NATIONAL CITIZENS INQUIRY

Quebec, QC **Day 2**

May 12, 2023

EVIDENCE*

Witness 14: Shawn Buckley
Full Day 2 Timestamp: 11:03:24–12:01:45
Source URL: https://rumble.com/embed/v2ktd8s/

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Louis Olivier Fontaine
So tonight, we will have a testimony by Mr. Shawn Buckley. So good evening, Mr. Buckley.

Shawn Buckley
Good evening.

Louis Olivier Fontaine
First of all, I will ask you to identify yourself by stating your full name.

Shawn Buckley
Yes, my name is Shawn Patrick Buckley.

Louis Olivier Fontaine
Okay. Now, I will swear you in. So I will ask you to swear to say the truth, the whole truth, and nothing but the truth.

Shawn Buckley
I do.

Louis Olivier Fontaine
Tonight, the object of your testimony will be the changes to the drug approval test for COVID vaccines.

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* Because the testimony took place entirely in English, the transcript is drawn from the English language video, which can be heard without a French voice-over – editor.

Maybe first of all, I will ask you to explain how your background is relevant to this testimony, this presentation.

Shawn Buckley
Okay. Before I do that, can I just deal with a bias issue?

Louis Olivier Fontaine
Yes, of course.

Shawn Buckley
Yeah. The Commissioners and some people that will be watching will know that I've been counsel on these matters at some of the hearings, and also that I've been involved in some of the organization of the National Citizens Inquiry.

And so the bias issue is that when you know somebody, and especially if you might have positive feelings or work with them, you're more inclined to find them believable. So it's kind of like a positive bias that we need to guard against. I wanted to get that out in the open, both for the commissioners and anyone watching, to basically be aware that there is that bias. It kind of forces you to take the position where you're not going to find me credible, but you have to apply your critical thought before you accept my testimony.

Now, the one saving grace is that I'm really just talking about: What does the law say? So I'm going to throw some slides up saying, "Well, here's the drug approval test normally and here's the test that was substituted." And this is very easy for anyone to verify.

So my testimony is going to be very technical. And then also, we have entered—as Exhibits QU-2 and QU-2a—a French and English version of a discussion paper that I had written on this subject for a non-profit association called the Natural Health Products Protection Association. And at the end of that discussion paper, there are links that make it very easy for people to follow to the drug regulations, to this interim order that I'm going to discuss.

We wanted to have another lawyer who is a drug approval expert come and testify but they're far and few between, and none of them have actually looked into the interim order that we had contacted. So here I am as the only one I know of in Canada that's looked at this issue. But it's so pressing that we felt the need to put this evidence in front of the commissioners and the public, but have those caveats in place.

To my background: I was called to the bar of British Columbia in February of 1995 and I've been a member in good standing ever since. Very early on, so probably starting about 1995, I started to have clients dealing with *Food and Drugs Act* matters. And probably 40 to 50 per cent of my entire career has involved dealing with the *Food and Drugs Act* and Regulations, largely defending companies and practitioners that practice alternative medicine and, specifically, manufacture or sell natural health products. I think there was about a seven-year period where I defended everyone that had charges in Canada that would fit into that description, so I've got extensive experience. I've been called as an expert in food and drug regulation on the Standing Committee of Health; I've been called as an expert in constitutional law in the Senate, so I've got a lot of experience in the area.

Louis Olivier Fontaine
So how many lawyers would have that kind of experience in Canada, according to you?

Shawn Buckley
Well, as far as defending people, I probably stand alone.

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With my level of expertise in the *Food and Drugs Act* and Regulations in the area of natural health, I'm probably number one. But generally, if we were to move more into the new drug approval process, I would guess about ten.

Louis Olivier Fontaine
Okay. So the first question I would be asking you would be: What are the normal regulatory requirements for the approval of drugs such as the COVID vaccines?

Shawn Buckley
Well, okay. So now, assuming that nothing happened— Because the approval of the COVID vaccines became a political issue, not a health issue. So if that hadn't happened, we have new drug approval regulations. For a condition like COVID, you would fall under the new drug approval process, and anyone wanting to look at the drug regs you'd look at C.08.001 and just go from there. As long as you're at C.08, you're in the zone.

And they're very simple. What you basically need to approve generally, to get market approval to introduce into the human population a new drug, is you have to prove it's safe. So you have to establish its risk profile. So how safe is this? You've got to completely satisfy the Minister that the drug is safe. And then you have to deal with its benefit profile. Is it effective? Does it work? Because there's no point introducing in the human population a drug that doesn't work for the purpose you're trying to use it for.

And then, although it's not written into the regulations, the third thing that happens—and it happens as a matter of common sense—is: now that we understand the risk profile, and now that we understand the benefits profile, do the benefits outweigh the risk? Because, again, there's no point allowing a drug onto the market if the benefits don't outweigh the risk. Now, one thing that people need to understand: you cannot get to the risk–benefit analysis unless you've established the safety profile and unless you've established whether it works. If you haven't gotten there, you can't do a risk–benefit analysis, and pretending that you can is a fraud. I just point that out because these three things are the minimal requirements for a health decision for drug approval.

So if the purpose is deciding, "Do we allow a drug onto the market or not?" the minimum requirements, if you're actually making a health decision, is establishing whether it's safe, establishing whether it's effective, and then doing that cost–benefit analysis where the benefits outweigh the risk. Anything shy of that and you can't call it a health decision. It's how we know that— it's one of the things we know that tells us this was a political decision to approve the vaccines.

And I'll just go on and explain. Here, I've just set out what the regular process is, but the Trudeau government made a political decision that they wanted all of Canadians to become vaccinated. And I say this with— And I'm going to use this interim order as an example but

I mean, we lived through mandates. So we had the federal government tell us that we couldn't fly or go on a train unless we had a vaccine. They told us that we could not be federal civil servants or contractors for the federal government unless we took the vaccine. They used fiscal and other means to encourage provinces to follow suit and to encourage private industry to follow suit. And we've had public health officers, both provincially and federally, say the mandates were in place to encourage people to get vaccinated. So we know there's a political decision to try and get every Canadian vaccinated. Well, we have a problem with our regular drug test, because if we're going to apply the regular drug tests to the COVID vaccines, they have to be able to pass that test. But if you're making a political decision, then you've got to come up with another test.

So on September 16th, 2021, an interim order was made. Now, our *Food and Drugs Act,* section 31.1 has a provision that allows the Minister of Health, in certain conditions, to exempt a drug or a class of drugs from the application of parts of the Act and Regulations. And so the Minister of Health made an interim order under section 31.1 of the *Food and Drugs Act*,

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basically setting out that COVID-19 drugs, which includes the vaccines, don't have to go through the regular drug approval process. And it actually then created a different process— so a different set of laws— that applied only to COVID-19 drugs. Now, the Minister of Health can make the order, but it's only good for 30 days unless it's approved by the Governor General in Council. Now for those of us that aren't lawyers, when you read "Governor General in Council," you know that means the federal cabinet. So the Prime Minister and the other ministers: Minister of Health, Minister of Finance. That's for colloquial terms: the Governor General in Council. So the Trudeau government, the Cabinet, made a decision to approve this order and it was approved and it was published in the Gazette, so it's good for a year.

Now, basically, the order tells us that this is a political decision. Because what the test is— And I'm going to put it up on the screen and show you in detail, but it doesn't require proof of safety. In fact, the word "safety" isn't even mentioned in the test. It doesn't even mention safety in the test, which we'll all find interesting from our messaging, right? Because we've been told the vaccines have been proven to be safe and effective. I'll explain that that's political messaging. So there's not a requirement for the drug companies to prove that the vaccine works. In fact, the word "efficacy" or "works," that type of language, isn't in the interim order at all.

A couple of other interesting things happen that tell us this is a political decision to get Canadians vaccinated. The interim order exempts the application of certain parts of the drug regulations. Now, in Canada, you cannot import a drug unless it's been approved of by Health Canada. So if you're making the drug in Canada, you've got to get it approved before you can sell it, but you can't import finished drugs for human consumption unless they've already been granted market approval. Well, this interim order exempted the federal government from this so that the federal government could purchase, import these vaccines, and distribute these vaccines before they're approved.

Understand what happened is: the federal government imports COVID-19 vaccines; the Canadian government distributes them to the provinces; and they're not approved. And this is written into the interim order before anyone has filed a submission to have the vaccines approved. So the federal government, the Cabinet—when they're writing this, they have no idea whether these are safe. They have no idea whether they're effective. They

have no idea whether this is a good idea or a bad idea when they write this law, and they wrote themselves into a conflict of interest. It's a bit of a conflict of interest to import a whole bunch of drugs, distribute them through the provinces, and then wait for yourself to approve them. But if it's a political decision, then this makes perfect sense.

The one that really I find interesting is, in our regular drug approval world—and its regulation C.08.006—the Minister of Health has a really, really important power that should never, ever be taken away. And the problem we face is that the Minister can approve a drug for the market. But what if we learn after it enters the market that it's unsafe? I mean, Vioxx comes up as an example where we learned after the drug was approved that it was causing deaths and it was eventually withdrawn from the market. So this regulation C.08.006 allows the Minister to withdraw from the market a drug that's already approved for several reasons. So for example, let's say subsequent evidence shows it's not safe. What if subsequent evidence shows that it's not effective? What if it comes up that fraud was used to get the drug approval? The Minister can withdraw the market authorization. But curiously—and listen carefully, because you have to ask yourself how this is in the public interest—for COVID-19 vaccines, this interim order, this new way that they're going to be approved, took away from the Minister for a year the power to withdraw the vaccines from the market if subsequent safety concerns arose, or if evidence came to light that they didn't work,

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or if evidence came to light that the application was based on fraud. Now, that's not a health decision, to remove that power from the market. It tells us that the decision to approve the vaccines was a political decision, not a health decision. Now, if you don't mind, I'll just walk through and actually show people the law because it's quite shocking.

Louis Olivier Fontaine
Go ahead.

Shawn Buckley
David, now if you could throw the slides up [Exhibit QU-2b].

So the first slide, all this is, is every time Health Canada approves a vaccine, they create a webpage for it, where they put the information about the approval and other information. And I've just taken the French and English first page of the Pfizer vaccine to use as an example and I've highlighted the first sentence. Now, I can tell you— I mean, I took these screenshots maybe last week. The date will be on the bottom of there, so it's in this month. But if you had looked last month or a year ago or two years ago— As long as the Pfizer page has been up, it starts with the same sentence. And that sentence is: "All COVID-19 vaccines authorized in Canada are proven safe, effective, and of high quality." And that bold is Health Canada's bold. I put the highlighting on, but they've put this in bold.

Now, I've already told you that these vaccines are approved under a test where you don't prove safety and you don't prove efficacy. So you might wonder why that language is there, but that language is political messaging. And it's essential political messaging. Because if you made the political decision that you are going to try and get every Canadian possible vaccinated, you have to have political messaging that supports the decision. And this is the minimal political messaging that will support Canadians getting vaccinated.

Could you imagine if Health Canada communicated the truth that the vaccines are unsafe? Or what if they said, "We don't know if the vaccines are safe?" That is not messaging that is consistent with getting your population to take the vaccine. What if the messaging had been "Well, the vaccine isn't effective." Or "We don't know that the vaccine is effective." That's not messaging that is consistent with the political decision to have people vaccinated. A lot of us have been confused, within the drug approval world, with messaging like this. And it's just simply a failure to realize that this is political messaging that is absolutely necessary. It's essential for the political goal, which was to have us vaccinated. And I'm not second-guessing the political goal. I'm just pointing out that that's what this messaging supports.

Now, the next photo: I want you to pay close attention to that rabbit. Because when I'm done this presentation, that's going to be your expression. You're going to— Your mouth is going to be open. And if you had paws, they are going to be grabbing the ground in sheer terror.

So this I've already said, I've pulled this out of the discussion paper. But it's just where I point out and I've highlighted what I've already explained to you. But there's maybe a couple of other points I can make before we go on to the actual text of the legislation. So I've said, "Listen, you've got to prove something safe. You've got to prove it's effective and you have to prove the benefits outweigh the risks." But where I could strengthen this is I've put in here the word, "objective." So they've got to objectively be proven to be safe. And we will go into the legislation where this is very clear, and there's got to be objective evidence that they work. And I think I've already explained the cost–benefit. You cannot— You just simply can't do that analysis unless you've proved safety, unless the risk profile is known, unless the benefits profile is known.

So this is the test. We just have the French test— This is straight out of the drug regulations, the French test on the left and the English test on the right. So C.08.002(2): "A new drug submission shall contain sufficient information and material to enable the Minister"—and this is the important part— "to assess the safety and effectiveness of the new drug, including the following—" and then there is a long list. You know, right down to ingredients and brand name and things like this.

Now, I'm going to get to— I've reproduced g) and h), which are two parts.

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But that red part is really the important part. You have to understand that in the regular drug approval process, you've got to do all these things, but they are to help the Minister assess the safety and effectiveness of the drug. That's what the Minister's looking at: safety and effectiveness. Everything you do in the new drug approval process is to give the Minister sufficient information to enable the Minister to assess safety and efficacy. I put ellipses there because, like I say, there's a), b), c), and a whole list of things, but when we get to g), remember the word "detailed reports." So this is our regular process: "detailed reports of the tests made to establish the safety of the new drug."

So in the regular process, to enable the Minister to assess safety and efficacy, which is what it's all about, you've got to have detailed reports about safety and h) substantial evidence of the clinical effectiveness. So "substantial evidence," and this is, again, to help the Minister assess safety and efficacy. The point I'm trying to make is: in the regular test, it's all about safety, it's all about efficacy, and it's robust evidence. We're talking detailed reports, substantial evidence.

So I've told you, "Okay, but wait a second. This doesn't apply to COVID-19 vaccines. We have a new test." I'm just going to jump it. So back—remember we see this C.08.02? I'm jumping up two slides and I've just moved it to the bottom left, okay? So bottom left, that's what we just looked at. And if we move to the bottom right, we are now looking at the interim order and what it's supposed to focus on. And I put in red what's important here.

So on the left, our regular drug approval test, it's all about "sufficient evidence and information materials to enable the Minister to assess the safety and effectiveness of the new drug." Under the interim order, "contains sufficient information and material to enable the Minister to determine whether to issue an authorization." Do you see the word "safety" or "efficacy" there? So safety and efficacy is the focus under the regular test. But for COVID-19 drugs under this interim order, the focus is just: can we enable the Minister to issue the authorization?

Now remember, this is a political decision. And there's a long list of things to provide here. The only thing in that list concerning safety and efficacy is this o): "the known information in relation to the quality, safety, and effectiveness of the drug." Compare that over to the other side, g) detailed reports, substantial evidence. So instead of detailed reports on safety, instead of substantial evidence of effectiveness, the only requirement is to give the known information in relation to the quality, safety, and effectiveness of the drug.

It gets worse. Because you don't even have to provide the known information. Under the interim order, section 3(2): "If, at the time an application is initially submitted to the Minister, the applicant is unable to provide information or material referred to—" And then there's a list and I've highlighted (o). You basically don't have to. You just have to, in your application, explain to the Minister how you're going to get it to the Minister later on.

It's shocking.

Now, the next slide: this is the test. And I've highlighted the words "must issue," because this is really important. Remember, the focus isn't safety and efficacy, it's whether or not the Minister can grant an authorization. Now 5, it says: "The Minister must issue an authorization" basically, if these a), b), and c) are met. It's not "may." And the Minister's Health Canada. It's not like the Minister of Health sits down and does this, it's the Health Canada bureaucracy that does this.

So Health Canada must issue an authorization if this test is met. Now what's important about this is: Health Canada could believe it's not safe. Health Canada could believe the vaccine doesn't work. Health Canada could believe this is a bad idea, that the benefits do not outweigh the risk. And yet if this test is met, Health Canada has to, by law,

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issue a market authorization for a COVID-19 vaccine.

Now, the first one, a), just basically refers to—we've already looked at 3, you've got to do this submission. So that doesn't really concern us. The second one is, there's some sections where the Minister can ask for some more information. The real test is c). So c) at the bottom, I'm just going to bounce ahead two slides where that's bigger. But c) begins "the Minister has sufficient evidence to support the conclusion—" That's the test. This is the wording that the COVID-19 vaccines are approved under.

So I'm just going to skip ahead to where I have that bigger. We've got the French wording on the left and the English on the right. I should just say that the French wording in the interim order is different. And it's a little different than that, and if you look at the French discussion paper, it will become apparent. In Canadian law, if you're trying to figure out what the meaning of a law is you look at both the French and the English versions because they're of equal value. And you're supposed to use both to inform yourself of what the meaning is, and that's what courts do. I'm going to show you later on that Health Canada, for the purposes of approving COVID-19 drugs, have full stop used the English wording—so the test as it's set out in English. I'll show you a piece from an affidavit where that is crystal clear. But I just wanted, for the purpose of the presentation, how anyone pulling up the French version will see that it's a little different than the first point I make in English.

This test begins: "the Minister has sufficient evidence to support the conclusion—" And I'll just stop there because this is really clever language. And this is language meant to deceive us and this is language that tells us this is a political, not a health, test. Because if you were— and remember, the Minister is Health Canada— if you were supposed to prove something to the Minister, it would read, "The Minister has sufficient evidence to conclude." So do you understand this? Let's say Pfizer's making an application under this test. If Pfizer has to convince Health Canada of anything, it would read: "The Minister has sufficient evidence to conclude."

I put this on the next slide. You see on the indenting there, the English side is on the right. The wording in the test is, "The Minister has sufficient evidence to support the conclusion." That doesn't mean that Pfizer has to convince Health Canada of anything. If Health Canada had to conclude this, if it was an objective test, it would read where I have that indented below: "the Minister has sufficient evidence to conclude." And this is important. Because if Pfizer has to prove something to Health Canada, if it read, "the Minister has sufficient evidence to conclude," we may still be in an objective test. We may. But what does "sufficient evidence to support the conclusion" mean? I went to a dictionary; I went to a thesaurus. I mean, "conclusion" is synonymous with "argument." Like, I think we're in a pure subjective test here: the Minister has sufficient evidence to support the conclusion, not even their conclusion. So it means Pfizer just has to make the argument for what follows.

Let's go back to the test. So what follows then? "The Minister has sufficient evidence to support the conclusion that the benefits associated with the drug outweigh the risks, having regard to the uncertainties relating to the benefits and risks and the necessity of addressing the urgent public health need related to COVID-19."

Whoa, that's clear, isn't it?

I'm just going to jump ahead. One thing that's really interesting to note there— And like I say, this is the test. Not only does it not require there to be proof that the vaccine is safe, the word "safety" doesn't even appear in the test. The text is there for you to read. The word "safety" doesn't appear at all.

Jump to the next slide. We can say the same with "efficacy." So not only does the test not require proof that the vaccine works,

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it doesn't even have language. It doesn't have the word "efficacy," or "works," or "effectiveness."

Now, I'll just stay at this slide. It uses risk–benefit language, which is again clever— whoever drafted this spent a lot of time. So it uses risk–benefit language without actually requiring there to be proof that the benefits outweigh the risks. And it's subtle, you have to look at it for a while. And remember I was pointing out, you actually can't do a risk-benefit analysis if you haven't established the risk profile, you haven't proven safety, and you haven't proven efficacy. You haven't set out the benefit profile. It's impossible to do a risk–benefit analysis without establishing the risk profile and the benefit profile, which is what you do in the regular test. But again, it's not that the Minister has to conclude; there just has to be an argument that the benefits outweigh the risk. Now, I'll stop.

In the regular drug approval world, if Health Canada's not sure: "Wait, I don't know if this is safe. I've got evidence suggesting it's safe, but I'm really unsure," it stops there. You're not going to get a drug approved if Health Canada isn't confident, reasonably confident, about what the safety profile is. And the same with efficacy. In the regular drug approval world, if Health Canada finds itself after reviewing an application: "Well wait, there's some evidence that shows it works, but it's really not clear, I'm not sure." If there's any doubt, it stops there. They're not going to let a drug into the human population when they're unsure. And yet here, because this is a political test— Remember I told you the bare minimum for a health test? Understanding safety, understanding efficacy, and then doing a risk–benefit analysis: that's the bare minimum. I mean, I could sit here for two or three hours and explain how that's really even insufficient for good health outcomes, but that's the bare minimum for a health decision.

But this test tells us this isn't about health. So after it tells us, "support the conclusion that the benefits associated with the drug outweigh the risks," listen to this next part: "having regard to the uncertainties relating to the benefits and risks." In the regular world, if there's any uncertainty about benefits and risks, there's no way there's approval. But here, Health Canada is being told. And if Pfizer meets this test, they have to approve. Remember, there's no discretion here—this is mandatory. There has to be an argument that benefits outweigh the risks and, by law, you have to take into account that you might not know the benefits and risks. It's, "having regard to the uncertainties." And then it's kind of like— It's almost an impetus to approve because, by law, they have to take into consideration "the necessity of addressing the urgent public health need related to COVID-19."

Now, how does that end up in a drug approval test? Basically, telling us we have an urgent need. So you mean: we don't look at safety, we don't look at efficacy, we don't actually have to have proof the benefits outweigh the risks, and you're telling us to approve anyway? This is a totally subjective test. It's not objective at all. It can in no way be described as a health test, a test that's supposed to help us health-wise.

And this slide just explains what I just said. It uses risk–benefit analysis without actually requiring proof of benefit and risk. And logically, you can't do that. I mean, I basically call it a fallacious test because it is. The test is logically inconsistent with itself, if you understand drug approval regulation at all. So any lawyer that's a drug approval expert looking at this will go, "Okay, this has nothing to do with health. This is a political test." And I've already told you that the Minister had to approve if unsure.

Now, this slide is important because remember I told you, the French version is a little different than the English version. There was a Federal— There actually were a number of Federal Court decisions. And the Health Canada employee, Celia Lourenco, who was the final approval on every COVID-19 vaccine in Canada, she swore an affidavit that ended up in the Federal Court and filed T-145-22.

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And in it, she discusses her approval of two of the vaccines. And this is her paragraph for the Pfizer vaccine. But her paragraph for the other vaccine is very similar. And I kind of cut out the first part, where she's given us the dates and stuff like that, and got to the juicy bit and put it in red—just to emphasize that she's clearly telling us she's using this test in the interim order.

"The evidence supports the conclusion"—oh, that's our wording, isn't it? —"that the benefits associated"—the test says, "with the drug," well, they've just thrown in the name of the drug. So "the evidence supports the conclusion that the benefits associated with the Pfizer BioNTech COVID-19 vaccine outweigh the risks, having regard to—" Remember, the test is "the uncertainties concerning the benefits and risks," which she tells us what the uncertainties are now: "having regard to a shorter term (median of 2 months) follow up of safety and efficacy at authorization." That is a shamelessly small period of time, a median of two months, to assess safety and efficacy. And she carries on, "and the necessity of addressing the urgent public health needs related to COVID-19."

So her affidavit is the smoking gun that tells the world clearly that Health Canada approved the COVID-19 vaccines using the interim order test. Because, make no mistake, Pfizer and the other companies could have applied under the regular test, but they didn't.

Now, there was a little bit of a shell game played. Remember in the United States, there was the Comirnaty kind of thing, where they applied under the regular test with a vaccine with that name but then they never made that vaccine available. So if you were getting the Pfizer vaccine in the States it was the one under the emergency order, but you might think that it was the one approved under the regular test.

We did it a little differently. We approved it under this interim order. But the way our law works is, if Cabinet approves an interim order within the 30 days and then it's gazetted, it only lasts for a year. So before the year ran out, what the Trudeau government did is they actually took the test in the interim order, they took most of the provisions—not all of them—and they moved them into our regular drug regulations. And they tweaked it a little bit, but the slight tweaking of wording really is of no consequence. So now, in our regular drug regulations—that's C.08.001 and onwards—we have the regular test that applies to every other drug. And then we have this test from this interim order that applies to COVID-19 drugs.

And once these were added into the regular drug regulations, Pfizer and the other companies reapplied for a regular DIN, a regular Drug Identification Number, and it was reported in the media, "Well, they've reapplied under the regular drug regulations." And so everyone thinks they've gone through the regular testing when they just basically relied on having passed the same test that they were applying under before. So our smoke and mirrors on the Canadian public was a little different.

This last slide is just again emphasizing the one point I made earlier. Because it truly is amazing to think that here the Minister—in our regular drug regulations—has the power, if a safety concern comes up or an efficacy concern comes up, to withdraw a drug from the market. But for a year that power was taken away from the Minister for the purposes of COVID-19 drugs. Now, that power's back now, that time period has expired. But if this was about health you'd go, "Well, that's not consistent with health, withdrawing that power." But if you understand, no, this was a political decision where we wanted Canadians to get the vaccine, and it wasn't a health decision, then it makes perfect sense.

So that's really all I wanted to say. I didn't need to be long or anything like that. And I think I stuck to what the law said.

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So people can verify and go and check out that this really is the wording and what I'm saying really is in there.

Louis Olivier Fontaine
So thank you, Mr. Buckley. Maybe the Commissioners have questions for you.

Okay, no questions, so— Oh, sorry.

Commissioner DiGregorio
Thank you, Mr. Buckley, for giving us that presentation.

As a lawyer and as a tax lawyer, I read legislation all the time and so I'm very familiar with the tricks that can be played with words and how important every single piece of word in a legislative test is. You mentioned having to prove something versus just having an argument for something. You discussed having a requirement for the Minister to approve something versus just giving the discretion to the Minister to approve something, and so what you've demonstrated to us here is really quite shocking to me. Sorry, that's not a question, that's just my first comment on what you've said to us.

So, if I can just take you back a little bit to the regular drug test and the three requirements that you talked about—which is, proving safety, proving efficacy, and then doing a risk versus benefits weighing—who is it that those things have to be proven to? I know you said Health Canada, but is there a board established that does that or what does that look like?

Shawn Buckley
I think it depends on the drug and kind of the severity and ranking. Health Canada has a number of drug-approval scientists. For a regular application, it would just go to one of those scientists. I mean, it might be a collaborative effort. The COVID-19 vaccines, my understanding from Cecilia Lourenco's affidavit was, I think there was a team of 23 people—it was 20-something, I think it was 23— that she said her team was. And then they also seem to rely on recommendations outside of Health Canada.

Now, the interesting thing is, it depends— Again, because drug approval has been political for a long time— I don't know if you're aware of a former Health Canada drug approval scientist Shiv Chopra. He and I became friends. He's deceased now, but he wrote a book called *Corrupt to the Core* about Health Canada and he had become a whistleblower and forced the Senate to call himself and three other drug approval scientists to the Senate about, basically, corruption at Health Canada. One of the drug approval scientists, Dr. Margaret Hayden, gave an interview to the CBC after testifying in the Senate. And she said something that should concern all Canadians. She basically said, "Look, after you've been at Health Canada long enough as a drug approval scientist, you basically learn how they're going to get around your decision not to approve a drug."

Understand, this is a drug approval scientist that's hired by Health Canada to basically apply this test about safety and efficacy. And that person concludes the benefits don't

outweigh the risks, this is a bad idea, we shouldn't do this. And then what happens is the management, who invariably are not doctors or scientists, will appoint an outside counsel—so outside of Health Canada—a panel of experts to reassess. And then that panel will approve the drug and you won't know who voted "yes," who voted "no," so there's no liability on this panel. There's no liability on the management, who doesn't make the decision, but based on the panel recommending that Health Canada will approve the drug. And she was saying, after you've been at Health Canada long enough, you know that's how they're going to get around their own people's decision that it's not a good idea to approve a drug. So we've been facing political decisions for a long time. This just went to a different level.

Commissioner DiGregorio
So perhaps that panel isn't necessary when you have an interim order.

I wanted to take you to the language on the website, the Health Canada webpage you showed us, and that particular bolded language about all COVID-19 vaccines are proven to be safe, effective, and of high quality.

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And how you've shown us that that is inconsistent with even the language under which they've been approved in Canada. Should the website say that they've all been— What is the language, "there's sufficient evidence to support a conclusion that the benefits outweigh the risks," yada yada yada? Would that be a better statement to have on those websites?

Shawn Buckley
It would depend on the purpose of the website. So, if the purpose on the website is to support the political decision to have Canadians vaccinated, I think the language they have there is the minimal political language. If the purpose on the website is to communicate truthfully—basically, what was and what was not proven—then yeah, I agree that they should follow the language in Ms. Lourenco's affidavit.

Commissioner DiGregorio
Yeah, I'm not sure that all of the "safe and effective" messaging that we heard across the country in 2021 would have flown quite as nicely over the tongue if you had to repeat that entire giant test.

Shawn Buckley
Well, that's why I say this is the minimal, what's there is the minimal language for the political goal. Regardless of where you are in the conversation on COVID, who would support all these restrictions—which are premised on the vaccine being safe and effective? I mean, we're not going to accept restrictions on not being able to fly because someone didn't eat cornflakes. Nor would we because someone didn't take a vaccine that Health Canada is saying, "Well, we don't know if it works, and we don't know if it's safe." We wouldn't support any of these restrictions without the messaging.

So that's why, in my opinion, that messaging is the minimal messaging that's necessary to support the political decision.

Commissioner DiGregorio
My final question relates to the power that the Minister of Health has to make these interim orders to exempt drugs from the normal approval process. In your opinion, is there ever a reason that the Minister should have this power, or should the safety and efficacy tests that are in the Act or in the Regulations always need to be met when a new drug is introduced in Canada?

Shawn Buckley
Remember when Bruce Pardy was testifying in Toronto about how we've moved to an administrative state? And this is a relatively new section, so I'm guessing it's maybe been there 20 years. It was used similarly during this swine flu period and the interim order that kind of showed the way for COVID.

But no, in my opinion, if we are going to have a government that's responsible for things, then this should be done in Parliament. And if we really actually did have a crisis and Parliament was informed with the truth, I'm confident that we could handle things like we've handled things in the past. I mean, we've gone through pandemics and we've gone through wars and we didn't have the administrate having these types of powers.

If I can just segue: the Minister of Health now, and this happened in my career, was given the power to exempt any food or drug from any part of the Food and Drug Regulations. But there used to be safeguards. So when the power first came in— And this is administrative state creed. So the power first comes in, and the Minister can only do it if the Minister determines it's safe, and it has to be published in the Canada Gazette so that everyone can see. So let's say you were concerned about some food or some drug you are taking. Is this compliant with the Food and Drug Regulations? You could at least hire a lawyer like myself and I could go through the Gazette and see whether it's been exempted. But then they went further and basically permitted the Minister to exempt any food or drug, and the safety requirement was taken out, and the requirement to publish it was taken out. So now you couldn't even hire me to tell you whether any given food or drug complies with our Food and Drug Regulations.

And especially in the area of food regulations—I mean, it's basically accumulated wisdom. So let's say we want to introduce orange popsicles for the first time. Well, they have to be what we call "ultrasafe." And ultrasafe is just one death per million per year. So if there's 36 million of us, as long as only 36 children die with a certain level of orange dye in our popsicles, then that's ultrasafe and we'll approve it and we'll put that level in our food regulation. So it's kind of accumulated wisdom: we can't increase the amount of that dye or we'll kill 37 kids instead of 36 and that's not permissible.

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But when you create a situation where you can't even tell if a food or drug complies with this accumulated wisdom, it becomes quite problematic. I have to tell you that, when they took that power away, the publishing requirement, I thought, what are they hiding? So I went back, and just on my own, okay, well, what are they exempting? And they were exempting all this—like, beer and wine and spirits and all of this allowing genetic stuff in, so I just I switched to European or organic beer. Yeah, because you just don't know what's in this stuff anymore.

So it's interesting. From a lawyer that's practised in the area of mostly drugs but also in food, because they interlace, it's troubling when you feel that the law no longer serves the populace—that it's actually become adversarial.

Commissioner DiGregorio
Thank you.

Commissioner Drysdale
You know, you talked about how the regulations were changed and the tests were changed within the regulation, but one thing I don't think you spoke about I'd like you to comment on, is that fundamental definitions and words changed. You said in one of your statements that words are important. And we've heard through days of testimony that the word "vaccine," the meaning was changed; the word, "pandemic," the meaning was changed; the word "biologic," the meaning was changed, because they took a genetic treatment, which was the mRNA biological treatment and said it was a vaccine, so it could skip certain requirements of revision. One of the favorite ones I've heard you say before is how they changed the word "snitch" to "ambassador" and the last one was "safe and effective."

They seem to have changed the fundamental meanings of these fundamental words. How do you account for that? Is that a lead-up to what happened?

Shawn Buckley
Well, I mean, the problem is— I think what we're experiencing truly is what Bruce Pardy, or Professor Pardy, described as the administrative state. And you can't just have a law that just on its face says something, or people will wake up, right? Which is why I'm suggesting that this political language is necessary. So when the state became adversarial against us, they started just passing, you know, playing these tricks.

Equally disturbing, and I can speak about it in the *Food and Drugs Act* area but it applies everywhere, is we've basically put the administrative bodies in the position where they can destroy any company or any person for perceived administrative wrongs without you ever seeing the inside of a court. So for example, in the *Food and Drugs Act*, they created a new term, "therapeutic product" because the populace wasn't willing to accept these penalties for natural health product manufacturers. But I mean, the Minister can make an order just saying that you're to do this or that and it's literally a million-dollar-a-day fines for violation. And I mean, they could destroy any small business and you never have the right to go to court, and it's never adjudicated.

I know years ago during the Harper administration, when Tony Clement introduced Bill C-51, An Act to amend the Food and Drugs Act, and then Harper introduced Bill C-52, this Consumer Product Safety Act, both of them had basically the same language to introduce all these huge penalties. And it's always in the name of safety. But when you give bureaucrats the ability to destroy businesses and people in the name of safety without there being a neutral arbitrator, there's a problem. And when I say, "safety is used as a weapon," because I'm involved in the natural health community, I campaigned on Bill C-51. And we got that where that has only come back in pieces over the last years, but an election was called and Harper reintroduced Bill C-52 and I wasn't fighting that. I vicariously fought that when the two bills were together and I remember— I don't know if it was Irwin Toy, it was some big manufacturer of children's carriages and toys and all of this called me and said, "Are you going to fight this?" And I was like, "No, I'm the natural health product guy.

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Why aren't you guys fighting?" And he says, "The industry can't fight this. It's safety. We'd just get slaughtered in the press."

It's another example where it's this kind of, like— People have to understand that whenever the word "safety" is used by the government, they're being duped. I mean, if we were to back up 20 years and say, "What laws did we not have that we have now that we really needed?" Were we less safe 20 years ago? I'd argue we were more safe. And were we less safe 30 years ago? I'd argue we were more safe. And so the law isn't the answer. It's the application of the law. And we cannot be moving ourselves and—well, we're already there. We're in a full-on administrative state, where in pretty well every sector you can be completely destroyed if you tick off a bureaucrat. Yeah, and the rent-seeking is just outrageous, so.

Commissioner Drysdale
Well, that seems to be a trend and just— Because we've had this testimony earlier with regard to the *Broadcasting Act*, they've now given even broader powers to a regulatory agency, the CRTC, which they never had before. So that they now have the ability to crush individual content-makers. And in that instance, it's safety. They don't use the word "safety," they use "disinformation," "misinformation," and "Canadian content."

So is that another example of what we're talking about where, rather than writing a specific law, they're handing it over to a bureaucratic board?

Shawn Buckley
Now, I have to confess that I don't recall if they were changing penalties, but I do know that they were giving the CRTC authority over online content now and that the justification is to protect Canadian content and Canadian values. Obviously, I find that extremely threatening to give the government any more control over speech because, without free speech, you have tyranny. And it's one of the biggest problems. I mean, is an inquiry like this going to be legal in a year? Or are we going to be streaming online things that go against government values? I don't know.

It is funny, I often wonder. Pre-COVID, I used to lecture fairly regularly at health shows. I would just wonder, well, at what point is what I say going to become illegal?

Commissioner Drysdale
Perhaps we'll go back to the way it was in the 1950s when they set up those giant radio transmitters offshore or in Mexico and broadcast in North America.

Shawn Buckley
I'm game.

Commissioner Drysdale
Thank you, sir.

Louis Olivier Fontaine
Okay. So that was a very interesting presentation, Mr. Buckley, so thank you very much for your testimony.

Shawn Buckley
Thank you.

[00:58:39]

Final Review and Approval: *Jodi Bruhn, August 20, 2023 (updated to include a missing exhibit number and clarify the testimony's language and URL source on November 25, 2023).*

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