Officials Neglect Covid Vaccines' Side Effects

By Allysia Finley

Brianne Dressen was an energetic mom, an avid hiker and a preschool teacher—until she got a Covid vaccine.

Ms. Dressen, 42, was among the first Americans to be vaccinated. She volunteered to participate in AstraZeneca's trial, and she received her first dose on Nov. 4, 2020, at a clinic in West Jordan, Utah. "I am pro-science and pro-vaccine," Ms. Dressen says. "I was more than glad to participate in the scientific process."

But even highly beneficial vaccines can have rare serious side effects. Minutes after the shot, Ms. Dressen's arm began to tingle, her vision grew blurry, and sounds became muffled. The clinic suggested she see a neurologist, who directed her to the emergency room. The ER couldn't figure out what was wrong and sent her home.

Her condition steadily deteriorated over the next 2½ weeks. She experienced extreme nausea, diarrhea, dizziness, painful vibrating sensations, pins and needles in her arms and face, numbness, tremors, brain fog, heart palpitations and fever. Physicians were mystified. They diagnosed her with a "silent migraine" and "anxiety due to the Covid vaccine" after a hospital stay. She was provided occupational and physical therapy but spent weeks in bed, unable to tolerate sound, light or even her children's touch.

In the ensuing months, she faced not only debilitating symptoms but also bureaucratic indifference—though government officials tried to be helpful at first. On Jan. 11, 2021, her husband, Brian, a U.S. Army chemist, contacted Avindra Nath, intramural clinical director of the National Institute of Neurological Disorders and Stroke. Dr. Nath responded immediately that he would discuss her condition with other National Institutes of Health neurologists. He asked for blood and spinal-fluid samples for analysis, and he ominously mentioned that "the current political climate is another aspect that we need to keep an eye on."

COURTESY OF DANICE HERTZ

Danice Hertz

Dr. Nath didn't elaborate, but by now the politics of the Covid vaccines are familiar. Bitter disputes over mandates fed skepticism of the shots and claims, often false and outlandish, about their dangers. At the same time, public-health authorities, anxious to promote vaccination, played down risks that were real if rare, leaving patients like Ms. Dressen in limbo.

After failed attempts to work remotely with Ms. Dressen's home medical team, Dr. Nath invited her to an NIH facility in Bethesda, Md., for examination. Physicians there diagnosed her with postvaccine neuropathy and severe postural orthostatic tachycardia syndrome, or POTS, which causes rapid heartbeat on standing up. She was treated with intravenous immune globulin, an infusion of antibodies from healthy donors that can modulate an overactive immune response.

The treatment helped, but symptoms persisted and would wax and wane. She learned that many others were experiencing similar symptoms after getting vaccinated. She organized online support groups, but Facebook shut them down under its "misinformation" policy, which bans information that is "likely to directly contribute to the risk of imminent physical harm, including by contributing to the risk of individuals getting or spreading a harmful disease or refusing an associated vaccine." This includes "claims about the safety or serious side effects of COVID-19 vaccines"—even, it appears, when such claims are truthful.

The Facebook censorship and government inaction spurred her to launch React19, a "science-based nonprofit offering financial, physical, and emotional support" for people who suffered severe reactions after Covid vaccines. React19 has more than 21,000 members in the U.S. and another 20,000 in 24 international partner organizations. It also has a Facebook page.

"We are not antivax and are neutral on the Covid vaccines," Ms. Dressen says. "But doctors need to be aware of what's going on so they can treat patients." Ms. Dressen and others have pressed the NIH, the Centers for Disease Control and Prevention and the Food and Drug Administration to acknowledge their symptoms so patients don't feel shunned and can obtain the medical care they need.

Interviews with React19 members and emails they shared with me show that public-health authorities haven't been transparent about these adverse events. Officials privately expressed concern to patients but kept mum about the issue in public and failed to keep promises to investigate the side effects thoroughly. With the Covid public-health emergency over at last, perhaps they will get the attention they deserve.

Danice Hertz and Brianne Dressen suffered severe neurological symptoms after receiving shots.

Ms. Dressen says NIH officials were initially solicitous. They brought at least a dozen patients like Ms. Dressen to their facilities for tests and treatment as part of an informal study. "Good that you are getting the word out," Dr. Nath wrote her on June 27, 2021. "Maybe the issue has not received the deserved attention, but there [sic] now an increasing number of publications in the literature documenting the complications. Considering over a billion doses administered, the complications are still rare. From my stand point the important message to get out is that they are treatable, so should treat early or do it in the context of a clinical trial. Keep me posted."

But the NIH didn't get the word out. Ms. Dressen kept updating Dr. Nath and his assistant clinical investigator, Farinaz Safavi, about her symptoms. She complained about the cost of her intravenous immune globulin treatments—$2,200 a month out of pocket. She told Dr. Nath that she had communicated with FDA officials, including Peter Marks, head of the Center for Biologics Evaluation and Research, which oversees vaccines.

FDA officials, she told him, were passing the buck to the NIH. "You and I both know that it isn't fair to your small team there to take on all of these people," she wrote on Sept. 16, 2021, referring to other patients with postvaccine neurological conditions. "Is there something I am missing with this? Or someone I should be appealing to there at the NIH to encourage further research? Funding for care?"

"Ordinarily when any drug is released it is the manufacturers responsibility to investigate and treat the side effects," Dr. Nath replied. "Where are the vaccine manufacturers in all of this? Have you tried to contacting [sic] them? It cannot be the government's responsibility to pick up after them. They are a profit company and they should be the ones taking change [sic]. Don't you think?"

Ms. Dressen says AstraZeneca offered her $1,243.30 if she agreed to waive "any additional claims." She turned it down. AstraZeneca says the offer was a reimbursement for medical expenses and tests rather than a legal settlement, and its independent experts determined the injury wasn't vaccine-related. AstraZeneca's vaccine was never authorized in the U.S. (It has been in Canada, Europe and the U.K. and is widely used in poor countries.)

Other React19 members I spoke with said they didn't receive responses from Pfizer or Moderna about adverse-event reports they filed with the companies. A Pfizer spokesperson said its "medical team thoroughly assesses and reviews medical documentation to further understand the event," and "reports are shared regularly with federal and global regulatory and health authorities for further review." Moderna didn't respond to requests for comment.

The U.S. Countermeasure Injury Compensation Program, which covers vaccines and treatments used during public-health emergencies, has received 11,686 Covid-related claims, only 23 of which have been ruled eligible for compensation. React19 members say their claims are under review or have been rejected.

In the fall of 2021, as some Americans resisted vaccination, the Biden administration mandated vaccines for healthcare workers and employees of large corporations. Although it was becoming clear that vaccines didn't prevent infection, officials claimed mandates were necessary to ensure "employee safety and health."

At the same time, FDA and NIH officials received a growing number of reports of severe side effects—including from medical professionals who had been among the first to get vaccinated. One was Danice Hertz, a 66-year-old now-retired gastroenterologist in Santa Monica, Calif.

Dr. Hertz received her first Pfizer dose on Dec. 23, 2020. Within 30 minutes, her face began to burn and tingle, her vision grew blurred, and she became lightheaded. She took Benadryl and prednisone at her home to no effect. Over the next 24 hours, she developed intense burning in her face, numbness in her mouth and scalp, chest pain, dizziness, twitching and a feeling that her whole body was vibrating. "I had pain to the degree of screaming out loud."

She contacted a neurologist at a local hospital, who was flummoxed. "I was in bed for several weeks and barely able to emerge," she says. After consulting two dozen doctors around the country, she was diagnosed with small-fiber neuropathy, tinnitus, dysautonomia, POTS and mast cell activation syndrome, a condition that causes severe allergic symptoms affecting multiple parts of the body.

Dr. Hertz spent her days in bed searching the internet for a medical explanation: "I was desperately ill. I was unable to get medical care. I was suicidal at times. A lot of others went through this. I wrote goodbye letters to my family. It was too miserable to live with this."

On Feb. 4, 2021, she stumbled on an article from Neurology Today in which Anthony Fauci sought to correct his earlier recommendation that people with a history of Guillain-Barré syndrome, a rare disorder in which the immune system attacks the nervous system, shouldn't get vaccinated because it might trigger a recurrence. After drawing pushback from the medical community, Dr. Fauci retracted his statement because it clashed with the CDC. "As soon as the CDC recommendations came out, I began advising people according to the recommendations. I do stand corrected," he told Neurology Today.

Dr. Hertz posted in the comments section on the article that she developed severe parathesias—pins and needles, a classic symptom of Guillain-Barré and other neurological disorders—30 minutes after vaccination. "Despite my multiple reports to Pfizer, the CDC and FDA, no one has recognized my complication or reported it," she wrote. "I wonder how many other cases there are like mine." The FDA has reported a link between Johnson & Johnson's vaccine and Guillain-Barré syndrome.

She says she filed nine reports with the Vaccine Adverse Event Reporting System, or Vaers, the government surveillance system that is supposed to track possible side effects, and "nobody has ever contacted me." She also filed reports with Pfizer, which she says didn't respond.

But two weeks after posting her comment on the journal article, she received an email from Sheryl Ruettgers, who had experienced similar symptoms. Ms. Ruettgers said she also filed a Vaers report and had contacted Dr. Marks of the FDA's Biologics Center.

COURTESY OF BRIANNE DRESSEN

Brianne Dressen

2021, Ms. Dressen emailed Janet Woodcock, then acting FDA commissioner, attaching letters from 17 other patients detailing their post-vaccine nervous-system problems.

Dr. Woodcock replied solicitously: "We take your experiences seriously and are evaluating all reports of adverse events associated with vaccination. I will follow up with individuals who do research into these types of conditions." She added: "I hear you and understand that you are asking that more attention be directed to what you are experiencing. I will see if more studies can be undertaken. It is not really possible to provide good medical care without understanding what is going on with the patients."

The correspondence between FDA officials and React19 members continued. Dr. Woodcock responded to each of Ms. Dressen's emails with compassion and promises to investigate. "I need to get with people who are studying this issue," she wrote on July 22, 2021. "I know I need to make progress on this and I have been working with the Biologics Center on this issue."

Dr. Marks also repeatedly assured Ms. Dressen that the agency was investigating and that its reporting systems would identify "safety signals." "We have a staff of epidemiologists at FDA involved in safety surveillance activities, and these individuals are looking into this," Dr. Marks wrote on Nov. 12, 2021. "Though I am unable to give you a definitive time when they will be done with their analyses, I will certainly let you know when I hear anything."

Tired of waiting, React19 began doing its own research. On Jan. 9, 2022, Ms. Dressen sent FDA officials an email with 850 case reports and medical-journal articles related to severe adverse vaccine reactions. She noted that the European agency responsible for regulating vaccines in October identified parathesias as a potential Pfizer vaccine side effect.

"Thanks so much for all of this information," Dr. Marks replied. "We really appreciate this and will start working through the papers and contacting investigators to better understand things."

Ms. Dressen kept sending Dr. Marks published research on neurological adverse events, and Dr. Marks kept assuring her the FDA was investigating. FDA leaders regularly met with React19 members. "We were getting lip service over and over again," Dr. Hertz says.

Public-health authorities, perhaps worried about vaccine hesitancy, haven't been transparent about adverse events. Their lack of candor can only fuel public distrust.

"I read a transcript from a web-lecture you gave on 1/29/2021 highlighting your commitment to medical safety as it relates to the vaccine," Ms. Ruettgers wrote to Dr. Marks on Feb. 21. "I have been unable to find answers and have been frustrated by the lack of transparency as it relates to adverse reactions." She didn't receive a response.

Dr. Hertz soon received more emails, including one from Ms. Dressen. They organized an email list and later a Facebook group. In March Dr. Hertz also contacted Dr. Nath and sent her lab work to the NIH for analysis. Dr. Safavi noted in an email to her that more than 1,000 neurological side effects had been reported in Vaers, "but in order to present it to scientific community we have to gather as much information as we can before sending it out."

"We need to be patient and scientifically follow the appropriate path to br [sic] able to push this work forward," Dr. Safavi wrote on April 17, 2021. Over subsequent months, Dr. Hertz and Ms. Dressen referred members of their group to the NIH, whose neurologists reviewed patient medical records and helped them obtain treatment.

While NIH scientists were privately validating their vaccine-related injuries, FDA officials had yet to acknowledge them. On May 24, Vaers reports filed by members had been deleted and 22% lacked a permanent identification number so they weren't publicly visible.

A CDC spokesperson says that "all reports to Vaers are publicly available and can be examined," but "due to privacy and confidentiality, CDC cannot confirm which reports have been reviewed and what the review revealed." For reports classified as serious, CDC says, it requests and reviews all available medical records.

"Serious" is defined as death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomalies, or birth defects. A CDC presentation on Jan. 26, 2023, showed that 883 Vaers reports of "pain in extremity" following Moderna and Pfizer bivalent boosters were categorized as nonserious.

"Vaers is not designed to determine if the vaccine caused the reported adverse event," the CDC spokesperson says. "The determination of the cause of serious adverse events is done by healthcare providers." But React19 members say the CDC didn't follow up on their complaints.

Doctors are typically reluctant to ascribe a rare adverse event to a vaccine unless the FDA and CDC validate the association. Postvaccine neurological symptoms are relatively rare, and it is nearly impossible to conclude whether they were caused by the vaccines. Some patients who get infected with Covid also report developing neurological disorders after their illness. It's unclear if these symptoms are more common after vaccination or infection, or if they have become more common during the pandemic than before.

More than 600 million doses of Pfizer and Moderna vaccines have been given in the U.S., so even a 1-in-100,000 adverse effect would result in 6,000 cases. Postvaccine neurological conditions appear most common in young and middle-aged women, the demographic most prone to autoimmune diseases.

It's possible vaccines are the proximate but not the ultimate cause—that they trigger autoimmune conditions in patients with underlying genetic predispositions. That hypothesis is bolstered by the observations from the NIH's informal study, which it published in a preprint paper on May 17, 2022. Of 23 patients studied, the median age was 40, and 21 were women. The paper concludes "that a variety of neuropathic symptoms may manifest after SARS-CoV-2 vaccinations and in some patients might be an immune-mediated process." An NIH spokesperson says the observational study has concluded. In an April 25, 2023, article for the journal Neurology, Dr. Nath wrote that "there is a great need to conduct research for identifying the underlying factors and subcellular mechanisms that result in the neurological manifestations from vaccines."

Ms. Dressen says institute scientists stopped corresponding with React19 members at the end of 2021. "Sorry, we do not have any clinical trial for such vaccine related complications. It is best for such patients to receive care from their local physicians," Dr. Nath wrote Ms. Dressen on Dec. 15, 2021.

The NIH says the FDA and CDC are best able to address questions and concerns about possible vaccine side effects and that its clinical center is a research hospital, not a routine medical center.

FDA officials continued to meet and correspond regularly with React19 members until this past December. They still haven't warned the public about potential vaccine-related neurological complications. "FDA has made us many, many promises, and I think they've followed up on one or two," Ms. Dressen says. Public-health officials, she adds, have misled the public by claiming they have a robust system to identify rare adverse events from vaccine: "I trusted that these programs that they are telling the public are there, but they are not."

Officials may worry that recognizing severe side effects will fuel vaccine opposition and hesitancy. But the lack of transparency can only feed public distrust. And the lack of recognition "has left us as further collateral damage from the pandemic," Ms. Dressen says.

One silver lining is that advocacy is giving purpose to the lives of those who have been harmed. "I worked 12- to 14-hour days as a physician," Dr. Hertz says. "Now I have a new job—advocating for the injured, helping them get medical care and treatment. People contact me every day. So I feel like I am helping and using my medical background to help people. This new job honestly saved my life."

Ms. Finley is a member of the Journal's editorial board.