NATIONAL CITIZENS INQUIRY

Saskatoon, SK **Day 2**

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EVIDENCE

Witness 4: Dr. Luz Maria Gutschi (Parts I and II)
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PART I

[00:00:00]

Shawn Buckley
I'd like to begin by asking you to state your full name for the record, spelling your first and last name.

Dr. Luz Maria Gutschi
My full name is Luz Maria Gutschi: L–U–Z M–A–R–I–A G–U–T–S–C–H–I.

Shawn Buckley
And do you promise to tell the truth, the whole truth, and nothing but the truth so help you God?

Dr. Luz Maria Gutschi
I do.

Shawn Buckley
Just by way of introduction, my understanding is you're an expert pharmacotherapeutic specialist. And you're going to have to explain for us what that is.

Dr. Luz Maria Gutschi
I'm a pharmacist by training and have some extra training in what we call pharmacotherapy, which is therapy using drugs, as well as drug assessment skills, which includes looking at the data and assessing the drug for safety and efficacy and for application to individual patient care.

Shawn Buckley
Okay. And as far as the drug assessment thing, you've done reports for the Canadian Pharmacists Association and for various regulatory agencies.

Dr. Luz Maria Gutschi
Correct. I've written a few chapters for the Canadian Pharmacists Association on vitamins and minerals, and on lifestyle management. And I provided expert scientific advice to the Patented Medicine Prices Review Board [PMRB], which is a quasi-judicial board that regulates the prices of pharmaceuticals and vaccines in Canada.

Shawn Buckley
And then you've also been a clinical pharmacist for the Canadian Forces Health Services Centre.

Dr. Luz Maria Gutschi
Yes, I ran an [inaudible] clinic. In addition, I have practiced in intensive care units for 10 years, and have developed an expertise in antimicrobial management, including what we call antimicrobial stewardship and infectious diseases.

So quite a variety of experiences that I've had in my career.

Shawn Buckley
Right. Now we've entered—you sent me a CV that we've entered as Exhibit SA-2a, which also includes that you've got a doctorate in pharmacy.

Dr. Luz Maria Gutschi
Yes.

Shawn Buckley
And assuming I haven't changed your CV, you adopt it as true?

Dr. Luz Maria Gutschi
Yes, that's true.

Shawn Buckley
Okay. Now, you've got a presentation for us today [Exhibit SA-2]. We've invited you to speak about the manufacture of the mRNA vaccines. And I'm going to ask if you can proceed with that.

Dr. Luz Maria Gutschi
Yes, thank you. And I will try to do it as a—

First of all, before I start, I would also like to thank the Thesens for their testimony. It was very emotional for me as well, as I've had some— I understand that I've seen these— I'd

just like to say, “thank you” for their testimony. It was very emotional. And I think this is a great thing that we get to hear what happens with vaccine injury, among other things.

What I’m going to talk about is fairly technical, which I apologize for. However, I feel it is necessary for people to understand how these products were regulated from a regulatory perspective, and what the implications are for the future. Most of this was independent, as I basically stopped working a few months before the pandemic was announced.

Because of my infectious disease training, I was very interested in a pandemic and was following all along. And when I heard about the vaccine, I started doing what I would normally do in order to assess a drug.

One of the first things I do is I go to the European Medicine Agency [EMA], which is not typical of most people. Because in my previous experience, I had found that their reports were very complete, with lots of information that usually assisted me in my analysis.

For background, all regulators work from a Common Technical Document that’s called the eCTD, which is: the same information, the same basic information, is shared among all the regulators in the Western world—

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the EMA, which covers all the European Union, except for Switzerland and the UK, and then Canada, the FDA [Food and Drug Administration], and Japan and Singapore as well.

In this case, this product was reviewed as a rolling review assessment, which means they started assessing each piece of information as it came in, as it became available. What is normally done is the manufacturers would make an entire submission, bring it in, and the regulators would look at it. It does not change safety, efficacy, and quality requirements—that’s what we were told. I would say technically, that is true—the requirements were not changed—but there are implications for a rolling review, in my view, for assessment of the drug.

The pivotal trial, the trial that showed that we had 95 per cent vaccine efficacy, was published in November 2020. And shortly thereafter the vaccine was approved under Conditional Marketing Authority. That’s what they call it in the EU. It is an EUA [Emergency Use Authorization] in the US, an Interim Order in Canada. The Public Assessment Report that I used for this assessment went on the web on 2020. And actually, it was corrected in February, but I think I read it in January 2021.

I expected what is known as “regulatory flags,” which are specific obligations. These are obligations placed on the manufacturer in order to get full authorization that they had to meet. Canada has something similar, and so did the FDA. I expected that with regards to safety and efficacy and clinical data from the clinical trials in humans.

What I did not expect is that I saw four specific obligations out of the six that were manufacturing–based. And I read this and thought, “My goodness, how could they let this go on and actually give this to people?” I was really quite impressed. But I thought in my innocence that it would just take a little bit of time, and they would fix some of these manufacturing defects. So I told my family, “We’re going to wait until they fix these things,” because that’s likely, “and then we’ll reassess at that point.”

In addition, there's a leak of confidential documents to the dark web in January 2021. I found out about it in September. And it supplemented quite a bit all the information that was on the European Public Assessment Report [ePAR].
First, I'd like to talk about the steps in manufacturing this product. It is very complex with lots and lots of parts to it, or components, and each of those components have to be of very high quality. There are a varied number of manufacturers, number of suppliers, ultra-cold storage, and rapid transportation between sites. They'll have, like, 108 hours by the time they made the mRNA, and had to run over and put them in the lipid nanoparticles.

There are advantages to an mRNA vaccine, especially for a pandemic. Number one: it's fast. You can make a sample for 20 or 30,000 doses in 10 days from start to finish, and regular vaccines will take months. And the other advantage is that it is cell-free. We are not using cells, which are bound to be complications—such as putting it on chick embryos or other cells like insect cells or tobacco that we use, whatever.

The steps are: You make it in a production bioreactor, which actually does include E. coli. You digest out the DNA so that you can extract the mRNA, and then you have a lot of purification steps. You put it into the LNPs [lipid nanoparticles], which then require a bunch of purification steps. And then you bring filler finish, which is actually quite a big step. Manufacturers usually subcontract that out, and that is the steps for quality control, dilution, sterile filtration, capping it, labelling it. Then they put it in the deep freeze and sent it out as required.

Oh, dear, I'm stuck. Shawn, I'm—

Shawn Buckley
You're having some technical difficulties, are you?

Dr. Luz Maria Gutschi
Yes, I am.

Shawn Buckley
And you see, usually we have these at the beginning of the day. So it's nice to shake this up.

[00:10:00]

Dr. Luz Maria Gutschi
Lovely, I might have to go to my other computer if that's all right? Or I'm just going to have to— It's not working.

Shawn Buckley
If you need a couple of minutes, we actually have a video that we skipped over that takes about 6, 7 minutes that we could segue to, and then have you pick it up from there?

Dr. Luz Maria Gutschi
Fine. Let's hope I can get it to work. Thank you very much.

Shawn Buckley
Well, thank you, Maria.

So just to announce: We watched a video yesterday and what we've done is we've just had one of our video people put together clips for Saskatchewan. Because sometimes it's good to remember, even though it wasn't that long ago, just some of the things that we've experienced. So, okay— And our video lady is just looking for that, so just be patient and we'll just wait for Maria to get back on track.

[Video] Scott Moe
So effective immediately, public gatherings are now limited to no more than 25 people. Night clubs, bars and lounges must be closed. Effective on Monday, restaurants are required to close except for takeout and delivery services. Personal services, such as hair salons, are also ordered to close.

Dental, optometrist, chiropractic, podiatry clinics are also ordered to close except when offering non–elective procedures. Daycare facilities are limited to eight children unless they are able to…

Shawn Buckley
We have Maria logged in, so it might flip back or forth a little bit. We can give you a few minutes, Maria.

David, I think we might just take a break and we'll come back in about five, six minutes.

[00:13:10]

PART II

[00:00:00]

Shawn Buckley
Welcome back to the National Citizens Inquiry. We're sorry that we had to take a break, but when you're doing things online with virtual witnesses and the like, invariably you have some technical difficulties.

I'm pleased to have Maria Gutschi back on the line, and hopefully Maria, we're good to go. I'll just ask you if you can continue with your testimony.

Dr. Luz Maria Gutschi
Thank you very much. Can everyone see the screen in here?

Shawn Buckley
We can. We've got a slide "Regulatory review: Vaccine or gene therapy?"

Dr. Luz Maria Gutschi
Yes. So I talked about all the steps in manufacturing and the complexity of it.

One of the questions many people have is: Is it vaccine or is it gene therapy? And by definition, with the FDA and as well as the EMA, it is objectively a genetic therapy. Because it includes ribosomal nucleic acid, which is a nucleic acid or genetic therapy, and it acts inside the cell by translating those nucleic acids into a protein—in this case the spike protein. So objectively, it is defined as human gene therapy product. It does not necessarily affect our genetic makeup, but under regulatory, it is being classified as a vaccine for evaluation purposes.

We did a deep dive, some of my collaborators and I, to look at how the process occurred. In the early 2000, for example, the EMA and even the FDA had looked at mRNA- and DNA-type products and had classified them as gene therapy products, and they were being assessed as that.

Somewhere between 2004 and 2008 though, these products then became classified as vaccines such that, in 2012 in the EMA, the mRNA products were going to be evaluated as if they were a vaccine. Similarly, the FDA specifically said that guidance for gene therapy products do not apply to vaccines for infectious disease.

What we call in regulatory affairs the indication: What is the use of this product? If it is used to prevent an infectious disease, then it went down the vaccine regulatory pathway. And both the EMA and the FDA also specifically excluded them from long–term studies for genetic therapies. Because I could see a potential possibility where you would assess it as a vaccine for efficacy or under the clinical trials—you know, works as a vaccine; you do the clinical trials as a vaccine trial—but then assess its adverse events as gene therapy products. But these were specifically excluded.

Regulatory guidelines that are used in Canada, the EMA, and the FDA, was the WHO [World Health Organization] 2005 guidelines, who actually give nucleic acid vaccines the status as a vaccine. It delineates the controls, Good Manufacturing Practices for purity and quality, and supporting studies for a new formulation, which is the case for these mRNA products.

It's interesting that Moderna, even in its Security and Exchange Commission filings as late as June 2020, will admit that mRNA is considered a gene therapy but it is not assessed as such. And the BioNTech founder, Ugur Sahin, in 2014 wrote in a very seminal paper that they were uncertain where it would be classified. Because it would be classified either as gene therapy, somatic cell therapy, or biologic—and biologic includes vaccines.

So the issue with this mRNA product is that we really have two separate products. We had one product that was made in a different manufacturing process for the clinical trials, that pivotal November 2020 paper, and then we have the product that was used and rolled out commercially. While they were in the clinical trials that manufacturing process was not amenable to making millions of doses. It was an engineering issue that had to be resolved to scale up to make a large amount.

What they did—

[00:05:00]

On the left-hand side is this two-step reaction that you make. Now comes the technical part: You have to make a DNA, right? And from the DNA you make the mRNA, and the DNA is a

template in a line, and on the left-hand side is a two-step process. And on the right-hand side, the commercial product was a one-step process. And so it wasn't as accurate, and it had more contaminants.

And then came the purification steps. With the purification, they used something called magnetic beads to take the beads out that would suck the mRNA out, and then it would be denatured, and then the beads would get demagnetized, and you'd have nice little mRNA. With the commercial product, they had to scale it up and use a lot of filtration steps. And as a result, there were a bunch of unforeseen circumstances.

Overall, what the regulators were worried about—and these came very loud and clear in the documents, in the ePAR as well as the confidential documents—was the quality and purity of the mRNA; the different manufacturing process on scale-up; contamination; what was being produced by the mRNA, the spike protein; what they call characterization; and potency or pharmacology.

First, let me look at mRNA because it's absolutely, I find, critical for people to understand. Number one, the mRNA in these products—both in the clinical trials and here, are biosynthetic and modified. I think people think it's just simple mRNA from the virus, for example. Nothing could be further from the truth. They have been modified a great deal. I call it a biosynthetic, sometimes I call it a bioplastic mRNA.

On the left-hand side, this is how Moderna actually explains mRNA. It's a string of code basically, that goes through— The yellow thing is the ribosome, which is a little kind of a factory, and the little string coming out is the amino acids. Those get folded up into the spike protein. At the beginning, you have a 5' cap, which is kind of the beginning of a sentence, or the start. It's a capitalized word. You have what's known as untranslated reasons. They're just regulatory functions. Then you have that section, a coding section.

For coding, you have something called codons, or three nucleic acids make one protein. It's a triplet to make a protein. At the end, you've got a stop codon that tells it to stop making the protein. Then you have a long poly(A) tail, which sometimes wraps it out and keeps that ribosome steady so that it can continue to make the protein.

What they've done with the mRNA is that these individual codons: they've substituted another nucleic acid. You end up with the same protein. You end up with the same amino acids in the same sequence so that you really have no change. That's called a synonymous mutation, so that there's no change in the end product.

However, there are potential issues regarding how it's translated and other issues with the mRNA. Why do we actually do it? Why did BioNTech and Moderna do it? That's because the virus— If we put the virus mRNA into the lipid nanoparticles particles and they go into the cell, the cell realizes it is foreign mRNA and will mount a response to get rid of the viral mRNA, just like when you would get infected. So it gets destroyed before it can be made into the protein.

In addition, you actually facilitate the translation into protein and you make more protein than you normally would. It's also important to realize that we have human elements in this modified mRNA at the 5 end and at the 3' end. They are proprietary, or there's a patent for those. We think they come from the hemoglobin. The particular amino acid that they substituted was something called N1-methyl-pseudouridine. It is found in humans but in very, very small amounts. The organism that has the most N1-methyl-pseudouridine I found is a group of bacteria called archaeobacteria,

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which are ancient. These are bacteria that are found in the bottom of the Mariana Trench near those sea trenches growing at near-boiling water temperatures and at pHs of 1. They can tolerate a lot. So this nucleic acid is extremely stable.

What happened with the roll-up and the commercial or the scale-up is that you had a lot of truncated and fragmented mRNA. You need a full intact mRNA with the 5' cap and the poly(A) tail to make the protein. What we found was up to 50 per cent— They were running 55 to 60 per cent intact mRNA and the rest was truncated and fragmented. You could see these little bumps. Not only that, but the bumps were at specific times—or specific lengths, I should say. That usually meant there was a problem with the actual process, the IV transcription. As the mRNA was made, it would stop and wouldn't continue on, so you had that fragment length.

So they had a big meeting with Pfizer and said, "What's going on here? Can you please discuss this and tell us what the impact on safety and efficacy will be?" Pfizer said, "We really don't think it's going to be a problem. The bumps are the same. We just have more of them and it's unlikely to impact safety because they would be degraded and not translated since they don't have all the elements that are required for that to occur."

In the end, though, what the EMA was very concerned about is that we did not have the same product for the commercial batches as we did in the clinical trials. Normally under regulatory affairs, what most regulators would do with this amount is that we would ask for another clinical trial to ensure that we got the same safety and efficacy as we did in the original clinical trial that was published in November 2020. They had a big meeting. This slide is from a meeting they had with all the regulators, including Health Canada, the FDA. And said, "This is our concern: What are we going to do with it?"

I don't know what the outcome was. All I know is, as of December 2020, these amounts of impurities were accepted, and it was still given its conditional marketing approval despite these problems.

Back to the mRNA that are biosynthetic and modified. These issues with this modified biosynthetic mRNA was a potential problem that was recognized even by the founder of BioNTech: that with prolonged treatment, you might have adverse events within the cell. You could have toxicities or immune pathology because, even though they are less immunogenic than viral mRNA, they may have some actions that we don't know about. Especially in this little area here: We don't know how it's going to be metabolites and risks with metabolites, how it's going to be broken down, and potential unwanted cross–effects. These things needed to be assessed. Again, I reiterate, it has non-natural nucleosides as well as human.

Well, what happens to this modified mRNA? No RNA or protein metabolism or excretion studies will be conducted, said Pfizer too, and that is in keeping with the WHO guidelines. "We don't have to do it, so we're not going to do it." That was said to the EMA as well. Because they were following the guidelines, they said, "okay."

What do we find? We find that the mRNA doesn't get broken down very easily because of the N1-methyl-pseudouridine. We found back in early 2022: detected in the blood at 15 days; January 2023, we find it a month here, 28 days in the liver; and this seminal paper found it up to 60 days in the lymph nodes, both the vaccine and the spike mRNA. And we don't even know how much longer it would be because this is where they stopped.

And in case we didn't know that this N1-methyl-pseudouridine lasts a long time, this paper in 2015 showed that if you put just one of these in luciferase, they got protein production for up to 21 days.

The second outstanding issue is the spike protein production.

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One of the things we do from a regulatory perspective, this is not really— If I want to label this as a vaccine, and I will use that term because regulatory-wise that's the way it was seen— It is really a pro-vaccine, because the active drug is the spike protein, not the mRNA. The mRNA acts as a pro-drug which gets converted to the active drug. This is not uncommon in pharmacology. We have a lot of pro-drugs we use. There are certain major advantages to using them sometimes. But what we normally would see is that if we have a pro-drug, we want to know the structure and the function of the active drug as well.

And this I found as the specific obligation number one. When I read the ePAR in January, I was quite struck with the language used by the regulator: "A severe deficiency of the characterization section is" that we don't know what that spike protein looks like and you haven't given us enough information for us to assess whether or not that pro-drug is converted to the active drug in a way that satisfies regulatory processes.

And this language was quite strong, and I was quite amazed because this shouldn't really be an issue. This really shouldn't be a problem. That was one of the things I told my family. If I don't even know what the spike protein looks like, I'm not going to take this until I find out.

Figured it was just a matter of time. June '21 came along: nothing. And as well, December '21 came along: nothing. I looked for any evidence of the spike protein for two years. And I called this "Censored" because this little pharmacy school in Ohio published this in March of 2022. And you could see here that you actually—this is Moderna, though—had protein production up to 12 days. And these researchers were quite surprised by that.

And I want you to read this section here out of their paper: "In communications with Moderna and Pfizer regarding the proteins expressed by their synthetic mRNA vaccines, each company's medical information group disclosed that they had not examined the protein dynamics for more than 48 hours" after it was transfected in cell culture; that's how we measure it. "Owing to its proprietary status, they would not disclose any information related to the nature of the protein that was expressed."

This would mean that the spike protein is proprietary, or it's information that is only kept within themselves. That does not mean the regulator does not have access to that information. Regulators deal with proprietary information all the time. When I worked for PMPRB, we knew the prices that they were probably planning to price the drug at, which is really proprietary information. So there was no excuse as far, or there was no real reason why Pfizer and Moderna couldn't give the information regarding the spike protein.

It actually did come out. I found out about it with the judicial drop, the Judicial Watch documents in February of this year; we did get what they provided to the EMA. And as you can see here, the EMA was still not happy with this information, because the sizes weren't what they expected it to be. Pfizer said, "Well, that's because there's sugars on this spike protein," which is true: the virus spike protein is covered with sugars, which affects the kinds of antibodies that are made. So the EMA said, "Well, strip off the sugars, redo it and verify it with more quantitative tests called mass spec." And eventually this was done, but

not done until February 2022, when the EMA say, “Okay, we’re satisfied.” But as far as I know these things were not verified with mass spec. So the complete knowledge of this spike protein is still outstanding.

The second related problem is: Does it get converted? And if I transfect or I put those lipid nanoparticles on cells, do they go in and do I get a spike protein? This is measured through cell flow cytometry assay, which you see here. In the top line: you see this S1 green, that spike protein? Hah! You know the cells do make spike protein. It does not quantify if the expressed spike protein will be elicited

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or have the desired immune response in vivo, in active living organism, and it does not quantify how much spike protein is made. And the EMA still have problems with some of this testing.

I will give the commissioners the YouTube video that my friend— David Weissman goes to these FDA meetings. The FDA has a vaccine advisory group that advises them. And eventually in June, Dr. Portnoy asked Dr. Gruber from Pfizer how much spike protein is made and for how long. And Pfizer’s answer is, “Well, we really don’t understand that. We really don’t understand the way vaccine works, but we feel it’s an academic problem or an academic question, because we’ve got the antibodies. So it doesn’t really matter so much how much protein we make or for how long.” And this is where it stands.

At the end, the head of Pfizer R&D, Kathrin Jansen, who retired in November said, “We flew the airplane while we’re still building it.” And I think that’s really quite true. They went from step to step and really were behind the eight ball the entire time.

What you see behind this clip from Dr. Jansen is the European Medicines Agency’s procedural steps and scientific information after authorization. There are 80 pages of this stuff. If you read it, you see there’s a change to an importer or to a batch release site, a site where any manufacturing took place. We change in manufacturer starting materials, change in how you make it, lots of changes in tests and et cetera. And what Jansen said is, instead of scaling it up to a big, big thing, they scaled it up to six or seven little factories, which of course means you had even more issues with contamination and fragmented.

One thing that I didn’t actually— okay, so do I have enough time? I just want to go briefly over lipid manufacturing. Lipids are made spontaneously. They’re not like a chemically made thing. You have the lipids in ethanol, and they’re synthetic as well. The mRNA is in water and what you do is you mix it at very high speeds, like a jet mixer. And Pfizer and Moderna don’t even know how it works. This is under separate patents and the pH is changed, and by its swirls and all this stuff, they basically self–assemble into these little nanoparticles.

There are lots of issues with the little nanoparticles. They are sometimes not that stable. Over time they get bigger—and sometimes it takes six months—but they naturally grow bigger. And one of the reasons we have PEG on the outside is to stop them from getting bigger when they bump into something else.

We think of them as being round, with the lipid nanoparticles on the inside. This is a picture of one that— And you can see a few are empty: you don’t see any mRNA. And if you stress them—this is freeze and thaw, freeze and thaw; this is more than one freeze and thaw—they’ll start to what we call “agglomerate,” or start to clump together and fuse, and

sometimes you can release the mRNA out. We're not sure. And that's also dependent on pH. And also, the Japanese found if you shook it for five minutes, like really shake it, vortex shaking, the lipids all fall apart.

But a regulatory assessment of the LNPs was as novel excipients. What does that mean? It means the excipients are separate, non–pharmacological. They have no intrinsic activity of their own, they just enable the drug substance to be applied to the patient in the right form, and supports the way and place of action without being active themselves.

Under the regulation, the WHO 2005 regulations, you do get some toxicology profile, repeat those toxicity, some kinetics or biodistribution, and a few tests on general toxicity, teratogenicity, which I will not address.

What was not assessed by the WHO guidelines? No assessment of how long the actual individual lipids really last in the body. They did some preliminary work and supposedly we call a half-life of 25 days.

[00:25:00]

So you multiply that by five—that's what we do in order to determine how long it takes to get rid of all of those little lipids, not the nanoparticles, but the lipids. Thank goodness they're very small amounts, so the EMA said, "Well, it looks like it lasts a long time, but they're tiny. It's really small amounts, so I don't think it's going to be a problem." No verification of that though.

Drug interactions were not assessed because vaccines don't cause drug interactions. But in this case, this particular product did, and we had a few patients end up in hospital quite sick with interactions with an anti-schizophrenic drug, clozapine, because it is so inflammatory and transiently in the liver that it can interfere in some patients with some drugs.

We have an issue called CARPA. This was an outstanding issue for me. And it is complement-activation-related-pseudo-allergy. It looks like an allergic reaction but it's not, and it's due to the fact [inaudible] take on a nanoparticle. This is known. We have a drug that we give in chemotherapy, which is a nanoparticle with a chemo inside: doxorubicin used in breast cancer. And we have lots and lots of CARPA–like reactions from this, and it's well known, and we have lots of protocols on how to manage it.

CARPA, if you're not managing or looking for it, can be dangerous because there's amplification and patients can get pulmonary hypertension. They can drop their blood pressure, they can have bronchospasm, and it looks like an allergy. But it is not the typical anaphylaxis of IgE allergy—though it's treated the same. We don't look at secondary pharmacology and pharmacodynamics. Genotoxicity and carcinogenicity was not done, because these are natural MRNAs—I disagree with that characterization—and natural lipids—I also disagree with that characterization. So therefore, we don't need to worry about it. That was the rationale used for the WHO 2005 guidelines.

The environmental risk assessment: Well, you would do that for gene therapies, because you would look to see where the genetic therapy in the lipids go to, whether or not they're excreted as exosomes. In fact, we found that to occur with the Pfizer vaccine in a paper done here in 2021 by Bansal, where they found— Exosomes are little bits of the cell wall, and inside was a spike protein and partially digested lipoproteins. And these can move to

other parts of the body and actually transfect and provide the spike protein into another cell.

In addition, there's a product that's very similar that is a gene therapy product that has similar lipid nanoparticles, doesn't have mRNA. It's a non-coding, and a very, very small RNA. They found that they have some—they call them exosomes as well, that float around for a long, long time. And my colleagues and I are wondering if this is the rationale for shedding. It needs verification, it has not been studied; it is just a potential possibility as one reason why spike protein or mRNA can last in the body for some time. And it doesn't cause as much cytokine stimulation compared to intact LNPs, which can be quite immunostimulatory.

Speaking of that, here are some of the toxicity assessments done with rats. Just this month, they actually published the rat liver studies, or the rat toxicity that they did. And this is a picture right from the trials that was used for the regulatory assessment. You can see a bunch— This red in the middle, off in the lower left side, is an artery with blood in it, and little white dots that they think is a bit of lipid accumulation. It wasn't considered really super important, but it was a potential possibility that meant that we have some toxicity in the liver.

And what happened here is that the results of this study was September of 2020. And we had already started the clinical trials. Under normal circumstances, we'd either do a reassessment or amendment on the trial and measure, say, the liver function tests in a set of people, to ensure that this potential signal that was found here is not found in humans.

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And actually, the EMA said, "Well, you know, it doesn't look too bad," and I would agree with that. "But we also have the patient data that's coming in and assessed in clinical trials, so we'll be able to know if this is an ongoing issue." Unfortunately, to best of my knowledge, the people who know the clinical trial data better— I don't believe that liver function tests were measured on a regular basis, and someone could correct me if I'm wrong on that.

On the biodistribution side, I think most of the people understand some of the issues regarding the biodistribution. And I will say a few things. One, if it was assessed as gene therapy, that signal that stopped at 48 hours—because we only have data to 48 hours—would not have stopped at 48 hours. It would have continued until we had those signal detection. This biodistribution study labeled the lipid nanoparticles. The issue with that is it doesn't tell you how much spike protein is made. So just because the lipid nanoparticles that we see, and were tagged, went to these organs, it doesn't necessarily mean that there's a lot of spike protein made. It is likely, but that assumption needs to be tested.

In addition, if the lipid nanoparticles have luciferase in it—which is the issue that was here—instead of the actual mRNA that is in the vials, that is in the commercial product, there's no guarantee that the biodistribution will be the same either. Because sometimes packing—you know, those mRNA, the packing within a lipid nanoparticle—can sometimes change its biodistribution.

Most importantly, there were no Specific Obligations imposed on either the toxicity issues or on the biodistribution issues, which means that there are no further studies that might be required for future mRNA vaccines. And this, in my assessment, should be changed.

Lastly, assays and tests. This was a new platform, as they say in regulatory language. We had no standards against which we could measure things. What is the right test to measure how much RNA is in those vials? Do you use this, do you use that? And even if you know which tests to use, how are they going to be done? This is what we call a pharmaceutical standard, or United States Pharmacopeia.

We use this in hospital. There are certain criteria on how we have to clean our hoods, and we can't just use any old alcohol: a specific alcohol. And we have to do it in a certain way, with a certain amount of coverage. It is very well spelled out so that you can guarantee every little pharmacy, hospital pharmacy in Ontario or whoever's following, are doing the same thing. That's a compendial standard.

There are no compendial standards for many of the tests that are used. They are currently being proposed and in talks. So hopefully that will improve things quite a bit.

The contaminants that are found in making the mRNA: We had some previous testimony about the double-stranded RNA contaminants, the entire plasmids, which is a risk—a huge risk perhaps—for genomic integration. Though I remain actually— I think that may not be, but that's just me. Double-stranded RNA. Endotoxin. Endotoxin. Endotoxin: Is what's found in the E. coli cells that you use to make the plasmid DNA. Very hard to eliminate from these products. Endotoxin is ubiquitous and it's extremely toxic. This is what causes septic shock. And this is what I saw in ICU, in the patients who got sick with gram negative bacteria: It's the endotoxin that causes much of the damage in septic shock. We need to have compendial standards. We need to make that endotoxin as low as possible. And that is an ongoing issue that needs to be resolved.

The EMA reviewer, I think was summarized here, had some very poignant observations. They said, "inherent variability in making this product." "We are going to have difficulty testing," especially on the potency side. "It's a brand-new technology," we don't know where it's going further. "Potential toxic impurities,"

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and a "risk of bioavailability issue."

These guidelines are wholly inadequate. And in fact, the WHO is actually making new guidelines, which I think are still not going to be sufficient, because they're still not going to be assessed as gene therapy products.

This is what was discussed and how these products, especially the Pfizer product, was analyzed by the European Medicine Association.

And that is my testimony.

Shawn Buckley
Thank you, Maria. I'll ask the commissioners if they have any questions.

Commissioner Massie
Thank you, Dr. Gutschi, for this presentation. I have a couple of questions. The first one is, given the change in regulation, I was not aware that the classification of these mRNA–based vaccines had been amended so long ago; I thought it was more recent. So, I'm wondering—

because they hadn't mandated it more than 10 years ago, and they were probably already testing some mRNA vaccines for a number of indications like cancer and so on—why is it that the industry and the regulatory agency have not taken the steps to ensure quality attribute in production and biodistribution and so on? It seems to me that there's kind of a gap—

Dr. Luz Maria Gutschi
A big one.

Commissioner Massie
—in the quality that you would expect normally for still a new product. I mean, this is not a product that has been used that broadly.

Dr. Luz Maria Gutschi
Correct. You would expect that some of the quality issues would have been worked out ahead of time. And I don't know why they had so much— I think they weren't expecting the issues with the IVT that they found with the in vitro transcription. And all the truncated— That they weren't expecting. They were trying very hard to get the double-stranded RNA out, and the endotoxin out, and the DNA out. I think they had worked that out pretty well.

The problem I have with those contaminants is that we're not taking into consideration they're transfected, so that they're in the cell as opposed to outside the cell that you would get, say with endotoxin; you would have the endotoxin outside the cell and you wouldn't have it in. I'm not sure that was taken into consideration. But you're right. And it's not only the way I feel; it's not only that these things should have been thought upon, or it's maybe the scale-up was an engineering issue that lab and other researchers did not consider. It is sometimes how I feel as a pharmacist when orders come to us. It's like, "How am I going to operationalize that order? Because there's a bunch of steps here you guys haven't considered." And maybe there was that gap of understanding: the engineering aspect that wasn't there, number one.

And number two: It was obvious to me that it was going to be approved December 2020 no matter how bad it was. Because all of the issues that were coming up in November, I think, some of them might have been able to be solved by, say, March of 2021. Hold it off for three to four months. And that wasn't done. That's another question that I had.

But I agree. I think there were a lot of unforeseen situations that was on the biotechnical engineering field that was not considered by the researchers. That's my feeling.

Commissioner Massie
My other question has to do with the requirement by EMA on the quality—critical quality attribute of the product. If I remember well, what was qualified in the batch produced for clinical trial didn't seem to be the same level of quality in the large-scale commercial product. And I think I heard you mention that they were asked to try to get a solution for that, but it seems that this was not possible or was not done, and then it seems that the solution was, "Okay, we'll just raise the standard."

Was that what happened? And what kind of concern would that raise with the quality of the product?

Dr. Luz Maria Gutschi
Oh, it's huge.

[00:40:00]

The critical quality attributes are what has been placed— So you come up with a standard batch that you think is your quality batch. It defines how much the RNA integrity, how much purely RNA, how much of the contaminants are allowed, and how good the LNPs are. So it was quite a long list. And that was defined, as you said, for the clinical batches. And they basically dropped it all! Including the double-stranded RNA, because it was a big fight you could find in there where they said, "The standard that you put forward, Pfizer, we don't like." And yet a month later, it was accepted.

Yes, it seems to me—and this is just my impression—that the batch standards were lowered. So that basically anything that came out of the factory was acceptable. So that there would be very few batches that would be turned away. That's the way it looked like to me, that any batch was going to be accepted.

Including batches with stainless steel particles in them. I don't know if anyone remembers that story of Moderna's: In September '21, a bunch of doses were sent to Japan, and they had stainless steel particles you could see with your eye in them. And they should never have left the factory floor, or the fill and finish. Remember I said they have optical eyes, and they have people actually looking at them before they're sent out. I cannot understand, based on all my years of experience, how something with particulates that you can see with your eye—with the naked eye, you don't even need an optical or anything—left the factory floor. And yet it did.

Commissioner Massie
With respect to batch quality, we've heard in other testimony that it's possible that the activity of the different batch would actually vary, meaning the level of spike protein or the quality of spike protein that was produced from a given batch. And we've also learned that there seems to be some batch from the VAERS [Vaccine Adverse Event Reporting System] database that seems to have more adverse event associated with it.

You could look at it from two different angles. The one that has the highest amount of adverse event could have been the batches that were more active, if we speculate that the adverse event is the result of spike production. Or it could be because of all kinds of contaminants in the batch that are triggering unknown reactions in people.

What is your take on that?

Dr. Luz Maria Gutschi
I think it's all of them. But one that I am concerned about—that really, I think, needs some more work—is that CARPA syndrome I talked about. We do know that in the beginning, Pfizer's product line— Just as it was leaving, just as they were approving it, they found particulates in the Pfizer product. And if you look at the monograph—this is the stuff that the pharmacists look at—it says you should be looking at the vials. Each of them. If you see particulates, you throw it out; you don't use it.

And what was happening there: The lipid nanoparticles were agglomerating and they were getting big and they could get more toxic that way, and cause what I think is that allergic CARPA reaction.

I'm also thinking that it's not only the mRNA, it's that the lipid nanoparticles were made in such a way that they weren't stable enough. One of the reasons is that the buffer that was used by Pfizer did not keep those LNPs from agglomerating. So they changed to the Tris Buffer in October '21, which is the same one as Moderna had, and that stabilizes the nanoparticles. That might play a role.

Those lipid nanoparticles are quite fascinating, and it's taken me a long time to wrap my head around them. And they can be quite toxic under certain circumstances. So let's not rule out the lipid nanoparticles. And let's not rule out that you can have differences from vial to vial in addition to batch to batch. Okay?

One thing that I found out recently: Remember I showed you they mix them at the end? The lipid nanoparticles are diluted out and they're mixed in a big bioreactor. What they found is that you don't have the same mRNA at the top of the vat, the middle of the vat, or at the bottom of the vat.

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So it's quite possible as they're filling their batches that not every vial has the same amount of mRNA. That is a possibility as well. And that is the difficulty of making a stable solution of the lipid nanoparticles.

Commissioner Massie
Yeah, on that note, I was wondering about— You mentioned that the lipid nanoparticles were assembled from lipids, right? Is there an issue, to the best of your knowledge, with the source of lipid, where they're getting it? And do we have assurance of reproducibility of the lipid quality?

Dr. Luz Maria Gutschi
In the beginning, that was an issue. And the EMA identified, "How do you make it? Were there contaminants in there?" Et cetera. That has gotten better. That is the one thing in these products that has improved: they've gotten new manufacturers; the quality has improved so that it is much more reproducible. It's easier to make lipids than it is mRNA. However, most interestingly is that you do have some metals like arsenic and lead in it just from the process, in very tiny amounts that normally would pass toxicology because it's an exposure— Tiny amounts: we have it in our food, we have it in other drugs that normally would not cause a big problem.

But what they found is that those metals act like a catalyst. And you ended up with reactions in between the lipids and the mRNA so that they formed what is called chemically an adduct. And when you have adducts you don't have the mRNA available; it basically is ruined. So that might be another reason why some batches or some vials did not have mRNA available to be translated, because it was adducted to the LNPs.

Yeah. All kinds of problems with manufacturing this product.

Commissioner Massie
Maybe one last question. The scale-up or the commercial production of these mRNA required an incredible logistic, in terms of having different manufacturing sites, different sources of material that would come from different places, and the assembly of the final product may be in other places. So that requires that every step at these different sites is properly, I would say, controlled for quality—examined and checked.
Do you think that the regulatory agencies had, or currently have, the resources to do the typical inspection that they would normally do for production of such large quantities of an injectable product?

Dr. Luz Maria Gutschi
No, I don't think they were done. I think the Americans tried and the Europeans tried. But it was hard to do. Some of them were done virtually. And they're just behind, right? You get qualified a year later rather than before you start making it. You basically get the paperwork. Paperwork looks good but this site inspection could sometimes take a year.

And that's not only for this product, okay? This is true for many, many drugs and many, many products we have on the market. That office is understaffed and the site visits of manufacturing plants is a huge, huge problem all across the Western world.

So, no, I don't think so. I don't think they were kept up. And who knows? Yes. Another problem.

Commissioner Massie
Thank you very much.

Dr. Luz Maria Gutschi
You're welcome.

Shawn Buckley
So are there any other commissioner questions? There are, okay, and I have a couple more too after they're done.

Commissioner Kaikkonen
Good afternoon. I'm just going to ask a more practical question. On your "Not Assessed" slide, one of the points was the drug interactions were not assessed. So if I extend this thought a little bit further to vulnerable populations living in government subsidized low-income housing, or a group home, for example, where mandates were demanded, vax for all occupants: Could this mean that there were no medical considerations, interventions, or oversight for pharmaceutical medications already prescribed?

And I'm going to take it to the bipolar population. Where they're diagnosed as bipolar, they didn't go to the pharmacy where the pharmacist may have had access to their already-prescribed medications. Rather, a nurse came into their facility and vaxxed them. I'm just wondering what your thoughts are.

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Dr. Luz Maria Gutschi
I would say, at the rollout or in the beginning, this was not considered at all—that there would be any drug interactions with this vaccine. In general. And so that wasn't under consideration. I think astute pharmacists found that they were seeing deterioration in some of these patients that you're talking about and had access to their drug files. And with Clozaril in particular, because you're measuring the white counts, which are directly related to the levels of Clozaril, you could see that happening before your eyes. So that is how that was picked up. And it just required a mind to ask these questions and assess them. And so then the case reports started coming in that this is a potential problem.

But originally, no. That would not have been given a consideration. At all. And it is a concern to me because you read case reports, and you see people getting acutely psychotic or acutely having some mental health issue for a few weeks after vaccination. And the vaccine as a cause was never, ever considered. Except in retrospect.

Commissioner Kaikkonen
Thank you. That's all.

Commissioner Drysdale
Good afternoon, doctor. There was just a few things that I thought I heard you say, or picked up, and I wanted to confirm my understanding. We've heard a fair bit of testimony concerning the vaccines. And one statement I believe you said is that you did not feel it was likely that there would be genomic integration.

Dr. Luz Maria Gutschi
Yeah. That has to do with the circular DNA that Kevin McKernan has found contaminating them. I am not certain that the— I don't have the expertise to say that. I'm just saying that needs to be looked at as a potential risk, but I am concerned with the actual action of the mRNA within the cells as well. So let's not forget that. That's really what I'm trying to say.

Commissioner Drysdale
But I want to make sure I understand this, because I've asked this question from a number of different witnesses who talk about— Hopefully I get the term right, I'm not a doctor or a pharmacist. "Reverse transcription," was a word that was used before.

Dr. Luz Maria Gutschi
I'm sorry. Reverse transcription, I'm not that familiar with it, because it's very a genomic thing. So I can't make any comments regarding that particular aspect of these vaccines. If it was assessed as a gene therapy product, though, this would be assessed right off the bat, right? So that you would have the answers to that.

Commissioner Drysdale
That's an interesting thing that you talked about. You went through the definition of a gene therapy—and this clearly is a gene therapy. I need help with this, because then I heard you say, "Well, they said it was a vaccine. And then they assessed it as a vaccine, but it's really a gene therapy."

Is that, is that like— Oh gosh, I'm trying to think of historical examples where something with— Oh, I know one: Mr. Buckley mentioned a number of times that certain provinces had snitch lines but in Manitoba, they called them "ambassador lines." So you went from being a snitch to an ambassador. Are we talking about the same thing? It really is this, but we'll just call it this.

Dr. Luz Maria Gutschi
It is very, it's regulatory kind of language. In regulation, oftentimes the indication, what its use is going to be, dictates the kind of clinical trials. So Pharma gets very good at picking out what they think their drugs should be used in for the first indication, even though they really plan to use it in this disease. They will do the studies for this one, which opens up the door for the second. So it is probably an issue with how regulation works.

In this case, though, I think it was a bit egregious, because it is a gene therapy product. It probably needs its own regulatory path, in my view. Right? Because you would design the clinical trials to meet what you would need for vaccines,

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but all the other kinds of tests you would do for a gene therapy product. So that would be what I think should happen. And I think that's probably the route that they'll take.

Commissioner Drysdale
I want to comment— I don't want to lose the thought about genomic integration. My understanding of what that means is, in my terms, that there's a potential—perhaps unrealized or unevaluated—that the effect of this could be to change the genetic blueprint in the receptor's body. And the genetic blueprint is the DNA, as I understand it, actually is the instruction set or the recipe. I'm trying to speak in terms that I can understand—I'm not a doctor—and that perhaps the folks listening can understand.

The DNA, as I understand it in talking with previous witnesses, is kind of a drawing or a map or a recipe as to how to make other cells. And if you integrate something foreign into that, who knows what that plan is now telling us? So we could have issues with cancer. We could have issues with—I'm being silly, but—instead of getting a liver, you get a heart. Is that what we're talking about?

Dr. Luz Maria Gutschi
Yes. Well, it's the mRNA itself— I guess there are studies that show it can potentially be reversed, that's the mRNA, it can be reverse transcribed in, so you don't need DNA in there. And it all depends where it gets reverse transcribed in, is my understanding. So if it's done in cells that are rapidly dividing or in germ cells, like in ovaries or testes, much more important than, say, it's reverse transcribed into a muscle cell, because it's not going to make anything, necessarily.

Then we have the second part, which is the contamination with intact DNA plasmids. It's much easier for them to do genomic integration. And that is, I think, the testimony that I also listened to from Laura Braden.

So there's two separate issues: The intact DNA plasmids, which are contaminants that should not be there, and that's one issue. And then the mRNA itself, can it go and reverse

transcribe? And those are issues that need to be resolved. And I really can't comment any further than that.

Commissioner Drysdale
I understand. But again, this was not something that was given to a hundred test subjects in a laboratory. This was something that people were— And I'm not sure, I'm not a lawyer either and I do not understand the difference between "coercion" and "forced." People keep saying that the vaccines were coerced into people. And when someone's threatening their job, and someone's threatening your livelihood, and someone's threatening your children, I don't know what the difference between coerced and forced is, and maybe we can get Mr. Buckley to shed some light on that.

But this was not something that was given to a hundred test subjects that agreed. This was something that was given to billions and billions of people in the world, and we don't know these fundamental questions.

And what Dr. Braden was talking about: This reverse transcription or this integration into the genome, we could have unleashed a Pandora's box on our planet. And we don't know the answer to this.

Dr. Luz Maria Gutschi
Yep. And I would say the mRNA itself, the biosynthetic mRNA, you could describe the Pandora's box even just for the modified mRNA.

Commissioner Drysdale
Two last, more easy, questions. Did I also hear you say—because I asked this question previously of other witnesses—and I thought I understood you to say that the vaccines that were used in the trials were not the same vaccines necessarily that came out in production when you went to your drugstore and got it put in your arm.

Dr. Luz Maria Gutschi
Correct. That is a big, big issue. Because of the production and the manufacturing and the quality between the two products, they are, in my view, totally different products, and should have undergone some kind of verification that the commercial batch products was going to give you the same safety and efficacy as those in the clinical trials.

Commissioner Drysdale
One last question, doctor. In December of 2020, we heard from testimony, Health Canada came out with a written statement to all Canadians that this vaccine could be trusted, that it was produced in a rigorous process,

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and that it was being monitored in a strong monitoring system. In your opinion, is that statement correct?

Dr. Luz Maria Gutschi
When I heard that, I went: Did you read the ePAR? I said, "How could they say that is a strong, high-quality thing?" I guess their definition is not mine, is all I can say regarding that. That's not what I would expect of a good manufacturing product.

I'd like to make one more note regarding this. We have regulators— Or for instance, the incorporation of the FDA in 1906. Their role was for quality control, was for labeling and adulteration. Because prior to that, kids were dying because they were given syrups that contained cocaine in it, or heroin, that was not on the label. The role of the FDA when they were first put into being was not for safety and efficacy, it was for quality control. And I feel that all our regulatory agencies have failed their basic mandate.

So yes, their definition does not meet mine.

Commissioner Drysdale
Thank you very much.

Shawn Buckley
Maria, I've got a couple more questions that just came to me as the first question—

Dr. Luz Maria Gutschi
Of course!

Shawn Buckley
Because Commissioner Drysdale was asking you about reverse transcriptase, and you're talking about— Well, you're insinuating it could be worse if this would collect in things like ovaries or testes, which I think you referred to as germ cells. But isn't it true that the research is showing that is exactly where these mRNA particles congregate?

Dr. Luz Maria Gutschi
Yeah. So, it could be a potential—yes. The biodistribution study needs to be redone because I'm not sure how much it actually shows. It could be worse than what we think. And it could be better, I'm not sure; considering the side effects that we see I don't think so. But it could be actually worse than what was the data that we actually have. So I just want to keep that in mind, that that is a potential possibility.

As far as all this molecular genetic stuff, I'm a pharmacist by training. This is new to me, so my expertise is really limited in this area. I don't want to step outside my bounds.

Shawn Buckley
But you are an expert in the manufacturing process, and you've used some wonderfully technical terms. But a lot of the people participating are not going to understand those.

Dr. Luz Maria Gutschi
I know.

Shawn Buckley
And when you and I were discussing things, you actually said, “Are you going to ask me this question?” Which used a non-scientific term. That was: “How did the European Medicines Agency change their mind on the good manufacturing practices nightmare?” And it’s the word “nightmare” that’s jumping out, because that’s a very scientific term such as “train wreck.”

How would you describe in layperson terms the quality that was coming out at the end of the manufacturing process?

Dr. Luz Maria Gutschi
I thought it wasn’t even fit for veterinary purposes. Nothing against— They’re actually very good drugs, but I thought this was swill.

Shawn Buckley
You mean veterinary drugs are good drugs.

Dr. Luz Maria Gutschi
Yes, they are good drugs. “I wouldn’t even give my dying cat this,” is what I said when I first read it. I said, “How could anyone let this product leave their factories?” I was absolutely horrified when I first read the ePAR. And then when I read the documents that were leaked, the confidential documents: It was at least a little bit good to hear that the EMA, the bench regulators, the regulators who are actually looking at the data, were also concerned. So it wasn’t just me. They were also quite concerned with the quality.

It’s obvious that something happened between November and December 2020. That all the issues that were brought up. There was large turnover in EMA after these drugs were approved. There were some high-profile people who left. I feel that, yes, there was a lot of internal turmoil. And that this normally— Even for a pandemic! Which is usually what I am told while it was a pandemic. And I’m thinking, it’s not always better to do something than not to do something.

So, “We needed a vaccine, it’s better than nothing!” And I think that is a fallacy, and it may not have been better than nothing.

[01:05:00]

Shawn Buckley
So let me lead you a little bit. Am I correct that the European Medicines Agency identified some atrocious quality control issues?

Dr. Luz Maria Gutschi
Yes, they did.

Shawn Buckley
I mean shocking quality control issues.

Dr. Luz Maria Gutschi
Yes, they did.

Shawn Buckley
And then, within a short period of time, they basically gave Pfizer a pass on these quality control issues.

Dr. Luz Maria Gutschi
Correct.

Shawn Buckley
And following that, there was an exodus of personnel from the European Medicines Agency.

Dr. Luz Maria Gutschi
There was a few high-profile— I can't remember the person's name. There was one or two that left that were— And I remember reading about it but I don't have that collection, that actual news item. But there was somebody who did. Same thing in the FDA as well. And we know Marion Gruber left in mid-2021 because of the way the FDA was reviewing these products.

There were some people who were quite upset about this internally, that I'm certain of.

Shawn Buckley
Right and, "this" meaning basically giving pharmaceutical companies a pass on quality control that is literally dangerous.

Dr. Luz Maria Gutschi
I believe so. And I want to make one point regarding that. It's unusual for pharmaceutical companies themselves, manufacturers, to make drugs of this low quality. It's bad for their brand. It isn't necessarily about money. Because these drug companies, if you remember, they would always fight against generics: "We make the drugs better than generic manufacturing. Our quality is better." We have biosimilars, like different companies. We have generic Humira now. And there was a big fight in the—

Shawn Buckley
If you don't mind, I'm just going to focus you because we are short on time. And I was just trying to get the answer from you that this was a shockingly unsafe quality.

And then the final question. You teased us when you were giving your presentation, and you said, when you first saw these quality concern things, that you and your family would wait to see if they were resolved. Were they ever resolved for you and your family?

Dr. Luz Maria Gutschi
No, we suffered. None of us got vaccinated. My daughter— She has a PEG allergy, did not get a medical exemption. She was seven months pregnant and had to leave early and has

not gone back to her hospital job. My son lost his position as a young trumpet player in an orchestra, which is extremely difficult to get. And my husband, he got his privileges taken away as a physician working in a hospital.

And me, I was always worried I was not going to be treated well, because I have a chronic condition and concern about being admitted to hospital. So yes, it was difficult for all of us. None of us got vaccinated. And it was not a good time.

Shawn Buckley
Thank you. I don't think there are any further questions. Maria, on behalf of the National Citizens Inquiry, we sincerely thank you for testifying today.

Dr. Luz Maria Gutschi
Thank you very much for all of you and for everything that everyone is doing. Thank you.

[01:08:53]

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