with hierarchies of evidence, but in science not all science is the same. We've heard lots of people talk about how we need to follow the science. In my area, what we know is that not all science is the same: Some science, some trials are designed in a way that can prove something. And other science is meant to generate hypotheses that then go on to fuel the concept of phase III trials that then can prove things.

And so what you see on this slide set is hierarchies of evidence and the top of the hierarchy of evidence is the Level I evidence and that is a phase III randomized controlled trial, preferably placebo controlled. And the reason why that is so important is that there's all sorts of factors that can influence the outcomes in research. And by randomizing patients to one arm or the other, what you are able to do is control for baseline factors or factors that might otherwise influence the outcomes. So we're generally confident at the end of a randomized controlled trial to see if there's a difference between the two arms that that's attributed to the actual product. The reason why we're looking at the phase III trial is because that is the Level I evidence that they used to promote this particular drug.

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One of the things that I do whenever I'm doing an analysis, the first thing you look at is conflicts of interest. And a conflict of interest means that you want to be looking to make sure that the people who designed the trial didn't have other objectives or influences in mind. For instance, the most obvious conflict of interest would be a financial conflict of interest. If somebody were to gain or stand to gain a lot of money for a trial to have a

certain outcome—like for instance a pharmaceutical trial being positive, knowing that the whole world would take your drug—then you'd have high motivation to make sure that the benefits of the drug outweighed the risks. And so what I'd like to show you today is that the actual trial that was used by Pfizer was actually sponsored both by Pfizer and BioNTech, meaning that all the money and the resources that went into running that trial came from the pharmaceutical company. So right away there, we can see that if something's sponsored, it's not independent research: It's something that's been developed by the company that has a lot to gain. It stands to gain a lot from positive results.

What I also want to highlight is that the two founders of BioNTech were part of the author list and they went on to gain at least $9 billion, their company went on to profit $9 billion. So again, this is high stakes. This is probably the highest stake trial that's ever been done that I can recall. The other thing that we want to be aware of is that the lead author and the senior author, the two authors that are responsible for the research actually either had stocks or were employees of Pfizer. So again, the key roles and the founders of the trial that were responsible for designing, running, analyzing, and reporting these trials all were people who stood to gain by the actual trial. Now that doesn't actually say that it was biased, but I'm saying that it has a great potential for bias.

The other thing that we need to remember is that Pfizer has a long history of fraud. They've been convicted of fraud and they've also been convicted of manipulating the data and that's on the public record. And so when we start to analyze a trial, we basically want to be looking at the actors: who ran the trial, how much they stood to gain, and whether they have an actual record in that particular department.

The other thing I want to highlight is that on the record, *The BMJ* journal published a whistleblower report actually indicating that Ventavia, which was the clinical research organization that ran the trial, actually was fraudulently manipulating data. And there's a case in courts right now where they've been accused of that. So as it relates to previous trials, they've manipulated data. And as it relates to this particular trial, there's a court case ongoing presently looking into the falsification of data.

So this is a very, very busy slide, and the thing that I'd like you to understand when you're looking at this slide is the amount of red. So red are the people in the system related to recommendations that are made for COVID that stood to benefit from a positive outcome.

Now it's a very complicated slide, and I don't want to spend too much time working through it. But I do want you to know that generally speaking, a guideline, which is that blue bar that's in the middle, is produced based on a group of scientists—that in this case and for immunization it would be NACI [National Advisory Committee on Immunization]—and that group of independent scientists are supposed to review the published literature. If you look to the top of the chart, you can see a rectangle that says published literature. So these trial results were published, they were presented to Health Canada, and in conjunction and under the guidance of NACI, they reviewed this particular trial and then found that the benefits of this particular drug, the COVID-19 mRNA product, were worth approving in Canada. And what that means is that they felt that it was sufficiently safe and effective and that—

Generally speaking, the test is that it's safe and effective and that the benefits outweigh the risks. However, there has been a lot of global industry influence in various aspects of the system. And I'm just going to walk you through some of those influences: for instance, the World Health Organization, which was quarterbacking the pandemic response, is actually funded in large part by the Gates Foundation that has investments in pharmaceutical

companies; the NIAID and Anthony Fauci, who is quarterbacking the response in the U.S., the NIAID has a strong relationship with Gates as it relates to viruses and vaccines; and

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in addition, they hold a patent for the spike protein that was used in some of these mRNA products, and they are able to profit, because they have the patent, by recommendations related to this.

We also know that there has been a lot of activity on the part of our government. There is a Health and Biosciences, Economic Strategy Table, that's been at play for the last four or five years. And that group of people have recommended that we deregulate our regulations. And they actually put a new test in for the mRNA product. And the new test was that it basically didn't have to approve safety anymore. All that it had to do was prove that there was sufficient evidence to conclude that the benefits outweighed the risks, which is a very loosey-goosey type thing. What they were able to do is push those products forward with preliminary data and in a way that made the public think that they'd been proven safe when they hadn't been.

I don't want to go on too much more. But I do want to say that these same global entities are directing the public resources that have directed the research related to COVID. And they've also made partnerships with our universities. So the experts that we rely on in order to be able to provide sound guidance to us are actually people who have partnerships with these companies that are producing these products. And then the media, the last thing, is also somebody that relies very heavily on these companies for advertising dollars.

So the long and the short of it is—almost through every channel that we have and check in our system to make independent analysis, there is some sort of financial interest in these particular mRNA products being put forward. And so when we go to look at the data, which we're going to do now, what I'd really like to have you think about is all of the motivation coming in from every sector of our guideline development process that was pushing for this particular product to be sold. And therefore the stakes and making sure that the benefits outweighed the risks of this particular trial, which was the cornerstone of the whole enterprise and all of the people involved, comes down to this particular study.

So let's just walk through the study. This is a chart, and I just want to take a brief moment to talk about this. Whenever you go to look at the design of a trial, the first thing you have to ask is, why are you making this product? And when we're going to look at the clinical trial, we're going to see if the trial was designed in a way that would tell us what we need to know and what we want to accomplish.

So this particular chart looks fairly complicated. And this is based on Stats Canada data from March 2020 to February 2021. It plots the number of cases, and that's the blue line that's floating along the top of a chart; the hospitalizations are the red line; the ICU admittances, which is a little blue line; and then the deaths, which is the red [sic] [dark blue] line. And it plots it for each of the age groups. So those less than 19 years to the left, moving forward to those that are 80 years and older on the very far right. And by looking at those lines, if we just were to follow, for instance, the red line, which indicates hospitalization, what we see is that the hospitalization for most of the segments is very, very low per 100,000. So within 100,000 people, it's not very high. But then when you get to 70 and older, and even the 80 and older, what we see is you have a lot of hospitalization. Also, you have an increased amount of death per 100,000 on that side of the thing.

And one of the things that is really interesting about that is that there's been two reports that have been written: one is the CIHI report that talked about the COVID response and long-term care homes, and the second one was an Ontario COVID Commission. And both of those reports basically indicated that the reason why you have high rates of hospitalization and death in the long-term care facilities is because they've been chronically underfunded. And, of course, you have susceptible individuals in there, and they were completely under-resourced, so they weren't able to stop the spread of the disease. So these long-term care residents were trapped, and the virus was circulating extensively through there. And so one of the things that we see when we're looking at that is that probably it means that the elderly are probably most susceptible to COVID-19. And then secondly, what it tells us is that there are physical reasons because of community spread

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that these elderly people were hardest hit.

And that is not something that can be solved by an mRNA product. However, that was used as the basis for creating the perception of a need for that product that we were then told that we needed to vaccinate everybody in order to protect these people. However, that actually probably wasn't based on the in-depth analysis that had been conducted, the reason; however, that's what was put forth.

This is another thing that I'd like to look at. This is Our World in Data, and it's basically a time analysis of the different variants. On the far left, you can see that there's a red patch, and the red patch there represents the original virus. And this particular trial that we're going to be looking at was conducted during the time when the original variant was circulating. And the very initiation of the vaccinations—the vaccine campaign occurred on December 2020 during the time that the original strain was circulating. However, what you can see very clearly by the change in colour moving to the right-hand side of the screen is that that original variant has been completely replaced in Canada. The original virus has been replaced by various variants, all the way to which we now have the Omicron variant, which is probably from about the middle part of the screen to the right. And the original mRNA product was not very effective, or it was considerably less effective, on these new variants than it was on the original product.

One of the things that we would say right away is that these results, before we even look at anything, are clinically irrelevant to a large degree because the pharmaceutical companies are arguing that you need boosters because the original injections are no longer beneficial. So if we're going to follow that line of argument that we need boosters, then that would mean that those products are no longer effective. And so therefore, the phase III trial that is the cornerstone of this whole campaign would be clinically irrelevant and should be disregarded out of hand based on that alone.

The other thing that we need to look at when we're looking at a clinical trial and whether it's been well-designed is the type of therapy that we're looking at. I work in the area of cancer, and so we work with biologics. And biologics are basically different human products that have been used for therapeutic purposes. And so this mRNA product is what the FDA would categorize as gene therapy and so would the Health Canada. And gene therapy, according to the FDA, has very many undesirable and unpredictable outcomes, and many of them can be very delayed. And so what that would mean is that we'd want to see a trial that extensively studies these products for a long period of time. The FDA recommends for many gene therapies that they be studied for 15 years.

What we're going to see when we look at this particular trial is that these products were put on the market after two months of phase III study. When we think about that compared to the amount of time that is recommended for this, we could, again, out of hand say that this trial was conducted— That the preliminary results should not have been sufficient for this type of product. And in our area of cancer, even when we're dealing with people who are end stages of life, we would never recommend a product that's been put on the market for two months. And yet what we did is we turned around and we gave these biologics to healthy people indiscriminately without exception. And right away, that should have never been done.

What we're going to look at now just very quickly, before we even get into the actual trial, is the phase I/II trials. Basically, before you conduct a phase III trial, you have a phase I trial. In the phase I trial, basically what they did was they wanted to see if the mRNA product could produce antibodies. So that chart on the right looks fairly complicated, but the two red bars are basically the reason why they felt that they should move forward with this product as a vaccine. So they chose the 30 microgram dose. And if you look at that after one dose of the mRNA product, you basically have some antibodies that are produced, and those are those little green dots. What they did right there in that phase I trial is they compared it to the antibodies of somebody who'd actually contracted and recovered from COVID, 14 days prior. And what you can see is that the number of antibodies and the level of antibodies is actually comparable between one dose of the mRNA product and one dose of natural acquired immunity.

So right out of the gate, we knew that these mRNA products were probably about as effective as natural acquired immunity.

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And yet throughout the pandemic, one of the main messages that we received was that natural acquired immunity was insufficient. And yet Pfizer actually published this trial that demonstrated that one dose of the mRNA product was equivalent to naturally acquired immunity. They went on to give a second dose and then argued that the level of antibodies produced by a second dose at a much later time frame was better than naturally acquired immunity. And they didn't go on to actually consider whether a person would naturally be infected again and also have the same stimulated antibodies.

The other thing that we need to remember is that antibodies at the time when they actually produced this trial were not considered a valid test for immunity. So they had no basis for thinking that these particular antibodies that were being produced would go on for immunity. And, in fact, the FDA and the CDC both indicate that antibody testing is not a proper measure for immunity. So they had no basis to move forward with this particular phase III trial.

Let's just take a look at the actual trial design. This is something that I look at all the time, which is a schematic of how the trial was run. And it's probably too complicated for most people in this audience, but I do want to underscore a lot of things about the trial design that were concerning for myself and my team. The first one: If you look on the far left, the blue box indicates who was involved in the trial. Now, if you recall that schematic that I showed you earlier—the only people who were really at risk of severe disease were people who were in long-term care facilities where the virus was circulating. These were people at high risk. And the people who were actually studied in this particular trial were healthy individuals. So this actual product was never tested within the phase III context in the

sense of being able to prove anything in people who were actually at risk for COVID-19. So that's the first thing.

The trial was run, as we looked at previously, in the pre-Omicron area. So we have questions as to whether the data is actually clinically relevant. And the other thing that's really important to note is that the study was run in people who had never had prior COVID. And yet the majority of people, even by the point when we started rolling out these vaccines, had been exposed to COVID-19. And, so again, this study would be clinically irrelevant and should never have been used as the basis for promoting these particular vaccines. What they did again was they compared two doses of the mRNA product to placebo. But again, as we looked at before, they'd already proven that natural acquired immunity was very active.

So what they should have done is they should have compared it to naturally acquired immunity or something along those lines or designed a study that would factor that in. So when you make a comparison that you know is never going to fail, that's called "stacking the deck." And that's one of the things that they did when they actually designed this particular trial.

The other thing that they did was they only measured immunity seven days after the second dose. So that's just one point in time. So when they were making their statements about this particular vaccine, what they really should have been saying is, "seven days after your second dose, you're protected." Because that's all that this particular trial was able to actually argue.

The other thing too is that they did minimal safety testing. When I say minimal safety testing, one would expect that you would want to do preclinical or subclinical as well as clinical testing, that you'd want to have these people in a clinical setting and monitor them very carefully. And yet what we find is that they really only monitored them very carefully for about seven days after each shot, and then allowed them to report on their own if they were experiencing any adverse events. And so that would be very concerning if using a biologic in cancer, and we would have never allowed that. And yet that's how this particular trial was designed.

And finally, the last point that I really want to make about this trial is that it was stopped two months after it began or after about two months of follow-up. So we never really understood anything long-term about this particular product. This is just looking at the actual design of the trial.

One of the last things that we want to remember is that this practice of mass vaccination is only reasonable if you have a product that is actually able to stop transmission. And in the actual primary publication of this particular trial, they indicated that one of the unanswered questions or the limitation of this particular trial is that they don't know if it stops transmission. So there was never any basis for the practice or the recommendation of mass vaccination or any of the catchy tags that they had about

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"the vaccine is the best way to protect you and your family" because they actually had no data to support that statement.

I'm just going to talk about the last point around trial design and that was that there were major groups of people, the high-risk people, who weren't included in this particular trial.

So I'm just going to walk you through— The immunocompromised, again, not studied; those with multiple comorbidities or non-controlled chronic illnesses, classified as high-risk, not studied; pregnant women, not studied, but recommended in there; the frail elderly, they weren't included in the trial either; and the COVID-recovered weren't included in the trial. And yet all of those people were told that they needed to take this particular product.

The first results of this particular trial were published in December 2020, and the trial was touted as being 95 per cent effective: "this is an incredible success; it's an incredibly effective trial." And the safety at two months, we were told, was similar to other viral vaccines. So they immediately approved these agents using this modified test that was an industry-derived test, a change in the regulatory status in Canada.

Then they basically did something where they said, "Now that we're giving this to everybody, it's unethical to allow the people on the placebo arm of the trial to continue. So what we'll do is we'll cross them over, and we'll give them the opportunity to receive the vaccine." And so, 89 per cent of the people who should have been on the control arm, which would have allowed us to prove harm, were actually put over onto the mRNA product arm. And what that did was that it erased the ability for us to show both that it was safe long-term but also any way of showing that it was harming anybody long-term.

And so one of the reasons why pharmaceutical companies like to cross over early is because then they can promote their drug, and there would be no recourse in the sense that nobody would be able to prove that the drug is harmful, and so they do very well in the courts.

Let's take a look at efficacy. We move on, and they published results six months later, and again, promoting it as highly effective with a 91.3 per cent efficacy for stopping COVID-19 and 97 per cent efficacy for stopping severe disease. That was going to go on as, you know, "I got COVID, but at least it wasn't as bad as it could have been," and that was based on this particular trial.

So there is the data, and I want to show you right now that there's different ways of reporting data. You can report the investigational agent relative to the placebo or you can just talk about absolute benefit. And one of the things that companies like to do is they like to talk about relative benefit because it makes the numbers seem really exciting and really big. And that's what they did with this particular product: they said that it was 91 per cent effective in terms of symptomatic cases and 97 per cent effective in terms of severe cases.

But if you actually look at the absolute risk change, which is the far-right corner of this particular table, only about 4 per cent of people actually benefited from this particular vaccine, and in terms of stopping severe disease it was 0.1 per cent. The numbers, for instance, 1 versus 22 [sic] [23] are very low. And if you actually look at the number of people that were lost to follow up just before they reported these results, it was in the hundreds, and so therefore, if you have that many people lost to follow up and an event rate that is at 23, you should have said, "The data is unreliable and we can't move forward with this particular thing." But instead, what they said was, "It's highly effective, let's keep going."

Another thing that they did to make this result seem a little bit more favourable than they were, is they combined two cohorts. They reported the adult cohort at six months with the younger cohort that had less than six months. And because the efficacy of this particular

vaccine wanes, by combining and rolling in the outcomes for the younger cohort, what they were able to do is bump up the efficacy and make it seem like it was being more beneficial in adults than it was. And in the subtext of that particular article, it talks about how the vaccine efficacy was dropping from about 6 per cent every two months. So they knew that the vaccine efficacy wasn't holding, and yet they continued to promote it.

This is a quick chart from another paper,

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and it's a matched retrospective cohort paper that's really complicated again. But what this particular study did was they did that trial where they compared the vaccine to natural infection. What they actually found was that when you compare natural immunity to vaccine-induced immunity, that you get a 50 per cent lower relative reduction in the chance of catching COVID if you have natural acquired immunity compared to the vaccine; so therefore, the natural acquired immunity is substantially better than the vaccine. And yet again, this has been published for a while now and hasn't been emphasized.

And again, this particular paper talks about severe COVID-19, and it shows that you're 80 per cent less likely to get COVID-19 if you have naturally acquired immunity compared to whether you're being vaccinated at one year. In my particular field, if you get something that has a hazard ratio of 0.24, it's a home run, and everybody— Practice should have changed immediately, and yet they continue to promote these particular drugs.

Let's just talk about safety. So I would say, if we were to summarize efficacy, they made the wrong comparison in order to be able to show that their drug is better. They used a metric for conveying the benefits of that drug that emphasized the thing, and then they combined cohorts in order to emphasize the benefits of this particular drug.

Let's just consider now what they did in terms of safety in manipulating those data. So here we have what they called reactogenicity, and that just means that seven days after you receive a vaccine, they measure how you react to it, the adverse reactions. And then they basically dismiss that as just a normal course of getting a vaccine.

But one of the things that I want to highlight in looking at this is that the little orange bars above each— Well, let's just start at the beginning: With each dose, at least 60 per cent of the people who received that dose actually experienced COVID-like symptoms. These vaccines are actually inducing the same type of illness that we were trying to prevent. Now, you can't call it COVID because the definition of COVID is these symptoms plus a positive PCR test. But of course, these people wouldn't have the code for the full virus because they weren't there. But if you actually did encode for the spike protein and tested that, then you would probably say that these people have the part of the virus that causes illness.

And so, what we're doing is we're inducing COVID-like illness in the people that we are giving these doses to. But we're calling it "not being infected," that wouldn't be technically correct. And the other thing too is that 3.8 per cent at the very least, and for some other things more, at least 3.8 per cent of the people are getting so sick with this COVID-like illness that they're not able to carry about their work. And yet the people who are promoting these mRNA products basically said that these vaccines were safe.

So we're causing 60 per cent of the people who get them—and this is based on their own data—to get ill, the illness that we're trying to prevent by actually giving these products. And we're causing 3.8 per cent of them—and I can use the word "cause" because this is a

randomized controlled trial—are getting so sick that they can't carry about their daily activities. And this is only because we're looking closely for the first seven days. And they don't look carefully after that. So it could be going on much longer, but we wouldn't know because they stopped looking.

And another way to minimize your safety issues is to not test for it. So the fact that they stopped testing at seven days is probably a clue right there. And the other thing to recall is that this happens with each dose. So we're causing people to be sick with each dose. And the other thing too is that the amount of adverse effects increases with each dose. And yet we recommend boosters without any further safety studies.

So what I would probably say here is that they managed to dismiss considerable adverse reactions or safety issues by calling it reactogenicity and dismissing it. And also, by only measuring for seven days, you have much fewer safety issues if you don't look for them.

But they did have one group of people, and they did look fairly carefully. And these were people who were able to report if they had an adverse effect at some point after

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they received the shots within the first month. For those who were reporting severe adverse events and serious adverse effects, they were able to follow those people for six months. And then after that, they stopped looking. So again, not long enough for a biologic, which should be studied for 15 years—at least gene therapy.

I'm just going to talk about severe adverse events. Now a severe adverse event as defined in this particular trial is something that interferes with your daily activity, requires medical care, an ER visit, or hospitalization. So this is not something to be taken lightly. And what we find when we actually look at the study is that there were 262 people who experienced severe adverse events in the mRNA product arm, and only 150 in the placebo arm. Even though the people in the placebo arm had more COVID documented, they actually had less adverse effects, one could assume, related to illness. They had less illness or less adverse reactions than the people who actually received the mRNA product. And that was an increase, a relative increase of 75 per cent.

So when they were telling you that it was 91 per cent effective at stopping COVID, that would mean mild COVID potentially. What they weren't telling you is that there was a 75 per cent increase in the number of people who are actually getting seriously ill from these shots. And they buried that data in the supplements of the actual trial so that it was very hard to see. And they didn't talk about it when they were making their conclusions.

And the other thing, too, is that if you look at serious adverse effects—which are basically those adverse effects that require in-patient hospitalization, are life-threatening, result in death, or permanent disability—this is serious. You actually have 127 people on the product arm and 116 on the placebo arm.

Finally, I just want to look at deaths. And what we see here is that there's 15 deaths that occurred on the mRNA product arm and only 14 on the placebo arm at the point before unblinding. And then we went on to have five additional deaths after those people who received the placebo went over and took the product. So at the end of the study, at six months, in the six months report, we had 20 people who had died after receiving the mRNA product and only 14 who had died after receiving the placebo. So again, that would have been a reason to pause and for sure not promote these vaccines as life-saving. There's

nothing in this data here that would support them being beneficial in terms of preventing death.

And if you look at the types of death that occurred, what you see is that only one less COVID death occurred because of the mRNA product, but you had four additional cardiovascular deaths that occurred on the product arm. And so, what I would say, and what our team would say immediately when we looked at that, is that that is a signal for causing death or it's probably fueling cardiovascular disease. What we would have wanted to see is all of these adverse reactions categorized and analyzed. But that was missing from the report. So we really didn't know why we had those deaths, but we would have definitely saw that as a signal and basically put the brakes on this particular product.

On the point of all-cause mortality, one of the things that we feared when we saw that particular chart way back in December 2020, and the reason why our firm started doing pro bono work in this particular area, was that we feared that when this was rolled out to healthy Canadians that this would actually end up causing harm and even being fatal to younger people who weren't even at risk of COVID-19.

This particular chart is data pulled from Health Canada. It's data that goes from about February 2020 to February 2022, and it basically maps out what we would call excess death from those 0 to 44 years: so it's the younger population that was not at risk of COVID-19 from that first graph. What you see is that the moment that the pandemic was declared and we went into lockdowns, it was excess death in the younger category or the younger group. And then again, when these little squiggly lines at the bottom of the graph after the second dose of the vaccine was administered, you see another spike in excess deaths.

So what that suggests then is what we feared: that these particular mRNA products may very well be causing death. And the little blue line at the bottom is the number of COVID-19 deaths that occurred in this particular cohort. And you can see that these people weren't dying from COVID-19,

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they were dying from something altogether different that was timed very closely with delivery of that particular vaccine.

This is the end of my presentation.

One of the things that I'd really like to highlight in all of this is that this would seem, at least based on our particular analysis, that there was a high likelihood of a biased representation and reporting—there was a lot on the line for these particular companies. And that they presented the data, although they went through the steps, they basically did not align their conclusions with the data: for instance, we weren't alerted to the fact that there was additional death; we weren't alerted to the fact that there were more serious and severe adverse effects that were proportional to the benefit of the product. And finally, I think that this is potentially what I would expect to see from manipulation on the part of a pharmaceutical company.

However, I would say that this is gross regulatory failure on the part of our government in protecting Canadians. This drug should have never been put on the market. This trial, if scrutinized carefully, one would have seen the biased reporting. And finally, if they had been looking carefully, they would have been able to see where the real-world outcomes

are lined up and would have been able to respond and pull this particular product appropriately. That's all that I have to say today. Thank you for giving me the time.

That's it.

Wayne Lenhardt
At this point do the Commissioners have any questions? Yes, Dr. Massie.

Commissioner Massie
Well thank you very much for this presentation.

I think we've seen part of that in previous testimony. I'm not even sure if I will come back with the same question, but let me know if you already answered my question. My first question has to do with looking at the pandemic as we were trying to look at the cases and hospitalizations and death.

One of the questions I have with that is, a lot of that is based on the PCR testing, very often without symptoms depending on how you qualify the symptoms. Do we have an issue with describing the extent or the severity of the cases by the attribution to COVID, in this case, because we've seen that from previous results that it's clearly affecting more elderly population, people with comorbidities. So to what extent can we actually be convinced that this is what we are trying to address with these measures, in this case with vaccine?

Deanna McLeod
So I think you raised a really excellent point: that clinically speaking, the primary role in diagnosing somebody should always be based on their symptoms. And up until now, you use a test, for instance a PCR test, to validate the symptoms. However, what we did was we flipped things on their head with this particular pandemic, and we led with the PCR test. And we would even consider somebody to have disease if they weren't symptomatic. So that's a very unusual arrangement; it's not something that we see anywhere else.

And the other thing, too, is that if you were to rely on a test like that, what you should have done is validate that test. That test was never clinically validated, to my knowledge, and therefore, it should never have been used. And to your point, if you hadn't been using that test, then they basically would have been causing symptoms that they were trying to prevent in the people that they would see, and it would have been obvious.

But by the use of a test that they could actually change the outcomes to—by either running the test more times or lower, based on the threshold that they used—they can game the results for that particular test. And on that note as well, they didn't actually report the threshold that they were using for positivity in that trial. So that was another way that they could have been manipulating things. And, of course, if I were a pharmaceutical company and I wanted to make sure that my product looked the best, then I would make sure that I used a test that I could manipulate for sure.

Commissioner Massie
One of the questions that was confusing at the beginning is that I guess everybody was hoping that vaccination would be one way to accelerate the way out of the pandemic,

presumably by reducing transmission. And there's been the admission that this was not formally tested.

Would there have been a way to somewhat come up with a surrogate marker for transmission? And I'm thinking now that if we agree that

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to some extent, the threshold of the PCR cycle is an indication of the viral load. I mean, if you have very low PCR cycle to get a positive result, you assume it's because the viral load was higher to begin with. Whereas if you have to really push it to a high level, maybe the viral load is very low. I'm thinking that if you have a very high viral load, maybe you're a good spreader because you have a lot of virus. If you have very low viral load, you're not a very good spreader. So would that not have been a way to measure that in fact you can suppress or reduce transmission following vaccination?

Deanna McLeod
For sure they could have done viral assays and assessed the level of virus in people. So I think it was feasible. However, I think that one of the things that seems to be clear to me now, after having looked at a lot of the conflicts of interest, that this was intended to go forward regardless of results. And therefore, there was a selective focus on certain results in order to push the ability to produce these products globally. Although I think that they probably could have devised a test, and in fact tests are validated all the time. I think that there was a lot of motivation not to do that so that they could continue with their narrative. That would be my thought on that one. But I'm not an expert in testings per se, but more in clinical trial analysis.

Commissioner Massie
The other thing I'd like to ask is about using the antibody titer as a surrogate marker, knowing that on the FDA side, it's clearly spelled out that this is not a reliable marker. It follows from there that other markers should or could have been used as a surrogate marker, like T cells and other markers of other immune cells. I suppose that, based on my knowledge of immunology, these kinds of assay are not that complicated to run if you have the resources to do it.

Why haven't they been deployed in this assay to really prove that the vaccine was very close to what you would expect from natural immunity, that is, it was mimicking the kind of immune response you were getting from natural immunity? Is it something that was too cumbersome or too difficult to run in a clinical trial?

Deanna McLeod
That's a really great question. I think you touched on something called a surrogate. A surrogate is something that you test right now that points to an outcome that you could get in the future. When you're running a clinical trial, it might take too long to figure out if it's going to stop hospitalization or death. So then you measure something up front in order to see, and you hope that it points to something in the distance, so for instance, hospitalization or death and that that would be lowered. So if the surrogate's lower, then that would be lower.

However, in order to use a surrogate marker in a clinical trial, you actually need to validate that surrogate, and it's called a correlative prevention when you're looking at vaccines, and that is not established. So the use of antibodies was completely out of bounds in terms of the surrogate for protection because even the *New England Journal of Medicine* recently indicated that it's not a correlative prevention, especially not now that we're in the post-Omicron era. And so, of course, that would have been good and they could have done it.

But again, I think that we need to really consider that the course of the disease is 14 days. So using clinical endpoints would have been the better thing, and you can figure out within two months or three months whether somebody's going to die from COVID. And so, the actual clinical endpoint was well within reach of this particular trial, but they didn't actually measure it.

And so my question then is why did they use a non-validated surrogate instead of something that could have been measured, which is the actual outcome? And I would again say that it's easier to game a trial and the results if you use surrogates, especially non-validated ones.

Commissioner Massie
I guess my last question has to do with the two-dose regimen that has been the standard. We've heard, I think, from some of the health public authorities that once you get the first dose, I mean, you're fairly well protected, even though it's not perfect, you have a very good protection. And this was probably used as a common message in some areas where, for some reason, the stock of vaccine were not coming as quickly as possible.

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I know in Quebec, they actually decided to space a little bit the second dose, which it seemed in retrospect was probably good in terms of boosting immune response. My question is, okay, you do a second dose and then you see an increase in antibody, it's not going to be a big surprise.

So what is the threshold that we can expect in these first or second or even third doses to establish as a baseline to match up natural immunity?

Deanna McLeod
I think you would probably have to devise studies like the Qatar study that actually compared the vaccines to natural acquired immunity. But again, as a company, if you want to promote your product, then you don't want to compare it to something that is actually effective. What you want to do is you want to compare it to something that's ineffective so that you look positive. You can't win a test whenever the candidates are well matched, right?

So as citizens, what we would want to see is compare it to the most clinically relevant outcome, which would be natural acquired immunity. You know, and I was even saying—I'm already immune. And even up until this point, if you had natural acquired immunity, nobody would expect that you would actually need a vaccine.

However, again, for this particular enterprise of vaccinating people and rolling out a vaccine in record time and proving that we are innovative and working together globally to do something together, we were part of this whole movement. That's inconvenient, I would

say. And therefore, even though I think I agree with you, it would be the best comparison, it certainly wasn't the best one to forward their agenda.

Commissioner Massie
Thank you.

Wayne Lenhardt
Are there any other questions from the Commissioners? Yeah, Ken.

Commissioner Drysdale
Hello again. Good afternoon. I recently read an article, and I'm just wondering whether you've heard of it or can validate it or not. But I recently read an article that a group in the United States has sued the FDA in order to find out what the placebo was that Pfizer or BioNTech used in their testing.

So my first question on that is, have you heard that? And secondly, how important is it in the selection of the placebo in a test?

Deanna McLeod
Generally, a placebo would have been considered saline, so I'm curious to know what this particular group is thinking it might have been.

Commissioner Drysdale
According to the article I read, the judge ruled that they would not reveal the placebo because it was a trade secret.

Deanna McLeod
A trade secret water or sugar water, that's interesting. So yeah, maybe it was the lipid nanoparticle product without the mRNA, but I'm not familiar with it.

I do know that it did cause side effects, potentially adverse effects, so it is possible that it wasn't inert, which is what you'd hope for in a placebo. But again, I think one of the things that I find concerning is all the secrecy surrounding this. Transparency is often a good sign for honest enterprise. And when you start to see contracts that can't be revealed and things that are cloaked in language of trade secrets, I think that that would be a good sign as consumers, or potential people who would be considering these things, to not take it based on that alone. They're not willing to share the results. If they're not willing to explain to you how it's done, if you don't see the quality control studies then I would probably say that it's something that shouldn't be considered.

Commissioner Drysdale
Did I also hear you right that they never tested this for cancer effects and carcinogenic effects?

Deanna McLeod
Yeah, so that's a very good question. There's this whole phase of clinical research that should occur before you go into clinical trials. So clinical trials is the testing that you do in humans. There's phase I, II, and III, and then there's preclinical. And if we were to think about it in broad strokes, you'd want to test it in cells, and then tissues, and then systems to make sure that it's safe.

What they did was they used an adaptive clinical trial design: the FDA and Health Canada allowed them to collapse all of those things and kind of do it in tandem. And part of that was they didn't do all of what they normally do. So what they normally do is tests about reprotoxicity. That's reproduction toxicity. You want to make sure that it's not going to hurt somebody's reproduction.

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Oncotoxicity, which is the one that you're talking about, that it's not going to cause cancer. Teratogenicity, which isn't going to cause defects, or genotoxicity, which isn't going to cause genetic harm. And they failed to do all of those tests, which would have normally been done. Again, that would be another reason why it would have been unethical to even enroll people to clinical trials without those tests done, but certainly not to give it to healthy people under the guise of a vaccine.

And as it relates to oncotoxicity, that's my particular area of specialty. So whenever you're dealing with biologics, they can either turn on pathways that lead to cancer or turn them off. We're hoping that we use biologics that turn them off. That's what I've been studying for 23 years, maybe not 23, but maybe about 15. And we immediately went and looked to see if they were turning on some of the pathways that lead to cancer and published a video on our YouTube channel stating that we were concerned about this, and our video was taken down as misinformation. But that is definitely an area that we're going to be pursuing more recently because there's certain databases that now are emerging where we can actually look at some data to see how this has had an effect on cancer rates. So more to come on that area.

Commissioner Drysdale
Throughout the pandemic I kept hearing criticisms of other potential treatments like hydroxychloroquine. And what they were saying about that was there weren't any independent peer-reviewed studies.

Would you consider this study done by Pfizer to be an independent peer-reviewed study?

Deanna McLeod
Certainly not independent, I think we could check that box off. Peer-reviewed, it did pass peer review. However, I think that what we really need to remember is that the *New England Journal of Medicine*, which is where they publish this, has partnerships with pharmaceutical companies and, at least in the area of cancer, they've signed a first priority deal. I don't know what it is. But the moment that breaking news comes out that they get first shakes at it. And they've been working with pharmaceutical companies for a long time to get ground-breaking publications out the same day that the results are presented, for instance at a conference or something along those lines. And that even some of the senior editors of the journal actually are the Principal Investigators of a lot

of the mRNA trials. So there's conflicts and, of course, the sponsorship of the journals is from pharmaceutical companies. So you know they're tainted, as well.

So it is peer-reviewed for sure. But the reviewers, I would have liked to see their conflicts of interest because I don't know if it was unbiased. How about that?

Commissioner Drysdale
I also want to be clear on something that you talked about. You showed a chart, and the chart was about adverse reactions, and I believe it showed that seven to fourteen days following injection that patients would develop symptoms that very much mimicked COVID-19 itself.

Deanna McLeod
That's correct.

Commissioner Drysdale
And I note from that, and from a previous testimony, that most jurisdictions I'm aware of said you were unvaccinated for 14 days following the shot, which was a period of time that you would be demonstrating, potentially demonstrating, side effects from the shot.

And do you have any opinion as to whether or not side effects following vaccine may have been counted as COVID-19 cases in what they defined to be "unvaccinated" people.

Deanna McLeod
It's a good question. I definitely think that the term of "unvaccinated" was such that anybody that was suffering from side effects from the shot that it wouldn't be counted. Or if they did have a strong reaction, whether it was confirmed via PCR test or not, would have been categorized as unvaccinated. So for instance, if receiving the shot would have caused you to be hospitalized immediately following the shot, then you would have been hospitalized, but you would have been considered unvaccinated. In those charts that they showed in Ontario, for instance, they said, "Oh, my goodness, it's a pandemic of the unvaccinated," that very well could have been based on that definition, people who were having reactions to the shots.

Commissioner Drysdale
Right. So the potential symptoms of the shot could have been mistaken as COVID, and I wonder whether even a PCR test would have detected that. On other testimony, we heard that

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the PCR tests weren't testing necessarily for the COVID virus but bits and pieces of material that could have been attributed to dozens, if not hundreds, of different viruses.

Deanna McLeod
I'm, again, not an expert in the testing. But I can say that if they hadn't tested and they assumed that it was COVID, then that definitely would have been attributed to somebody

that's unvaccinated, even though they were vaccinated because of that pause. I think that again if we were to be thinking about it— I'm always thinking about mode of action because that's how you think when you're developing cancer therapies as you always start at that point.

But if we knew that the component of the virus that caused illness was the spike protein, how could it possibly be logical that we would ask the body to produce the very pathogen that we know to be the issue, and in copious amounts, and not expect any outcome from that. You know, it's nonsensical just from a biological point of view or mode action point of view. So I think that what they really want to do is they like this mRNA technology and they want to use it in many different areas, and they needed a way to get it promoted, and so they used the crisis as an opportunity.

But the reason why they like mRNA technology is when you're developing a drug, there's a clinical development stage that is very expensive. And so, if you can collapse the clinical trial, do this adaptive trial design, then you can get it done much more quickly, and if you can use surrogates then you get it done more quickly, so the cost of producing your drug goes down.

The other part that's expensive, especially when it comes to vaccines, is the manufacturing of the drug. So there's a lot of living systems and isolation and testing and standards. But what if you could imagine, if you had a 3D printer, an mRNA printer, in the back shop, and all you had to do is hit a button and then it could produce something? It's very cost effective to produce the mRNA shots. And so, industry wins in the sense of low cost for development, and industry wins in the sense of low manufacturing capacity. And then if you can position it as a vaccine and give it to absolutely everybody, then the sky is limited in terms of your market.

So really what this is, it's a product that's been strategically positioned by global entities to make maximum profit. And again, I would argue, at the expense of the global citizenship because they certainly didn't prove that it was safe or do rigorous enough safety testing to ensure safety before it was pushed forward on global citizens.

Commissioner Drysdale
It is my understanding of the mRNA technology, at least to be used in humans large scale, because my friend Dr. Massie will tell me that the technology has been around for a long time but not to be used in humans. So you would think that something like this—that has never been used in a mass of humans before and the effects could not be known—would have taken a much longer time to evaluate and it would have many, many different studies to evaluate different things.

Would that not be a typical expectation for some new technology platform?

Deanna McLeod
Yeah, I think you're absolutely right that when you're looking at novel technology, it's novel because you don't know very much about how it works and, therefore, safety should be your primary concern. And thoughtful, careful testing over time would be the best way to move forward, unless you're a pharmaceutical company wanting to profit off of a crisis and then expedited testing would be better because that gets it out on the market. The argument is that people needed it, they were dying of COVID-19.

However, if you harm the masses in order to try and treat a group of people, it breaks the ethical principle of minimal intervention, which is you should always look for the intervention that is least invasive or intrusive. And it also does something that we call a morbidity transference: so basically, you're transferring the morbidity or the sickness from the elderly people and you're putting it on the backs of the healthy people of the world calling it vaccination. However, that would probably be an inappropriate term because a vaccine, although some could enhance immunity—immunomodulator would be the proper term—

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there would be no basis for mass vaccination unless you can prove that it stopped transmission. And in their very first publication, they clearly stated that the study was not able to do that. So again, what I would say is that we've got capture from entities in our healthcare system. Our health authorities had other motivations or other interests at play other than our well-being in order to push these particular products.

Commissioner Drysdale
My last question is, based on your review of the testing protocols and data, in your opinion, is this a safe and effective vaccine?

Deanna McLeod
I would say that it fails the efficacy test. I would say that the trial is probably clinically irrelevant because it doesn't compare it to naturally acquired immunity and it's been done on a virus that's no longer circulating in the sense that other variants are circulating. So right away, I don't think that there's any evidence to say that it's beneficial to people who've got naturally acquired immunity, and there's no evidence.

And in terms of safety, I think that the studies prove that it's the opposite; I think it proves that it harms. And in terms of efficacy, at least based on the actual phase III trial, that I would probably say that there is negligible benefit.

Commissioner Drysdale
I have many more questions but thank you very much.

Deanna McLeod
Okay, thanks.

Wayne Lenhardt
Are there any other questions from the Commissioners? On behalf of the National Citizens Inquiry, I want to thank you for providing your testimony.

Deanna McLeod
Thank you very much.

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