Susan Frantz-Bohn / FDA

We are ready to proceed when you all are.

Lorrie McNeill / FDA

Okay. Wonderful. Good morning, everyone. Thank you so much for joining us this morning to share your experiences following vaccination with COVID 19 vaccines. My name is Lorrie McNeil and I'm the director of the Office of Communication Outreach and Development in FDA's Center for Biologics Evaluation and Research or CEBR for short, as you may notice, we are the center within FDA that's responsible for regulating vaccines. Joining us today from FDA are Susan Franzt-Bohn, the deputy director of the Office of Communication. Diane Bartell, the director of the Division of Communications and Consumer Affairs. And Paul Richards, the chief of the Consumer Affairs branch. Excuse me. Unfortunately, Dr. Marks, the director of CEBR, is unable to join us today due to a conflict. We look forward to hearing from each of you during the meeting.

I'd like to start off with a housekeeping announcements. First of all, we understand that that each of you would like to share your personal experiences and how the adverse events you've experienced have impacted your lives. Given our limited time today, we would ask that you limit your remarks to 5 to 7 minutes each for this portion of the meeting.

We'd also like to ask you if you're comfortable to turn your camera on when it's your turn to speak. And provided you're comfortable again doing so. We'll also ask you when it's your turn to unmute your microphone. I think a box will come up in the middle of the screen asking you to do so. I'd also like to note that FDA will not be recording or transcribing today's meeting in any way due to the potential inclusion of personal health information.

In our discussion. Finally, is for any reason you're having any technical difficulties today? Please raise your hand and we'll reach out to you. You'll find this option across the bar at the bottom of the screen under the reactions icon. And you can just click on Raise your hand. So with that, I would like to turn it over to Mrs. Dressen, for introductions.

Brianne Dressen / REACT19

Hi. Thanks so much for having us. Yes, we were told that Peter Marks would be here, so we look forward to speaking with him at some other time, hopefully soon. I am Brianne Dressen. I am a preschool teacher here in Utah. Thank you for meeting with us and putting this together and taking the time to hear our voices. We are going to first start with Dr. Krystal Schaffer and then after she speaks, we'll hear from Dr. Jennifer Burke Berkman and then Dr. ARPA, who is Dr. [??], Patel, and then Dr. Felicia Jonker is going to go and we'll finish with the Denise Hertz. Dr. Denise Hertz.

ER and ICU Physician

Hi, can you guys hear me ok?

Lorrie McNeill / FDA

Yes, we can, thank you.

ER and ICU Physician

So thank you for having the meeting today. My name is [redacted]. I'm the current attending physician at [redacted] Hospital, in Pennsylvania. In terms of my medical background, I was Chief Resident and emergency medicine residency at Wellspan. Chief fellow at University of Pittsburgh Medical Center, and Critical Care Medicine Fellowship. I currently split my time 50 50 between the E.R. and the ICU, and I'm a director of EM critical care.

This pandemic has been awful. My hospital this past winter had an incredible surge of patients and I was responsible for an unsafe amount of patients in the ICU, especially overnight. At one point we ran out of [echo circuits], leading me to make tough ethical decisions that still haunt me to this day. To say that I was excited about the vaccines when it first became available is an understatement.

The risk benefit ratio was and still is clearly in favor of a vaccine, and I still believe in the vaccine strongly. Despite my own vaccine induced health issues and despite the health issues that I've seen and my patients. I'm here today because I'm concerned that there's a failure in your vaccine safety monitoring systems, that is preventing you from recognizing and thus further investigating safety signals regarding adverse events caused by the vaccines. Your agency has stated that with rare outcomes you have to start using the vaccine to see them. Thus you need a robust safety monitoring system to find this and I am concerned that you don't currently have this. I believe this because I am an example of a rare outcome that the FDA is not recognizing or investigating. And in terms of my personal health history, I'm 34. I had no past medical history prior to getting vaccinated. 13 hours after my second dose of Pfizer my life change. I have symptoms since this time that are still ongoing to this day, which is nearly eight months later. I am disabled from them and I'm currently on my third leave of absence from work due to them. Every single physician that I have seen sights the vaccine as a direct cause of my ongoing health issues.

My main, and most disabling health issue has been vertigo. Which I've been diagnosed with vaccine induced [sudo]neuritis, but I have other symptoms too. Without concrete diagnosis, they've been progressing and escalating over time. I have issues such as chest pains, ascending paresthesia's, intermittent muscle weakness, brain fog, inappropriate tachycardia, pre-syncope. These symptoms when [I list them?] and it's listing on VAERS makes it sounds more benign and insignificant than what they actually are.

When I tell you that I'm currently scheduled for testing over the next few weeks to rule out perimyocarditis, Small Fiber Neuropathy, POTS, and Dysautonomia, the conversation suddenly changes and gives you a much better sense of the level of disability that I have and the level of concern that other physicians have. My repeated work absences unfortunately negatively affect my community and

my colleagues and especially have affected the critically ill pediatric and adult patients who need [echmo?] as their last hope for survival and I cannot currently accumulate them.

I am especially concerned about the VAERS reporting system. The system is cosponsored and monitored by the FDA as a passive surveillance system intended to help identify potential signals of harm. I had concrete data to demonstrate my concern. This year, I have submitted 17 reports to VAERS. 18 including my own. 11 of these patients that I have that I submitted, they had their symptoms start within seven days of receiving the messenger RNA vaccine.

16 of them were hospitalized, 12 of them in the ICU. Six of them died. VAERS asked for stat medical records for one of them. A patient whose medical records was not collected includes a 44 year old gentleman with normal BMI, no medical problems, no family history, who's asserting that the day after receiving a second dose of Moderna, felt fatigued, felt this way every single day, until day 12, when he had acute cardiac arrest. There is no justification for not investigating, at minimum, all deaths reports to VAERS, especially in the young and previously healthy. Of nine other patients that I had who were hospitalized, who did not die, VAERS asked for only two of their STAT medical records. A 29 year old female was not included in these medical records requests . And for her, 4 days after receiving her second dose Moderna, she was given TPA due to concerns for a stroke.

Also included on this "no further investigation list" is somebody that I submitted that I was concerned was a marker of vaccine enhanced disease. On the VAERS website there is a link between 2015 article entitled Safety Monitoring and a Vaccine Associated Event Reporting System. And I quote from this article , "for reports classified as serious, the VAERS contractor requests associated health records, including hospital discharge summaries, medical laboratory results, death certificates and autopsy reports, series events include at least one of the following deaths following vaccination, life threatening health event or lasting disability. My own case and those patients I reported demonstrate that this follow up is not occurring as published guidelines indicate that they should.

And you have a process and system failure as a result. So in sum,, even though the risk benefit ratio clearly favors the use of the vaccines, the FDA is responsible for identifying the minority harm from the vaccines so that they can take steps to mitigate this risk for this minority. And if they can't mitigate it, then at minimum providing guidance to medical community to aid and the identification and treatment of such adverse events.

I, as well as my patients listed above, are proof that the current systems in place intended to allow the FDA to perform this duty have failed. This FDA failure is transmitting to a failure of the medical community to properly recognize, diagnose and treat such patients. Thank you for this time and the opportunity to speak with you today.

Brianne Dressen / REACT19

Dr. [redacted]

Anonymous Physician

Good Morning. Can you hear me? Alright

My name is Dr. [redacted]. I'm an M.D. as well as MBA in health care administration. I came from Canada to live the American dream. I went to Emory University for my family medicine residency, were I also served as chief resident. I'm a fellow of the American Academy of Physicians and also worked as a research coordinator for the highly regarded Podiatry Institute in Atlanta.

My most recent job is as an outpatient primary care provider. I'm a 40 year old, healthy former ballet dancer, and up until I got my second Pfizer shot, I still danced and worked out six days per week, even while pregnant. The pandemic has hit us all hard, especially me. I was cut off from my family in Canada and still am today.

I said goodbye to my dying grandfather over the phone. I worked in my clinic during COVID while pregnant and had to precure my own and 95 masks due to the lack of PPE within my hospital system. The only bright spot was when I welcomed my first baby, a daughter, one year ago in August. Unfortunately, my Canadian family has still not met her to this day.

When I returned to work after the baby, the vaccine was just available. My office staff was too scared to get it, so my partner and I decided to get it to and show them it was safe and the science was strong. At four months postpartum, I got my first shot in December 26, 2020. I started having flushing tachycardia, elevated blood pressure and dizziness 11 minutes afterwards.

I was monitored for about an hour and its self resolved. A nurse told me they had seen a few flushing reactions, but that it wasn't a big deal. The same thing happened after my second shot on January 15th, except this time it started 2 minutes after. The episode lasted 20 minutes. And then I left. And then it happened again, but worse while I was driving home on the freeway. My face was on fire and I felt like I was going to pass out. I barely made it off an exit and into a parking lot. After that, I started having severe flushing, tachycardia and dizziness episodes more frequently, even at night. My whole body would tingle, even my tongue. I eventually collapsed at my practice on February six and was taken by ambulance to the E.R..

My d-dimer was extremely high, but my CT pulmonary embolism and everything else was negative. I was told that I likely had postpartum anxiety and to get some more sleep. The E.R. doctors said there was no known adverse vaccine events like this. Over the next few months, I underwent over $100,000 in workup with doctors who had no idea what was going on.

I was fortunate to be accepted into a study by the NIH and was diagnosed by them with immune mediated, Dysautonomia, POTS, and small fiber neuropathy induced by the Pfizer COVID 19 vaccine. I progressively lost the ability to walk more than 100 feet at a time and spent days in bed. I spent two weeks at the NIH away from my baby and was admitted for five days of IVIG.

It was heartbreaking because before I left the NIH for the NIH, my baby had just started saying, Mom. And when I returned, she didn't say it again for over a month. I was unable to work for 12 weeks. I was still very weak when I returned. However, my employer denied an ADA accommodation and told me Enough is enough. Do you know how much money you cost us?

They threatened to fire me if I didn't see my regular patient load. I was unable to do so and they terminated me without warning or notifying my patients on July 2nd. I made 3 VAERS reports since December 2020. I wrote a 60 day follow-up letter from them in June. And then they urgently requested my medical records July nine.

I have never heard back after I uploaded three documents, which is the maximum allowed. I requested a key to upload more and even call them about this. They said to wait a bit longer for the email and that they really just wanted to see a copy of my vaccine card. I also responded to all V-Safe reports. I self-reported to CISA but got turned down by the pediatrician who was evaluating adult cases because she felt I likely had a history of COVID causing my symptoms and that I needed bloodwork to prove I never had it.

I eventually got this blood work months later at the NIH and it was negative. I emailed Janet Woodcock about my issues in February and she stated she couldn't help me. She admitted in another email to someone else. She has been in contact with Dr. Nath at the NIH, and is aware of them studying our vaccine reactions. This means the FDA knows what is happening to us.

I am angry because the FDA issued a warning about single digit myocarditis, myocarditis, cases. It has completely ignored the immune mediated neurological complications that they know about between my patients, my friends, my husband contacts thousands of people know my story. The fact that the government keeps it secret breathes distrust in the vaccines. The NIH has studied at least 50 to 60 people with the same type of reaction in person, and they do many more telemedicine evaluations.

They told me they get hundreds of emails per day about these vaccine reactions. I was offered a national interview to discuss my experience, but turned it down out of fear of repercussions to my job and my license. I am still pro-vaccine, however, I feel like collateral damage. My life matters. My thousands of patients need me. My family needs me. I still can't dance. I wake up and feel like an arthritic old woman. I want another baby. And I don't know if that can happen. If the FDA would be more open and honest about these reactions, it would improve treatments and actually increase trust in vaccines. We know that. You know, why aren't you saying anything? Why aren't you issuing a warning?

I did my part when I lost my job and my health. I want you to do your part. Thank you.

Speaker 3

REDACTED

Speaker 4

REDACTED

Brianne Dressen / REACT19

Dr. Hertz.

Dr. Danice Hertz / REACT19

Hi. Thank you so much for having us here today. My name is Dr. Danice Hertz. I am a 64 year old retired UCLA trained gastroenterologist. I was in private practice for 33 years and retired just a few months before the pandemic started. I received the Pfizer COVID vaccine on December 23rd of 2020. I was eager to take a step toward putting COVID behind us.

I was told the vaccine was safe and effective and was given no warning about any potential side effects. Little did I know my health would be robbed from me that day. I soon went to bed with agonizing, burning pain and numbness in my face, scalp, tongue, eyes and limbs. I felt internal vibrations, tremors twitching, as well as a very tight band around my chest.

My vision became blurred, my eyelids swollen, and I had loud ringing in my ears. I experienced left sided chest pain, shortness of breath and tachycardia. I had profound fatigue, walking a few steps was a major effort. When the symptoms peaked, I felt like I was being electrocuted. I saw many doctors who did not recognize what was wrong with me and told me I was fine.

I told them I was not fine. I sought help from experts across the country, including the NIH. I was eventually diagnosed with mass cell activation syndrome and was put on many medications with minimal results. My case was presented at CDC [lab rounds], and they agreed with this diagnosis. The symptoms have gradually lessened, but are still present every minute of every day and are still at times unbearable.

I am worn-out being so ill and in pain for so long. I believe that there is some physiological process occurring in my body post-vaccine that we don't yet understand. I have cried out loudly to the heads of the FDA, CDC, NIH and Pfizer. To no avail. Instead of running to help us and look into these reactions, in fact, you have run away from us. My many reports to V-Safe, VAERS and Pfizer have gone unnoticed. I started writing comments after articles on the Internet and people contacted me from all over the world with similar neurological reactions to the vaccines and similar inability in getting medical care. We formed a group of 150 people and are fighting for recognition and help. We have hit a brick wall with every effort. There are other vaccine injury groups with thousands more VAERS reports many thousands with neurological results from these vaccine. Why is nobody following up? Why won't anybody help us?

The people in my group all believed in the vaccines. We all believe that every efforts should be made to stop the pandemic. We are pro-vaccine and pro-science. We are Americans and humans deserving of medical care. We are being ignored by our government and the medical community. We are collateral damage from the pandemic. We have a new disease. We are calling it post COVID vaccine long haul reaction.

We need Doctors to be aware that these reactions are happening. We desperately need medical care. We need to have top level research to study what has caused these reactions and how to treat them. I am pleading with you, the FDA as well as the CDC, NIH and vaccine manufacturers to help us. We can continue our campaign to control the pandemic and help the vaccine injured at the same time.

Ignoring us is not acceptable. Burying the facts is just plain wrong. It is un-American. It is inhuman. Thank you so much.

Brianne Dressen / REACT19

Thank you, Dr. Hertz. I'm going to try to make my comments pretty quick. So my name is Brianne Dressen, and I am a not a physician. I'm just a preschool teacher here in Saratoga Springs. I'm the parent of two small kids and I was previously healthy. I had I was so confident in this that I enrolled in the clinical trial here in the United States for AstraZeneca. Unfortunately, my reaction started within an hour. It started with tingling down my arm. I ended up with severe, blurred vision and double vision by that night. And I had extreme sensitivity to sound by the time I went to bed the following morning after a typical vaccine response with fever, myalgia overnight that had resolved and by the morning I got up to get ready for work and I had a slumped left leg. And so I was walking into the left side of doorways. Sensitivity to sound was still there, as well as the vision problems. I still went to work and of course by the end of the day things were so unbearable for all of the sensory input that I had to have the lights turned off in the classroom. And I just remember telling the little kids over and over, "Well, you're voices are a little loud today."

So I called the test clinic and fortunately I didn't hear back. Called them the next day, things were worse. I was trapped in my room and darkness and silence by myself. And I didn't hear back. And so I heard back from on the third day, I went in for an a neurological evaluation and they said, well, you probably have MS.

So it was off to the E.R. we went because no neurologists in town could see us for, you know, three months. Unfortunately, that was one of many hospital visits and within two and a half weeks, my function had declined to the point where I could no longer walk. I was incontinent. I couldn't have a bowel movement. My heart rate was skyrocketed. I had extremely high blood pressure, and I began to have this extremely painful electrical sensation surging through my body that continues to this day. When I was admitted to the hospital, obviously it was during the clinical trial, so it was expected that nobody really knew what was going on. I wasn't blinded from the clinical trial and then I was dropped.

I am unsure what happened to my data. I do believe that if my case was reported to the [DSM-V], it would have showed anxiety because that's what my medical records showed. So my legs stopped working because of anxiety. And unfortunately, we fast forward a little bit to now where there are thousands of us that have found each other.

What has happened to me and my misdiagnosis is and the lack of understanding is still happening today. It is just as relevant. The conversation has not changed from when I first went into the hospital. This conversation is the exact same conversation that the vast majority of us are experiencing and having with our physicians. That this is something in our heads that, this is not happening. Here in Utah, just two weeks ago, they released a PSA from the most major hospital system here in the state. They are the largest employer here in the state and they run over 80% of the hospitals. And in their PSA, they said that vaccine reactions are not happening and that this is misinformation and it is dangerous and it needs to stop.

So you can imagine hearing that someone and there are hundreds of us that I know of here in Utah that have had this very similar neurological reaction to hear that from the very top that's in an approved message being sent out to the entire state, and that it is okay for that to be aired instead of there are some rare reactions. Let's talk about those. Instead, It's nope, it's not happening. This is making a complete stop gap in people's ability to get medical care because this reaction is not being acknowledged. Unfortunately, I wake up every single day trying to convince myself that it's okay and I have to live this way for the rest of my life. Unable to work the burden on my family—with a incredibly painful electrical sensations surging through my body 24/7. I went eight months without any appropriate diagnosis because nobody understood what was going on, because it's not being talked about. I was I was one of the few fortunate to fly out to the NIH where I was finally able to receive appropriate diagnoses, non-length dependent neuropathy, short term memory loss, sensory neuropathy of my hands, severe POTS, severe autoimmune dysautonomia.

I was then given IVIG, which fortunately made it so I didn't feel like I was dying all the time, so it dialed it down just a little bit. I subsequently came home with a stack of documents from the NIH and my physicians here because this still is not being acknowledged, dropped it. No interest in taking care of it.

No interest in medical care for me, for follow up. Tthe stories that you heard today, there are thousands that each one of us have heard, this suffering that is upon us is profound. We are being silenced. And that's not an exaggeration. There is a reason that these physicians came here today with this special request, that this be confidential And it is because of the very real risk that there will be repercussions with their jobs. They have a very real illness and they should and absolutely deserve to be seen and heard and believed by their medical care teams. We absolutely believe that the vaccines do play a role in prevention of death and to mitigate the spread of the disease.

Unfortunately, we wrote a letter because nothing was happening to help us, so we unified and we wrote a letter in May and we sent it to the heads of the FDA and the CDC and as well as to the White House. And it described the nature of the reaction, which is a broad, myriad of of symptoms and our plight and our complete lack of to get medical care.

Unfortunately, every single word that we wrote in that letter is just as relevant now as it was then, if not more so. We need help and we needed help months ago. We have been pleading and begging for months. The time is now and we definitely need acknowledgment and it needs to be communicated to the medical community. This is completely unfair to the patients, but this is also not fair to the physicians and practitioners who are met with this reaction when we show up into the ER’s.

At the NIH, they have repeatedly told me and others that this can be mitigated with early intervention and possible immunotherapy. It breaks my heart to know that there are people like me that did their job to protect those around them and getting this vaccine only to be met with a reaction and they go to the E.R. and the tools that should be there to help them are not available.

I plead with you to please make a place at this table for us, because as of right now, there is not a seat at the table. There isn't even a crumb on the floor for us. Thank you.

Lorrie McNeill / FDA

Thank you all for sharing your story with us. Obviously, it is very powerful for us here and very important for us to hear. I do have a couple of questions, if you will. Allow me. Mrs. Dressen, you mentioned the TV ad in Utah that's airing. I would be very interested in seeing it or if it's online somewhere so that we can review it.

Obviously, you know, there there's some sharing of responsibility and regulating advertisements that appear on TV, but from an FDA standpoint, our role is to make sure that the information is truthful and not misleading. We also work with the Federal Trade Commission on advertising, so from that standpoint, I'd be very interested in learning more about that because, you know, that obviously would be concerning. If they they're saying in their advertisements, there are no adverse events because obviously that's not the case.

Brianne Dressen / REACT19

I yeah, I'm more than happy to provide the link.

Lorrie McNeill / FDA

If you are willing to do so. You know, I would be interested if you could send me-- I believe everyone said that they had submitted reports to VAERS. And and Dr. [Redacted], I think you also mentioned reports that you submitted on behalf of patients, including a number of reports of fatalities. If you all would be willing to send the VAERS ID numbers to to me, I can give you my email address before we end.

What we can do is flag those for the folks that review adverse events in the FDA. As I'm sure you are aware, VAERS is co-managed by FDA and CDC and our folks interact very regularly with the staff at CDC who evaluate the reports. The my understanding for the reports of death and Dr. [Redacted] , this is specifically related to the reports that you mentioned, that all of those reports should be followed up and record requested.

And so in particular, I'd be interested in those so that we can make sure that we flagged them for our folks. But for everyone who submitted something, you know, I cannot make any promises as far as follow up goes. But I would like to bring your reports to the attention of the medical officers here to make sure that they have seen them. So that's something that you'd be willing to do. I'd be more than happy to take those numbers and make sure they get to the right folks here. Yes, Dr. Hertz?

Hello? Can we unmute Dr. Hertz?

Dr. Danice Hertz / REACT19

Thank you for your effort to help us as individuals. I think our message is not that as individuals, we want you to help us. Right now, many, many thousands. We don't even know how many because as you know, only a small fraction of reports are being made to VAERS that are actually happening. I mean, there are many, many people that don't know about VAERS, and it's a complicated system.

I myself, as a physician, had to learn how to do it. You know, it wasn't that easy. We're speaking for the masses and we want the FDA to come out and say these reactions are happening maybe at a very small rate. When you look at the total number of people getting vaccinated. But it has to be said, because we can't get medical care. I myself have seen at least ten physicians in Los Angeles. I've picked the best of the best, no one had, still to this day, they don't know anything. When I have a follow up appointment, I asked them, have you learned anything? Do you have any other ideas? Nope, sorry. That's not acceptable. We need to educate the medical community so that they can take care of us as individuals and the many, many, many thousands out there that we don't even know about.

So we appreciate your effort to help us as individuals. Yes, we can get you our numbers. That's not what we're here for. And yes, we want help as individuals, but we feel it is the FDA's responsibility to our country to make a statement of some sort that these neurological reactions can occur. And, you know, and they and this is what we recommend is treatment or what I don't know.

I know we don't make treatment recommendations. But yes, they are real and and that physicians need to be aware of them so that they can help their patients. That's what we're here for. So thank you for helping us.

Lorrie McNeill / FDA

But thank you for that. I completely appreciate and agree with the purpose of today's meeting. And I think, you know, helping me put it into context for our folks with the individual reports, but also the context of our conversation without, you know, obviously, you know, as we said at the top, we respect your personal privacy. We will not share any information outside of the FDA.

But I think it's important for me and the folks in my office to provide the context of this discussion to the medical officers. So thank you for that. Yes, I think I do this right there.

Anonymous Physician

Hi, I was going to add to that. Yes. I would love for you all to review our specific cases. You know, my VAERS reports weren’t acknowledge till six or seven months later. I would also encourage I know you work in tandem with the NIH and they have had in-person at least 50 to 60 patients as well, whom you could derive data from and they've also conducted hundreds of telemedicine interviews with people who have had these kind of reactions. So I do believe they have a lot of data that might be useful for you.

Lorrie McNeill / FDA

Thank you. That's helpful. And if you could let me know, I'll give you my email address before we finish, if you could let me know who in NIH you would recommend

Anonymous Physician

Absolutely—

Lorrie McNeill / FDA

that would be terrific. Yes.

Brianne Dressen / REACT19

Okay. So, yes, we the NIH, they have all of the information necessary. They also coauthored a article that I sent to that see Peter Marks, I think Paul Richards was on there too, and Janet Woodcock and they actually in there on page 11, it's in there. But they do describe, you know, several of the neurological side effects that can occur.

So by the AAN it has been communicated. Mayo, also has communicated these reactions so it's on their website under precautions. Unfortunately, you know, just to add another layer to what's happening with us, we've reached out to several research groups instead of including, you know, like those organizations that are advocates for patients like Dysautonomia International, and MECFS and Solve M.E. in even the long haul alliance.

Unfortunately, because of the stigma that's connected to this, they have been extremely hesitant to collaborate and bring us on and all of that, which is unfortunate because in my discussions with the NIH, I have, you know, hey, we're having a meeting with the long COVID alliance. Hey, we're having a meeting with these people. And they've been extremely excited to see that we're trying to collaborate and build these relationships that will help these patients.

But unfortunately, we can't get our foot in the door because there's at least one or two members in those organizations. That's like, Nope, we can't mess with the vaccine. Injured people is too ugly to touch. It's going to damage our reputation. I can't tell you how many times I have heard that from these organizations. It will damage our reputation.

It will we will lose credibility. So this is just an added layer of the challenge that we are up against because we're trying to advocate for ourselves and for these patients, but we can't get anywhere with any of these research institutions. We also have several researchers that we've discussed this with. They don't have funding, obviously, because this isn't happening.

So how can we even begin research? So we're several months behind on the research on this. Also, it's not being openly discussed between these researchers because they are concerned about the repercussions that will happen to them if they do publicly discuss this or openly discuss this at all. And so there really is this heavy tone that is, you know, so it's one thing to be sick. It's another thing to be sick with something that's brand new, right, that nobody understands anything about. But then it's a whole other layer to have this, you know, we're trying to function under this veil of quietness and delicateness with everybody that we talk to, because we need anything we can get from people, from these researchers, from officials at the NIH or whatever.

But I mean, you know what I'm saying? Like, so there's this whole layer that's keeping all of this suppressed that's completely halting any progress in understanding in medical you know, in medical

care for anybody. And Dr. [Redacted] and Dr. Hertz and I like we wrote letters to all kinds of medical organizations asking people to see even just a small handful of us, because it's not like it's not a huge number like long haulers, but it still is happening.

And we haven't received a single email back from any credible, legitimate medical organization. But I will say that we have been working with the NIH since January. That's when I first reported my reaction to them, and they took the information and they, you know, they got running, they have my CSF and my blood and all that stuff. We also are working with a couple of researchers at Mayo, and there's a group in L.A. They're a private company and they're researching this as well.

Unfortunately, when I talked to every single one of them, they said, we need funding and we need this to be we need encouragement from people in an authoritative position, so those from a federal level that can help open the door so this can be looked at. I do know that the Canadian COVID commun-- immunity Task Force, they have something started and where they're looking at it and they also have a little bit of a website started where they're tracking the symptoms and they're disclosing some of the issues and kind of seems like that would be kind of a commonsense thing to do.

Unfortunately, we're so behind the ball at this point. We have people that are so desperate for care that they're running out to these illegal establishments that are infusing them with who knows what. We have two people that got mono from these illegal things, so we are not getting help from our own medical teams and people are so desperate to get help, they're willing to do anything and so they are harming themselves even further.

SPEAKER 3

REDACTED

Lorrie McNeill / FDA

Thank you for that

Susan-Frantz-Bohn / FDA

Are there any other comments before we close? Mrs. Dressen?

Brianne Dressen / REACT19

So I just have a question on behalf of everybody. So obviously our main goal is to be able to begin dialog with you, which I really appreciate you being willing to do. But number two, and probably more important is to somehow figure out how and when this can be communicated with the medical community. I know, like here in my own state, I reached out to my state health department after I got home from the NIH and they said specifically, they cannot help me until this is communicated from a federal level.

And I've been in dialogue with Janet Woodcock and a few others at your organization for a couple of months now. I've provided all of our researchers information well before now. You know, we've been begging, literally begging. I mean, it's it's so it's not like we haven't been trying. And so I do think that we are long overdue for something to happen.

And we would like to know what kind of timeline we're looking at for some kind of communication to happen with the medical community. In regards to this issue. We understand that it's complex. It's not like blood clots where you just look and you can see them, you know, like on an MRI. Unfortunately, it is happening and more and more people are going to grow more and more desperate and sick.

And and it's just not fair. You know, we've been doing this for months. This isn't the agencies know this is happening. They've known for a long time that this is happening. So there probably is an effective way. And I'm just a preschool teacher, but I mean, you know, I sit down with my preschool kids and like even they would say, okay, well, you're sick, so people should help you. And it's like, yes. So we do need to be able to establish some kind of timeline on when this will happen. So I guess we're just asking, when can we expect to see some kind of advocacy on our behalf from the federal level?

Lorrie McNeill / FDA

It's a great question. I wish I had an answer for you today. I don't. But I can commit to you that I will go back and talk to Dr. Marks, who extensive apologies for missing today and the folks in our office of Statistics and Epidemiology who are the ones I mentioned earlier who evaluate the adverse events. And I hope that we can maintain an open dialog.

You know, it's you don't hear from us, you know, email us, call us. I know you Pauls email. Let me give you mine because I do promise to give everyone that it's the spelling of my name, which is on the screen. So so it’s lorrie.mcneill@fda.hhs.gov.

Well, thank you all again. We really appreciate you taking the time and sharing this information. Well, this is very important for us to hear. And , as I said we will look forward to seeing anything, any additional information you'd like to send in to me or to Paul. Mrs. Dressen, you have his email, too, and we will definitely be in touch. So thank you for meeting. Take care.