

From: no-reply@regulations.gov <no-reply@regulations.gov>

Sent: Monday, October 25, 2021 11:30 PM

To: shdegaray@outlook.com <shdegaray@outlook.com>

Subject: Your Comment Submitted on Regulations.gov (ID: FDA-2021-N-1088-0001)

Please do not reply to this message. This email is from a notification only address that cannot accept incoming email.

Your comment was submitted successfully! Comment Tracking Number: kv7-ith7-wabm

Your comment has been sent for review. This process is dependent on agency public submission policies/procedures and processing times. Once the agency has posted your comment, you may view it on <u>Regulations.gov</u> using your Comment Tracking Number.

Agency: FOOD AND DRUG ADMINISTRATION (FDA)

Document Type: Notice

Title: Vaccines and Related Biological Products Advisory Committee; Notice of Meeting;

Establishment of a Public Docket; Request for Comments

Document ID: FDA-2021-N-1088-0001

## Comment:

Docket No. FDA-2021-N-1088 for "Vaccines and Related Biological Products Please read the attached document "FDA Comment Maddie de Garay" regarding her adverse reaction to the Pfizer Covid Vaccine during the trial for 12-15-year-olds at Cincinnati Children's Hospital where she was also treated and our request to not approve the EUA for 5-11 year olds based on our daughter Maddie's severe adverse reaction to the Pfizer Covid Vaccine during the trial. I also included supporting documents to prove she was in the trial and got the actual vaccine.

Uploaded File(s):
FDA Comment Maddie de Garay.pdf
Email with Frenck requesting adverse reactions reported.pdf
Maddie de Garay email for Pfizer Trial.pdf
IMG\_3777.jpg
IMG\_3778.jpg

For further information about the <u>Regulations.gov</u> commenting process, please visit <u>https://www.regulations.gov/faq</u>.