NATIONAL CITIZENS INQUIRY

Toronto, ON **Day 1**

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EVIDENCE

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Shawn Buckley
Deanna, can you hear me?

Deanna McLeod
I can. Hi, Shawn. How are you?

Shawn Buckley
I'm well. It's good to see you. I'm going to ask if you could, for the record, state your full name and then spell your first and last name for the record.

Deanna McLeod
My name is Deanna McLeod, and so you want me to spell it now?

Shawn Buckley
Yes.

Deanna McLeod
Okay, so that's D-E-A-N-N-A, McLeod is M-C capital L-E-O-D.

Shawn Buckley
And I'll ask, do you promise to tell the truth, the whole truth, and nothing but the truth?

Deanna McLeod
Yes, I do. To the best of my abilities.

Shawn Buckley
Just to introduce you to the Commissioners, you've studied Immunology and Psychology at McMaster University?

Deanna McLeod
Yes, that's correct.

Shawn Buckley
And then you worked in the pharmaceutical industry for ten years in medical, in marketing and sales, and you specialized in the field of oncology.

Deanna McLeod
That's correct.

Shawn Buckley
You became concerned with the tendency towards biased reporting by some pharmaceutical companies.

Deanna McLeod
That's correct.

Shawn Buckley
And then you actually founded an independent medical research firm in the year 2000 to assist clinicians in preparing objective, evidence-based guidelines.

Deanna McLeod
That's correct.

Shawn Buckley
And your company is called Kaleidoscope Strategic. So, it's an independent medical research firm.

Deanna McLeod
That's right.

Shawn Buckley
And since March of 2020, you became very interested in COVID science. And my understanding is that your team has spent more than 3,000 hours conducting COVID-related research.

Deanna McLeod
At the very least, yes.

Shawn Buckley
Okay, you smile, so it's been more. We've asked you to come here today to share your research concerning children and vaccinations, and my understanding is you have a presentation to do for us.

Deanna McLeod
Yes, that's correct.

Shawn Buckley
So, I think screen share is enabled, and if you would like to...

Deanna McLeod
Okay, let me just see. Let me know when you can see my screen here.

Shawn Buckley
And we can see your screen, and we've got it on full screen with a slide that says, “It's time to stop the shots.”

Deanna McLeod
Fantastic. So let me know when you’d like me to start.

Shawn Buckley
Oh, you can start right away.

Deanna McLeod
Okay, well, thank you very much for having me. It's a real privilege to be testifying at this Inquiry. And what I'd like to do today is walk through some of the data related to use of the COVID-19 vaccine, specifically in children, and children will be defined as anyone less than 18 years of age. And presently, I'm just going to summarize really quickly some of the NACI recommendations.

So, children 16 years and older were lumped in with adults, and the vaccines were rolled out right at the beginning in early 2021. And then subsequently, Health Canada approved the vaccines for children 12 to 15 years old, followed by children 5 to 11 years old. And finally, most recently, children 6 months to 4 years old. So that's referring to the primary series, which is the initial two doses for everybody above five years. And for those less than five years, it's three doses.

And so NACI, which is the group that basically creates the guidelines for immunization in Canada, also recommends boosters in children five years and older, preferably the Omicron booster. And most recently, their guidance specified that a spring booster might be necessary for those who are immunocompromised. So, basically, our health authorities in

Canada are recommending not only the primary series for most children, but a series of boosters as well depending on how old they are, and especially use of this Omicron booster.

So, what I'd like to do today is to walk through the clinical data that supports those recommendations. So, our firm specializes in analyzing clinical trials. And what we do is we see if the data, the rigor of the data, supports the recommendation. So, we'd like to walk the group through this type of analysis today.

So, when we're looking at children, one of the things that we really need to remember is that they have a number of quality life years ahead. And so, when we're thinking about use of an agent, what we really want to do is we want to make sure that it's been rigorously tested for safety.

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Because, if there is something that is unsafe, it has the potential for injuring a child, and they would lose a lot of quality life years. That would be more quality life years loss, than, for instance, somebody who has one year to live who's injured by a vaccine. That would also be a loss, but not to the same degree as, for instance, a six-month-old who's injured by a vaccine. And so, the precautionary principle, and a lot of the rigor and testing, was put in place whenever we had thalidomide – which was approved as something safe and appropriate for morning sickness – and we only found out that it actually caused considerable harm to the unborn child, which was only really recognized whenever they were born. And there were quite a few deformities, especially in their hands and legs.

So, the other thing that we want to consider when we're looking at these COVID-19 injections is the type of product they are. So, these are considered gene therapy, and so they're gene-modifying products. And if you look at the FDA, what they'll do is they'll say that for gene therapy – and this qualifies because it teaches our cells to produce a protein via mRNA – that the types of side effects that could happen with gene therapy as a class are broad and difficult to predict. And therefore, 15 years of safety testing is recommended for gene therapy products.

And so, what we're going to be looking at is: are the trial designs that were proposed for these vaccines rigorous enough to identify all of the different safety issues that could arise from using gene therapy? And finally, at the time when these vaccines were being approved for children, we knew that there were rare side effects, one of the most concerning of which was myocarditis. And so, because you can detect myocarditis at a subclinical level by measuring troponin, we'd want to see rigor in testing – both clinical in the sense of symptoms, but also a lot of lab-testing in order to see if there's any type of side effects that are occurring that aren't quite clear from a clinical perspective. And so, we'd want to see rigor in testing in terms of a lot of subclinical testing, i.e. tests of, troponin levels, inflammatory markers, all sorts of different things, because we know that we're dealing with gene therapy, and we also know that we can expect certain types of side effects.

When you're conducting a clinical evaluation, basically the first question that you answer is: Do they need them? And so, when we're talking about kids, if we realize by looking at the data that they aren't needed, then that would be the very first reason why we would not proceed. Because you should never give something that isn't needed. That would be applying the principle of minimal intervention.

So, the second thing that we'd want to look at is: do they work? If they don't work, then again, you don't give them to anybody.

And finally, we'd want to make sure that they're safe. And again, safety being particularly important in this particular context, because children have so many quality life years ahead of them, and we definitely don't want to be injuring anybody.

So, let's ask the first question: do they need them? So, this is basically a plot that was taken from the Canadian COVID-19 Immunity Task Force. And in this plot, it basically shows that at this point in the pandemic – we're three years in now and Omicron, which is a highly contagious variant, has been circulating widely for quite some time – they found that if you did antibody testing or seroprevalence testing, that 80 per cent of children in Canada now have antibodies, which basically confirms that they've contracted and recovered from a COVID-19 infection. So, we can expect, based on any principle of vaccine or natural immunity, that these people would have some degree of immunity to SARS-CoV-2. Now we know that children were never really at risk of COVID-19, because there were very few severe cases of COVID-19 in children and almost no deaths whatsoever. So, we know that they're quite healthy. And now we know that they also have widespread, long-lasting, and robust immunity.

So, how robust is their immunity? So, this is a study, and I'll just walk you through this one table. And this is a publication that was published by *The Lancet Microbe*, and it was a retrospective study from Qatar.

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And they were basically comparing natural infection – which is what we talked about the children having – versus the Pfizer vaccine, versus natural infection, versus the Moderna vaccine. So, both of those vaccines were promoted as having about a 90 per cent efficacy. So, what we want to know now, what this study is going to show us, is how much more efficacious is naturally acquired immunity than these two vaccines. And so, when they conducted the study, what they found was that when you compared naturally acquired immunity to the vaccine immunity, the people who had naturally acquired immunity had a 53 per cent reduction in the rate of infection compared to vaccines. So, this is much more effective than the actual vaccine. And when we do cancer research, if you have a hazard ratio of 0.47, that's a very, very potent intervention, and that would be highly recommended.

Now, what they also looked at were cases of severe, critical, or fatal COVID-19. And what they found was a hazard ratio of 0.24. That means that the people who have naturally acquired immunity are 76 per cent less likely to get an infection compared to the vaccine arms of the study. And so, what this is showing, beyond a shadow of a doubt from an observational study, is that the naturally acquired immunity is much better than vaccine acquired immunity.

And therefore, based on these two slides, the fact that kids are not at risk in the first place; secondly, that they have extensive naturally acquired immunity as shown by seroprevalence tests by the COVID-19 Task Force in Canada; and the fact that studies show that naturally acquired immunity is much more effective than vaccine acquired immunity: we would basically say to the first question that, no, there is no need to vaccinate children based on a lack of need.

So then let's go on to the second question: do they work? And now, when we're looking at clinical evidence, not all the science is the same. And I know that throughout the pandemic, many people have said, “we need to follow the science,” as if there was one science and one

answer. But the truth of the matter is, what you need to do is you need to, kind of, prove that something is better than something else. And the best way to do that, the most reliable and the trusted way of doing that, is a randomized controlled trial, which would be considered level one evidence. And when you have randomized controlled trials, and you have that level of data, then you're able to say that something causes something else. Any other level of data – for instance, these types of studies down here – you would have to hesitate in a causal relationship. Because you can show an association, but you can't show that something proves something unless you've randomized it and you've controlled for baseline influences.

So, let's look at the type of study. So, there's a lot of observational trials that are out there. And that's where they look at real world data, and they say: “we deployed this vaccine at this point, and the rates of hospitalization are lower.” But observational studies can't actually prove that something works because correlation does not equal causation. Again, you need to have a randomized controlled trial. And because naturally acquired immunity is the current standard, in the sense that children have extensive naturally acquired immunity, we'd actually have to compare the vaccine to somebody with naturally acquired immunity to figure out if the vaccine would be beneficial at this time. And because children are not, the only risk that they have is hospitalization, we'd want that to be the main endpoint, and we'd want to make sure that it would address hospitalization in a post-Omicron era.

And so, we basically need to show a study that compared the vaccine to naturally acquired immunity, looking at hospitalization as the main endpoint, at a time when Omicron is circulating widely. And if you provide descriptive statistics, which is, basically, you might randomize something but you can't statistically prove that something is better than the other, then that isn't sufficient proof to prove efficacy.

So, here is what our team thinks would be the ideal trial to prove that COVID-19 vaccines are beneficial for children in Canada at this time when Omicron is circulating widely. You basically want to look at children who are at risk of severe COVID-19 only,

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because healthy children are not at risk of severe COVID-19. You want to do it during the time when Omicron is circulating widely. Because it is a gene therapy, you'd want to make sure that the population size was enormous, 80,000 – the original trial was probably about 40,000; that it was randomized; that you compared the gene therapy to naturally acquired immunity; and that you looked at hospitalization, And, that you followed this for 15 years, as per the gene therapy guidelines from the FDA.

But again, when we're looking at the vaccine trial design for the COVID-19 vaccines, we see that the studies were conducted in a pre-Omicron era, which basically makes them clinically irrelevant for a post-Omicron era. They were conducted in children who were healthy and had no prior COVID-19, which doesn't reflect at all the children today. The population size was very small for their main endpoint: it was less than 500 children per cohort. And instead of comparing the gene therapy to naturally acquired immunity, they compared it to the use of the vaccine in young adults.

So, what they actually compared for their primary endpoint, or their primary comparison, was the gene therapy versus the gene therapy. And that's called a “no-lose trial design.” It's when a company basically wants to show that their trials are positive, they'll do a non-inferiority trial against their own product, because they want to stack the comparison so

that, if they felt that they would lose to naturally acquired immunity, they would choose the comparative that they know that they can beat or be equivalent to. And so, this is not a surprising trial design for a company that basically wants to make sure that they get positive trial outcomes.

And again, what we'd want to see is hospitalization as the endpoint, but what they actually looked at was neutralizing antibody titers. And I don't want to bore you with something that's too complicated, but basically a neutralizing antibody titer – what they're doing – is considered a surrogate or a correlate of prevention. They're going to argue that, because the antibodies change, then there's some sort of level of immunity, and therefore that immunity would extend, for instance, to lower rates of infection perhaps, or lower rates of hospitalization.

But according to the *New England Journal of Medicine*, a recent article published there, they've argued that in the post-Omicron era, antibody levels are not a surrogate or a correlative prevention for hospitalization, and so it should not be used.

They had a component of the trial design where they did compare the gene therapies to placebo. But one of the things that should be noted in this particular area is this is descriptive statistics, and they can't be used to prove superiority of the vaccine, even though the rates of efficacy were rated, and we were told that it was superior to the placebo. Because they didn't do any statistical treatment on this data, you can't actually use that as proof of superiority, again.

So, at this time, there is no trial that's in existence that shows us that this COVID-19 vaccine is superior to naturally acquired immunity – the current standard – and that it is able to reduce hospitalizations or severe COVID-19 in a post-Omicron era. So, because there are no trials that actually address the question that we need to know, which is the clinically relevant question, we could probably stop our analysis right now and say that there is no data available to support the use of these COVID-19 vaccines at this current time, which is the post-Omicron era, addressing the issue in question, which is hospitalization in children who have naturally acquired immunity.

However, we will go and look at the results of the trial. We're going to be looking at descriptive statistics. So, this is what the regulators and health officials use to support the recommendations for use. Right now, we're going to be looking at 12 to 15-year-olds and 5 to 11-year-olds. And, basically, what we see is that the COVID-19 vaccines have little to no clinical benefit. So, although there were many that argued that the vaccine was 100 per cent effective, that was a relative risk reduction comparing zero episodes of symptomatic COVID in the Pfizer injection arm versus the placebo arm.

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The absolute benefit made available to children was 2 per cent.

So, only 2 per cent of the children who actually received the vaccine benefited from it, whereas the rest of them did not benefit from it. So, when you see an absolute risk reduction that's that low, you have to question whether it's really worth pursuing. And again, we know that children don't have severe disease. This is just a runny nose or a fever, and that's not something that we necessarily have to treat with children because it isn't severe. And if we do look at the number of severe cases, you can see that there were no severe cases in either group, i.e. children are not susceptible to severe COVID. And that applied for the 5- to 11-year-olds and the 12- to 15-year-olds. So here, we have no benefit

in terms of severe disease, and only a minimal absolute benefit in terms of mild disease. We look at the younger cohort, the initial trial design was to be giving them two doses. And whenever they completed the protocol-specified two doses, the relative risk reductions were 14.5 per cent and 33.6 per cent for the two cohorts, which basically means that the vaccines didn't work.

So, what they did was they did what we would call a fishing expedition, where they changed the protocol so that it could be adjusted to be positive, and so they added a third dose. In our particular area, if you see somebody who makes this post-hoc adjustment, you basically throw the data out and you don't regard it, because you can almost make anything look positive if you work at it hard enough. So here, they added a third dose, and again, only about a third of the children continued on to the trial to get that third dose. And when it looked at symptomatic COVID-19 cases, there was only a difference of three cases between the two groups. So, you've given the vaccine to all of the children in the vaccine group, and there's only a difference of three cases which, again, was touted as an 82 per cent benefit, but really was only a 2 per cent absolute risk-benefit. And again, here, in the six months- to two-year-olds with the third dose, there was only a difference of one infection between the two of them. And they called that a 76 per cent relative risk reduction or called it efficacious, but really it was only a difference of about 1 per cent between the two groups.

In terms of severe cases, I would argue that there probably were no severe cases, although there might have been one that was considered a severe case in the placebo arm, although it wasn't confirmed. So again, you have less than 2 per cent benefit for treating all the children.

So, again, if you were thinking about the principle of minimal intervention, you would say: is it warranted to give a vaccine or a treatment to *all* the children when it really only benefits a very small amount? At that point, what we would probably suggest is that you would treat the children who have difficulty, or who might be more susceptible – or treat them, period – and you would probably opt out of a preventative approach in this particular case.

I'm just going to zip through this slide here.

One of the things that is also really important is they did a point-in-time comparison. So, they only really ever measured the antibodies about a month afterwards, and they measured the symptoms about seven days after the second dose. But what they failed to do is watch how the benefit changed over time. And so, here is probably one of the better studies. It's a *New England Journal of Medicine* publication. It's looking at the six-month follow-up after a fourth Pfizer vaccine dose in adults. We're going to argue that probably the efficacy of these things is going to be similar. Its probably going to see similar waning in the children as you do in the adults.

In this particular study, what they saw was that the benefit peaked at four weeks. So, remember, they've only identified the benefit at seven days. And so, three weeks later, they basically see that the benefit has peaked. It's at its height. And then it wanes slowly afterwards. So, by 13 weeks, it's basically gone completely.

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So here, we have a benefit that helps 2 per cent of children seven days only after they get the injection, but is gone probably within three weeks later, and might even become

negative over time. And so again, I don't think that we have sufficient efficacy data to show long-term benefit for these particular vaccines.

So, because the vaccines wane, the boosters are required. And because we're now in a post-Omicron era, we've been proposed that the Omicron booster is the solution to the problem of waning efficacy. And so, this is basically the results of the BA1 Omicron booster trial, which was used to support the recommendation for use of these vaccines in children. This particular vaccine being the Omicron booster. And in this middle panel here, what you can see is that 78 per cent of the participants had no previous infection. So again, because most children today have had a previous infection, the results of this trial are probably not very clinically relevant, but they were used to support the vaccine. So, let's just take a look at them.

And our regulators argued that the level of antibodies were higher for the Omicron booster than they were before they received the booster – on day 29 after their booster – than they were before the booster. So, you see this jump in antibody levels like this, and that the antibody levels for the Omicron booster jumped higher than they did for the regular booster. And therefore, they argued that the Omicron booster was more effective than the regular booster. Now, again, if we go back to what we know about correlates of prevention, it is clear that antibody levels are not a correlate of prevention for hospitalization, for instance, or even symptomatic COVID-19 in a post-Omicron era. So therefore, all that we can say, based on this, is that both groups got antibodies after they received the injection, and we can't infer anything regarding the actual immunity.

However, they did happen to measure the immunity in this particular study. And what they found is, in the group that had lower antibody levels, they had 1.5 per cent infection rates. And in the Omicron booster arm, they had higher rates of infection following those antibodies. So, this goes to prove that antibody levels are not a correlate of prevention, and that there were higher rates of infection on the arm that was the Omicron booster arm. And regardless of the results of this trial, i.e. showing higher rates of infection and not being a correlate of prevention, our health authorities went ahead and approved this particular thing for children without any specific testing in children. This actual study was run in adults. So, the study, in my mind, would be negative. It would not be applicable to children, and yet our regulators – and particularly NACI – recommended these agents in children.

So, on to the next question. I would say for the question where it says ‘Do they work?’, the answer probably would be that there's insufficient data to support the fact that they work. And until they prove that it works, then we should assume that they don't work. In terms of safety, again, when we're looking at new agents, what we want to see is pre-clinical testing. And the one thing to note about these particular agents is that the normal type of testing that you would do, the rigorous pre-clinical testing for the COVID-19 jabs, were not done.

So, in terms of oncotoxicity, we want to make sure that it doesn't cause cancer; reprotoxicity, we want to make sure that it doesn't cause infertility; and genotoxicity, we want to make sure that it doesn't harm your genes or your genome. And so, none of these tests were done. And so, the thought of giving these to children without having done these basic tests is very disturbing.

And if we look at the clinical testing that was done, we would want to see extensive testing because, again, we're looking at gene therapy, and the FDA recommends up to 15 years of safety testing for gene therapy. We know that inflammation is a known side effect, whether it's myocarditis or pericarditis or encephalitis, or any of a number of different

inflammatory reactions that we've seen associated with this. And so, what we want to see is clinical testing,

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in the sense of monitoring of a broad range of symptoms. But we also want to see subclinical testing. We'd want to be measuring troponin levels to see if there's any cardiac damage. We'd want to see D-Dimer levels to make sure that there's no coagulation occurring. We want to see C-Reactive Protein to make sure that there's no inflammation.

But, when we looked at these studies, what they did was they basically measured reactogenicity, which is COVID-like symptoms for seven days only, after receiving the injection. And then if somebody had a severe or serious symptom, they would follow that person for up to six months. And when they, basically, recommended that these particular COVID-19 vaccines be released to market and used in children, only two months of data had been collected. So, that's two months of data out of the 15 years that should be done for gene therapy. And even within that context of running a study for two months, they only actually looked for side effects for about seven days. And so, that would be nowhere near sufficient to be able to characterize the side effects profile of something like a gene therapy over that time. And they did not look at subclinical testing. So, there could be damage that isn't clinically obvious yet that's occurring. And knowing the mode of action and how these COVID-19 vaccines work, it would have been important to do that type of testing.

And I'm just going to pause right now and say that if I see this type of negligence in terms of safety testing, I would probably assume that there's an entity that is benefiting from promoting these particular vaccines that has an alternative agenda that isn't the benefit of children in mind. And that would be something where you would tend to see minimal safety testing or misreporting of safety testing, and you'd see the benefits exaggerated and the safety issues minimized in this particular scenario. And I would probably say that what I'm seeing here fits that particular profile of somebody minimizing safety issues and maximizing efficacy beyond what's actually true.

So, again, when we were talking about what they monitored very closely, they looked at COVID-like symptoms for seven days following the shots. In the left-hand panel, they looked at pain at the injection site. And on the right-hand panel, they looked at systemic events, so those are those flu-like symptoms that you'd expect when you get COVID-19. Now, I just wanted to remark that after these injections, after the second injection – and these types of side effects occurred both at the first injection and the second injection – what you see is almost 80 per cent of the kids having pain in their arm where the injection occurred, probably about 30 per cent of them having significant pain in their arm, and probably about 1.5 per cent of them, or 1.5 in 100 children's arms were so sore that they actually couldn't use them the next day.

And so now, if we think back to the fact that only 2 per cent of the children actually had a runny nose, the only benefit for the vaccines that was shown is that 2 per cent of them had less of a runny nose than the other ones. Here we are giving 1.5 per cent of the children, almost the same amount of children, a sore arm to the point where they can’t use it.

If you look at fever, another 2 per cent of them had a fever greater than 40 per cent, which is actually very serious. In terms of fatigue, another 2 per cent were so tired they couldn't get out of bed and couldn't carry on their daily activities. They may have required medical care or a visit to the ER, or the hospital because of it. And again, 2 per cent of them had very severe headaches and 2 per cent of them had chills.

So, for a 2 per cent benefit in reducing COVID-19, which is what an ARR of 2 per cent is, you also caused 2 per cent increases in severe outcomes for these children. And now it's difficult to say whether this was all the same child or different children. But it could be that they are 2 per cent of different children, so the net could be as high as 8 per cent severe outcomes in different children for a 2 per cent benefit.

Again, if we were to consider that right now – just the clinical benefit ratio considering the risks over the benefits – you would probably say that, at this point, it's negative already. However, it's important to look at the overall. Remember that they were following severe and serious adverse events for a month to six months, and at the two-month follow-up for this particular trial, we noted that the severe adverse events for children who received the Pfizer jab versus the placebo were higher. So, there were seven severe adverse events in the COVID vaccine arm, versus two in the placebo arm. So, that's a relative risk increase of 249 per cent. And if we look at serious – which is basically people who have to be hospitalized, inpatient hospitalization, have life threatening, maybe death, or even being permanently disabled: again, you have more of those in the Pfizer COVID-19 jab arm than you do in the placebo arm. And that's a relative risk increase of 299 per cent.

So again, coming back to our original focus, you have children who are not at risk of severe COVID-19. You can see that they didn't have any COVID-19 severe cases in the actual trial. But here, you can see that those who were vaccinated were 12- to 15 years old, actually had more severe and serious events occur to them than they did from COVID-19 at all. So, what I would argue here is that the vaccine is less safe than not having it at all, or than naturally acquired immunity and letting children handle it on their own.

So, again, our regulators are recommending booster shots to these children. And so, this CDC graph basically shows the side effects that you get with each dose of the vaccine. So, this is the first dose. This is the second dose. You can see that 80 per cent of children, or greater than 75 per cent of children, for the second and the third dose – the third dose being the booster – have side effects or systemic reactions that are serious enough that, at least for the third dose, 26 per cent of them can't carry out their daily activities. Twenty percent of them are unable to go to work or school after they've received that third dose. And 1 per cent requires medical care.

Again, if we were to go back and think about naturally acquired immunity and the fact that it's much superior to COVID-19 vaccines, then we would say it's not needed. If we looked at whether the vaccines are working, we'd probably say they aren't. But one of the things that's very clear, is each time we give one dose to a child, we actually cause a severe amount of adverse events, to the point where 20 per cent of them are unable to go to school following the injections.

So, let's talk about myocarditis. So, this is a well-recognized side effect of the COVID-19 mRNA vaccines. At this point, there's as many as 1 in 5,000 males aged 12 to 24 that can get myocarditis after the second dose. And we now know that that's an underestimation because there are studies now that look at troponin levels. And I think it's 1 in 300 people who get the COVID-19 vaccine actually have elevated troponin levels, meaning that it's a sign of cardiac harm.

And we do know that severe myocarditis weakens your heart and that your heart muscle can't regenerate. And it could infect the transduction of the heart and, therefore, result in severe outcomes, especially with exercise or exertion. The mortality rate is up to 20 per cent higher for people who have myocarditis at six and a half years. So, this is nothing to

disregard. And especially if we're thinking about injury in young children and the fact that they're going to rely on a strong heart for the rest of their life. Any type of damage that occurs presently might have unknown consequences long term.

So, the last thing that I'd like to touch on is excess death and all-cause mortality in Canada presently. These are data pulled from Stats Canada. What we can see is, leading up to the pandemic, or the COVID-19 crisis, there was no excess death. So that's this looking down here. And with lockdowns, when lockdowns were initiated, in the age group of zero to 44 years,

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there was an increase in excess death that was timed after the lockdowns. And here we can see that the first dose of the COVID-19 vaccine was administered to people, generally speaking, so that would not have included children. And then a second dose was administered here. And with this second dose, what we can see is another increase in excess deaths across Canada, timed with the second dose of the vaccine.

Now, it's hard to prove that this was related to the vaccine, but we do know that the excess death is occurring in those who are zero to 44 years, which is the segment of children, and that it is timed with the vaccine. So, if you look at the number of COVID-19 deaths in that age group, you can see that the deaths are minimal compared to the excess deaths during that time. And so, what we would do is we would look at that and would say that that's a concerning signal. There's a temporal association that would need to be investigated and proven to be untrue, or that we'd want to see extensive safety testing before we would move forward with recommending a vaccine that had this type of association in children.

So, just winding up, do they need them? No. Do they work? No. Have they been proven safe? No.

And these are the countries that, at this point in time, have basically chosen to *not* pursue COVID-19 vaccination in children and young adults. Among those are a bunch of studies from Europe; again, England, Australia has made those changes. And more recently, the World Health Organization has categorized, as of yesterday, children as a low risk of severe COVID-19 and, therefore, do not recommend vaccinating them moving forward.

So, the question that I have at this point is: how is it that our regulators are recommending these types of treatments with data that clearly does not support their recommendations? And so, one of the things that we do when we're looking at data that looks like this – where the efficacy and the safety have not been sufficiently supported – is we look to see if there's any conflicts of interest in the people who are responsible for making those decisions. And so, Dr. Carolyn Quach-Thanh is the NACI chair at the time that the COVID-19 vaccines were approved. And so, those would be when COVID-19 was declared and the COVID-19 vaccines were approved.

One of the things that we noted was that she received a $2.6 million grant from the CIHR to study various aspects of COVID-19 right when the pandemic was declared. And she's gone on to receive more than $10 million in grants to study COVID-19 and various topics since the time of the pandemic. And so, I would probably argue that that's a lot of money going into somebody's research career on a product that may or may not be beneficial for children.

And then Dr. Shelley Deeks is now the NACI chair, and she was the co-chair at the time that the COVID-19 shots were approved. And she received a $3.5 million COVID-19 readiness grant before we even knew whether the vaccines were going to be beneficial in adults, before we had any phase three data. So again, it would seem difficult to me to think that people whose careers are focused on studying COVID-19 and COVID-19 vaccination would be able to objectively evaluate data on these particular vaccines and their benefits.

And so, I'm just going to end with that there and turn it back to you, Shawn. We've covered a lot of data there. But I think that there's enough to say that it's questionable as to why these vaccines were ever really approved in this particular cohort of children at the time that they were.

Shawn Buckley
Yeah, and I'm curious Deanna, because you had hinted during your presentation that you kind of questioned who benefited from this. You were basically saying that the benefits were exaggerated, and the opposite with the safety concerns.

[00:45:00]

And you're kind of teasing us to suggest, I believe, that it would be Pfizer, or do you think that legitimately the approval bodies are compromised in this situation?

Deanna McLeod
So, I think that the manner in which the trials were conducted and reported basically maximized benefits and minimized safety. But it is our regulators and our health officials who are responsible for identifying these things and for basically ensuring that we've got data that proves benefit before moving forward. And so, I would say for sure that Pfizer and Moderna, basically, presented the results in a manner in which it would further their financial gains, and that the people who should have been catching these things weren't catching these things. And so, I also wonder what other interests are at play in our regulators and in our health officials that they would go forward with these types of recommendations based on this particular level of data. It's very concerning.

Shawn Buckley
Now, you've presented us with an analysis of the data by the pharmaceutical companies. Have you looked at adverse reaction reports in either Canada or other countries? Because my understanding is that Canada is getting a reputation for under-reporting adverse reactions.

Deanna McLeod
That's a great question. So, I tend to stay away from relying on adverse event reporting from Canada. I know that they basically say that the passive surveillance system that they have in place is sufficient to detect safety issues, and that they're monitoring it very closely.

However, there's a few problems with that. One, it's passive surveillance and, therefore, it under-reports the level of adverse events. It was never designed to be able to characterize the safety profile of a gene therapy. If you send somebody home and you tell them that the vaccine was safe and is no problem, then the last thing that they're going to be looking for is safety issues or adverse events reporting.

What should have been done is you should have been under clinical supervision, carefully monitoring people for any type of adverse events – and a broad spectrum of adverse events because we know that we're dealing with gene therapy, which causes inflammation and spreads throughout. And that the lipid nanoparticles bring the mRNA material all through your body, and that the mRNA produces a spike protein which produces inflammation. So, we should be expecting to see inflammation throughout the whole body. And so, you should have a safety protocol that is rigorously and actively monitoring that type of thing.

And so, to think that a passive surveillance system would be adequate for that purpose is laughable. And, you know, if we did look at the VAERS system, the adverse events reported in and around the COVID-19 vaccines compared to all other vaccines for the last 30 years is not even comparable. There's been so many adverse events reported through these types of systems that, you know, it's almost shocking.

Shawn Buckley
Does that still apply for children or are you referring just to adult numbers?

Deanna McLeod
I haven't teased it out for children specifically, but you can expect that if you see the same drug being used in adults as in children that you would see a similar profile. Although the dosing is slightly different for children, I don't think that the actual profile of the vaccine would look very much different.

Shawn Buckley
So, would it be fair to say that, as far as Canadian statistics go, we have in no way a reliable reporting system for vaccine injuries outside of the clinical trial data?

Deanna McLeod
That's correct. In fact, our firm compared the rates of adverse events reported through CAEFIS to the actual clinical trials and, whereas the clinical trials were catching 70 per cent adverse event reporting, CAEFIS captured about 0.1 per cent. So that’s, like, not even 1 per cent of the actual side effects were being captured by that system.

[00:50:00]

Shawn Buckley
So, is there a country that you would think has the most robust adverse reaction reporting system for children? And if you have an opinion on that, can you share with us what that country's data is showing?

Deanna McLeod
Yeah, again, I stick to what you can prove, which is stuff that you would see in a randomized controlled trial. And so, I haven't spent too much time looking at passive reporting systems, because they're very difficult to interpret and it's difficult to use them to prove anything. However, again, I would go back to saying that the UK Yellow Card system is probably one of the better ones. You do see the same spectrum of adverse events as you would with adults, but with a heightened adverse event reporting in and around

myocarditis and pericarditis, especially after the second dose in young men. Especially when you mix doses, particularly when you give Pfizer and then Moderna, or Moderna then Pfizer.

Shawn Buckley
Right, I'm going to ask the Commissioners if they have any questions for you. And there are questions for you.

Commissioner Massie
Thanks, Deanna, for your very well-crafted presentation. I have a couple of questions. The first one is about – I understand the challenge to demonstrate the efficacy of vaccines, because unless you have a very good animal model that would be fairly representative of what would happen in humans, you cannot purposefully infect people to see whether the vaccine works. So, you have to rely on surrogate markers. And in this case, it seems that there's been a lot of emphasis put on antibody titer. And if I'm not mistaken, when you look on the FDA side, this spelled out specifically, that the antibody is not a good surrogate marker for protection against infection. So, why is it that we keep seeing that in all of the presentations from the company?

Deanna McLeod
That's an excellent question. And I'll answer it from a research development and an accelerated approval scenario. So, in cancer, which is where I work, again people look for surrogate markers, and because, again as you mentioned, you want to be able to identify benefit early and have it point to the ultimate benefit that you want. So, for instance, response rate might be considered a surrogate for survival in cancer. But in order to establish a surrogate, you need to clinically validate it, and you need to make sure that it's the case across different settings and, in this particular scenario, across various variants as well.

And so, although there was quite a bit of testing done in the original trials where they felt that it was valid, in the sense that the antibodies could predict symptomatic COVID-19 in the pre-Omicron era – and I would probably argue that that's not the case in the post-Omicron era – they now acknowledge that it isn't a correlate of prevention, which is the proper terminology for it in the in the vaccine world. And it isn't a correlate of prevention for hospitalization, and for in the post-Omicron era. So, to your point, this antibody testing that perhaps they used because they wanted to find a surrogate, is not validated – and it has not been validated, so they cannot use it. But, why have they been using it? And I think that, when I see this type of thing, it's because regulatory bodies have bowed to the pressure of somebody in order to expedite approval.

So, if you want expedited approval of something, if you want to have accelerated approval – get it to the to the market much more quickly – you tend to rely on surrogate markers. And so, I would probably think that there is some sort of organization, entity, that is highly motivated at getting these vaccines to market as quickly as possible. I know that there's quite a few people who are considering this perhaps a global goal, to be able to work together to get things to the market much more quickly. But I think that that's only a benefit if you've done the rigorous testing that you need to make sure that these things are safe and effective.

[00:55:00]

Because, if we're getting things to market that are harmful, and we're making sure that they're in the arm of every single person on the planet and it hurts them, especially our children and our future, then that's of grave concern.

Commissioner Massie
I also have a sort of a question about the documentation you've presented. I know that you have done a more extensive analysis on the conflict of interest. I think you did a presentation on that, which was more detailed, if you want. Because one of the questions that I had is: Is there any sort of practice or regulation that would prevent the people that are called on, in our institutions, to qualify the relevance of any medical treatment, would have to actually be shown to be exempt of conflict of interest? It's probably not enough just to declare it at one point. Is there something that is preventing these people from acting there? Obviously, it doesn't seem to work if there's anything. Are you aware of anything like that?

Deanna McLeod
Well, I think that whenever conducting conflict-of-interest work – and, we have another presentation at the Citizens Inquiry here coming up that will delve into that in a little bit more detail. And you can go on the Canadian COVID Care Alliance to see a more detailed analysis as well.

But, on that note, I think that the normal way that you look at conflicts of interest is to simply look at: has a pharmaceutical company that stands to benefit from positive recommendations – in this case would be Pfizer and Moderna – have they directly paid anybody who's involved in the decision making? And in our particular situation, NACI would be the body that's responsible for the independent evaluation of the COVID-19 vaccine data and formulation of recommendations, and that those recommendations are then taken into consideration by each of the provincial authorities that make recommendations. So, I would probably put them as responsible for things in Canada. And if you did look at strictly Pfizer or Moderna giving them money, there is definitely some level of conflict of interest.

But the thing that we noticed the most is that the conflicts of interest are coming from a global level. So, they're being channeled down through traditional funding levels – for instance, with the Tri-Council. However, the research agenda is being set by global bodies, for instance, GLOPID-R, which is a global research network whose membership are vaccine manufacturers and NGOs that have a pro-vaccine agenda. And so, what you see is the projects that are being funded and the people who are being rewarded for positive recommendations around COVID-19 vaccines are those that are in line with those global entities.

And so, I would probably argue that you have somewhat of a hijacking of our healthcare system through even normal funding means – for instance through Tri-Council funding – because they have bolted on to these research agendas and goals of these international organizations, for instance, the World Health Organization and GLOPID-R. And therefore, you can see a vaccine readiness grant of $3.5 million going to the person who's going to be deciding whether the COVID-19 shots should be approved in Canada.

Why is she getting ready for COVID-19 vaccines before we even know that they're safe and effective? Why is anybody considering them? You know, the amount of money that went

through our government to people to decrease vaccine hesitancy leading up to the rollout of these COVID-19 vaccines was incredible. Why were we telling people to not be hesitant around COVID-19 vaccines before we knew that they were safe? These are, I think, really important questions that we need to be answering: Why were we having such a pro-vaccine stance, and why were the studies designed to make the vaccines look so favorable? And why didn't our regulators stop these vaccines because they didn't have the sufficient level of safety and efficacy data needed, especially in children? Those are the questions that I think need to be pursued and investigated a lot further.

[01:00:00]

Shawn Buckley
So, Deanna, finally just add to what you're saying is: as you're aware, the regular drug approval test in C.08.002 of the drug regulations was abandoned for COVID-19 drugs. And the interim order that substituted the regular objective test of safety and efficacy and produced a subjective test did something also interesting: it exempted the government and COVID-19 drugs from several provisions of the *Food and Drugs Act* and Regulations. And one of the regulations prevents the importation of a drug if there isn't a drug approval. And that was exempted. So, Her Majesty purchased a large amount of these vaccines and was permitted to import them and distribute them to the provinces, while waiting for herself to approve the vaccines. So, it was kind of a classic conflict of interest, where the minister was allowed to purchase and import and distribute while she waited for her servants to approve them. So, there's just so many interesting things about this rabbit hole.

Deanna McLeod
And I think, I'm very hopeful that this Inquiry will serve the purpose of evaluating all of these things. Because, one of the things that we need to really be mindful of is, if a pharmaceutical company sees that this tactic has been successful, I will guarantee you that this is not going to be the last time we see it. And so, the onus is upon us to identify how it happened, and to stop it from happening in the future, or we're going to have – you know, once the fence has been breached, or once the wall has been breached, you can expect the hordes to enter. So, I think we need to repair the wall, or this won't be good for our children, or anybody else moving forward.

Shawn Buckley
And I'll ask the Commissioners if they have some more questions.

Commissioner Massie
Would you make your documents available so we can actually review them in more detail?

Deanna McLeod
Absolutely. Yes, no problem.

Commissioner Massie
Thank you.

Shawn Buckley
So, Deanna, if you can forward them to me, I'll just have them enter it as an exhibit, so that the Commissioners can review your slides.

Deanna McLeod
Okay, well thank you very much.

Shawn Buckley
And there doesn't appear to be any more questions. So, on behalf of the National Citizens Inquiry, we thank you for your presentation.

Deanna McLeod
Okay. Thanks very much for having me. Have a great day.

Shawn Buckley
You, too.

[01:02:50]