NATIONAL CITIZENS INQUIRY

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EVIDENCE

(Translated from the French)

Witness 2: Dr. Jérôme Sainton
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[00:00:00]

Chantale Collard
Hello. Chantale Collard, lawyer and attorney for the National Citizens Inquiry today, May 13. I see on the screen Dr. Jérôme Sainton. Hello. Dr. Sainton, can you hear me?

Dr. Jérôme Sainton
Hello.

Chantale Collard
Yes, good morning. First of all, on behalf of the Inquiry, I'd like to thank you for agreeing to testify as an expert witness. I'm going to identify you. All you have to do is state your first and last name.

Dr. Jérôme Sainton
My name: Sainton, S-A-I-N-T-O-N; Jerome, J-É-R-Ô-M-E.

Chantale Collard
Okay. We'll now swear you in. Jérôme Sainton, do you affirm to tell the truth, the whole truth and nothing but the truth? Say, "I do."

Dr. Jérôme Sainton
I do.

Chantale Collard
So thank you. Dr. Jérôme Sainton, I'm going to give a brief description of your background and then you can add to it. Then we'll move on to more technical questions, which you'll be

able to answer. So you're very versatile, Dr. Sainton. You were originally trained as a scientist with a degree in agricultural engineering. You also studied computer science and statistics. You then changed direction to study medicine and at the same time epistemological and ethical philosophy. You are currently a general practitioner with your own practice and patients. You are also a bioethicist working in the field of palliative care and, more generally, on the relationship between ethics and technology.

During the COVID period, you were a doctor in the field during the pandemic. You worked for SOS Médecins [SOS Doctors in France], both in the office and in patients' homes. Can you tell us about that period as a doctor in the field?

Dr. Jérôme Sainton
Well, we were perhaps the doctors closest to the wave that was arriving, and so we were confronting the unknown virus with few—or even no—resources. And I was able to measure the extent to which a certain pattern was repeated: namely, that the serious patients who ended up hospitalized or even in critical care were always rather elderly patients who had stayed home alone with no medical consultation and were always on Doliprane [acetaminophen] and no other treatment. That was kind of the recurring theme.

And what was disturbing quite early on—and this may link in with the previous testimony—was that medicine was governed by press releases. This had already been the case before, but it became much more pronounced and acute. Authorities would say: "You have to do it this way, you have to do it that way." And medical deliberation, moral deliberation—which had already been cut back to a mere pittance with the modern functioning of medicine—now disappeared completely. That's a brief summary. It would take a very long time to describe, but this is what I can say were my first impressions of the experience.

Chantale Collard
Thank you. You've done a lot of assessments. You say you did the safety assessment of the Comirnaty vaccine. Can you tell us what that involved?

Dr. Jérôme Sainton
So you may be referring to the fact that—

Chantale Collard
How the risk management plan—

Dr. Jérôme Sainton
This may complement the presentation I just gave.

[00:05:00]

Very early on, things were out of balance and disproportionate to what seemed to be good medical and moral sense. This prompted me to do my own research in conjunction with other colleagues. In medicine, we learn to reread scientific and medical literature, to do our own research, and to read and deconstruct articles to understand them, criticize them, summarize and compare them, and to corroborate sources. And so this was a project that I

undertook very early on. And so if you're talking about Comirnaty, you may be referring to one of the research projects I carried out—

Chantale Collard
Yes.

Dr. Jérôme Sainton
—which I recently published in an international peer-reviewed journal [Exhibit QU-4]. It's about the evaluation of the safety of COVID vaccination by Comirnaty—that's Pfizer's vaccine—in pregnant women.

Chantale Collard
Exactly.

Dr. Jérôme Sainton
This is one of the research projects I've done that I can tell you about.

Chantale Collard
Yes, so how does the manufacturer's risk management plan assess vaccine safety?

Dr. Jérôme Sainton
Yes, that is typically one of the questions I've been working on. I'm going to share my screen with you because I have some slides that may help. There, I think you can see it clearly?

Chantale Collard
Yes.

Dr. Jérôme Sainton
Pfizer's risk management plan for assessing the safety of its product in pregnant women has gone through several versions: nine in all. We're currently on the ninth version. The first version that came out with the vaccine said, "The safety profile of this vaccination is not known in pregnant or breast-feeding women." And they specified that there are pregnant women who might want to be vaccinated and they added: "despite the lack of safety data." Elsewhere in the same document, they stated that it was not known whether vaccinating pregnant women with Pfizer's vaccine could have unexpected adverse effects on the embryo and fetus.

So that's the version that came out with the product. Pregnant women were in fact excluded from the pivotal study: the one that gave marketing authorization. This remained the case for quite some time, until early 2022. And I note that in September 2021, there was a statement came out specifying— Here we are at the end of 2021, so almost a year later, we're still in the same vein—Pfizer still said: "The safety profile is not known." And they specified: "Administering Comirnaty to pregnant women should only be considered if the potential benefits outweigh the potential risks to the mother and fetus." That's stating the

obvious but perhaps they saw fit to put it in writing. And by the way—we can talk about this later—it wasn't really possible to know both the potential benefits and the potential risks, but that's a detail.

It's not until February 2022—you'll see later why this is important—that Pfizer began to change the language in its risk management plan. Pfizer said: "The safety profile is not completely known in pregnant or lactating women. However, 'post-marketing' studies are now available." So Pfizer still admitted its lack of knowledge, but this lack was now partial. That's February 2022. This would be the pivotal month when different recommendations around the world started to change noticeably.

I won't go into it in detail—I explained things well in the article I published. But the post-marketing study spoken of here is methodologically rather a poor study. It was extremely limited and also flawed, and had to be corrected three months after publication. Among other things, it had to be corrected for the fact that, at the outset, the study could be used to claim: "There is no risk of miscarriage." That was precisely the point that had to be corrected three months later: to say that they actually knew nothing of the sort.

[00:10:00]

Well, I won't go into statistical detail. Here is shown memo 94—about the risk management plan—and it refers to a very weak study which was not sufficiently reassuring. But Pfizer remained cautious, saying the safety profile was "not completely known." I'll end on this comment. Not only since February 2022, but since the very beginning—we saw the small variation in 2022—the safety profile is "not completely known." There are terms that have always been used and that you'll still find online today. Meaning that the manufacturer's risk management plan today—the first line I've highlighted, page 93—at one point talks about trials and the fact that pregnant women were excluded from the pivotal study. Why? To avoid its use in a vulnerable population. We're reminded of a fact that has always been known, especially in medicine: pregnant women are a vulnerable population. It's a key word to remember.

Chantale Collard
At risk.

Dr. Jérôme Sainton
The MAH [Market Authorization Holder]—some component of the manufacturer—agrees that monitoring the safety of vaccination in pregnant women is critical. It's something that remains [in place] from beginning to end. In the same vein, they tell us, "It is important to obtain long-term follow-up on women who may be pregnant or who are of child-bearing age who come to be vaccinated, so that possible negative consequences on pregnancy can be estimated." These are all terms that are still present in the current risk management plan. And finally, from the outset and to the current date, the manufacturer has said: "We anticipate that use during pregnancy will be submitted to the regulatory authorities. We expect that there is likely to be little intentional vaccination of pregnant women." I think this is important to know because—I could elaborate later if you wish— that's not what happened.

Chantale Collard
Yes, and Dr. Sainton, I'd like to ask you: How has this assessment been integrated by the European and French regulatory agencies?

Dr. Jérôme Sainton
I'll tell you about that in a moment. I'll just mention that Pfizer even planned a clinical trial dedicated to pregnant women. You can see it in version [2.0] of their risk management plan: a study on 4,000 pregnant women in the last trimester of pregnancy. And in February 2022, we learned that since almost all the pregnant women had been vaccinated, the study could not be continued. It ended with results from less than 400 pregnant women and only in the third trimester. And even 4,000 people wasn't going to be a robust enough study to see anything. The strength of a study comes from being able to highlight what's interesting. The pivotal study—the one that provided the authorization—involved 40,000 adults; and even with 40,000 adults, the study wasn't robust enough to show anything interesting. So if ten times the number was insufficient, then starting a study with 4,000 wasn't robust enough. And in the end, they had less than 400 people.

So Pfizer's study of pregnant women—planned from the outset—collapsed. And in any case, it was never of the right size.

To answer your question, how has this risk management plan been integrated by the agencies? Here in Europe, it goes through the European Medicines Agency [EMA]. Well basically, as of the end of December 2020, the European Medicines Agency's online fact sheet read: "Data on the use of Comirnaty during pregnancy are very limited." And that's all they said. They continued by saying: "A decision to vaccinate a pregnant woman should be made in close consultation [with] the healthcare professional after considering the benefits and risks." So it's very cautious.

[00:15:00]

At the end of November 2021, the European Medicines Agency softened its stance and said, "The data are no longer 'very' limited; they are limited." That's the only thing that changes. And from February-March 2022—those pivotal months—that's when the European Medicines Agency said: "Comirnaty can be used during pregnancy." We can see that the European Medicines Agency is much bolder than Pfizer, which remained extremely cautious. As far as the EMA is concerned, from March 2022, it's good to go.

And to answer your question completely: in France we saw a further deterioration in caution. What I'd like to remind you is that whether it's Pfizer or the European Medicines Agency, from February-March 2022 onwards we see a change in narrative. Pfizer remains very cautious. Then, in March 2022, it is the European Medicines Agency that says: "It's all good. Pregnant women can be vaccinated." But in France, our Conseil d'orientation de la stratégie vaccinale [vaccination strategy orientation council] said in April 2021: "All pregnant women must be vaccinated." And then at that point they even said: "Maybe we should wait until the second trimester." I think it's a month later they said: "Even in the first trimester, you're good to go."

And a few months later in France, in July 2021, we had the government's decision in conjunction with what's known as the Haute Autorité de santé [French National Authority for Health]. They decided to make vaccination compulsory for caregivers. And at that time, the Haute Autorité de santé made absolutely no mention of the issue of pregnant women.

And so, implicitly—and this is indeed what happened—pregnant women were obliged to be vaccinated. In this case, it was absolutely compulsory.

Chantale Collard
Obligatory.

Dr. Jérôme Sainton
And that's as early as July 2021. So when you place these dates in relation to what we've seen in risk management by the manufacturer and the European Medicines Agency, there's something shocking; and we really have a progressive deterioration in caution. That's all I can say to answer your question.

Chantale Collard
You've answered the question very well. But do you have any idea what should have been done to properly assess the benefit-risk balance so that this vaccination is only considered when the potential benefits outweigh the potential risks to mother and fetus?

Dr. Jérôme Sainton
Yes, according to the terms in the risk management plan itself. So the answer is yes and no. I also have a few slides related to this question.

Yes and no. In the long term, by definition, no. There's no way of knowing. Firstly, we don't really know if COVID absolutely must be avoided in the long term. But mostly, the new technology— I'd like to remind you that this vaccination isn't just about mRNA. There are many new elements to this vaccination. It's virtually experimental. For one thing, a more conventional product requires at least five years of data, if not ten, to be able to talk about long-term risks. Even more so for this completely new technological configuration. So we can't give a correct assessment of the benefit-risk balance. We just can't.

I can suggest something here. In a pinch, they could have done something to try to properly calibrate a short-term benefit-risk balance. At least, they could have put things in place to know what they were doing in the short term. Let me put it this way. It's a little technical, but I've tried to be clear in this slide, to explain a little how a benefit-risk balance works in medicine and medical research.

I'm simplifying a little— On one side, you have the benefits. What are the benefits? It's the product. It will reduce the risk of a serious event linked to the problem, namely, COVID. In this case, what is the reduction in the risk of a serious event for the mother or child in utero, linked to COVID?

[00:20:00]

And I'm talking about a reduction in absolute risk—it's a little statistician's detail; perhaps we'll have time to talk about it later—and not a reduction in relative risk, which is very sellable, with big figures that say nothing about the real benefit. So absolute risk.

This reduction in true, real, absolute risk is—if you like—one side of the scale: the benefits side (a). And on the other side, the side of risks, is the product—in this case vaccination—which itself may induce a risk of a serious event for the mother or child. Again, it may

induce an absolute risk. We'll call it (b). And then in order to have a favourable benefit-risk balance, the first must be much greater than the second. And I mean far superior. You don't want simply "superior" or "equal," unless you're a utilitarian and you're willing to kill as many people as you save. We need a balance that is substantially in surplus, especially for pregnant women.

I remember a class in which our professor—the chair of pharmacology at the faculty where we were taught medicine—said that he did not even give paracetamol [acetaminophen] to his pregnant wife. So in the case of pregnant women, we normally don't mess around. For pregnant women, the right medication for every illness is childbirth. I'm joking a little, but it's a reminder that for a vulnerable population, Pfizer's terms are fair. We don't treat them the same way we do other populations.

Chantale Collard
Dr. Sainton, I'd like to ask you a quick question. You say that the benefits must far outweigh the risks. We're not talking about 50 per cent plus one here. What percentage are we talking about?

Dr. Jérôme Sainton
Well, that's it. So for our benefits to be well in excess of the risks, we'd first need to have an idea of the benefits. What risks could we reduce? So we first had to properly analyze the risk posed by COVID to pregnant women and small children, and then determine how much that could be reduced by vaccination.

Well, I chose a study; I didn't look for a study that suited me, but I found this one very interesting. This study happened in England, but the official data were based on a study carried out in Scotland, to demonstrate the benefits of vaccination for pregnant women. It was a forward study that followed all pregnant women in Scotland during the ten months of vaccine deployment. They looked at all those who were vaccinated and those who were not. I'll skip the details; everything is explained in detail in my article.

So this study was biased. It was highly questionable and you could reject it. I've explained why but it doesn't matter. I take it with its biases, as less is often more, if you will. Even if it were perfectly accurate—which I don't think it is but I'm really taking the highest possible view of this study—well, at best, it reduced the absolute risk of a serious event linked to COVID in pregnant women and their unborn babies by between 0.01 per cent and 0.001 per cent. So these are really super-low reductions in incidence. Basically, to give you an idea, vaccination may have saved the life of one pregnant woman in those ten months, but this is for an entire country. And even then, we're not sure. I won't go into the statistical details, it doesn't matter. The point is, we're certain about actual things. This study had shown vaccine efficacy, et cetera, but in the end, when you try to see its benefit and measure it, to size it up, it was really very, very, very, very modest. That's the least we can say.

[00:25:00]

With an estimate of risk reduction, we are able to design a trial. It will enable us to establish our short-term benefit-risk balance. I'll skip the calculations; we know how to do them. Mathematically, it's very simple.

We know that to have a 95 per cent chance of detecting an event that occurs at a frequency of 0.01 per cent— Ninety-five per cent is the risk we use in statistical science when we say,

“This is not due to chance. We’re measuring something real.” It is already very lax. Normally, we have to be more demanding in medicine. But basically, let’s accept this. We are very favourable to the vaccine hypothesis. We are not really being very demanding. So to detect a single occurrence of a frequency of the order of 0.01 per cent, we’d need a randomized trial of 60,000 subjects. Well, a trial of 60,000 subjects hasn’t been done.

That’s what they should have done. And even that wouldn’t have been enough because if you detect only one occurrence, that’s not enough. You need a few more occurrences to be able to start making statistical tests. So not even 60,000 subjects; you would need more. Yet everything that’s been done in randomized trials has been less. I remind you that Pfizer’s pivotal study involved 44,000 subjects, and with only that, it was not robust enough to see certain things: the benefit in severe cases; the risk of poor tolerance and of serious adverse effects. Likewise, we were borderline. Our statisticians are obliged to cumulate several studies with Moderna, et cetera, to begin gathering some statistics. So in this case, when Pfizer tells us: “We’re going to do a special trial on pregnant women with 4,000 subjects,” and at the end they say, “We didn’t succeed; we only have 300 pregnant women left”—

Chantale Collard
Very little.

Dr. Jérôme Sainton
That’s what we should have done. But to answer your question, even then, we would only have touched on the basis of a short-term benefit-risk balance. Again, that would have given us an idea of the benefit possibly being a little greater than the risk. It would have been modest, but at least we would have had something rigorous. I’m not saying it would have been satisfactory, but at least we would have had something rigorous. So much for answering your question.

Chantale Collard
Dr. Sainton, you’ve come to talk to us mainly about pregnant women. Have you looked at other specific populations besides pregnant women?

Dr. Jérôme Sainton
Yes, there are two other specific problems with this vaccination, two other specific populations. Pregnant women were a special population that needed to be treated separately and this was not done in practice. There were two other specific populations: children, in which I didn’t take much interest; on the other hand, I did take a great deal of interest in the population of COVID convalescents—those who had already had COVID. And today this concerns just about everyone. Well, has it broken through the media filter?

And finally, there was a meta-analysis published in *Lancet*. A meta-analysis is what brings together the analyses of several studies, and in fact allows us to approach a degree of certainty. A few weeks ago, *Lancet* published an article telling us—well, they mainly studied what had happened before the Omicron variant but it gives us a good idea—that convalescence, the fact of having been infected with COVID, protected very well against reinfection. It protected well over time and was at least equivalent to, if not better than, what the vaccine regimen of the time produced. In simple terms, it was two doses before Omicron, three doses after Omicron. I’m simplifying, it’s not exactly that. The schedule at the time was two doses.

And so the effectiveness of natural immunity was better. Well, I'm sorry to say, we knew that back in 2021.

[00:30:00]

The first meta-analysis was carried out in 2021 by Mahesh Shenai, with whom I was able to speak, and was published— but not in a journal as prestigious as the *Lancet.* As early as the autumn of 2021, they had shown— Here is a table, but I'm perhaps not going to comment too much, it's a bit technical. But basically, you have this [vertical] line, and what stands out on the right of the line indicates a true difference. Statistically, we can see the difference. In short, natural immunity, compared to vaccination, was always either better or at least equivalent. So this shows that we already knew about the [relationship in 2021].

And here [the second vertical line] is something very interesting. They also looked at whether there was any benefit in vaccinating COVID convalescents. The answer is yes, but with the naked eye, you can't distinguish things; you see, it stands out. You can't see it with the naked eye; you have to actually calculate. This shows that the benefit was in fact weak, modest, an understatement— it was three times nothing.

When we put this in relation to the risks of vaccination, well, obviously, the balance was not *a priori* positive. Addressing vaccine politicians, Shenai and colleagues concluded: "In conclusion, an automatic exemption from vaccination, based on history of infection or serological evidence of immunity, should be urgently considered until the benefit-risk balance is better defined." This call for caution, which seemed to be the most elementary form of rigour, went completely unheeded.

And for the record, I said exactly the same thing myself. And I did a mini-review of the literature at the same time as Shenai and his colleagues—there were dozens of references, which is quite substantial—which I forwarded to the Haute Autorité de santé in France, where I concluded the same: that the most elementary rigour dictated that convalescents should not be systematically vaccinated. It was common sense.

Chantale Collard
That's right.

Dr. Jérôme Sainton
I sent this work to the Haute Autorité de santé: I didn't get a reply. Some colleagues tried again; they asked my permission and I gave it. They took over my work. With a syndicate, they sent this file to each of the Haute Autorité de santé committees in France. There was never any response. Never.

Chantale Collard
No response, never.

Dr. Jérôme Sainton
I sent it in December 2021. I'm still waiting for a reply.

Chantale Collard
You're still waiting for an answer? You still haven't received it?

Dr. Jérôme Sainton
Yes, not even a polite reply. I didn't even get, "We received your mail, it doesn't correspond to our request. Thank you for your participation." No, no, I received nothing.

Chantale Collard
Radio silence.

Dr. Jérôme Sainton
All I got was an acknowledgement of receipt of the registered letter. I don't know if it's like that in Canada, but in France, you can request an acknowledgement of receipt by mail. The post office only replied that receipt acknowledgements had been received, but that's all.

Chantale Collard
Hopefully you'll have an answer very soon, Dr. Sainton. Finally, in conclusion, are you interested in any other aspects of COVID vaccination?

Dr. Jérôme Sainton
Yes, the big project—what I'm presenting to you now—is thousands of hours of work. Something that immediately became apparent as the work progressed was that there were some pretty impressive biases that tended, in all the studies, to systematically overestimate vaccine efficacy. And so this was one of my projects. While the first work I showed you on pregnant women was peer-reviewed and published, this work is more in the pre-publication stage and under review, and I've had excellent feedback on it. It's not published yet; it should be shortly, but the reviewers approve.

[00:35:00]

I'll just give three examples of bias. So what is a bias? In science, a bias is a systematic error. So systematically, we're no longer going to be on target. Systematically, we're going to miss the target. It's not a question of imprecision; you can be very precise. It's like rifle shooting. If you're very precise in all your shots but you're off target, being precise won't help in the slightest. If you have a bias, there's a systematic error, and you don't hit the target. This is more serious than the problem of imprecision. A first problem is a bias that can be called extra-methodological—a colleague, Michel Cucchi, on the Independent Scientific Council in France has done a lot of work on this—an example being that all publications over the last three years, with the exception of Mahesh Shenai, have only communicated relative efficacy instead of absolute efficacy.

So it's hard to explain what this means in statistical terms. To imperfectly illustrate the difference between relative and absolute efficacy, relative efficacy is a little like testing the strength of a bicycle helmet at the factory: you measure its strength, but absolute efficacy is a little like its usefulness in the real world. And the problem with the pharmaceutical industry in general—which was already too biased beforehand but was always biased during the COVID crisis—calculates the strength of the helmet at the factory and says, "Oh, everyone must wear it, even those who don't ride a bike." That's the bias from talking only

about relative risk reduction rather than absolute risk reduction. It's about making even non-bikers wear helmets. That's the problem.

And what's rather embarrassing in this story is that ten years ago, the FDA, the Food and Drug Administration, had clearly written in black and white ten points identified for improvement for studies in the general area of evidence-based medicine, particularly when it came to establishing risks and benefits. We're right on topic. The FDA had ten priority points for researchers to consider. The first, which I haven't included here, was to put a cost on things. That goes without saying. The second priority was to stop communicating only relative efficacies but also to communicate absolute efficacies. Because they said—and they wrote it down in black and white—that patients are "unduly influenced" when risk information is presented only in terms of relative efficacy or relative risk.

But in fact, as we can see from the FDA document, it's not just patients, it's prescribers too. Studies have been carried out on doctors showing that if doctors are only given terms of relative efficacy, we tend to prescribe all the time. If reports are substantially adjusted by absolute efficacy, we won't have the same enthusiasm to prescribe. And I get the impression that the [regulators] didn't follow their own recommendations when they did their job. That's the first bias. It's fundamental; it alone can change everything. Now that's a bias; in fact, it's enough all on its own to change everything.

[00:40:00]

The second bias is a multiple bias. There are several types of methodological biases involved. Here, I've expressed vaccine efficacy in terms of relative efficacy; so the *y*-axis is relative efficacy, and the *x*-axis is time. Well, look at what vaccine efficacy does, in blue. And in general—if you can see my mouse pointer—it's almost always been identified there, especially at the beginning. It is always identified here. It's very rare that it's been identified before [in pink]. It's almost never identified within two, three, four weeks after the first injection, and never within the first week or two after the second injection. The same goes for after the third, et cetera.

And it's very rare to see efficacy beyond four months—five, six months at most—after injection [in pink]. But more and more studies are showing that, in fact, in the very first weeks after injection, efficacy is not only very mediocre, it's even negative. We now have enough studies to think that this is not just a coincidence. And just after vaccination, we have several studies showing negative vaccine efficacy. This means that vaccinated people are more likely to become infected than non-vaccinated people during, say, the first two weeks after the first injection, for example. This was particularly the case with Omicron.

There's undoubtedly an immune imprinting phenomenon, even if there are other possibilities behind it. Immune imprinting, in fact, means that the vaccine has targeted the peak protein of the Wuhan variant, but Omicron had deviated so much, evaded so much, that the immunity acquired by vaccination of the actual Wuhan variant lost its footing against Omicron, to such an extent that it can even facilitate infection. So there you have it. Here again, we're in an area where it could be that the vaccinated infect more, and therefore transmit more, than the unvaccinated.

In green, I've shown you what the effectiveness of natural immunity would look like. All this is a schematic. I don't claim that the scales are perfect. It's just to give you an idea.

Chantale Collard
It presents the idea well.

Dr. Jérôme Sainton
That's it.

Chantale Collard
So we understand that people who have been vaccinated are more likely to transmit the disease—contrary to what we were told, which is that this was an epidemic of the unvaccinated. You've just demonstrated this, Dr. Sainton.

Dr. Jérôme Sainton
Absolutely. So for many reasons, we can't prove it one way or the other. On the one hand, the question of transmission is very complex—much more complex than just knowing whether you're infected or not, that sort of thing. It's more methodologically complex to set up. The second thing is that I'm speaking in the conditional tense because we have several studies which can be summarized in this diagram; we must remain cautious. But if in fact it were confirmed then we have vaccinated people who, at the start of their vaccination period, served to cause the epidemic's explosion rather than its containment.

Chantale Collard
That's what we're seeing.

Dr. Jérôme Sainton
And when the Delta variant appeared in India, for example, we know that it exploded at the same time as the vaccination campaign was launched. And everyone said, "Oh yes, but that's because those who have been vaccinated have risky behaviours. They've just been vaccinated, so they have risky behaviors." That's not an acceptable justification, especially since there are studies showing that— In fact, it was found when we reworked the raw data from the Pfizer and Moderna double-blind trials. I'd like to know how—in the Pfizer and Moderna trials—risky behavior was observed after the injection but not when the placebo was given. Anyway, no. If ever this were to be confirmed—and there's a growing body of evidence to support this—we may well have had epidemics of the vaccinated. It's entirely possible.

Chantale Collard
Listen, Dr. Jérôme Sainton, thank you very much. There will probably be questions from the commissioners, so please remain at their disposal.

[00:45:00]

Commissioner Massie
Thank you very much, Dr. Sainton, for your overview of an analysis that is quite complex if we want to understand the phenomena. Unfortunately, we can't measure everything. I'd like to come back to the studies from 2021, where there were indications—actually, where we were trying to determine whether there was a benefit to be gained from vaccination,

either for people who were not cured, not convalescing from COVID, or for people who were convalescing. And as you mentioned, these studies—the meta-analyses—showed that the benefits were very slim.

From what you presented in your last diagram, what I think is extremely important is the temporal dimension of those studies. In a meta-analysis, we take data collated in each of the studies. If those analyses were made in the most favourable or the most positive conditions for demonstrating a benefit of vaccination, aren't we precisely in the process of having a very significant methodological bias, which casts many doubts on the conclusions we can draw, from even these meta-analyses?

Dr. Jérôme Sainton
Absolutely. However, this is mitigated by the fact that, fortunately, some studies have gone beyond four or six months. And so these studies, as they appear in the meta-analyses, will be expressed. But as they are few in number, there will be a certain imprecision in the later temporal window. And so in particular, this decline in vaccine efficacy may appear, but with such a problem of precision that we can't allow ourselves to draw a definite conclusion. I don't know if I've answered the question.

Commissioner Massie
Yes, that's a very good answer.

Dr. Jérôme Sainton
Yes, of course, by selecting small windows each time, we bias the measurements. We're more interested in taking photographs that suit the situation rather than tracking them with a time-lapse camera. But this bias is tempered by the fact that, since there have been sufficiently long studies, the data will appear—but with too little precision because there won't be enough studies measuring things over the long term.

Commissioner Massie
Finally, my other question concerns: in so-called real-life analyses of the claimed efficacy of gene injections, when we try to compile the benefit, we're always somewhat confronted with the problem of following up—to say the least—an approximation of the benefits we can measure. We tend rather to rely on indicators such as: "What type of antibodies can I measure?" and "When I take booster doses, will more antibodies give me the benefit I hope to obtain from vaccination?" However, we know that it's not just the quantity of antibodies, but also the quality—the kind of antibodies generated by these booster doses—that can ultimately affect the profile of protection we hope to obtain from vaccination.

And you mentioned that in the Omicron phase—and with all the booster doses that were recommended based on meta-analyses that suggest a benefit of protection—there was this somewhat vague notion of hybrid immunity that I'd never heard of before COVID. Regarding the type of antibodies, there are studies which show that repeated doses generate antibodies such as the IgG4 type [immunoglobulin type G4], which are not very beneficial and are known to induce what we might call tolerance when we want to, for example, reduce allergic reactions.

[00:50:00]

Doesn't this phenomenon practically nullify the validity of measuring antibodies or antibody types in booster doses? Which gives us the illusion that we could have protection when in fact this protection wouldn't really be based on solid data showing that the antibodies or antibody types, which increase following vaccination, will indeed be beneficial? For the time being at least, this is mainly what is being used as a marker, if you like, for potential vaccine efficacy in booster doses.

So this approach is focused solely on antibodies. We don't look at cellular immunity; there are lots of things we don't measure. To what extent is this also an additional bias in these analyses?

Dr. Jérôme Sainton
Of course. I've only shown you a few biases, and I'm not going to answer your question as an immunologist: I'm not one. Already, IgG4-induced tolerance is one of the possible explanations for the negative vaccine efficacy I've shown you. There isn't only immune imprinting. There are other phenomena. That one is probable. But to answer your question, yes, very little has been done to distinguish between the quantity and quality of antibodies. Very little has been done to correlate antibody measurements with what would be measured in the field. So it's all very well to have antibody figures, but is there a clinical interpretation?

We've talked almost exclusively about antibodies, but immunity isn't just about antibodies: immunity is much broader than that. For acquired immunity alone, it requires consideration of cellular immunity and of passive immunity; in short, it's much broader. And finally, to go even further, you talk about indicators, but perhaps my colleague from the CSI [Conseil Scientifique Indépendant], Pierre Chaillot, told you about this. We've also worked with antibodies to measure vaccine efficacy by measuring indicators of hospitalization, intensive care unit occupancy, beds, and so on.

All this can be summed up by the disease of modelling. Whether it's for public health or even immunology, it's clear that a model is much more comfortable because you have complete control over things. The problem is that the model isn't reality—and the gap between the model and reality is a problem we've known about for years. It's really a phenomenon of our time which could be covered in philosophy more than anything else, in the philosophy of science. But during COVID management, we reached the acme through using only indicators, only modelling, and a decoupling from reality.

Immunity has been reduced to humoral immunity, which has been reduced to antibodies, which has been reduced to titration, and without ever considering what this means in the field. As a small example—and this ties in with COVID convalescents—we have a study which looked at COVID convalescents in whom no antibodies were found. It turns out their cellular immunity was so robust that they were nevertheless very well protected against reinfections of COVID. It's a detail, but shows the problem of decoupling the model from the reality. But of course, it's much easier to manipulate indicators and models. We are in a bit of an omnipotent state: if we're careless or clumsy, we can do as we please. Because a model will output what we put into it, it will show up in the end result: a model that has no connection to reality.

Commissioner Massie
I'd like to come back to the question of mass vaccination at a time in the pandemic when more and more people are likely to have had a first infection. So there's a temporal

deployment that can vary from one place to another, and it's very difficult to make comparisons between different countries or geographical areas if the deployment of vaccines or infections isn't done in the same way. In your opinion, would it have been prudent and rigorous to systematically test people for the presence of a previous infection at the time of vaccination?

[00:55:00]

Dr. Jérôme Sainton
Ah yes. For me, that would have been the most elementary rigour. In fact, when faced with the compulsory COVID vaccination of caregivers, some people would say, "Oh, caregivers, they already have other compulsory vaccinations so why don't they want to?" No, the other vaccinations aren't compulsory. They have to provide proof of immunity and, for example, if someone is already immunized against hepatitis B, we're not going to vaccinate him against hepatitis B. Yes, that would have been the most elementary rigour. It would have been the bare minimum of prudence. Yes.

Commissioner Massie
And I'm perhaps going to take you into another area, which is your philosophical and epistemological training, to ask you to propose an explanation for this apparent confusion— or at least this contradiction—in the case of this disease or new virus that has come upon us. We've essentially set aside all the elementary notions we knew about respiratory viruses; non-pharmacological measures; the fact that we're not treating this new disease because it's new; the fact that we're totally discrediting natural immunity.

It's clear that scientifically—at least from my point of view—it doesn't hold water. And yet this mental framework has been used absolutely systematically throughout our Western democracies, for reasons that I find hard to comprehend. Could you speculate, from your more epistemological or philosophical knowledge, why we've ended up in such a surreal situation?

Dr. Jérôme Sainton
So for me, there are two complementary elements. More or less, there is a decision-making sphere and the sphere of the common citizen to whom this is generally applied. In the first sphere, we've arrived at our current era which is, after all, the culmination of modernity. Modernity was founded on a Copernican revolution in our understanding of science. To put it more simply, before Descartes and Galileo, science meant observing and trying to understand reality. Since the start of modern times, we have had the preconception that reality can be mathematically measured. This is super-important, because from then on—and the fathers of modernity saw this plainly, and Descartes already spoke of this very clearly, as did Bacon—when nature is able to be mathematically measured, you'll be able to assert control. And that's what Descartes famously said: we can "render ourselves masters and possessors of nature."

So we're in a state of mind where the scientific spirit has suddenly been confused with the spirit of power. I'm simplifying; I'm not saying that the spirit of power is only modernity, et cetera. I'm simplifying, but we are, after all, the descendants of this technocratic epic. And we've arrived in the present with such great power—we were talking about the power of models and the ease of relying on models—that it's much easier, much more comfortable, and much less tiring for those in decision-making positions to rely on and favour

techniques of control and power. And as Tolkien said would happen, especially in a fallen world where evil and the love of money exist.

We will depend on models and set up tools of control. In other words, we'll manage the pandemic like a computer program: if you get a virus, you apply your antivirus, and then subscribe to that antivirus software.

[01:00:00]

It's much easier and much less costly intellectually, and it's obviously much more profitable and much easier to make money by following this logic.

Philosophically speaking, it's not neutral. And for the average citizen who's going to follow, he's not unharmed by all this. He's grown up in a technocratic society where there is a cult of science. So yes, on a scientific level I agree that what we've been through is absurd, but it's not at all contradictory because of what we might call the technological morality: "Vaccines are scientific," and "Those who don't vaccinate are anti-science," yada yada. It's not a scientific discourse; it's a religious discourse, where science is not quite deified but where technological power has become sacred.

There's an author in France—I don't know if he's well known on the other side of the Atlantic—named Jacques Ellul. He's been ostracized in France but he's made a good study of the technological system. He says, "It is becoming religious." Technology has captured the sacred and science is like a myth. It's the new discourse. So symbolically, there's an image of science on which our rulers have based themselves, and so on. So they are not relying on science itself, but on the representation of science—a religious representation. And those who don't follow are automatically excommunicated. And it's very difficult to set oneself apart from the common morality. Today's common morality is technocratic. Anyone who doesn't accept the alleged technological efficiency, the alleged rigour, is anathema.

So this all comes together quite easily. The evolution of mindsets, the way in which we have philosophically decided to understand the world and our relationship to the world—a relationship of mastery—means that in the end, things fall into place quite easily. So that we arrive at this aporia, if you like, this scientific contradiction. In other words, in the name of science we do something that is completely aberrant scientifically—and with this contempt for nature, for natural immunity, and other things.

And indeed, masks were glued to everyone as if it were natural to live and confront a virus by masking everyone, all the time, as if we had to live with these prostheses.

So there you have it. There's also a bit of a transhumanist perspective behind it, which is simply an extension of the technocratic epic we've been living through for centuries and which has accelerated in recent decades. I don't know if I've answered your question.

Commissioner Massie
Yes, you've answered my question very, very well. I think my colleague Ken would like to ask you a question too.

Commissioner Drysdale
[In English] Thank you very much for your testimony, Doctor. I have a few questions, and I have to rely on my colleague to translate for me.

Commissioner Massie
Ken has a few questions, then I'll do the translation for him.

Commissioner Drysdale
[In English] Being here in Quebec reminds me of how important communication is.

Commissioner Massie
Being here in Quebec reminds me of the importance of communication. Ken doesn't speak French very well.

Commissioner Drysdale
[In English] And I am a professional engineer, so I have training as you do in mathematics.

Commissioner Massie
As a professional engineer, I also have a background in mathematics.

Commissioner Drysdale
[In English] But I find perspective is very important for people who are not engineers and scientists to understand.

Commissioner Massie
But I think that for people who are not scientists or engineers, it's extremely important to have the right perspective.

Commissioner Drysdale
[In English] So when I listen to your presentation concerning risk and risk-benefit analysis—

Commissioner Massie
So when I listen to your presentation, you make a very pertinent analysis of the risk-benefit ratio—

Commissioner Drysdale
[In English] And I understand what something like 0.01 per cent means.

[01:05:00]

That means one in ten thousand.

Commissioner Massie
And I fully understand the figures presented and their relatively modest significance.

Commissioner Drysdale
[In English] And so, my question, again, with regard to perspective is: When you're thinking about risk to pregnant women—

Commissioner Massie
And my question concerning the outlook for pregnant women and the risks that have been analyzed—

Commissioner Drysdale
[In English] We have heard testimony previously that a person in the childbearing range in Canada had a chance of all mortality—of dying for any reason—of about 1 in 3,000 or 4,000.

Commissioner Massie
We heard from several other witnesses at the Inquiry who told us that the risk of a pregnant woman dying from any [cause] was relatively modest, on the order of about 1 in 3,000 or 4,000.

Commissioner Drysdale
[In English] And that same woman's chance of dying from COVID was 1 in 250,000.

Commissioner Massie
And these women's risk [of dying from COVID] was much lower, on the order of 1 in a 250,000.

Commissioner Drysdale
[In English] And in 2020, the risk of a woman dying just because she was pregnant was about 1 in 16,000, I believe. I'm going by memory.

Commissioner Massie
And to die as a result of pregnancy was about 1 in 16,000.

Commissioner Drysdale
[In English] So would you consider speaking in those types of terms to the public? In other words, a person's risk of dying in a certain age group was, say, 1 in 3,000. A person's risk of dying of COVID was 1 in 250,000. And a person's risk of being pregnant and dying from being pregnant was 1 in 16,000.

Commissioner Massie
So to put things in perspective, can you consider that the relative risks range from 1 in 3,000-4,000, 1 in 16,000, or 1 in 250,000 in the case of [women] who are pregnant and can die from COVID? Does this perspective—

Commissioner Drysdale
[In English] My point being that if we communicate to the public that their chance of dying of COVID is a number—whatever that number is—but they don't understand what the everyday risks of death are to them, then they have no ability to evaluate that risk.

Commissioner Massie
So the question is: To what extent do people have the capacity to assess the real risk if we don't put it in perspective or in relation to other risks?

[In English] So your question is—?

Commissioner Drysdale
[In English] I know your report is being submitted to the scientific societies but it's very important, the information that you're bringing forward. And my question is: Would you consider wording some of your information in that way so that the general public can understand the relative risks?

Commissioner Massie
So the question is: Are you ready to present your analyses in a way so that people can understand what they represent in a more concrete way—for people who don't necessarily have the capacity to assess risks in terms of numbers—because they're not generally accustomed to doing this kind of analysis? That's your question.

Dr. Jérôme Sainton
Yes and no. Yes, because I'm going to give an answer, but the no, I'll explain right away. In the work I did on risk assessment in pregnant women, I didn't assess the risk in pregnant women myself. The core of my work was to evaluate the risk assessment carried out by Pfizer, then by the European Medicines Agency, and then by the French authorities. It's not quite the same thing. But incidentally—and I've included it as an appendix to my article—I've given precisely this perspective you're talking about in order to make a proposal.

So I'm not qualified to give a definitive answer but I'll try anyway. Let me remind you that my work has been a critique, a re-reading of the risk assessment [done] first by the manufacturer itself, then by the European Medicines Agency, and also by our supervisory agencies in France. Having said that, I came across a study in Scotland—the prospective study I mentioned earlier—by Stock and his colleagues.

[01:10:00]

And to answer your question, I'll repeat here what I said earlier. Over the ten months following the roll-out of vaccination in Scotland—when pregnant women started to be vaccinated, they started here and then tracked what happened over the ten months. According to this study, which is open to criticism: roughly speaking, there was one

unvaccinated pregnant woman who lost her life to COVID who might not have lost her life if she'd been vaccinated. Out of the whole population of Scotland. I think this is something that can help put things into perspective: in the ten months following the roll-out of vaccination, particularly among pregnant women in Scotland, at the time when the variants were most dangerous—the first variants, Wuhan, Alpha, Delta—out of all the pregnant women in Scotland who could be followed up—that's just about all of them—there was one unvaccinated woman who died of COVID during her pregnancy. And we can perhaps imagine that she would not have died if she had been vaccinated.

I hope this answers your question. It may give you an idea of the low risk they had to be protected from. It's always difficult to put things into layman's terms—and maybe that's not my particular talent either—but there are still a lot of things in biostatistics that need to be put into perspective, such as the size of groups. At that time, there were pregnant women who had been vaccinated and none of them died from COVID during this study. There was one death, an unvaccinated pregnant woman who died from COVID: that is very, very few. That's one person, and we can't even be certain that vaccination would have saved her. We can suspect it from the study, but it is not certain.

Commissioner Drysdale
[In English] That's true, and we don't know whether or not she died with COVID or because of COVID, because of the testing.

Commissioner Massie
It's true. And what's more, given the nature of the tests that have often been used, we can't even know whether that person who died died with COVID or from COVID.

Dr. Jérôme Sainton
Absolutely. And this study was typical of one of the biases. I didn't have time to show you, but one of the biases that can change everything in a study: it's the classification bias linked to vaccination status. For example, vaccinated women between zero and three weeks after their first dose were considered unvaccinated. So who's to say that the unvaccinated woman who died wasn't a woman who caught COVID two weeks after her first dose? It's entirely possible given the size of the study, which makes for a completely biased methodology. We can't rule it out.

Commissioner Drysdale
[In English] Just my one last point— Sorry that there's a bit of a delay in the translation, so sometimes I have to wait for it. With regard to pregnant women, if I understand this correctly, pregnancy takes nine months: It would be possible then for a woman to get a first jab when she first becomes pregnant, a second jab a month later, and then get a booster before she's completed her pregnancy, is it not?

Commissioner Massie
So if I've understood correctly, since pregnancy lasts nine months, theoretically it's possible for a woman to have her first dose at the beginning, a second dose during pregnancy, and even a booster dose before the end of pregnancy?

Dr. Jérôme Sainton
Exactly.

Commissioner Drysdale
[In English] Did you look at any effects of multiple injections to people, pregnant or not?

Commissioner Massie
Have you looked at the effect of multiple injections, whether pregnant or not?

Dr. Jérôme Sainton
No, that's not one of the things I looked at in detail.

Commissioner Drysdale
Thank you, Doctor.

[01:15:00]

Commissioner Massie
Okay. Any further questions, colleagues? No? Okay.

Chantale Collard
So Dr. Jérôme Sainton, your analyses and research speak volumes. And on behalf of the Inquiry, I'd like to thank you very much for appearing before us. Thank you very much.

Dr. Jérôme Sainton
Thank you. And thank you very much, in fact, for allowing me to integrate my work and contribute my mark to a collective work. As researchers and analysts, we often have our shoulder to the grindstone. It's an expression in France. Thank you for integrating this work and connecting it, making links. Thank you very much.

Chantale Collard
Thank you again. We'll now take a ten-minute break before the next testimony.

[01:16:08]

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The evidence offered in this transcript is a true and faithful record of witness testimony given during the National Citizens Inquiry (NCI) hearings. The transcript was prepared by members of a team of volunteers using an "intelligent verbatim" transcription method, and further translated from the original French.

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