NATIONAL CITIZENS INQUIRY

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EVIDENCE

(Translated from the French)

Witness 3: Christine Cotton
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[00:00:00]

Chantale Collard
Yes, so hello. I'm going to lower the microphone a little. So, Chantale Collard. I'm acting as a lawyer for the National Citizens Inquiry today. I'm going to look at the camera. So good morning, Madame Cotton. Can you hear me?

Christine Cotton
Hello Chantal.

Chantale Collard
Yes, hello. So first of all, on behalf of the Inquiry, I'd like to thank you for agreeing to testify today. It is very important to us.

Christine Cotton
Thank you.

Chantale Collard
So let's proceed with the identification, if you don't mind. Simply give us your first and last name.

Christine Cotton
Christine Cotton.

Chantale Collard
Perfect. I'll also swear you in for formality's sake. Do you solemnly declare to tell the truth, just the truth? Say "I do."

Christine Cotton
I do.

Chantale Collard
That's perfect. So, Christine Cotton, I'm going to introduce you very briefly—but of course you'll then be able to add to it everything you've done as well as your work. So you're a biostatistician with 23 years' experience in the pharmaceutical industry. You were CEO of your own company for 22 years in a clinical research organization [CRO]: a subcontractor in charge of monitoring, data management, statistics. Your customers have included AstraZeneca, Pfizer, Sanofi, App Science, Bayer, Aventis, and many others, as well as various hospitals, to name but a few.

And you have experience with all types of trials in a variety of therapeutic fields: oncology, central nervous system, gastrointestinal system, autoimmune diseases, osteoarticular system, odontology, pneumology, ophthalmology, nutrition. You have a really wide range of skills. Notably you've also done phase I, II, III, and IV clinical trials and observational studies. Is that a good summary? But I can see that you really have a very specialized field.

Christine Cotton
Yes, I've worked in a huge number of pathologies, including viral diseases, hepatitis C. I worked in tuberculosis, in renal transplantation—well, when you're a subcontractor, you have a lot of clients—so in diabetes. So I've effectively participated in nearly 500 clinical trials.

And what you need to know is that it's not at all a doctor's job to carry out a statistical analysis of a clinical trial; it's a biostatistician's job. And I've been doing it for a very long time.

Chantale Collard
So Christine Cotton, we're very curious to hear the results of your research and clinical trials, particularly the poor efficacy assessment. I don't know if you have a PowerPoint with you.

Christine Cotton
Maybe I can share my screen.

Chantale Collard
Yes, please do.

Christine Cotton
So here we are. I don't know if you can see it clearly?

Chantale Collard
Yes.

Christine Cotton
So I examined all the documents from the Pfizer clinical trial. A clinical trial involves dozens, if not hundreds of people. I've drawn up a small document. In summary, there are those who recruit the participants. Then of course there's the sponsor: the one who launches the study. We have the data management team, which creates the system for recording the data. There's the statistics team. We have the monitoring team, which views the sites that recruit patients in order to verify their documents. There's the pharmacovigilance team of course. We may have laboratory services to analyze a whole range of parameters. We have the quality assurance team, which makes sure that all these people are working correctly.

So the statistician comes in at the beginning, since he writes the methodology for a clinical trial.

[00:05:00]

He guarantees the validity of a clinical trial. And he intervenes at the end when we have all the data, and sometimes during intermediate analyses, since he's the one who plans and validates the trial—there is often a group of us, depending on the importance of the trial—and ensures that accurate results are delivered. Because in this business we can't afford to make mistakes.

So he delivers the results and a medical writer writes up the clinical reports. So obviously, as a biostatistician, I know how to read all the clinical reports, since I was the one who wrote them—or at least half of each report—in collaboration with the doctor who wrote them.

So what we know about COVID clinical trials—that's COVID clinical trials in general: we know that it usually takes around 15 years from molecule discovery and so on to obtaining marketing authorization. These trials benefited from what is known as accelerated development, meaning that each phase began before the previous one was completed. So obviously we didn't have all the results each time. A phase would begin without having the results [from the previous phase].

So the Pfizer clinical trial—since that's the one I've been looking at in great detail—basically should have lasted about two years. A certain number of visits were planned at which the participants—those who had been recruited, who had volunteered, and who signed an informed consent form—would go to the site that recruited them to undergo a series of tests. Obviously, if they had COVID before visiting the site, they would come forward to say they have such-and-such symptoms. In that case, they would be given an appointment for a PCR test.

What we've known since December 2020 is that pregnant or breast-feeding women are never included in clinical trials, as they are part of the protected population. We also know that immunocompromised patients were not included; patients with comorbidities—diabetes, pulmonary pathologies, et cetera—were not included; and patients with autoimmune diseases or inflammatory problems were not included. In other words, the most fragile patients.

We also know that interaction with other vaccines has not been studied. Neither has transmission been studied. While there's been a lot of fuss about this uninvestigated transmission, it is quite usual. The main problem with the Pfizer clinical trial is not at all

that transmission wasn't studied— that was playing to the crowd. Symptomatic cases were not studied.

So what did they do? Since the study lasted two years, they proceeded with interim analyses in order to provide results before the end of the trial. So at each interim analysis, each time they provided results on a population—whether adults over 16, teenagers 12-15, the 5–11-year-olds, babies, and so on—we systematically had a maximum of three months' follow-up for the participants. So in other words, we count COVID cases over these three months; and therefore we also examine tolerance over these three months. So it's a short period of time and obviously we can't draw any conclusions about medium- or long-term tolerance when our hindsight each time is of three months max, or even less than two months 50 per cent [of the time].

Chantale Collard
That's very quick.

Christine Cotton
Yes. On this basis, we can't say that it's safe. I mean, when we say "It's safe," yes, it's safe according to the results over the examined period. So, as you can see, it changes quite a few things.

So what is very, very important? This famous efficacy criterion. We've been told, "We have 95 per cent efficacy. That's fantastic," and so on. So in fact, when we look at this efficacy criterion, the famous 95 per cent is an efficacy calculated on mild or moderate COVID cases confirmed by PCR. And how you eventually know if you're a COVID case is whether you have a certain number of symptoms: fever, aches and pains, diarrhea, vomiting, and so on. Yet the vaccine induces these symptoms. So there are a certain number of symptoms that the patient will eventually have; and instead of going for a COVID test because it may potentially be COVID, we record it as a reaction to the vaccine.

[00:10:00]

So what we know from the documents made public by court decisions. Thanks to Aaron Siri in the United States, we can retrieve the database—that is, the tables, what's called SAS, that is, the software on which the statistical analyses are carried out and which was used to analyze this trial— We know, in fact, that there were fewer PCR tests done for the vaccine [group] than for the placebo. So we realize that if we don't do PCR tests, there's no risk of being a PCR-confirmed COVID case, since we didn't do the test. And we also know— If you don't understand, if you have any questions, please interrupt me because I'm running on!

Chantale Collard
In fact, you are comparing what is typically done in clinical trials with what has happened since 2020. We can really see that there's a difference with the protocol.

Christine Cotton
Exactly. In other words, clinical trials involve methods, regulations, and a heap of rules to be followed, which have been in place for years and are known as good clinical practice. And if my trial doesn't respect good clinical practice in the choice of its efficacy criteria, in the analyses carried out—it's worthless.

Chantale Collard
There we have it.

Christine Cotton
There you are. So that's why you have to understand what clinical trials usually look like in order to know whether this one is valid or not. You have to know all these good practices, for which there are hundreds of documents governing all the tasks of all the people that I mentioned earlier. And if the tasks are poorly performed, then I have deviations from good clinical practice. So I have some that are very serious and others that are less serious.

What we also know from this trial is that participants were allowed to take antipyretics. That's for fever. It's going to suppress certain symptoms. And we see that many more participants took these antipyretics in the vaccine group. So if I suppress symptoms, I'm not likely to do PCR tests, so that's called a methodological bias: a statistical bias that prevents me from correctly assessing my efficacy.

So in fact, what we know for sure is that this choice of efficacy criterion only measures part of the disease. To really measure the disease in its entirety, there they should have used a criterion which they did in fact measure, that is, the antinucleocapsid serology. This tells us who and how many had COVID during the trial. And when we calculate efficacy on this basis, we no longer have 95 per cent; we have around 55 per cent.

Chantale Collard
There was no measure of antibodies if I understand correctly, Madame Cotton?

Christine Cotton
Well, that's another matter. We'll get around to antibodies. This is really about who's had COVID and who hasn't. And we're no longer talking about mild to moderate COVID confirmed by PCR test. Now it's: Who has had COVID?

So the goal is really to prevent you from catching COVID! It's not to prevent catching mild or moderate COVID confirmed by a PCR test. So the choice of efficacy criterion is clearly wrong. Do you understand the problem? So this 95 per cent efficacy measures an efficacy that doesn't exist in reality, and which never existed!

Chantale Collard
Based on erroneous results and based on an erroneous method.

Christine Cotton
Precisely.

Chantale Collard
But later, it was said that 95 per cent had dropped to 85, then 70, and then more frequent downgrades.

Christine Cotton
Yes. Because we've seen that in real life, people catch COVID. In real life, it's not just mild or moderate. What was also very important at each interim analysis was that they never demonstrated an effect on severe cases. There was never any statistically demonstrated efficacy on severe cases in any of the reports that led to authorization: none. In adults, there is no efficacy on severe cases. For example, you see this table. We're told, "Oh well, there had been one severe case for the vaccine and three for the placebo, so efficacy is 66 per cent." But statistics is more than that. Statistics means looking at the validity of my results. And as it turns out, I've found no difference between the vaccine and the placebo groups in terms of efficacy on severe cases. Therefore, there was no proven efficacy, neither in 12-15-year-olds—since there were zero severe cases—nor in 5-11-year-olds, nor in babies aged 6 months to 4 years.

[00:15:00]

There has never been any proven efficacy in severe cases.

Chantale Collard
Incredible.

Christine Cotton
Then we have an imbalance in recruitment among centres. We have five centres that have recruited almost 10,000 patients among them. So when we have that, what do we normally do? We do a centre-by-centre analysis. So why wasn't this done? Anti-nucleocapsid serology with its 55 per cent efficacy rate was never included in the report. Why? It was never submitted. In other words, it's a criterion for which we've never had the results.

So when they did the analysis at six months, we had a little more hindsight on the tolerance. And now we had a table. So this is a publication they released, not after three months' follow-up, but after six months. And after six months, we had the deaths from COVID, for example. And there was one COVID death for the vaccine and two in the placebo. So we have no proven efficacy on COVID mortality.

Chantale Collard
None.

Christine Cotton
In addition, more people died in the vaccine group than with the placebo. So where is my actual effectiveness for mortality? It hasn't been proven in the studies.

Chantale Collard
There's a negative efficacy, you could say.

Christine Cotton
Not really.

Chantale Collard
There are more deaths following the vaccines.

Christine Cotton
Yes, that's it. There is no proven efficacy for mortality.

Now the real scam, so to speak, of the Pfizer clinical trial are levels of this famous neutralizing antibody. Here, on the left, are the results on monkeys. And here, at the bottom, you can see the time showing the antibodies being measured on day 21, day 28—so after the doses [were administered]—and day 56, that is, at two months. And here, you can see that the antibodies start to drop.

Now, this graph on the right is the result in the 18-55 age group. And there, we see that on day 28—so one month after the second dose—it's a little higher than at two months after the second dose. And yet, it's pretty convenient that we don't have a measurement of the levels. And why don't we have this measurement? Because we did an intermediate analysis at three months. Can you see the trick? And who authorized an interim analysis at three months? The FDA [Food and Drug Administration], in writing specific guidelines for COVID vaccines, authorized an analysis at three months. That's why there was no six-month measurement. And when they released the report regarding boosters, here are the six-month level measurements! Can you see them? It's the red arrow.

Chantale Collard
Absolutely. There's a big difference.

Christine Cotton
So if we'd had this first analysis at six months, would a health agency have given an authorization based on this drop in antibodies? I don't think so.

Chantale Collard
And why did they?

Christine Cotton
They gave it because at the time, this red arrow showing the neutralizing antibodies, which are supposed to represent immunity against the disease: well, we didn't have this result because we did an analysis after three months, not six! And the laboratory didn't schedule any visits between two months after the second dose and six months after the second dose. Why didn't they schedule any visits? In other words, you don't measure what you don't want to show.

Chantale Collard
There you are.

Christine Cotton
So how did they know it was going to drop? They knew it from the publication on the monkeys because we could already see it there. And they knew it because in the documents

submitted by the agencies in France—the ANSM [National Agency for the Safety of Medicines and Health Products], et cetera, or the HAS, Haute Autorité de Santé [National Authority for Health]—they already told us in December 2020 that a booster was being investigated. Ah, how convenient!

Therefore, not measuring the antibodies is how they hid the fact that they were decreasing. That way they received an authorization with a completely bogus efficacy since it doesn't measure the disease in its entirety. So they didn't measure the antibodies but they knew very well that they were going to decrease, so they prepared a booster. Then six months later—on December 22, 2021—they said, "Aw, that's too bad, we just noticed that the antibodies are decreasing. It's annoying, but we're going to need a booster."

Chantale Collard
Another booster.

Christine Cotton
So we needed a booster. After that, we needed a fourth dose, then a fifth— But this is inevitable since it only lasts three months. But we've known from the beginning that it lasts three months.

[00:20:00]

So let me summarize. Efficacy being 95 per cent: false. No proven efficacy in severe cases with each authorization. Antibody levels: they didn't measure them because they knew they were decreasing and that's why they were studying a booster. So protection and efficacy are zero! In terms of methodology: zero. So it's worthless.

If I move on to tolerance— When I read the reports, I don't have any major problems regarding tolerance. However, in the adult clinical trials, I know about the well-known Augusto German Roux, who contacted me from Argentina. He took part in the clinical trial and almost died. So he sent me all the letters he'd sent to all the health agencies to point out that he'd almost died and that it wasn't in the clinical report; that it wasn't reported as a serious life-threatening adverse event. It's not there. So that means that the tolerance is incorrect. As for teenagers: I'm thinking of the well-known Maddie de Garay case in the United States where the mother moved heaven and earth to have her daughter treated, but to no avail. So if these serious effects had been reported, it would have been much less safe than it was made out to be. So obviously, the tolerance is incorrect.

And then there are the risks. So what are the risks? Well obviously, it's having adverse reactions, but it's also all the unknowns. So as we saw at the start— Use in pregnant women since December 2020: unknown; it was not measured in clinical trials. Immunocompromised patients: unknown. For fragile patients with diabetes, chronic illnesses or cardiovascular problems: unknown. Use in people with autoimmune diseases with inflammatory problems: unknown. Interactions with other vaccines: unknown. How could we offer a flu vaccine on the same day if we didn't have any studies at the time of authorization? And we say, "Oh sure, we can do that." We don't have any studies that say it's safe! So obviously, long-term tolerance is indeed: unknown.

Chantale Collard
But pregnant women, Madame Cotton, I don't understand. I'm sure you'll tell me. Usually, they can't take any medication at all. It's always pregnant women who are prevented from taking even a simple aspirin or Tylenol, sometimes even food. How did we get pregnant women to take this injection when we know the risks?

Christine Cotton
Pregnant women have been classified as an at-risk population.

Chantale Collard
At risk of contracting the virus, and not at risk of vaccine side effects.

Christine Cotton
Exactly. So they classified them as at-risk and proceeded to vaccinate them without any clinical trial results. There was one clinical trial on pregnant women but it was stopped. Three hundred or so women were recruited out of the four thousand planned, and we never saw the results.

What's more, the laboratory isn't hiding anything from us—or nothing much—since in the results for the 12- to 15-year-olds, there's even a chapter written in plain English with links and everything you need. I retrieved everything. It's available; anyone could retrieve them. Every time there's an authorization, it's put online. It's not hidden. And in this report, there's a chapter called "Unknown Benefits and Risks." And in it they tell us point-blank that the unknowns for teenagers are the same as for people over 16: duration of protection, unknown; efficacy in certain populations at high risk of COVID, unknown; efficacy in those who have already had COVID, unknown—since in the clinical trial, these are people who have never had the disease; effect of illness on future vaccine efficacy, unknown; efficacy on asymptomatic infections, unknown; efficacy on the long-term effects of COVID, unknown; efficacy on mortality, unknown; efficacy on transmission, unknown.

They're not hiding anything; it's all there in black and white! So when health agencies see this, they should normally be alerted to exercise a little caution. So no, obviously it doesn't bother anyone that there are all these unknowns at the moment when authorizations are given. Then of course, because there are so many unknowns, they say, "Oh well, we'll study the occurrence of myocarditis and pericarditis. We'll study pregnant women. We'll do real-world studies or more clinical trials."

[00:25:00]

There you go. But in the meantime, authorizations are granted. So there was indeed a trial on immunocompromised patients and one on pregnant women. There you go.

And what has been known since October 2020— Since we had a presentation by Steve Anderson, who's not just anyone, as he's one of the people in charge of biostatistics [at the FDA] and also in charge of adverse reactions in this situation—what was known? Well, that possible events following vaccination had to be monitored. These could include Guillain-Barré, disseminated encephalomyelitis, transverse myelitis, convulsions, cardiac arrest, anaphylaxis, myocarditis and pericarditis, autoimmune diseases, death, pregnancy and birth problems, thrombocytopenia, et cetera. And something very important that we've known all along: what they call "vaccine enhanced disease." So instead of preventing us

from catching the disease, the antibodies we create aggravate it or cause us to catch it. This has been known since October 2020. It's online! If you click, there it is: it's not hidden.

In fact, the real problem is that with a file like this, the health agencies should theoretically have countered with: "You must add three months of follow-up; the data is insufficient," and then not rushed to give authorization. So why did the health agencies rush to give this authorization?

And then the last point concerns the quality of the data, following these notably good clinical practices. And we know from Brook Jackson in the United States that there have been problems at certain sites, that patients were not properly monitored. We know this with Augusto Roux in Argentina because that was tragic. So we have doubts about the data's quality. When you have doubts about the quality of the data, how can you not have doubts about the quality of the results? So clearly, this clinical trial is the worst I've seen in my career. Therefore, the efficacy is false.

Immunogenicity and antibodies [measurements] are incomplete. The tolerance is false, so the benefit-risk ratio is obviously false. And the FDA tells us that they audited the centres, but due to complications during the pandemic, they say they didn't in fact check the integrity of the data. So this clinical trial is a sham in every aspect.

Chantale Collard
A monumental fraud.

Christine Cotton
You bet! Frankly, at this stage, it's unprecedented. And it was done with the agencies' blessing.

Chantale Collard
There you are.

Christine Cotton
So the question is: Why? I can't answer that question.

Chantale Collard
I think people will draw their own conclusions from your presentation—which is crystal clear—and from your support[ing information]. It leaves me speechless to see that it was all false. We suspected it, but now you've proven it.

Christine Cotton
That is, it's all there in writing. But in order to reveal it, you need to know something about clinical trial methodology.

Chantale Collard
And you know what you're talking about, so there may be questions from the commissioners to complete your testimony.

Christine Cotton
Of course.

Commissioner Massie
Thank you, Madame Cotton, for that very enlightening presentation. You mentioned that in order to recognize the shortcomings that may have been present in this case, we need to have knowledge—among other things—of good clinical practices to understand whether we are really in a position to generate data on which we can draw reliable conclusions. Unless I'm mistaken, I assume that people who work in regulatory agencies—whether it's the EMA [European Medicines Agency], the FDA or Health Canada—in principle should have this kind of knowledge of good clinical practice.

Christine Cotton
Absolutely. So I've been involved in several FDA filings for laboratory projects of varying sizes and in those cases, we have [to answer] questions.

[00:30:00]

They ask us to explain why, and how we were able to prove this. So obviously, they [ask] about good clinical practice. I'm all the more familiar with it as I used to be my company's quality assurance manager. So we have standard operating procedures that we have to follow; we have standardized methods. So obviously all these people are perfectly familiar with them.

So have these files been reviewed by biostatisticians? Because when I talk to you about statistical bias, you have to know a little bit about statistics. But even so, I think an experienced examiner has to see that there are biases. If I don't dose and I do fewer [PCR tests] for the vaccinated [group] than for the placebo [group], obviously that's a bias because if people weren't tested, I can't know whether on not they have COVID. So I mean, you don't even have to be a biostatistician to figure that out. So it's incomprehensible. I mean, when I read all that, it's incomprehensible that the health agencies have accepted this file as it stands.

Commissioner Massie
My next question is a little technical: it's about PCR tests—because this was one of the key elements in the so-called claim for vaccine efficacy. Do we have any details in these files on the number of cycles used for the PCR tests?

Christine Cotton
I didn't find anything. So personally, it doesn't bother me too much because there's no reason in biostatistics for it to create a bias since there's no reason for me to have, for example, more false positives for the placebo [group] than for the vaccine [group]. So that's why I don't really bother mentioning the PCR test result in this analysis in terms of methodological bias since there's no reason to. If, for example, I have 10 per cent false positives or false negatives depending on the test or the number of cycles used, there's no reason for the methods to be different, or for there to be a difference between my groups. So it's not a bias for me. Do you understand?

Commissioner Massie
Yes, I understand. My next question concerns the evaluation of the populations: where we measured the number of weak symptoms in the placebo group and in the vaccine group. When I do the rough calculations, I think the challenge we're facing is: Will we have a chance of having enough events to be statistically significant? Roughly speaking, out of 40,000, with the number we have here, that's about one case of infection in four hundred. The first question is: Is one case of infection in four hundred —in a population in the midst of a pandemic—a good indication that we're in an important phase in terms of infecting people?

Christine Cotton
I was thinking about this when I looked at the calculation of the number of subjects. They had predicted that 1.3 per cent of people on placebo would contract COVID, which—in the middle of a global pandemic with lockdowns everywhere—is very few. I said to myself, "Well, for something so infectious, in the midst of a pandemic, if we calculate the number of subjects and see that only 1.3 percent of those receiving placebos—that is, salt water injections—will [contract COVID], in the end, this COVID isn't so infectious after all." Well then.

Commissioner Massie
And so the next question is: With the numbers we had available to assess this relative effectiveness, is it actually statistically convincing, let's say?

Christine Cotton
Yes—because it's a calculation. In any clinical trial, there is an assumption of efficacy, or in this case, percentages of sick people in each group. That's how we calculated that 44,000 subjects were needed for the trial. So that's not the problem. But this is calculated on mild or moderate, PCR-confirmed COVID cases. However, if we had said, "We want to use severe cases as an efficacy criterion," we would have needed many more patients in the trial, since they are rare. As you can see, I have zero teenagers [in the placebo group] and zero [in the vaccine group]. So I'm not likely to show a difference between the placebo [group] and the vaccine [group] because I don't have any cases.

[00:35:00]

So this is an unproven efficacy due to a lack of cases. I believe the choice was discussed well beforehand at meetings—WHO [World Health Organization], agencies, et cetera. And so they said that for severe cases, which would have been much more relevant—since it's the severe cases that lead to hospitalizations and deaths, and that's what we wanted to avoid—well, we would have needed far too many patients. So that's why they chose this one, which is totally unrepresentative of reality. They could have chosen to use antinucleocapsid serology, but that wouldn't have suited them because 55 per cent efficacy—as opposed to 95 per cent efficacy—is harder to sell.

Commissioner Massie
My next question concerns the deployment of the vaccine. In the early months that followed, there was a certain amount of data to which we didn't have immediate access, but to which we ended up gaining access a little later through requests for Access to Information. And initially and for a very long time, the idea was hammered home that

vaccination was actually significantly reducing the number of cases. It was even better than what was observed in clinical trials. So everyone had to be vaccinated if we were to emerge from this pandemic. Then suddenly, the Delta variant arrived and the vaccine no longer seemed to have the capacity to reduce infection and transmission.

Is there anything fundamentally different between the Delta variant and the other variants on which the vaccine had been tested? Or is it simply because the greater number of cases made it more difficult to demonstrate this in the figures we were accumulating as we went along?

Christine Cotton
So I don't agree that we didn't have access to the documents. I retrieved the documents as early as December 2020. In April 2021, I gave my first broadcast on the results of the four vaccines that had been released up to that point: Janssen, AstraZeneca, Moderna, and Pfizer. We had access to the clinical reports. I retrieved them all.

Commissioner Massie
What I mean is the documents that followed the rollout of the vaccines that Pfizer and the FDA didn't want to be made public for 75 years.

Christine Cotton
Yes, that is, they didn't want to make internal documents public. But the clinical reports were available. All the deliberations were available on the FDA's YouTube channel. You could have eight hours of deliberations with all the presentations from the CDC and Pfizer staff in particular. So we had everything. It's just that people don't know it exists and obviously, very few know how to read clinical trial reports. But I had already collected everything, so I already knew that there was no known efficacy for severe cases and that there were lots of populations that hadn't been analyzed. As early as April 2021, I did a broadcast to warn people that if they were immunocompromised, there were no results proving that it was effective.

So the second point is about the results we were getting, which kept being released: the efficacy of this and of that, and so many percentages, Well, these are real-world studies based on retrospective databases. In other words, we take databases and analyze cases on the basis of that. In my 23 years in the pharmaceutical industry, I've never carried out analyses on retrospective databases. Because in terms of the validity of the conclusions and the proof of the conclusions, it's at the lowest level. In other words, the conclusions drawn from them should be taken with great caution because, in terms of method, they're not worth much. So they could always bring up whatever they wanted because it was worthless, really.

Commissioner Massie
But when the health authorities tell us, for example, that this vaccine can no longer prevent transmission, it is implicitly suggesting that it did at the beginning.

Christine Cotton
They had drawn conclusions from a real-world study which tended to prove that it slowed down transmission. But then, we don't give marketing authorizations on the basis of real-world studies. We give authorizations on the basis of clinical trials.

[00:40:00]

That shows the point. In other words, that in terms of methodology, I can't give authorization based on a real-world study method. Why? Because it's not valid, or it's much less valid. And my conclusions are to be taken with much more caution than a clinical trial, which is randomized, where we've selected people who meet inclusion criteria, et cetera, who are followed in a certain way, all in the same manner. So otherwise, if real-world studies were all that it took to bring a product to market, we'd have stopped doing clinical trials a long time ago. See what I mean? I'll prove whatever you want with a real-world study. You choose your database well; you choose the methods that suit you; and then you prove whatever you want. Some people have managed to prove that Nutella reduces hypertension or the like. So from here on—

Commissioner Massie
Isn't one of the problems with the clinical trial that the inspections we should normally have had from the regulatory bodies were insufficient to ensure good clinical practices? Is this unusual? Or is this how it's usually done, or did we do less than usual?

Christine Cotton
So if you look at the number of audits carried out by the FDA, it has actually dropped. But it was a rather special period. So the real problem is, when they tell us they're going to audit: What does auditing mean? It means checking all the patients' source files. So I take out the medical file and I check what had been reported in the database— via a system called eCRF, "e" for "electronic", CRF, "case report form." I check that the data that is in there is indeed what is in my source file. It's the integrity, the validity of the data. Has it been entered correctly? Does it match? That is, I have to take data at random; I have to validate all the circuits and PCR tests and how soon they are sent out. All this is recorded in a centre that recruits patients. It's all part of good clinical practice. Did the people who called in saying, "I'm ill, I have such-and-such a symptom" get a call back from the centre staff? There are logs, tracking systems. Everything is recorded.

So that's why, when I wrote a report on this trial in January 2022, I asked for a full audit of all the centres' documents. So now we know who wasn't called back when they should have been tested on account of being ill. From this we know everything. And the FDA tells us, "Oh yes, but the integrity of the data has not been verified." If the integrity of the data hasn't been verified, then I don't know if my data is reliable and therefore, all the more so, my results.

Commissioner Massie
We had another witness who mentioned that during the clinical trial, a certain number of people had been excluded from the compilation and that this number of people was much higher in the vaccine side than in the placebo side. Have you seen any data to that effect, and how would you explain it?

Christine Cotton
So I think it's a question of defining the populations. That is, when we define the analysis populations, when we write the protocol—which was my job—we define the analysis populations and we exclude a certain number of people that we've defined as unable to fit into these populations. But that's a complicated subject to talk about because the reasons for exclusion are defined beforehand. And when we exclude patients, we're supposed to do so blindly; this is known as blind review. So to say there are more exclusions in the vaccine group, okay. But I don't have this blind review document, so I don't know how it was done. So I didn't talk about it because I don't think it's the main issue. There are so many other problems. So when we say, "We're excluding so-and-so, so-and-so, so-and-so," we're not supposed to know who got the vaccine or who got the placebo. And we do that before we do the analysis.

[00:45:00]

It's a document that's drawn up beforehand and then, when we do the analysis, we know what the product is because it's blinded. And we mustn't forget that in the Pfizer clinical trial, the only one who knows what the patient has received is the one who prepares the product and injects it. He's the only one who knows; the others don't. So, *a priori*, when we hold this data review meeting where we say, "So-and-so, so-and-so, so-and-so, and such-and-such number have deviations, and so we will exclude them from the analysis population," we're not supposed to know whether they had taken the vaccine or the placebo.

Commissioner Massie
Okay, thank you. You have any questions? Are you okay?

Chantale Collard
Madame Christine Cotton, listen: thank you for your truly enlightening testimony, in terms of both methodology and analysis of clinical trials. In any case, I've personally learned a great deal, even if I already knew a bit about it. So listen, thank you and I invite you to spread your message far and wide.

Christine Cotton
Oh well, I made quite a bit of noise with it, didn't I? I did go to the Parliamentary Office.

Chantale Collard
Keep making noise.

Christine Cotton
I'm not finished.

Chantale Collard
Thank you very much.

Christine Cotton
Thank you.

[00:46:36]

Final Review and Approval: *Erin Thiessen, November 12, 2023.*

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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