NATIONAL CITIZENS INQUIRY

Winnipeg, MB **Day 2**

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EVIDENCE

Witness 10: Charles Hooper
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Shawn Buckley
Charles, can you hear us?

Charles Hooper
Yes, I can. Can you hear me?

Shawn Buckley
Okay, so we've got a good Zoom connection. My name is Shawn Buckley. I'm going to be calling you as a witness today.

So can I ask you, first, to state your full name for the record, spelling your first and last name?

Charles Hooper
Charles Hooper, C-H-A-R-L-E-S H-O-O-P-E-R.

Shawn Buckley
And, Charles, do you promise to tell the truth, the whole truth, and nothing but the truth today?

Charles Hooper
Yes, I do.

Shawn Buckley
I just want to introduce you a little bit [Exhibit WI-9]. Right now, you are president of a consulting company, called Objective Insights. And my understanding is that your company

consults for pharmaceutical and biotech companies, that you basically help companies to make business decisions by doing forecast models that include epidemiology. So for example, if a company was going to introduce a drug for third-line non-Hodgkin's lymphoma, how many people are out there with that and what public policy implications would the company encounter? Your company does things like that. Did I explain that well?

Charles Hooper
Yes, you did. Thanks, Shawn.

Shawn Buckley
So now, you used to work for the pharmaceutical company, Merck, and you were actually there when they came out with ivermectin.

Charles Hooper
Yeah, I was there. I think it was just shortly after ivermectin first launched.

Shawn Buckley
Okay, and then we can't leave out that you worked at NASA as a scientific applications programmer.

Charles Hooper
Yeah.

Shawn Buckley
Okay. Now, you became an expert on ivermectin. I'm just curious if you can explain for us what led you down that path.

Charles Hooper
Well, that's actually a good question. So first of all, I knew a fair amount about ivermectin working at Merck. Merck was actually quite proud of ivermectin when it first came out. And so, when the COVID pandemic hit and I saw ivermectin mentioned, I looked into it a little bit more. I was kind of curious, having a little bit of background, and then that just kind of snowballed. And here we are.

Shawn Buckley
Right, so you just, basically, read every study there was on ivermectin and became an expert. And bearing in mind, you already have expertise in the pharmaceutical field and research.

Charles Hooper
Right.

Shawn Buckley
Now, why should we care about ivermectin?

Charles Hooper
Well, the COVID-19 pandemic led to substantial loss of life, along with large social and economic costs, and ivermectin was presented—and still is available—as a potential drug to treat COVID-19. And I think that it has some legitimate claim to being a good treatment for COVID-19. Therefore, many people who suffered and potentially died, maybe, shouldn't have or wouldn't have if ivermectin was more widely available.

Shawn Buckley
Right. Okay, so can you explain for us, when the pandemic started, obviously there was no vaccine or any other tool available. Can you explain to us the importance of the drugs that are on the market then, at the time, specifically ivermectin, and why it should have been considered.

Charles Hooper
Yeah. So when a pandemic happens, everything happens pretty quickly and drug development is a very slow and lengthy process. So we really have a mismatch of a fast-moving pandemic, a contagious virus, and then a slow-moving pharmaceutical industry and a regulatory environment.

And so, by nature, we really need to look at existing drugs that are either already on the market or are soon to be on the market because anything else would just take so long to be developed that the pandemic might have already run its course. So, we, by nature, have to look at older drugs, and it's actually a very well-known principle that using repurposed medicines,

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with established safety profiles is a pragmatic public health strategy.

So people looked around at potential therapies that could work and ivermectin showed up as one because of some of the characteristics it has to attack parasites. Those mechanisms also attack viruses.

Shawn Buckley
And that was actually known before the pandemic started, am I correct?

Charles Hooper
The antiviral activity of ivermectin? I believe so, and if it wasn't before, it was definitely early on in the pandemic.

Shawn Buckley
I'm going to ask you, in a bit, on your thoughts as to whether or not you think it is a safe treatment and an effective treatment for COVID. But right away, there was some controversy about ivermectin and can you share with us about that?

Charles Hooper
Yeah, so if you followed the news over the last few years, essentially everything that's been said about ivermectin has been negative if it's been said by the established authorities.

First, we heard that ivermectin was a veterinary parasitic medicine that was intended for horses and cows. And then, second, a number of health and regulatory agencies came out against its use, for example, the Food and Drug Administration in the States. And then even the originator and inventor of ivermectin, Merck and Company, came out against its use. And then, we also heard that the largest study that showed that ivermectin worked was retracted for data fraud. Finally, we were told that the biggest and best study of ivermectin —the TOGETHER Trial—showed that ivermectin didn't work.

And I think there's a need to set the record straight because that's not the whole truth.

Shawn Buckley
Okay, so can you set the record straight for us today?

Charles Hooper
Yeah, I'd be happy to. Okay, so can I give you a little background on ivermectin?

Shawn Buckley
Yeah, do you want a screen share? I think we're set up for that if you need to.

Charles Hooper
Okay. Let's see. Oh, here we go.

Shawn Buckley
Okay, so we're seeing your screen now [presentation exhibit number unavailable]. We're seeing a slide *Ivermectin for COVID-19.*

Charles Hooper
First of all, we mentioned just a minute ago that older drugs are the way to go when a pandemic happens. So the three drugs that I've focused on, other than ivermectin, to treat COVID-19, they were available at day 235, day 661, and day 662. That's Gilead Sciences' Veklury, the generic name is remdesivir; Pfizer's Paxlovid, which is a combination of two older drugs; and then Merck and Company's Lagevrio, which the generic name is molnupiravir.

A little bit of history about ivermectin: It's an important drug and some have actually estimated that its overall public health benefit might be on par with that of penicillin. It was discovered in 1975 through the work of two individuals, William Campbell, at the Merck Institute for Therapeutic Research, and Satoshi Ōmura, at Kitasato University. And this discovery earned them the 2015 Nobel Prize in Physiology or Medicine.

Ivermectin was first used as a veterinary antiparasitic, with human applications coming just a few years after that. And in the developing world, it's proven so effective that it's on

the World Health Organization's list of essential medicines and it has been dosed four billion times

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in parts of the world where parasites are common, such as Africa, Central and South America. It's been used to treat and prevent river blindness and other diseases. It's been used safely in pregnant women, children, and infants, which is saying a lot.

So my history with Merck goes back 34 years when I was newly hired there and ivermectin was newly launched. And people might say, okay, well, it's an antiparasitic, so why should we use it for COVID-19? Well, it turns out, in the pharmaceutical industry, a lot of drugs have application in multiple therapeutic areas. So just one quick example: The drug amantadine was originally developed to treat influenza, but Parkinson's patients taking amantadine for the flu serendipitously noticed symptomatic relief of their Parkinson's disease. Now, amantadine is regularly taken by Parkinson's patients.

So anyway, with ivermectin, it works through a variety of mechanisms to kill parasites and some of those mechanisms have been found to attack single-strand RNA viruses, such as SARS-CoV-2, which causes COVID-19. So this led scientists to test it in laboratories, in vitro, and they found that it did, in fact, kill 21 different viruses in cell cultures.

Shawn, should I just keep going?

Shawn Buckley
Oh, yeah, please. Please do.

Charles Hooper
Okay. So because ivermectin has been around for decades—it's safe; it's an oral pill; it's cheap; it's off-patent—it would be an ideal therapeutic for COVID-19 if it worked. So the question is, does it work? And here's where things get more interesting.

So Merck came out against the use for ivermectin and said, quote, "It is important to note that, to date, our analysis has identified no meaningful evidence for clinical activity or clinical efficacy in patients with COVID-19 disease."

Now, the FDA was a little bit less circumspect and the FDA tweeted, "You are not a horse. You are not a cow. Seriously, y'all. Stop it." But then the FDA also added a statement pretty much like I just read from Merck. But the FDA went further and the FDA put out a special warning to warn us against using ivermectin for COVID. And it said, quote, "You should not use ivermectin to treat or prevent COVID-19." But this statement went on and it included words and phrases such as "serious harm," "hospitalized," "dangerous," "very dangerous," "seizures," "coma and even death," and "highly toxic" [Exhibit WI-9a].

But this is a drug that is FDA-approved as safe for human use, so why would using this safe drug for a new condition make it dangerous? Well, the FDA didn't say. And in fact, a normal person reading this might think that the FDA was warning against some criminal agent who had laced pills with poison. Then, further, the FDA claimed, with no scientific basis, that ivermectin is not an antiviral, notwithstanding its proven antiviral activity.

So it would be nice to have somebody who's been within these organizations recently and involved in these decisions to explain them. But, absent that, what we can do is we can explore some of the structural reasons for why these organizations might have come out so strongly against ivermectin.

With the FDA, I think it's really two different things: it's the Emergency Use Authorization and then off-label promotion.

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So the Emergency Use Authorization is a regulatory pathway that the FDA may use to authorize unapproved medical products or unapproved uses of approved medical products in an emergency to treat serious or life-threatening diseases where there are no adequate approved and alternative therapies. This might have given the FDA a reason to want ivermectin out of the picture because if there's no approved alternative therapy, then the FDA could encourage companies, like Gilead and Merck and Pfizer, to keep developing their products. And what this really implies is that the FDA knows how long the drug development process takes and it takes too long, so the FDA, maybe wanting to help during the pandemic, wanted to get these new drugs out there. Also, I think it's possible the FDA wanted to incentivize the drug companies to keep researching these treatments because if the FDA said, "okay, maybe your drug will be approved in 10 years, long after the pandemic's over," then those companies would have very little reason to keep researching their treatments.

The second reason is off-label promotion. So once drugs are marketed, physicians can use them for any condition that they think will help the patient. And such usage is called off-label promotion because it's for a condition that's not specifically on the label of that drug that's been approved by the FDA. While this off-label prescribing is widespread and completely legal, it is illegal for drug companies to promote drugs for off-label conditions in any way, shape, or form. And during a particularly vigorous two-year period, the Justice Department collected over $6 billion in fines from drug companies in off-label promotion cases. So the FDA takes the position that it doesn't want to encourage off-label promotion, or off-label usage, but it knows it can't stop it.

So if the FDA were to make a statement on the efficacy of ivermectin for COVID-19, it would, pretty much, have to come out neutral or negative because if it promoted a drug for an off-label use, there would be obvious hypocrisy involved.

So Merck faced that same off-label promotion issue. You know, Merck is not going to promote a product and face substantial fines. Merck is too smart for that. Also, ivermectin has long since been generic, so Merck doesn't make much money off it. But Merck was hoping that its new drug, Lagevrio, molnupiravir, was going to be a successful treatment for COVID-19.

Now, sometimes, the sequence of events can prevent or work against the dissemination of balanced information.

Shawn Buckley
Charles, can I just step in and ask you a question? Because you were just offering an explanation, and I appreciate you don't know why the FDA made the statements that it did. But surely, the FDA could have just simply said ivermectin is not approved for treating COVID-19, and so, we don't know whether it would be effective for that. Which is very

different than, basically, making false statements that it's dangerous. Because, surely, it can't be dangerous with 4 billion doses out there and most of them would be non-prescription doses, just over the counter in other countries. So are you being a little gentle with the FDA in what you're suggesting to us?

Charles Hooper
Yeah. I really am curious what went on within the agency, but I don't really know.

[00:20:00]

But I do think that authorities in that position are culpable for what's happened because, essentially, they were spreading misinformation.

Shawn Buckley
Okay, and I'm sorry to interrupt, you were then going to go on about the TOGETHER Trial.

Charles Hooper
Yeah, so with the TOGETHER Trial. Sometimes the sequence of events of how information plays out can work against the dissemination of balanced information. The TOGETHER Trial was supposed to be the best and biggest trial testing ivermectin. But the press release came out at least a couple of weeks before the full study was published. Basically, the main news organizations, or some of the main ones, such as *The New York Times* and the *Wall Street Journal*— The only information they had was from the press release, and so, they basically parroted the conclusions of the study from the press release that said that ivermectin doesn't work.

Most people just stop there. The problem is, for those of us who like to scrutinize the studies, anything that we found was going to be weeks later, and at that point, it would look like old news. The news organizations might be hesitant to publish that because it could make their initial articles look premature or, perhaps, incorrect.

Anyway, after the full TOGETHER Trial was published, a number of researchers have looked into it and they've identified 75 serious problems with this trial. You know, even just a few serious problems would be cause for concern, but there were 75 problems identified. And worse, the trial that we were told proved that ivermectin doesn't work, actually, has results that suggest that it does work.

So in the TOGETHER Trial, the patients who were on ivermectin had a 12 per cent lower risk of death, a 23 per cent lower risk of needing mechanical ventilation, a 17 per cent lower risk of hospitalization, a 10 per cent lower risk of extended ER observation or hospitalization.

And then, using the results of the trial, I was able to calculate the probability of the benefit to patients who are on ivermectin. There were 10 different metrics in the trial and the benefit ranged from 26 per cent to 91 per cent. So 91 per cent was for preventing hospitalization. And for the most serious outcome, death, the probability was 68 per cent that ivermectin was helping these patients.

Now, another trial that got a lot of press was a trial that showed that ivermectin did work. It was a study by Elgazzar et al., but it was withdrawn on charges of plagiarism and faked

data. And so, this one study got a lot of press as if it was one of the only studies, but there's actually been quite a bit of research done on ivermectin for COVID-19.
So there's been 95 clinical trials, 95 studies, that have included 1,023 authors with patients in 27 countries, and the number of patients, if you added it up across all the trials, is 134,554. And if you pool all the results, the results suggest that ivermectin reduces the risk of death by 51 per cent.

So I just want to highlight that. This implies that if everybody had access to ivermectin, the death rate across the world could have been half of what it was and 29 per cent lower risk of mechanical ventilation, 41 per cent lower risk of ICU admissions, 34 per cent lower risk of hospitalization, 78 per cent reduced number of cases, 42 per cent improved recovery, and 45 per cent improved viral clearance.

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In these results, two of them are significant to P less than 0.01, and the other five of them are significant to P less than 0.0001.

So the other thing that the studies show is the earlier use is better. So, for example, the benefit is 82 per cent if it's given prophylactically, 62 per cent benefit in early use, and 42 per cent benefit in late use. So 45 of these studies were randomized, controlled trials and 80 of the studies were peer-reviewed.

Shawn Buckley
And, Charles, can I just stop you for a second? So you're basically, in that last slide, indicating that the most significant benefit is for early use. And what I find curious about that is, in Canada—I live in a province called Alberta—the College of Physicians and Surgeons in Alberta, concerning the COVID pandemic, basically made it clear to physicians that they would lose their licence to practise if the physicians treated COVID early on. So it was really only possible for doctors who wanted to keep their licence to treat COVID once the patient arrived at the emergency department. But what your analysis is suggesting is that was completely wrong, aside from the fact that it just sounds insane to tell doctors that they can´t treat an illness at its early stages. Am I correct that, based on your data, the College of Physicians and Surgeons in Alberta were completely wrong on this?

Charles Hooper
Yeah, I would agree with that. If you look at all the treatments that have any kind of efficacy for ivermectin, and this actually goes more broadly to viral diseases, you want to treat the patient pretty soon after they're infected. And in fact, if you treat them, something like, eight days after they're infected, the treatments basically have no benefit at all because this is a viral infection. It comes and it goes, and if you don't get it early, you're not going to get it at all. So it's a pretty established principle that, for a viral infection, you have to treat it pretty early.

Shawn Buckley
Okay.

Charles Hooper
So this just lends empirical evidence to that.

Shawn Buckley
Yeah, and I'm sorry for interrupting, just it was an interesting point you just made.

Charles Hooper
Oh, no, I appreciate your comments and points.

Okay, so we've talked about ivermectin. Now, there are some other drugs that have gotten clearance to be on the market to treat COVID-19, and I mentioned them in an earlier slide. But if you look at their efficacy, it's not as good as ivermectin. In fact, it's typically half or less as good as ivermectin. And further, the safety isn't as good.

So with Paxlovid, 15 per cent of the patients are contraindicated for Paxlovid, which means that they should definitely not get it. Remdesivir is associated with acute kidney failure. And molnupiravir is the most alarming: it's associated with creating dangerous viral variants and it's associated with mutagenicity, carcinogenicity, teratogenicity, and embryotoxicity, which in a little bit more plain English, means that there are risks to human DNA. So these drugs don't work as well, typically, as ivermectin; they're not as safe, and they also aren't as widely available and inexpensive.

Shawn Buckley
And yet they're permitted for treating COVID.

Charles Hooper
Right and they have the backing of the medical establishment behind them.

If you have any other comments or questions?

Shawn Buckley
No. Nope. Carry on. Thank you.

[00:30:00]

Charles Hooper
Okay, so I think to really understand how to interpret the results from clinical trials, we need to talk, for a minute, about the concept of statistical significance. And while it seems like an arcane and unimportant subject, we need to understand it because, essentially, it leads to many false conclusions, especially for ivermectin. What I want to do is show you the results of two clinical trials for ivermectin. Show you the results and then show you what the study authors actually said.

And so, again, statistical significance is a way that researchers try to make sure that the result is real and not due to luck. And so, what they've settled on is a number of 95 per cent. So they want to be 95 per cent sure that the results are real and not due to luck. What they do is if the results are good and the results are statistically significant, they say that the drug works. However, if the results aren't good or the results aren't statistically significant, they say that the drug doesn't work, which isn't true.

So here's one example: This is a study by Ravikirti et al., and as part of the study, they looked at the need for mechanical ventilation. Of the ivermectin patients, only one out of 55 needed mechanical ventilation. For the placebo patients, five out of 57 needed it. So if you just do the simple math, it looks like ivermectin reduced the risk by 80 per cent. But the authors concluded, "This study did not find any benefit with the use of ivermectin in… the use of invasive ventilation in mild and moderate COVID-19." And the reason they said that is because they were only 91.2 per cent sure that there was a benefit. In other words, it didn't match the 95 per cent threshold.

So here's another study: This is by Rajter et al. and this is, again, looking at mechanical ventilation. And so in this case, patients on ivermectin— so 36.1 per cent of them improved and got off mechanical ventilators, whereas only 15.4 per cent of the patients who got placebos got off the mechanical ventilators. So if you look at the results, you'd say that ivermectin benefited the patients by 2.3 times what the placebo response was. But, again, these authors reported no benefit and that's because they were 93 per cent sure that the results were true, but they wanted it to be 95 per cent sure.

Now why is this important and why does it affect ivermectin? Well, when a drug company does a clinical trial, it makes sure that the trial is big enough that it's going to get statistical significance. But with a drug like ivermectin, where there's no real money behind it, it's up to smaller organizations that don't have deep pockets to run the trials, and so, they typically run smaller trials. And so, frequently, you'll get a result like this where the study authors, based on using statistical significance, will say that the drug has no benefit. People who just look at the summary in that write-up of that study will say, "oh, ivermectin didn't benefit patients with mechanical ventilators." But if you look deeper, it actually does.

And so I wanted to just point out how ridiculous this can be. For example, imagine a pharmaceutical company testing drug X and there's two researchers, one researcher at each hospital, and they recruit 1,000 patients for this clinical trial, 500 at each hospital. So each researcher is managing 500 patients. Based on statistical significance, if they combine the results and publish together, they would say the drug works. If they, for whatever reason, maybe they had an argument over whose name should be first on the publication

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—you know, Jones and Smith or Smith and Jones—and they publish separately, they would conclude that the drug doesn't work. So could it be that the drug works if these two authors get along together and publish together, and it doesn't work if they argue and publish separately? Well, that's ridiculous.

And so what's happened with ivermectin is you've had all these little studies, some of which aren't statistically significant, but together they are. So what I showed a few minutes ago, all those results, when they're pooled, are highly statistically significant.

In conclusion, and then, if you'd like, I can talk about possible solutions to prevent a problem like this in the future.

In conclusion, whenever we have a pandemic, we need to rely on existing medications because new drugs just take too long to develop. And older drugs, such as ivermectin, they're a known quantity: they're safe; they're cheap; the manufacturing is established; and then it's just a question of if they work or not.

And with ivermectin for COVID-19, the clinical evidence is pretty overwhelmingly positive and it's substantially better than for other treatments, and it's safer than other treatments, and it's cheaper than other treatments. And those who dissuaded us from using ivermectin are responsible for some of the problems that this caused.

So I'd be happy to jump into possible solutions. Or I don't know, Shawn, if you have questions.

Shawn Buckley
I do want to actually ask you about that. But just following up on your last point about people being responsible, would it be fair to characterize it— You've made it clear with your presentation that there's 4 billion doses. Am I correct that in many countries, in fact, most countries where ivermectin is taken regularly, you don't need a prescription to get it. It's just over the counter. Is that fair to say?

Charles Hooper
Yeah, I'm not an expert in that, but I believe that's true.

Shawn Buckley
Right and would it also be fair to say, literally, ivermectin is one of the safest drugs on the planet?

Charles Hooper
I think, yeah. Based on what I know, I would characterize it as one of the safest drugs on the planet.

Shawn Buckley
So here we're faced with a pandemic where the media is telling us we're in great danger, and from a safety standpoint, there would have been little downside, even if ivermectin wasn't as effective as the meta-analysis that you've shared shows it is.

Charles Hooper
Right, there was very little downside risk to using ivermectin, and early in the pandemic, there were indicators that it did have efficacy. So the efficacy of ivermectin was pretty well-established— Well, established enough to make decisions around mid- to three-quarters of the way through 2020. So there was no reason after, say, the fall of 2020 to not be using ivermectin.

Shawn Buckley
Now, you had sent me some studies, and I'm not going to go through them, but I'm just going to indicate for the commissioners that we've entered them as exhibits. So you've sent me a study that you are an author in called "Ivermectin and Statistical Significance" [Exhibit WI-9b], and I'll just ask if you would adopt that as true today.

Charles Hooper
Yes. Yes, I would.

Shawn Buckley
And then, we've also entered as an Exhibit WI-9c, where you're one of the authors: "Ivermectin and the TOGETHER Trial." Would you confirm and adopt that that's true today?

Charles Hooper
Yes. Yes, I will.

Shawn Buckley
And then, we've entered as Exhibit WI-9d, an article where you're a co-author, titled "Setting the Record Straight on Ivermectin." And do you adopt that as true today?

Charles Hooper
Yes, I do.

Shawn Buckley
So now, I do want to ask you, and then I'll turn you over to the commissioners for questions, but how could we have done this better?

Charles Hooper
Yeah, that's a really good question and I've got some ideas. We could debate them, probably, for the next year,

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but let me just list them.

So one would be, allow drug companies to promote off-label uses. What this really means is drug companies have information about their drugs for certain diseases, and right now, regulatory agencies, like the FDA, don't allow them to share that information. So it's really a form of censorship.

The next idea would be to allow drug companies to benefit from finding uses for existing off-patent drugs. So, for example, if Merck really found that ivermectin worked for COVID-19, essentially, it might not make a dime from that investment. But if we change the structure somehow so that Merck did make money, then Merck might have been as interested in ivermectin as it was in its own drug.

Shawn Buckley
So can I just slow you down and spell that out because a lot of people might not understand what you're saying? So when a drug still has an existing patent on it, and Merck holds that patent, Merck can charge a high amount for the drug. And if somebody else wants to make it, Merck has to agree and then, basically, there would be a licence fee paid to Merck. But

when a drug like ivermectin is off-patent, then any generic drug company, or any other drug company, for that matter, can also make it and there's no financial benefit for Merck.

But you're suggesting in a pandemic if somebody like Merck could say, "Hey, wait a second, this data shows that it works for ivermectin," that then if there could be some financial incentive— like a licensing fee or something like that for its use for something like COVID— then that would be incentive for the drug companies to look into that and then, also, for them to share their data?

Charles Hooper
Yes, exactly what you just said. The financial incentive could be a number of different things. It could even be, like, a finder's fee or something that some organization pays to Merck, or whichever company it is. It wouldn't necessarily have to be Merck that would promote these uses for ivermectin.

Shawn Buckley
Right, but some financial incentive because we are dealing with companies that actually have fiduciary obligations to their shareholders, financially.

Charles Hooper
Right. And essentially, the generic market is so competitive, and the products are deemed substitutable that there's no way for a company to say, "Our generic is better," or "we know something about our generic, therefore you should pay us more money." Because as soon as that information is out there, then any customer could just use any generic and say, "Okay, well, this ivermectin is as good as that one, and I know that now it treats COVID-19, so why should I use Merck's?"

Shawn Buckley
Now, I interrupted you. It looked like you had a couple of more suggestions of how we could have done this better.

Charles Hooper
Yeah, so there are government agencies around the world that do a lot of medical-related research and the National Institutes for Health in the United States is one of those. And it has a budget, I think, of $45 billion a year. So in the beginning of the pandemic, if the NIH just said, "Hey, we're going to find all these old medicines that potentially could be used to treat COVID-19 and we're going to do thorough testing of each one of them," these studies wouldn't just be dribbling in. It would be well-designed studies with plenty of people, statistical significance, and you just do that early on. And that could have had phenomenal health benefits.

So just to keep going down my list. I don't quite know how you do this, but prevent agencies, like the FDA, from attacking older drugs. Or maybe a better way to do it is to allow dissenting opinions. So have, kind of, a red team that's set up to challenge the establishment views.

Another perspective on that is, I think power within these organizations has become too concentrated. Maybe spread it out some, so there isn't so much emphasis on the one organization having the one viewpoint.

[00:45:00]

And kind of along those lines, maybe clean the house within these organizations, that if there are people who are knowingly dissuading us from taking medications that have potential benefit, that's not who we want in charge of our public health organizations.

And then, my last two points are to use statistical significance more wisely.

And then, the very last point is something that has other benefits, also, which is taking the responsibility for efficacy away from regulatory agencies like the FDA. And I'll just try to explain this very briefly. From 1938 until 1962, the FDA only mandated safety testing for drugs. And then, after 1962, the FDA mandated safety and efficacy testing. And it sounds like a wonderful idea, but economists have studied it and it's pretty easy to make the case that things have been worse since 1962.

So if the FDA wasn't concerned about efficacy, but was concerned about safety, then any statements the FDA would have made about ivermectin just would have been about its safety. Which, I think, is pretty clear that ivermectin is a safe drug.

Shawn Buckley
Right, you've put a lot of thought into these and we thank you for that.

I'm going to ask the commissioners if they have any questions for you. And they do.

Commissioner Massie
Well, thank you very much for this very thorough presentation. I have a couple of questions. In fact, the way I look at that is it seems that these small molecule drugs that have been around for a long time, they lose their value after they're off-patent. Doesn't that call for a serious rethinking of the patenting of these molecules? Because why is it that, all of a sudden, a chemical that has been synthesized and proven to be safe and effective in many indications would lose its ability to function in other indications, knowing that it's generally the case that molecules that have been around for a long time have several indications? We know that from the practice. So why don't we come up with a different model? Copyrights, for example, on books or music could last much, much longer than the lifetime of a patent. Isn't that part of the problem we're facing?

Charles Hooper
I completely agree. So when a drug goes off-patent, it basically dies because there's no financial incentive to look for other uses for that drug at that point. The only research that's typically done on drugs at that point is organizations that don't really have a financial incentive. I think your point is actually very important. If we could, somehow, figure out a way to incentivize drug companies or universities or research labs to research new uses for off-patent drugs, I think we would find phenomenal benefit because a lot of these drugs have to be useful for other conditions.

And it could be an issue with patents or it could be just some other kind of reward for finding something that's useful. Or maybe have generics that aren't substitutable, so you could actually say that this generic is different than this generic. We'd have to think about solutions, but the potential benefit is huge.

Commissioner Massie
Another question that I had is, you're in the business of, I would say, advising different drug companies on strategies to develop new drugs or maybe find new markets.

[00:50:00]

I'm a little concerned that the position you're taking right now would probably put your position on this marketplace at some sort of a risk because it clearly goes against the business model of some potential clients. So I'm wondering whether you're concerned about that for your activity.

Charles Hooper
The answer is I'm not very concerned and that's because I'd be very interested in finding new uses for generic drugs, but, also, I'm interested in finding uses for new drugs, and so, that's what I help my clients with. I basically want good medicines to be out there so that people live long and healthy lives. Whether they're a currently generic drug or whether it's some kind of cell therapy that's coming down the road, cutting edge cell therapy, for example.

Commissioner Massie
Thank you very much.

Charles Hooper
You're welcome.

Shawn Buckley
So that's it for questions.

Mr. Hooper, on behalf of the National Citizens Inquiry, we sincerely thank you for attending today and sharing with us your valuable testimony.

Charles Hooper
Thank you for your time and attention.

[00:51:45]

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