Elizabeth Brehm

From: Richards, Paul [redacted]
Sent: Saturday, February 26, 2022 4:31 PM
To: Elizabeth Brehm
Subject: Letter - Patient Medical Treatment

Dear Ms. Brehm,

This message is in response to your letter dated January 14, 2022, on behalf of your clients - Mr. Patrick de Garay and Mrs. Stephanie de Garay, parents of Madeline de Garay ("Maddie").

Thank you for contacting the U.S. Food and Drug Administration (FDA) about this important topic.

We are sorry to learn about the difficulties that Mr. and Mrs. de Garay and Maddie have experienced, but thank you for sharing the information with us.

Within the content provided in your email it isn't clear whether a report related to the potential adverse event(s) was submitted to the Vaccine Adverse Event Reporting System (VAERS). If a report wasn't filed, the de Garay family may want to consider it.

Reporting is unlikely to answer the question of why any specific person experiences a potential adverse event after vaccination – or whether the vaccine causes the event. However, if data suggest a possible link between an adverse event and the vaccine, the relationship may be further studied in a controlled fashion.

Analyzing VAERS reports is a complex task. Both FDA and the Centers for Disease Control and Prevention's (CDC) review data reported to VAERS. FDA reviews reports to assess whether a reported event is adequately reflected in the Emergency Use Authorization prescribing information, or product labeling for approved vaccines - and closely monitors reporting trends for individual vaccine lots. Individuals (or guardians) will be contacted by VAERS if follow-up information (i.e., medical records or other medical documentation) is needed. Please be aware that not everyone who submits a report is contacted - and there may be a delay of when someone is contacted.

In addition, if the de Garays haven't already done so, they may want to request that Maddie's primary healthcare provider contact CDC's Clinical Immunization Safety Assessment (CISA) centers to determine if they might be able to review her case there. As mentioned in previous (unrelated to this specific inquiry) correspondence to you, CISA is a national network of vaccine safety experts from the CDC's Immunization Safety Office (ISO), seven medical research centers, and other partners, which provides a comprehensive vaccine safety public health service to the nation. CISA, in collaboration with CDC, serves as a vaccine safety resource for consultation on clinical vaccine safety issues, including individual case reviews, and to assist with immunization decision-making. The CISA Project provides consultation to US clinicians who have vaccine safety questions about a specific patient residing in the US. In addition, CISA provides consultation to US healthcare providers and public

health partners on vaccine safety issues, and reviews clinical adverse events following immunization (AEFI) involving the US-licensed vaccines.

It is my understanding that healthcare professionals can request a clinical consultation for particularly complex individual patient cases by contacting the CISA Project.

Additional information related to CISA – including contact information for how healthcare providers can request a COVID-19 CISA clinical consultation is available here.

In closing, FDA takes all reports of adverse events potentially related to vaccines seriously. We hope that Maddie's health is improving. Although we do not provide medical advice or guidance, we would be happy to contact the
de Garay family directly to provide information about how to file a VAERS report if one hasn't already been submitted.

Please do not hesitate to reach out to me directly if you have any questions, or if I can assist in any other way.

Best regards,

Paul Richards
Chief, Consumer Affairs Branch

Center for Biologics Evaluation and Research
Office of Communication, Outreach and Development
U.S. Food and Drug Administration
[redacted]