

From: Elizabeth Brehm <[REDACTED]>
Sent on: Monday, February 7, 2022 2:31:25 PM
To: 'Marks, Peter' <Peter.Marks@fda.hhs.gov>
CC: Aaron Siri <[REDACTED]>;
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'ige4@cdc.gov' <ige4@cdc.gov>;
'hus4@cdc.gov' <hus4@cdc.gov>;
'okv5@cdc.gov' <okv5@cdc.gov>;
'Qeo3@cdc.gov' <Qeo3@cdc.gov>;
'fqv9@cdc.gov' <fqv9@cdc.gov>;
'ezu2@cdc.gov' <ezu2@cdc.gov>;
'app4@cdc.gov' <app4@cdc.gov>;
'krb2@cdc.gov' <krb2@cdc.gov>;
'feu3@cdc.gov' <feu3@cdc.gov>
Subject: Madeline ("Maddie") de Garay's Medical Treatment
Attachments: M. de Garay std care ltr_2022_01_14.pdf (93.7 KB)

Dear Doctors:

It has been more than a year since Maddie de Garay, a previously healthy child, received her second injection of the Pfizer COVID-19 vaccine within the pediatric trial and suffered a severe adverse event resulting in multiple serious harms. It has been more than three weeks since the attached letter was sent to Cincinnati Children's Hospital on behalf of Maddie de Garay and her parents. The letter has gone unanswered. Not one person from Pfizer has reached out to the de Garay's about Maddie's injuries. Not one person from the FDA has reached out to the de Garay's about Maddie's injuries. Not one person from the CDC has reached out to the de Garay's about Maddie's injuries.

Adding insult to injury, Cincinnati Children's Hospital has failed to provide adequate health care to Maddie since her injection, nor have the de Garay's been able to find any doctor within any hospital system who is willing and able to treat Maddie once they understand her injuries are associated with her receipt of the Pfizer vaccine in a clinical trial. We ask that you please review the attached letter and provide a response. Notably, this letter details only the most obvious breaches in Maddie's care and reflects only some of the issues this young woman has faced and continues to face. We trust that you will offer her the assistance she so desperately needs.

Regards,
Elizabeth

Elizabeth A. Brehm, Esq.

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January 14, 2022

VIA FEDEX AND ELECTRONIC MAIL

Dr Steve Davis
Chief Executive Officer
Cincinnati Children's Hospital Medical
Center
Administrative Office
3333 Burnet Avenue
Cincinnati, Ohio 45229
c/o [REDACTED]

Dr. Tina Cheng
Chief Medical Officer
Cincinnati Children's Hospital Medical
Center
Administrative Office
3333 Burnet Avenue
Cincinnati, Ohio 45229
[REDACTED]

Re: Madeline ("Maddie") de Garay's Medical Treatment

Dear Dr. Davis and Dr. Cheng:

We write on behalf of our clients Mr. Patrick de Garay and Mrs. Stephanie de Garay, parents of Madeline de Garay ("**Maddie**") regarding violations of the standard of care in her treatment. Maddie received treatment at Cincinnati Children's Hospital starting January 21, 2021. Her presentations were for evaluation of side effects after receiving the Pfizer Covid-19 vaccination. Maddie was a participant in the vaccine trial. She was evaluated multiple times in the emergency department, and admitted to the hospital on three separate occasions (January 30, 2021, March 6, 2021, and April 9, 2021). She received specialty evaluations with neurology, allergy/immunology, gastroenterology, pain management, and behavioral medicine.

Upon review of Maddie's medical records, several breaches in standard of care were discovered. First, Maddie consistently had hematuria, and this issue was not addressed or it was simply ignored. The finding of hematuria is not a functional issue; an individual simply cannot make themselves have blood in their urine. Hematuria was found in one of her first emergency room presentations (January 21, 2021), and the finding continued in subsequent visits. It should be noted that blood would be present when Maddie was on her menstrual cycle, but there were several times when she was not on her cycle, and blood was still found in the urine. The diagnosis of hematuria was not listed in the medical records. More importantly, she did not have a work-up for this finding. A standard approach would start with repeating sample, sending urine cultures, and ordering clotting profile. If no obvious answers were provided with the aforementioned, proceeding with nephrology and urology consults would be appropriate. A kidney biopsy would also be a reasonable procedure if there was still no explanation for the hematuria. Considering the clinical picture with her recent vaccination, checking complement levels would be appropriate.

A second issue in Maddie's medical record is related to urinary retention. The medical record reflects that this issue was functional in nature. Prior to being given a functional diagnosis, Maddie did not appear to have any work-up for this issue. The symptom was simply being treated with a straight catheterization. The standard medical approach to urinary retention would be a urology consult, followed by tests including but not limited to checking post void residual urine volume, 24-hour urine creatinine clearance, and urodynamic evaluation. It is not clear that any of this was done.

One of the most obvious breaches in care occurred on March 5, 2021 when Maddie was evaluated by Dr. Amal Assa'ad from Allergy/Immunology. Maddie was referred to the specialist by Neurology (Dr. Wesselkamper) and by the pain doctor, Dr. Goldschneider. In Dr. Wesselkamper's note from March 3, 2021, he notes: "given the fact inflammatory responses have been seen in Covid-19 disease, it should be assumed it could happen with the immune response from the vaccine. Madeline has a history of sensitivity and if she got the vaccine, she may have just been sensitive to it. That possibility needs to be evaluated before starting the functional treatment pathway." Thus, Maddie was being referred to Allergy/Immunology for a **work-up** given her history of sensitivities. Dr. Assa'ad, however, did not perform a work-up. She relied on a previous sedimentation rate and CRP to rule out an inflammatory disorder. She never mentioned the elevated CRP value of 2.90 on January 23, 2021 stating "her work-up for inflammatory disorder with sed rates and CRP are normal." She does not document that Maddie was on steroids and antihistamines, both of which could affect the inflammatory marker results. She relies on her physical examination to simply rule out rheumatologic or autoimmune disorder. She does not document a full and complete neurologic exam, yet notes in her chart that the neurologic exam is not with localizing lesion. Finally, she justifies no further testing with the following comment: "contacted in follow up Dr. Frenck, PI on Covid-19 vaccine trial, Madeline has functional impairment not organic in nature. Discourage further workup since this is usually detrimental in functional disorders because it drives the patient to thinking that there maybe something wrong that is indicating all this work-up. It also delays the necessary psychological intervention that is needed to help resolve the functional disorder." Obviously, Dr. Assa'ad did not read Dr. Wesselkamper's note indicating that a referral to Allergy/Immunology was being made to **work-up** Maddie's sensitivity to the vaccine.

Finally, Maddie had an EGD with biopsies performed on March 12, 2021 by Dr. Starva Xanthakos. The official pathology report from biopsies showed in several fragments of gastric fundic mucosa a subtle mild increase in mononuclear cells within the interstitium consisting of lymphocytes, occasional plasma cells, and very rare eosinophils. Rare lymphocyte invasion of glands is identified. No organisms or granulomas present. This finding was never addressed in the chart. No follow-up was recommended.

In conclusion, we have detailed several breaches in standard of care that occurred at the Cincinnati Children's Hospital Medical Center. This is not intended to be nor is a resuscitation of all such breaches. It is the legal responsibility of the ordering physician to follow up, and appropriately address abnormal findings on diagnostic tests they order. Therefore, we request that

you promptly respond by January 28, 2022 providing a detailed explanation with regard to **each** breach in Maddie's care detailed above.

Sincerely,

A handwritten signature in blue ink, appearing to read 'A. Siri', with a stylized flourish at the end.

Aaron Siri, Esq.

Elizabeth A. Brehm, Esq.