NATIONAL CITIZENS INQUIRY

Winnipeg, MB **Day 1**

April 13, 2023

EVIDENCE

Witness 3: Deanna McLeod
Full Day 1 Timestamp: 05:43:22–07:18:47
Source URL: https://rumble.com/v2hz2rc-national-citizens-inquiry-winnipeg-day-1.html

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Wayne Lenhardt
Thank you, Shawn. I'm not completely up on your technology here, so this is going to be a virtual witness. Have we got that teed up, Shawn?

Shawn Buckley
Yep, she's right here.

Wayne Lenhardt
Oh, here she is.

Shawn Buckley
You start asking her questions, and she's good to go.

Wayne Lenhardt
Oh, there we go, yeah.

I have a CV for you, Deanna, and it's fairly impressive [Exhibit WI-7]. It goes back all the way to 1991 where you've published articles and done research and whatnot. I don't have your degrees though, so perhaps you could tell me what those are. And then we need to go through the little formality of swearing you in as a witness.

And it looks like you've got some interesting topics to share with us.

Deanna McLeod
Yes, for sure. So you asked about my educational background. So I studied at McMaster University, which is the home of evidence-based medicine and was trained as such. My focus was in immunology and cognitive psychology. So that's pretty helpful these days. And

I basically, instead of pursuing the degree of pre-med, which I trained for, or medicine, which I trained for, I actually shifted to the pharmaceutical industry and spent ten years there. So that's a little bit about me.

And did you want to do the swearing in?

Wayne Lenhardt
Okay, so the formality is, can you give us your full name? And perhaps spell it for us for the record.

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

Wayne Lenhardt
Okay. And do you promise to tell the truth, the whole truth, and nothing but the truth during these proceedings?

Deanna McLeod
I definitely do swear to tell you the whole truth to the best of my knowledge and abilities.

Wayne Lenhardt
I see that you've given us six topics that you'd like to cover. I think we have an hour to do that. So one of them is Pfizer six month data; second is safety surveillance issues; trial data for children; omicron boosters; and conflicts of interest. So I think what I'll do is just turn you loose to give your testimony.

The commissioners may have some questions. So if you're going to change topics on us, perhaps we could stop and see if there are any questions. And if not, then we'll just proceed to the end of your time.

Deanna McLeod
Okay, well, thank you so much.

Wayne Lenhardt
The floor is yours.

Deanna McLeod
Okay, great, thank you. I'm just going to share my screen here. Let me know when you can see it.

So the topic that I'll be addressing today— I believe I'm going to be testifying a few times, but the one that the Inquiry had asked for me to look into today, or the one that I wanted to pursue today, was a combination of conflicts of interest as well as the safety of the COVID-19 vaccines. And I believe that there's been probably a number of presentations addressing safety: Safety issues, maybe in the form of a patient, somebody who's been vaccine injured.

Or perhaps a number of very capable scientists who've come in and looked at adverse event reporting databases.

What I'd like to do is, I'd actually like to dial back a little bit. My particular expertise in the last 20 years has been in preparing evidence-based guidelines. My firm, which I started in 2000, works with clinical oncologists, people who treat cancer. And we work with them to survey the literature, analyze clinical trials, and prepare guidance documents in the form of either systematic reviews or clinical guidelines that basically help them guide therapy.

And so what we do is we apply the practice of evidence-based medicine. So we look at a clinical trial. We weigh the evidence. We survey the doctors that we're working with to see the degree of consensus. And then weighing a combination of the level of evidence and the degree of consensus, they'll make either a strong or a weak or not so strong recommendation. And so we're very, very familiar, my team and I, in weighing evidence and analyzing it.

And so what I'd like to do today is I'd like to take you through the evidence that these vaccines are safe because our public health officials have been claiming that they're safe. And also, interestingly enough,

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I know Shawn's on this call. I've taken a deep dive into some of the regulatory issues that explain some of the safety data that we've seen in the COVID-19 crisis, the COVID-19 moment. And so I'd like to have a conversation about the connection between those two things.

And at the very end, what I'd like to do is bring people's attention to the fact that Health Canada is proposing further amendments to the Food and Drug Regulations in order to expand the capacity to push through drugs like novel technologies, like the COVID-19 vaccines, via a back door that they created in 2019. And so what I'd like to do is just show you what a change in regulation means in terms of side effects. And then, maybe, loop back and talk about how the proposed extension to the regulations or the further proposed amendments, what that may mean for Canadians.

So with that very long-winded introduction, I'm just going to jump right into it. I'm going to call this regulatory responsibility.

I am not a lawyer like Shawn who is familiar with regulatory stuff. But we do consider regulations and the burden of proof when we're weighing evidence to prepare a guideline. And so I have a working knowledge of that area.

But one of the things that I'd like to emphasize right away is that our current system is based on testing to prove something. So in this context, when we're looking at the COVID-19 vaccines or perhaps the changes in the upcoming regulation, what we need to know is understand historically, especially as it relates to vaccines, what the standard for testing is. And so the standard for testing at the very top is anywhere between one to ten years. We surveyed the literature. And we basically noted that each step can vary in terms of its time. But in general, there's a sequence of steps that are always done in order to ensure safety. And so I'm just going to walk you through those right now.

The first one is in vitro and animal model studies. So that's called preclinical, so before clinic. Before it gets into people in the clinic, you do extensive animal testing. And some of

these tests can take up to three years. And generally speaking, you want to demonstrate safety in things that aren't human so that when you do proceed to humans in clinical trials, you know that there's a degree of safety. And that you know what to expect and what not to expect to some degree that you can then design your studies in order to be able to monitor potential safety issues. And so you test safety in cells, tissues, and animals before you move on to humans. And that has been one of the cornerstones of our clinical development process.

And so, when a regulator, Health Canada, wants to consider approving a drug, the pharmaceutical company or the manufacturer will submit a dossier of clinical trials. And they'll need to prove, generally speaking, that the preclinical data doesn't show any concerning safety issues. And then when they go to clinical trial, the ethics boards will allow them to go to a clinical trial to see— If the preclinical data is sufficiently safe or if there's no safety signals, then they'll allow them to go to a clinical trial. And they'll make sure that that clinical trial is appropriately designed in order to be able to monitor potential safety signals that showed up in the preclinical data.

So the other principle that applies when we're doing clinical research is you start with Phase I studies. And generally speaking, in my particular area, a Phase I study could have up to 20 patients in it. And so you test a new drug in a very, very small group of patients. And then you work your way up. A Phase II study could be 20 patients, could be a little bit more. Especially if it's looking promising, they might add it to about 80 patients.

And then a Phase III trial, depending on what kind of study it is, whether it's treatment or prevention, will have either hundreds or thousands or tens of thousands if you're looking to try a novel technology in humans that are healthy; so, you need to test it in a greater and greater and greater sample, depending on how many people and how healthy they are. Because what you want to do is you want to make sure that there's no risk of drug injury when you're looking at these particular drugs

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and whenever you're considering the data.

So the principle then is extraordinary caution and careful study over time in order to ensure that when you start to roll something out to the very broad population that all of the possible safety signals have been detected, not only in the short term but over time. And so you can see here that this band, vaccine development, has taken up to about 10 years at times. There have been rare cases where we've seen that time frame compressed to five years. A lot of people would say that that's a great success because they got a helpful vaccine out onto the market earlier. But every time we compress the timeline, we basically sacrifice or compromise on long-term safety. Because there's no way to figure out the safety of something in great detail and to fully characterize a safety profile if you've only done it in a short time. So that's one of the principles.

And so when Health Canada looks at a submission or a dossier that's been submitted for review, they basically look to make sure that each and every one of those steps has been carefully checked; that over time, there aren't any safety signals and that all the steps have been carefully done in order to be able to ensure at the end that you can say that something is both safe and effective.

And I was mentioning, too, that you want more study and more time when you're considering using something in a healthy population. And also, you would want to have

more study and more time when you're considering novel technology: novel meaning you don't know very much about it; you haven't used it in very many areas; we don't have very much experience with it. And also, you want to be able to be careful and more cautious when you're using high-risk products, products where there's a known adverse effects profile.

So with that said, there's Shawn. I actually put your picture in there, Shawn. Basically, this is something that he wrote that I read recently. And it's the test that you would need in order to be able to allow for a drug to be authorized in Canada. And so he's, of course, given many presentations on this. And so I don't really want to go into it much further than to say that in order to get authorization to market a drug in Canada, a manufacturer must meet the test that a drug demonstrates both safety and efficacy and that the benefits outweigh the risk. And so just with that in mind, that is our prudent, cautious, regulatory framework, which sets a very high standard and protects people from potential drug harm by having that high standard.

I just want to step into my particular area, which is this hierarchy of evidence. And this is going to make some people's eyes roll back. But it's very important to know that not all science is the same. And I know that through the COVID-19 pandemic and the COVID-19 crisis, you've got a lot of politicians sitting up and saying, "We're following the science. If you don't follow the science, then you're, you know—fill in the blank." But it is really, really important to know that not all science is the same: not all studies are the same, that you have different types of clinical trials and different types of studies. And each study can do different things.

But there's only one study that can ever prove something and that's the gold standard, that's a randomized controlled trial. And it's considered Level 1 Evidence or the highest level of evidence. And so what we want to see and what we look for when we're setting guidelines is Level 1 proof that something is safe and effective.

So what that means for us is that you have an investigational agent that's been compared to a standard of care. The comparator is very important, ideally. And that it shows that it improves outcomes for clinically meaningful benefit. So for instance, if you want to try and save lives, something that makes your skin clear is not going to be a clinically meaningful benefit. Or something that works for a short time, but doesn't work in the long time, that's not going to be a clinically meaningful benefit. So you want to make sure that the study is properly and appropriately designed to show a clear benefit in an area of clinical benefit.

So, with that said, Health Canada, generally, at least in the area that I work in, in cancer,

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relies very, very heavily on Level 1 Evidence in order to seek approval. There are very few circumstances when they'll give access to a drug or market access to a drug for less evidence. And then there's lots of follow-up that's required in terms of safety monitoring. But generally speaking, Level 1 Evidence is the standard that is used to ensure that any product that enters the Canadian market is both safe and effective and the benefits outweigh the cost. And that is really rooted in the Hippocratic Oath, which is to first do no harm.

And there was a time at which there was considerably more deregulation, where regulations were much more flexible. And basically, a drug called thalidomide was promoted. And that drug basically was intended to help relieve morning sickness for

mothers. And it was considered safe or it was purported to be safe. It was approved and given to a large number of women, so it was widespread use. However, it hadn't been proven safe. So when these babies were born, they had limb malformations. And so that led to considerable regulatory reform in Canada, U.S., and the U.K. and the establishment of the precautionary principle: being careful, overly cautious when it comes to drug approval so that we avoid any undue harm, as in these children who were born with unusable, at times, arms and legs.

So I'm just going to shift gears and talk about biologics. We deal with biologics all the time. And they basically are types of biological products that are used, at least in the area that I work with, to treat cancer, for instance. So they can target a given receptor or a small molecule that acts to shut down a pathway or turn on a pathway, depending on what we want to do in terms of treating cancer.

But one of the things that is very, very clear when the biologics first began to be used, almost two decades ago, was that considerable caution needed to be applied because it is understood that the risks related to these drugs can be serious and life-threatening. So biologics would be classified as high-risk drugs. And therefore, the burden of proof needed to ensure safety is higher than, for instance, a drug that has very few side effects.

So then, an abundance of caution basically characterizes our approach to biologics. And of course, in cancer we have the desire to help people because sometimes they have advanced cancer that might very well progress and result in the death of the person who has it. So then, what we want to do is we definitely want to experiment in considering novel technology or new biologics because they have such promising outcomes. But at the same time, the last thing that we want to do is add to the burden of disease of somebody who already has cancer. And therefore, there's an extraordinary push to make sure that these biologics are safe before use. And I've added a little bit of a note there, including gene therapy.

So gene therapy is one of the highest-risk biologics that there are. And the FDA basically requires that up to 15 years of long-term safety study be used when looking at gene therapy. That was the standard that was set out by the FDA, and it has been set out. And so in cancer treatment, there are a few areas where gene therapy is being developed. However, because it's so risky and because the safety profile can be very diverse, difficult to detect, and that safety issues can happen long term, it hasn't really moved forward in any considerable fashion. And so again, when we're considering the precautionary principle, the area where we should be the most cautious would be if we're using something like gene therapy, which is one of the riskiest or highest-risk biologics,

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in populations which are otherwise healthy.

So I just want to talk about a loophole that I discovered in reading a number of different papers recently. And this is the one that Shawn has mentioned at different times. But a loophole was created in our regulatory framework where the standard is that you prove safety, efficacy, and that the benefits outweigh the risks. Probably as early as 2016, a powerful advocacy group started championing for changes to our regulatory framework in Canada. And this is a paper by Ruhl. It provides this amazing timeline where there was an Advanced Council for Economic Growth [Advisory Council on Economic Growth] that was founded by our standing government in 2016.

And so the mandate of that economic growth group, think tank, was to basically figure out how you could grow the Canadian economy. Out of that particular think tank came six what we would call economic strategic tables or economic tables. The health and biosciences and economic strategy table is one of them. And the goal of that particular group was to sit down and say, how can we grow the health and biosciences sector in Canada?

So I just want to mention to you, at this point, that this has nothing to do with regulation and clinical treatment. In the sense that it is the pipeline for novel treatments, but the goal here is an industry, for-profit, motivated group that is basically now going to say, well, if we want to attract investments to Canada in the health and biosciences area, if we want international groups, global entities, to invest in Canada in our economy, then we basically need to initiate these conversations. And in the conversations, one of the things that came forward was that Canada has these pesky little barriers to innovation called high standards and high regulatory standards. And then basically, this group put out a report. And the report was designed to basically revamp or create a loophole in our regulatory framework that would allow novel therapies, as yet fully undescribed, not fully characterized, to get through a back door in our regulatory framework.

And so the pathway for creating this loophole was basically introduced through an omnibus Bill C-97 that was pushed through at the 11th hour in December 2020 by our standing government. And basically, the goal of that particular bill was to allow for an exception clause. It's like a loophole, an exception, a back door whereby the minister could designate certain drugs as exceptions to the rule. And that they could go through a different type of pathway. Not that 10-year pathway that is so pesky and a deterrent to innovation in Canada, but a pathway that is allowing them to do a number of changes. I'm just going to say what they are: so adaptive clinical trial design is one of them; rolling reviews, which is taking early looks and considering approvals based on early data; and the last one would be changing the terms and conditions of authorizations. So those are kind of three crazy words.

What happened shortly after the passing of that particular bill is that late in March 2020, the data for the COVID-19 vaccine was ready. And so the minister of health issued an interim order that enabled the COVID-19 vaccines to access this expedited pathway. So there were at least two orders that I identified. The first one was authorizing the change to clinical trials. So that's the adaptive clinical trials.

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And the second one was allowing them to start with rolling reviews. There were a few others, for instance. But I don't think that they relate so much to the safety issue, so I won't get into those too much. So basically, what that did is it allowed them to fast track this COVID-19 vaccine, clearly because there was a perceived public health emergency, so that they could get this novel technology, this novel therapy, onto the market to, of course, save lives.

So that's the little bit of backdrop behind that.

So this is the Honourable Jean-Yves Duclos. I've just put his brief bio up there. It's nothing too much. But I want to emphasize that Yves Duclos does not have a medical background per se, but that he is an economic expert. And one of the things that we need to consider when we're looking at guidelines is we're always very, very sensitive to what we would call a conflict of interest. And a conflict of interest is when somebody who has something to gain potentially financially, politically, career-wise, influences a guideline or a

recommendation process or participates in the development of something that would then lead to them profiting long term.

So we've already learned that our government had an intention to grow the economy and that that was the impetus for regulatory reform. It wasn't because our regulatory system wasn't doing a good job keeping people safe. It was because it was a corner of the government that basically wanted to grow the economy and wanted to attract investment from global entities. And therefore, at the behest of that group and those people who are going to profit from these regulatory reforms, Mr. Yves Duclos, who's an economic expert, basically allowed the process of regulatory reform to actually begin. And he's the one that issued the interim order that allowed the first product to go through this new framework and access this pathway of expedited review. And this is a little bit of a—

Wayne Lenhardt
Could I just ask you a question, please?

Deanna McLeod
Sure.

Wayne Lenhardt
Was there any mechanism for fast tracking this type of a vaccine prior to Duclos doing this?

Deanna McLeod
That's a really good question. So in my particular area, which is cancer, there is something called an NOC/c, Notice of Compliance with Conditions, which is kind of like this pathway. But it's used very, very exceptionally and only in small groups of people with very rare diseases where there's no other option.

Wayne Lenhardt
Okay, was it ever done in the past, or was it ever used in the past?

Deanna McLeod
So the Notice of Compliance with Conditions has been used for rare diseases in the past. But this particular regulatory loophole, this back door that was created, the COVID-19 vaccines were the very first novel, or what they would call "advanced therapeutic," to move through this system.

Wayne Lenhardt
Yeah, the timeline is fascinating here.

Deanna McLeod
Yeah, it is.
So this is just text from the announcement about this advanced therapeutic pathway that they created. And, you know, small text, and we don't have a lot of time. But I do want to highlight a few things.

So one of the things is they want to ensure high standards of patient safety, product quality, efficacy, and effectiveness. So that's stated in their, uhm, thing. But before the safety bullet, you can see that they want to maintain an appropriate yet flexible, i.e., being able to lower the standard or increase the standard, depending on what they would like to do, regulatory oversight. Or maybe we'll have some oversight, or maybe we won't have some oversight. So the flexibility and oversight are the things that are emphasized here.

And then the second one, which should be very concerning to everybody, is the second bullet point to promote innovation. So that is not a health-related outcome, whenever you're considering that the impetus for this change is because there's a group of people in Canada that basically want to increase their profits and draw business to Canada.

Now, in the actual document, and I don't have that here. One of the things that they say is they want to— This flexible regulation, what they're saying is

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they want to move beyond. "Beyond" meaning, they want to do away with the gold standard randomized controlled trial. So we need to translate that and say, "We don't want to have to prove that something is safe and effective or that the benefits outweigh the risks when we're seeking authorization of our products. We want to be able to move our products through, and we want you to give us a regulatory nod, even if we haven't proven them to be safe and even though the benefits don't outweigh the risks."

And I want to highlight the last one: Reduce barriers to bringing ATPs to market. So the barrier that they're referring to is they say, "We want to reduce the regulatory standards that we need to bring these advanced therapeutic products to market in Canada." And when they position it as— We want these products to get to patients in need, faster, right, and so, they put themselves in the position of champion and people who are life-saving. However, one of the things that everybody needs to understand is that the difference between early market access and late market access for a pharmaceutical company can sometimes be billions of dollars. So, if you can think about the billions of dollars that were earned by the COVID-19 vaccines by the pharmaceutical companies before they actually even received regulatory approval, will give you some reason why this would be in the interest of pharmaceutical companies.

And I also want to just pause and mention that, you know, when we were thinking about the cancer patient—so even somebody who has a very severe disease—if you push through a novel therapy and it's harmful, then you haven't helped that person at all. What you've done is you've added to the burden of their disease by adding adverse events or injuries to the burden of the disease. And so that is not helpful at all. The only way that we can actually help somebody is if we prove that what we're giving them is beneficial and that the benefits outweigh the harms. And that even then, if there is a risk–benefit ratio that that is clearly articulated to the person receiving the agent so that they can make an educated and informed choice about whether they feel that it's warranted or not. That's not something that can be imposed by somebody else.

So just to finish up on this particular slide regarding this advanced therapeutics pathway that they initiated. What they're asking to do is they want to prioritize innovation over safety. So you can see that innovation over safety. And they want the safety standards to be flexible. They don't want to have to always prove safety. They want to kind of, maybe, put something through and then just hope for the best, or something like that. Or, maybe, you

know, try and figure out a way to measure safety after people have been injured or to assess the degree of injury and then make safety calls. So it is really, really important to say that there is absolutely no way that you can be helping people if you're pushing through unsafe products, and especially, because it profits pharma.
So let's take a look at these products that they push through, the first one that they push through in this particular pathway. So again, whenever we're thinking about how rigorously you want to review something, how rigorously you want to study something, the degree of the standard that you want to set in order to put something through, you need to think about the nature of the product.

So I have here that the COVID-19 vaccines are genetic therapy, gene therapy. They're basically things that teach your body: They introduce mRNA, which is basically like an instruction manual. That mRNA gets delivered through these little lipid nanoparticles into your cells. The lipid nanoparticles are designed to go everywhere in your body and to cross protective barriers that your body has there for a reason so that things can't get into there. And then they introduce these instruction packets into your cell. And they teach your cells to produce a known pathogen. A pathogen means something that is known to cause disease, which is the spike protein.

So it basically introduces a pathogenic protein into healthy cells. And when your cells, basically, express this protein, it goes and sits on the outside of the cell. Then your immune system sees that cell and says, "This is a foreign cell. I need to basically attack that cell." So basically, what it does is, it is something that's engineered to cause your body to attack healthy tissue.

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It would be very hard for me to understand how this could be helpful for anybody who's healthy. However, that is the nature of the product. It's a biologic product that is basically introducing mRNA that causes your body to produce harmful proteins.

It was known before in the early data that, and we also know this for sure now, that even in the very, very early studies that this could cause clotting. And it is very easy to measure clotting or the potential for clotting in the blood before clotting actually happens, called a D-dimer test. We also know that it causes inflammation.

So based on all of these things, what we should have been doing is putting this into extensive years of testing to ensure that we can produce something that is very safe by careful study. So careful study. Then at the end, when it passes the test, then we can call it safe.

However, what they were able to do is they've changed the test for approval for this particular thing, for approving the COVID-19 vaccines. And now, you only have to have sufficient evidence to support the conclusion that the benefits associated with the drug outweigh the risks. So there's a little bit of word gymnastics there, as Shawn has mentioned many times over. That now, you don't actually have to prove safety or efficacy: remember flexible studies, flexible standards. You just have to produce some evidence that would support that conclusion, so the bar has been dramatically lowered. And this means that now, potentially high-risk, unsafe products, under-tested products, are going to be hitting the market and being delivered to people.
The thing is a public health need. And of course, there's no objective criteria to say what a need is. And anybody can generate a need for something, depending on how strong the media campaign is. And, in fact, a normal part of a marketing process is to develop need, to

highlight the need of your particular drug. And that's, you know, in the clause here. So it doesn't actually have an objective standard. It just has a subjective standard of need. And this is straight from Shawn's excellent presentation. I recommend everybody look into his work.

Basically, there was a clause in section 2.1. And I read this, this morning, and I thought was really interesting. It basically prevents the minister from revoking the authorization. So they're going to lower the standard to this potentially high-risk, novel biological therapy. They're going to give it to healthy people because it's a vaccine. That's what that means. And then, they're going to make it so that they can't pull it off the market. And in addition to that, leading up to this particular interim order, they had actually given the vaccine manufacturers indemnity, meaning you can't actually sue them if they were found to be harmful. So I don't understand why somebody who is priding themselves in the ability to brew safe therapies that are going to help people would need to have indemnity. So that would make me think twice right away.

So let's just take a look at the COVID-19 vaccine and the development sequence. So you can see here that whereas the norm would be 10 years at the outset— And we're going to be trying a novel biological therapy, high-risk, with known adverse events, then I would say that the appropriate thing would be 10 years if not following the FDA guidance of 15 years of testing. But what this interim order allowed them to do is go in the back door and do one year of testing. And what that meant was they did minimal preclinical testing, meaning they didn't take very much time to figure out if it was going to be toxic to humans before they threw them in clinical trials and started experimenting on them.

I'm not sure who the ethics review board was that allowed that. But that's what happened. They were able to combine Phase I, II, III trials. So you know, this step here: the Phase I/II was combined. You can see that here. And then basically, the Phase III studies were conducted for about two months or so before they took a sneak peek at the data. Which is what you call a rolling review. You can get an early look at the data, preliminary data. And then they basically were able to make a call as to whether to authorize it, which they did after two months of study in clinical trials, in a randomized context. Then they dismantled the clinical trials.

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We'll get into that in a little bit. And now they've been allowing these drugs to be used by people without any active monitoring. I'll get into what active monitoring means in a little bit.

But just a couple notes on the preclinical testing and what you'd want to see and what was done. So what you want to see is preclinical testing on two appropriate animals, so two animals that are similar to humans in the main mechanism of action. So that would be here, with the similar ACE2 receptor expression because that's the little receptor that the virus gets through. So here, instead of having two appropriate animals, they use two studies on rats to do a toxicology, meaning, is it toxic to the cells or is it toxic to the rats?

And some would argue that rats were not the appropriate match for humans and, therefore, would not have given a very good assessment of what safety you could expect in humans. And so some would critique that the only preclinical studies that they did was those toxicology studies. And then they did some about effectiveness of the drug.

But in terms of safety, they did the toxicology studies. But they didn't do it in the right model. And they should have done it in two different models. And the other really important test that you want to do before you start experimenting in humans is something called reprotoxicity, meaning they want to figure out if it's going to be toxic to your reproductive cells; teratogenicity, which means, is it going to cause deformities? Genotoxicity: is it going to affect your genome, your DNA? And oncotoxicity: is it going to cause cancer?

And so, of course, when I was looking at the data, I was very cognizant of the fact that they didn't do any oncotoxicity data. So they're using a biologic, which we use all the time to— We know that biologics can either activate or deactivate cancer pathways. But they didn't bother to test whether this agent could activate biological pathways, cancer-causing pathways, before they rolled it out. Before they started testing in humans. And even to this day, I don't think that there's any oncotoxicity studies that they've used. And so we may not know. But the key thing is that the reprotoxicity studies and the teratogenicity studies were ongoing at the time of authorization.

So not only did they—the authorization of clinical trials—they basically allowed them to start testing things on humans before they actually did the proper assessments to make sure that the products were safe. And to my knowledge, at least at the time when they started rolling it out to the general public, they hadn't done the genotoxicity studies or the oncotoxicity studies. So I don't know how carefully they've looked at this issue of whether these vaccines can be causing cancer before they started rolling it out to healthy people. And that is a really big issue.

So let's take a look at the study that they designed. And one of the things that you need to remember is just because you do a randomized controlled trial, doesn't mean it's a good randomized controlled trial. And it is only as good as how it was designed to assess the data. And I just want to highlight a few really key things that are really important.

So we know that COVID-19 is really a disease that affects the elderly and the immunocompromised and maybe people with comorbidities. And they tested this particular drug in people who were healthy. So you cannot get any sense of whether the drug is going to be toxic to a frail elderly person or a person with comorbidities if you're testing it in healthy people. So the only data that they had when they rolled this out was data in healthy people. And so, therefore, they rolled it out to high-risk groups with very, very little data. They had some elderly patients. They had a very small part that had comorbidities. But for the most part, it was untested, completely untested, in high-risk groups based on the Phase III trial that they used.

I'm not going to get into too much more. All that I want to do is I want to say that the only measurement that they used, the ultimate measurement, was basically, did it produce antibodies seven days after the second shot? So that's called a point-in-time analysis. And so the benefits of the vaccine were only ever measured in one point of time. And nobody knows if they were helpful or harmful leading up to that point in time or if they were helpful or harmful after that point in time.

So, to approve a drug based on one time point is outrageous.

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And in terms of safety, they only actually followed people up for about two months. So the safety data for all the people hadn't been actually even collected and organized by the time they wrote their first report. And based on that preliminary safety data— Remember that I

would have wanted to see 15 years of study for a novel technology like this, and they have two months. Well, let's just say a year, and their randomized controlled trial, which is the only way to prove safety, was ongoing for two months. So this is what this interim order allowed them to do. It allowed them to take a sneak peek at this early data. And then basically say, "The house is burning. We need to approve this drug and get it to people so that we can save lives," all the while pushing through an extremely high-risk biologic. And giving it to healthy people.

Now this is just a little bit of the profile of the people that I would have been looking for. I would have wanted to see extensive testing in these groups. So again, we talked about the fact that they tested the wrong population. But I would have wanted to see testing in people with comorbidities. Because we know that if this particular agent activates pathways for inflammation, then people with comorbidities, which generally have high inflammation backgrounds, might have more side effects than, for instance, other people. So I would have really wanted to see a lot of good, careful study in people with comorbidities.

Teens and children: I would have wanted to make sure that this is not going to cause cancer and that this is not going to cause infertility in this group of people. So I would have wanted to see extensive testing in small groups of people before we rolled it out.

Pregnant women/babies and being developed: Extremely sensitive time of life and any significant changes during that time could cause considerable long-term harm. I would have wanted to see extensive safety testing. They weren't even included in a randomized controlled trial.

The frail elderly: Almost anything that's toxic could kill a frail elderly person. They were not well represented in the trial. And then, these were rolled out en masse indiscriminately in our long-term care facilities as a means of protecting them. So we're giving potentially harmful high-risk agents to frail elderly people.

And then again, the COVID recovered: Because these people's immune systems have already been activated and can identify the pathogen. So it would be reasonable to think that they're going to have a stronger immune response.

Again, we've talked about the preclinical. They didn't do the oncotoxicity, the repotoxicity, the genotoxicity. So how we could ever even conceive of giving these to people of childbearing age or children is beyond imagining. Again, the standard based on the FDA's own guidance is 15 years of testing. We did seven months.

And what I want to talk about now is that, again, we knew that there would be cardiac harm. So we could have been measuring troponin levels to see if there was any type of damage to the heart at a subclinical level. We knew that coagulation was a problem. So we could have been looking at D-dimer levels. We knew that inflammation could have been a problem. So we should have been looking at the C-reactive protein. These are all ways of measuring to make sure that people are not being harmed. But these were not done in the clinical trial. So what that makes me understand is that these people didn't want to find a safety signal.

Again, seven days. So reactogenicity, which is the immediate reaction that you get after a vaccine, and that was the only very careful monitoring that they did. And they only did that for seven days. So why did they only measure it for seven days? Why didn't they measure it beyond seven days?

How do we even know what happened after seven days? How do we know that there's not toxicity that shows up a month later or six months later? But the careful scrutiny only really happened for seven days.

So again, what that tells me is they didn't want to. This is a study that's designed not to find safety issues. They monitored severe and serious symptoms. So if somebody reported something and said, "Hey this happened just after the shot," then they would monitor that. But that's different than actively monitoring them where you solicit things: "Did you have any cardiac problems? Did you have any inflammation process?" et cetera, et cetera. So they weren't actively engaging the patient to find out if there were anything above and beyond just immediate flu-like symptoms.

So again, the moment they approved the vaccine, they basically dismantled the randomized controlled trial. This is a trick that people use in order to be able to, again, hide any type of long-term safety issues,

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by dismantling the placebo group. Which means that you unblind the trial, and you offer the placebo group the vaccine. You then send everybody over, and I think that it's up almost 89 per cent of the people in this particular trial went over to the vaccine arm and proceeded on. So then basically, what they did is they dismantle; that's like hiding the evidence. There's not going to be any evidence that there's going to be long-term safety issues.

So I mean, I have no idea what's in the mind of these people who designed this trial. But if I were designing a trial where I wanted to hide the bodies, where I wanted to hide safety issues, this is exactly how I would do it. I would make a decision based on early testing, dismantle my clinical trial, and only do the bare minimum of safety testing and reporting in order to be able to move my product through.

So let's take a look at the side effects profile again. So this is seven days after the second dose, and this is the Moderna vaccine. Now the safety profile for the Pfizer vaccine is practically identical, so I didn't bother putting that in here. But I just wanted to show you that these adverse events here—adverse events are the side effects that happen, fever, headache, fatigue, myalgia, arthralgia, nausea and vomiting, and chills—those are the symptoms of COVID.

So the reason why we're giving the vaccine is so that people won't get clinical symptoms related to COVID, so COVID-like symptoms. However, in giving this vaccine, they basically cause COVID-like symptoms. They cause the very thing that they're trying to avoid from a clinical perspective in more than 75 per cent of the people who received it. And of those people, 55 per cent of them got so sick from receiving this vaccine, this genetic therapy, this biologic, that they couldn't carry about their daily activities. So more than 50 per cent of the people that got this particular drug after the second dose were so sick they couldn't carry out their daily activities. Fifteen percent of them, they were basically lying in bed and unable to move. They were completely prevented from carrying out their activities.

So you take healthy people, especially people who don't have comorbidities and aren't elderly. You take healthy people who can easily get through COVID, and you cause 55 per cent of them to be so sick that they can't carry out their daily activities and 15 per cent to be so sick that it prevents them from carrying out their daily activities.

So when we're looking at biologics, when we're studying them, we always look for the red. The red here, it's called the Grade 3 toxicity. And if you have a Grade 3 toxicity, you judiciously, you very, very, very carefully only ever give it out to people who it's been proven safe in. And you would only give it to very high-risk groups where the risk–benefit ratio is highest.

However, with a drug that we know is causing the very thing that it's saying that it's being given to prevent and that it's causing a severe manifestation of it in more than 50 per cent of the people, they actually called this safe. And the way that they got away with that is because they didn't call it a clinical outcome. If we were looking at clinical symptoms as a clinical outcome, we would have said, "This is causing COVID-like symptoms. This is causing the very thing that we want to prevent." What they called it was reactogenicity by adding a creative label to it, just saying it's the thing that happens after you get the drug. Everybody said, "Oh, reactogenicity. We don't need to worry about that." But in fact, the reaction to this drug is so severe that I would have written a strong cautious recommendation in a guideline that we would be developing, saying that this should not be given to anybody who's frail or elderly or anybody who is concerned.

So the fact that they started giving this to healthy people, including people of childbearing age and teens and children, is incredible. So just to note, this is what they were doing. So severe adverse event interferes with daily activity, requires medical care and an ER visit or hospitalization. So this is what somebody looks like if they've had a severe reaction. A serious event as described in this particular thing requires inpatient hospitalization, was life-threatening, resulted in death, or persistent disability. So we know that 15 per cent had severe adverse events.

But I want to take a look now to see what the data tells us in terms of immediately after they had severe adverse events.

But whenever you look at everything altogether, the solicited and the unsolicited adverse events, the vaccines were purported to be very beneficial

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because they said they were 91 per cent effective. That's a relative risk change. It's basically just the difference between two numbers. It's definitely not that meaningful whenever it's a preliminary study that's only two months along and you're only looking at one point in time. But what makes it really not very interesting from a clinical point of view is that the absolute change between the two groups was only about 4 per cent. So even at six months, which is what this data is, only 4 per cent of people even benefited from that vaccine.

But ironically speaking, if you were to consider the side effects profile that we know, the difference between 850 [placebo arm] and 77 [vaccine arm] were the people who didn't get COVID. But everybody in the vaccine arm pretty much got COVID-like symptoms. So you know, it's a little bit of a shifty, tricky little thing that they did there.

But what I'd love to bring your attention to here is treatment-related adverse events. So this is an adverse event. So something bad that happens after you get the vaccine or the placebo. And it could be from the disease or it could be from the drug. It doesn't specify. But well, this one actually is from the treatment.

And what they said is that in the treatment arm, 5,241 people received an adverse event from the vaccine versus 1,311. So basically, they're lowering the chance of getting COVID by 91 per cent. But if you use the same metrics that they use and do the relative risk change, they actually increase the relative risk of treatment-related side effects by 300 per cent. So they're basically taking healthy people, and they're causing them to have an adverse event. Whereas the decrease, the benefit, was 4 per cent, the increase, the risk, is plus 18 per cent. So if we were holding to our traditional means of following this, the risks grossly outweigh the benefits for this particular vaccine. And that's just looking at any old adverse effect.

If we look at severe adverse effects, let's go back. It's a 75 per cent relative risk rate increase and a plus 0.5 per cent absolute risk increase. And severe, remember that's somebody getting so sick that they can't carry out their daily activities.

And serious, I'm just going to tell you again what serious means: inpatient hospitalization, life-threatening episode, results in death, or permanent disability. You have a net increase between the two arms. Now if COVID was so dangerous that it needed to be treated and treated in everybody, then the serious adverse event, serious outcomes, should have been higher in the placebo arm. And we should have seen lower in the vaccine arm. But what this is telling me is that this vaccine is more toxic, or the manner in which we're doing it vaccinating healthy people with this toxic substance, is causing more harm than good.

I just want to be sensitive to time. So I'm just going to move it along a little bit.

They also looked at deaths. So deaths before they dismantled the trial were 15 [vaccine arm] and 14 [placebo arm]. So again, you would have to say that that's comparable. So you could never argue at the time that this was authorized that this was saving lives because it was comparable between the two arms. But what's really concerning is why— I mean, if you have healthy people and you're measuring this six months later, and one arm is getting COVID, which is deadly and they die, I mean that would explain why you have deaths on the placebo arm. But why do you have so many deaths in the vaccine arm in healthy people after six months? That's unusual even in a sample of 40,000.

If we look at deaths after unblinding. So after they invited these placebo group people to come over to the vaccine arm, there were five additional deaths for a total of 20 deaths on the vaccine arm and only 14 in people who'd received the placebo, after six months.

And again, this particular part here, where they talk about the five additional deaths. Instead of making that very obvious and bringing it into the text and reporting on it in their conclusion, which is what they should have done if they wanted to make sure that they were being abundantly cautious and protecting people, they should have basically written that up in the front and included it in their conclusions. But instead, they buried it in the text.

One last thing that I want to highlight is if you look at the deaths, the cause of deaths, you can see that there were those from a cardiovascular nature. There were nine cardiovascular deaths on the vaccine arm and five on the placebo arm. Now you can't conclude anything clinically from that. But what I would have said is we need increased monitoring for cardiac problems moving forward and that this should not go out without more careful study.

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And yet, what we did was we rolled it out.

So again, if we remember what our test is and what the conclusion of the study is— So I've walked you through the Phase III trial results. So our traditional regulatory system would mean that we'd have to prove safety. So we haven't been able to prove safety because the study actually proved the opposite.

And yet here is the conclusion of the initial paper from the *New England Journal of Medicine* that was used as evidence to support the conclusion that the vaccines were beneficial. It says, the "two-dose regimen of the Pfizer vaccine conferred 95 per cent protection against COVID-19 in persons 16 years and older. Safety over a median of 2 months was similar to that of other viral vaccines." So they didn't make any safety statements. They just sidestepped that all together. They didn't prove safety. In fact, what their study did was disprove safety, but they failed to actually highlight that.

So I just want to talk about something called risk management plan.

Wayne Lenhardt
Could I ask just two quick questions here?

Deanna McLeod
Sure.

Wayne Lenhardt
This data looks very similar to I think what they came up with in the U.S. Were there separate studies done in Canada, unique studies here?

Deanna McLeod
That's a really good question.

So again, remember how we were talking about global pharmaceutical companies. Basically, they have global pharmaceutical companies developing these products. And then, basically, our government wants these global pharmaceutical product companies to invest in Canada. They need that in order to spur on this bioeconomy, this innovation that they want to do here in Canada. And so the whole impetus for changing the regulatory framework was to allow more innovation or more investment or to give more leeway to these large pharmaceutical companies. And interestingly enough, it's those very same large pharmaceutical companies that are asking us to lower standards of regulation that designed this trial.

Wayne Lenhardt
Well, that was going to be my next question. I mean, the Canadian government has spent billions and billions of dollars buying these vaccines. And my understanding, I think, is that they're coming from somewhere else. They're not being produced in Canada.

Deanna McLeod
No, this is not helping the economy whatsoever.

Wayne Lenhardt
I'm sorry?

Deanna McLeod
This did nothing for the Canadian economy, except for burden our healthcare system with vaccine injuries, which is probably going to hurt our economy in the end and perhaps destabilize our health system, I would argue.

Wayne Lenhardt
Okay.

Deanna McLeod
So I just want to continue on. And I want to talk about something called a risk management plan.

So again, the normal pathway is that you have a randomized control trial, that it is continued right to it's full— That it's completed. That it's well designed. And it's designed to prove something that's clinically relevant and completed. And then, at that point, they submit their dossier with all their complete safety results, their complete efficacy results. And then the regulatory official starts to evaluate it. And basically it authorizes them or not, based on whether they meet the test that Shawn has described previously.

This alternative pathway, this back door that they've created, this advanced therapeutics pathway, basically says we want flexible regulatory framework, which means, "I want to do away with this standard of needing to prove it. And I want to be able to move forward to market despite whether I've proved it or not. And what I'll do is I'll do extra surveillance. I'll just do extra study for these. And we'll do risk management plans in order to be able to ensure that people are safe."

So what I want to do is I want to look at some of these risk management plans that are available and what they look like when we looked at it with COVID-19.

So now, I've just got my evidence metre here again. This is my Bible. And so what we're going to be doing is we're going to be moving from the realm of what you can prove, which is up here, Level 1 Evidence, and we're going to be moving down to an area here where we can really only make observations and identify associations. We can no longer prove anything.

So I just want to say from a pharmaceutical point of view, if I'm somebody who is a very rich pharmaceutical company and I want to make money, what I want to do is I want to push the burden of proof down the ladder. Because these studies here are very easy to game.

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When I say game, it's that it's easy to design them in a way that you can actually get them to say what you want them to say. So you can manipulate the people that you allow into your analysis. You can manipulate the way that you monitor it. And then you can manipulate the

way that you sample different people in order to be able to make the results look the way that you want them to look.

And so what they did was they basically said, “You know what, we’ll do more of these trials if you allow us to market so we can make lots of money by missing this one. So basically, preliminary data from this one. And then, even though it showed that it was not safe, we’ll do lots and lots of studies.” So you can see that there’s tons of observational trials done on the COVID-19 vaccines. And you know, they’ll say, “The effectiveness is this or the safety is this in this population.” But interestingly enough, none of those trials can be used as evidence to prove safety. But that’s good for the drug manufacturer because they can’t be used not to prove that it’s not safe.

So what you do is you let them out. And then, now, the burden of proof has shifted from the manufacturer that was needing to prove safety to now the public that needs to prove that it’s not safe. So the one making all the money that has the ability to run the design, the trials, is no longer needed to do those safety testing. And the public who has no money and doesn’t have the money to run a clinical trial, a randomized clinical trial, to prove that it’s harmful, basically, are unable to do so. So it’s brilliant from a pharmaceutical point of view if you basically want to make sure that you are never called to order in terms of your safety. But it basically puts the public in a very perilous position.

So this is a crazy-looking graph, but I’m just going to walk you through it. So these are the different types of studies again and their ability to figure out safety. There are the different ways that you can monitor safety after a drug has been out on the market, or just period. So this one is the randomized controlled trial. And so, if you recall, we just looked at the data. And this is data from the Pfizer vaccine here from Thomas. And it basically showed that 70 per cent of the people that get the Pfizer vaccine are going to have some sort of adverse reaction to it. Five percent of those are going to be severe. Remember, severe is like it makes it so you can’t carry out your daily activities.

Now there’s another way of monitoring something. So this is active monitoring. It’s where you’re actively looking for the side effects. You’re carefully looking at the person. And that’s called prospective active monitoring. And when you do that, you find out that 78 per cent of the people actually are getting side effects from this drug.

The next thing is v-safe. So they basically say, we don’t want to do this [prospective active monitoring]. And of course, they don’t want to do that because that’s the best way to find out what the side effects are. “We want to be able to do something else. We want to have a registry where we’ll give the person their shot, and then we’re going to send them off. And they’ll have a phone. And then they can look at their phone, and then they can basically report any type of adverse events that they have.” So when you do that, which is active monitoring, you get 71 per cent of side effects. So it’s capturing most of them. But you don’t really catch many of the severe ones.

If you look at unsolicited, meaning that you just don’t even tell somebody—if they just come and prompt you. Like you don’t prompt them, they prompt you to say that they’ve had an adverse event. You only get 30 per cent. And again, that’s within a clinical trial. So this is solicited and this is unsolicited.

What we’ve done in Canada is we launched these vaccines, and then we basically said, “We’re going to rely on our passive surveillance system.” Passive surveillance system is a system that’s available that if you have an adverse reaction, then you’ve got to remember you had that adverse of reaction. It’s got to be so bad that you go see your doctor. Then the

doctor has to spend an hour to fill in a form. And then that form gets screened by who knows how many people in between. And then that adverse event gets deemed as legitimate because it matches what they're expecting, not what's unexpected, potentially. And then, once it's legitimized and it's entered into the system, our Canadian system records .07 per cent adverse reactions. Now, this is the true adverse reaction profile because we did the Phase III trials. And this is what the government is relying on to call these vaccines safe.

Now, it's not that they're safe. It's that the ability to test for the safety is insufficient. So they're insufficiently monitoring safety. And therefore, in the absence of detecting any safety issues,

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again, they're not having to prove safety. Without any proof otherwise, they're calling it safe. And so our whole presentation of these COVID-19 vaccines have been turned around because they changed the standard. Now they're saying that it's safe, not because it's been tested and proven safe but because there's an absence of safety data that proves that it's not safe.

So this is the v-safe. This is active surveillance. And this was data that the CDC was collecting and kept from the public during the vaccine rollout. And it was made public through an ICAN [Informed Consent Action Network] lawsuit. And they basically created this dashboard, and it basically tells you— So this is data from the people who had the app, and they were actively being monitored. So we know that this is probably going to be the best sense of figuring out how everyday people responded and reacted to this particular vaccine. And we see here that 30 per cent, according to this particular monitoring thing, and again, it's probably not as accurate as the Phase III trials. Thirty percent of people monitored experienced a severe adverse event. A significant proportion missed work and school. And about 8 per cent required medical care following vaccination.

Now, if you're giving it to healthy people who are not going to need medical care from COVID-19 and then you give them the vaccine and they require medical care, it would be hard-pressed to understand how we're benefiting people.

This is the serious adverse event report from VAERS [Vaccine Adverse Events Reporting System]. So VAERS is the system that barely picks up anything. It's called passive surveillance. It's the one that's the least sensitive at picking up safety issues. And this is basically a sum of all of the different adverse events reporting for all the vaccines leading up to the time when we changed our standard and we started pushing through biologics and giving them to healthy people. And what you see here is that you've got a jump between less than, what, maybe two or three thousand to thirty thousand adverse events reported. And again, this is passive surveillance. So it's under reported by some very significant amount.

In terms of deaths, basically, we have an incredibly huge jump in vaccine-related deaths with the rollout of this particular vaccine. So again, what we're seeing is these are very strong signals saying that there's something that's not right. However, this is not sufficient evidence to be able to prove or disprove safety. So therefore, this vaccine continues to be distributed.

This is a pharmacovigilance report. Basically, it's a passive surveillance report. This was again something that the FDA received. And it was not made public.

It measures the adverse events, again passive, unprompted. People have to work really hard to get their adverse events reported. So they suspect that they had a vaccine injury, and they report it to the company. And the company basically creates this report. And I just want to highlight the fact that in this report, there were about 1200 deaths. So this is where somebody got the vaccine. And then, they basically said, you know, "This person died right after the vaccine. I suspect that it's the vaccine." And we can make note of this and we can say, "Oh, that's a signal." But it can never be used as proof to take the vaccine off the market because you can't prove anything with this.

So twenty-five thousand people had nervous system. So again, we were looking for inflammation. We were looking for cardiac problems. But neurological problems were a little bit of a surprise. I just want to highlight something, as well, that 71 per cent of all the adverse events were in women. If I were to see that, then I would say that's shocking. And that should be stopped and looked at right away.

Sixty-four percent of the adverse events that were severe and that were reported were in groups that had little risk of any severe COVID-19. So these were people who didn't even need the vaccine, and 64 per cent of the ones were in that group of people. And you know what they said, "Well, we monitored it for seven days and it looked good. It was great." And so what they didn't say and what showed up in this report is that a third of the people who are injured don't fully recover, based on their own data. That's two and a half months after. So again, I would say this is lots of evidence that it's not safe. But again, not enough evidence to prove that it's not safe.

I think I'm a little bit sensitive for time right now. So I'm just going to jump along here.

[01:15:00]

This is about boosters and particularly boosters and teens. So again, the primary series was the first two doses and the third dose is called a booster dose. Again, we're not surprised that the first dose was about 60 per cent of people had adverse effects. We are familiar with our 75 per cent number.

But what I want to show is with every single dose, it's like getting COVID-19 all over again. You get COVID-like symptoms. You can see them here and here. But what's really troublesome is the severity of the symptoms over time when you get boosted. So the first one, in terms of being unable to go to school, there was only a small amount. Then it increased to point where of the teens who are getting their boosters, 20 per cent of them aren't able to go to work or school for the week after they get their vaccines. So again, I'm hard-pressed to understand how this can be actually helping children, teenagers, specifically, who aren't sick and have no risk from COVID-19. How can making them so sick that they can't go to school be helpful? It's hard to imagine.

This is a study by Dr. James Thorpe. And he was looking at outcomes in pregnancy, fetal outcomes related to women who have been vaccinated during pregnancy. And he compared them to the adverse events that happen from the influenza or the flu vaccine. So COVID-19 vaccine versus flu vaccine. It's measured by dose, so they controlled for that. And again, so after the COVID-19 vaccine, menstrual abnormalities.

And this is a really weird chart. So what this means is if "1" is your baseline here and if it's to the right of this, it means that the COVID-19 vaccine is causing more harm or there are

more adverse outcomes associated with the COVID-19 vaccine than the flu vaccine. And when I'm analyzing a study like this and we're looking at hazard ratios, reporting ratios—

Go ahead.

Wayne Lenhardt
Deanna, we're starting to run short on time.

Deanna McLeod
Okay, how about I— Do you want me to finish it up?

Wayne Lenhardt
Thank you.

Deanna McLeod
Okay, so I am going to jump to this last section here.

So I think we've gone through enough data now to say that the problem with a risk management strategy—meaning that you move away from the standard of a randomized control trial that's able to prove safety to something less than that—you can't prove that it's not safe, and, therefore, harmful agents can continue on the market like the COVID-19 vaccine unchecked.

And I want to, at this point, raise everybody's attention to the backdoor expansion program that's underway. So right now, in this issue, government issue of the *Gazette*, Part 1, Volume 156, the government is moving to expand the number of agents that can move through this backdoor. So again, we've just walked through what it looked like when the COVID-19 products were put through this particular backdoor system, where they didn't actually have to prove safety and efficacy before they were authorized. And how the risk management plans were not effective in controlling and identifying safety issues that could stop the vaccine from being provided or protect citizens.

They now want to expand that to Class I to IV medical devices. This particular program was designed because they wanted to have a pathway for things that didn't fit the normal pathway. So it's supposed to be an exception rather than a rule. And one of them was to figure out medical devices that have AI interfaces or machine learning.

And so I would imagine, and I can't say for sure, that one of the elements that would fall into this new category of medical devices could be AI-interfaced medical devices that learn and interface with somebody from an implant, for instance. I don't really know, it's not very specific. But the terms are so broad that almost anything can get through the back door in terms of a medical device, including something that has AI learning and potentially a biological–technical interface with it. So again, I would probably say if we had something like that, then we'd want to have an abundance of caution. And we'd want to take time to really learn what that means for humans and how that would interact with that before we would move it forward or allow it to have a fast track through our regulatory system.

The other thing that they want to do is— They have product-specific biologics requirements.

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And that sounds really crazy, but it means that you have to test each biologic individually. So, for instance, you had to test the Pfizer mRNA vaccine, and then you have to test the Moderna vaccine.

So what they want to do is they want to just do one study: We'll just do the Pfizer study and then anybody who has an mRNA vaccine like that, all that they have to do is show that they're comparable. They don't have to do all their original research, and we'll approve it automatically. So again, I think that that's very concerning because when it comes to gene therapy or biologics, just slight changes in the actual compound can turn on or off different pathways in your body. And/or code for different proteins or sequences. And so, again, I would say an abundance of caution should be applied here rather than removing the product-specific classifications.

They not only want to have human drugs needed for emergencies, but they actually want to expand it into veterinary drugs. Potentially, I have no idea how this would work, but would it be going into our food supply? And would we be getting secondary effects from any of these biological interventions or gene therapy interventions that are in our food supply? I think that that's something that we need to carefully consider and study before we would open this back door process to them.

And again, they were able to push through the COVID-19 products based on an emergency and, you know, a pandemic, an infectious disease, a global health emergency. But now what they want to do is they just want to be able to push it through the back door if it's an emerging infectious disease. And that term is so broad that they can actually make up almost anything. It doesn't even have to be life-threatening in order to be able to access this back door.

And again, they want to not only use it for treatment, but they basically want to use it for prevention and diagnosis. And the key word there is prevention and diagnosis means healthy people. And so again, if we go back to our standards, we want more study for things that are being given to healthy people.

I just want to say that as the closing thing for my particular presentation is that there's a deadline for being able to oppose these regulatory amendments, the extension of the back door. I highly recommend that we shut the door completely, especially when it comes to novel high-risk therapies that are being given to healthy people. And you can do that by commenting up to April 26, 2023, at the *Gazette*. There is a link that I can make available or calling your MP and saying that you absolutely do not agree with this lowering of the gold standard and this new approach to agents and especially the fact that they're trying to push through so many agents through the back door now.

So we're at a very critical point in our healthcare. Basically, what we're doing by authorizing this back door is when we grant expedited approval to novel high-risk therapeutics without proving their safety, we're basically formalizing the practice of human sacrifice. We're basically saying that it's acceptable as a community to sacrifice the people who will be injured by this on the altar of innovation. And I would say that we need to make a firm moral stance that that's not who we are as a community and as a society. And that we need to go back to absolute standards that protect.

And so this last thing is my sister. She was one of the people who was sacrificed on the altar of this innovation. She was a woman who had cared for special needs children. And she died following the vaccine from heart failure. So it reaches us all. And so that's all I have to say.

I'm happy to take some questions now.

Wayne Lenhardt
Thank you for your presentation. Are there any questions from the commissioners for this witness? Ken?

Commissioner Drysdale
Oh, sorry.

Wayne Lenhardt
She's on the other screen, Ken.

Commissioner Drysdale
There we go.

Could I get you to go back to one of the slides you had? It was the one right before the slide that said risk management plan. I want to understand something here.

Deanna McLeod
Which one?

Commissioner Drysdale
Backward still. Keep going.

Deanna McLeod
Let me know, let me know when I arrive here.

Commissioner Drysdale
Keep going. A little more. Keep going. One right before that one. Okay, sorry I lied—

Deanna McLeod
Just let me know which one it is.

Commissioner Drysdale
Keep going. Wait a minute,

[01:25:00]

I think that's it. Well, I'm not sure, but—

I thought I heard you— When you were talking about the testing that they did and you were talking about that they had split approximately 40,000 people into two groups and one was a placebo group, one had received the injection. And then I believe you said— I'm going over what you told me, and then I'm going to ask you a question about it. And then you said that test went on for two months. And then they took the placebo group and gave them the shot, so they eliminated the placebo group.

Deanna McLeod
Yes.

Commissioner Drysdale
And this was for, of course, you're doing this to test the safety of this product. Correct? You're doing this test.

Deanna McLeod
Uh hmmm.

Commissioner Drysdale
And so my question is— If I was evaluating cigarettes in this way, would I have found any of the bad effects that cigarettes have on people in testing it for two months in a group of 40,000 people? So if I would have tested cigarettes for two months, would I have known that they cause cancer, they cause heart disease, they cause whatever the heck else cigarettes cause?

Deanna McLeod
Well

Commissioner Drysdale
So using this protocol, is it theoretically possible you could have approved something like cigarettes to treat it?

Deanna McLeod
Oh, cigarettes would have definitely been approved. I mean, you could probably make a study look like cigarettes are helpful, right? I'm not sure what your endpoint would be. But you certainly wouldn't be able to find the long-term safety studies that we find, the safety issues that we find, right, with cigarettes using this.

In fact, I'm hard-pressed to think of one trial for cancer where they've only studied something for two months. We would have never, ever accepted a trial that had two months of data and then was dismantled. We would have basically said that the outcomes from that trial are no longer valuable and that it would never have received approval, even in people who are, you know, late-stage cancer patients.

So to think that they stopped the trial or dismantled the safety component of the trial—you know, the part that is able to prove that it's not safe—after two months. In my mind, the only thing that is reasonable to think is that it was done on purpose. Because somebody who was passionate about keeping people safe would have never done that.

Commissioner Drysdale
You also showed some charts that showed how many people had severe reactions to the vaccine. And you define the different levels as— If it affected your normal daily routines or if it made it so you couldn't do your normal daily routines, and so that was charts with regard to the effects of the vaccines.

But I'm wondering, are there charts that show that for getting COVID in the first place? In other words, we keep hearing about COVID cases that had no symptoms. We keep hearing about all kinds of things. So are you aware of a chart similar to the one you're showing on the screen right now for people who actually got COVID? What's the percentage of them that have no symptoms? What's the percentage of them that can't go to school? And I'm wondering how they compare.

Deanna McLeod
Yeah, so the way that you would do that is that you would look at— I mean, in a placebo controlled trial where you're looking at the placebo versus the vaccine, what you're really comparing is people who've received immunity from a vaccine to people who may not have had immunity yet. So this is kind of getting complicated. But it's a gamed trial.

So we know that immunity protects people from disease. And so, if you only give immunity to one arm and not to the other, right, then you know that the one that basically doesn't have immunity is likely going to be more sick.

However, interestingly enough, in this trial, we know that more people got COVID. This is the placebo arm right here—dose two, placebo arm. So this is people who got COVID. This is the background amount of people who got COVID. So they didn't get the vaccine. They got a placebo. And they got COVID. And there's more of them that got COVID. So you should say, wow, if there's more COVID, then you should have more adverse events, right? These are the adverse events. So you should have more COVID-like symptoms if you got more COVID.

But if you actually look at it, the total amount of the symptoms that people get if you were healthy and you got COVID was less than 50 per cent,

[01:30:00]

dramatically less. Most of that was mild. Only, what is it? I don't even know what that is. Maybe 12 per cent of them had something that was enough to make them really sick. And then very, very, very few of them were enough to prevent activities. And then you compare that to people who got the vaccine and prevents activities. Severe, right, red to red, this is dramatically higher. Blue to blue, this is dramatically higher. And gray.

It's incredible that we're thinking that we're giving this to protect people from COVID-like symptoms—or COVID symptoms—by giving them more COVID-like symptoms. It's mental gymnastics to think that this is how we arrived at saying that this is safe, when we agree that COVID-like symptoms are bad because that's why we're doing the trial in the first place.

Commissioner Drysdale
Thank you.

Commissioner DiGregorio
Thank you for coming and giving us testimony again. Very, very helpful.

I have a couple of questions about this new framework under the *Food and Drugs Act* that you talked about today and this alternative pathway to approval. And I'm just wondering, so if a drug is approved by the minister to undergo this alternative pathway, which seems to expedite the process, is there a pathway or is there some mechanism built into that pathway to bring the safety considerations back into the normal sort of time frame or pathway under the regular authorization process? Or is it, you just get into this expedited process and once you have the authorization, you're good to go.

Deanna McLeod
I'm going to say a couple of things. One is that the proposed amendments are so confusing and convoluted. I've never read something that lacks such clarity, which makes me suspect that perhaps they don't want it to be clear what it is that they're trying to do.

So in terms of being able to address those details, I think that that should be something where we should be all stopping and asking those important questions. I can't answer them based on the available information. But I do know from my experience in cancer, where we do have similar pathways called NOC/c that are used to get life-saving treatments to people who are dying from cancer who have no other treatments, so serious diseases, no other options, that once the accelerated approval is given— So what they'll do is they'll say, "Okay, your randomized control trial, preliminary data, I'm going to give you access to the market now. But I want you to complete your trial, and I want you to do said types of monitoring studies in order to be able to prove the safety of your drug."

I think the number is only about 50 per cent of the mandates for additional safety monitoring ever get completed. I can count on one hand the times that they've actually pulled a drug from the market once it's on there. And I think that it's almost like saying, it's a ball rolling down a hill and once the ball's halfway down the hill, it's really hard to get it back up to the top. The amount of energy that you need to employ in order to get that ball back up the hill or get the cat back in the bag or to address everything and to get all the doctors, who thought that it's good, to change their mind— It's very hard to go backwards.

And so what tends to happen is that these products stay out there for a very long time. And I'm not saying that there aren't some pharmaceutical companies who are diligent, who do the proper monitoring afterwards. The momentum to have somebody actively monitoring it from the government and to make sure that they're doing the studies and to make sure that they're checking the databases, puts all of that burden of proof on the government and the taxpayer. Whereas it would just have been simpler to say only the things that have been proven safe get out of the bag. And that way, you don't risk anybody from injury, especially with high-risk agents.

So I don't know if that's helpful. But, you know, after being in this business for probably about 10 years or so and watching this in the cancer area, I would probably say that it

should be under extremely exceptional circumstances that we should ever allow backdoor treatment.

Commissioner DiGregorio
Thank you.

Wayne Lenhardt
Okay. Thank you very much, Deanna. And I'll call on Kyle for the next witness.

Deanna McLeod
Okay, thank you very much for having me. Bye now.

[01:35:25]

Final Review and Approval: *Margaret Phillips, August 10, 2023.*

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