

Exhibit 460

Report 54: Infants and Children Under 12 Given the Pfizer mRNA COVID “Vaccine” Seven Months BEFORE Pediatric Approval. 71% of Adverse Event Cases Classified as Serious

<https://dailyclout.io/report-54-infants-and-children-under-12-given-the-pfizer-mrna-covid-vaccine-seven-months-before-pediatric-approval-71-suffered-serious-adverse-events/>

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Report 54: Infants and Children Under 12 Given the Pfizer mRNA COVID "Vaccine" Seven Months BEFORE Pediatric Approval. 71% of Adverse Event Cases Classified as Serious.

January 31, 2023 • by Barbara Gehrett, MD; Joseph Gehrett, MD; Chris Flowers, MD; and Loree Britt

The War Room/DailyClout Pfizer Documents Analysis Project Post-Marketing Group (Team 1) – Barbara Gehrett, MD; Joseph Gehrett, MD; Chris Flowers, MD; and Loree Britt – produced a shocking review of the pediatric data found in Pfizer document *5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-FEB-2021* (https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf) (a.k.a., "5.3.6").

It is important to note 1) that the adverse events (AEs) in the 5.3.6 document were reported to Pfizer for only a 90-day period starting on December 1, 2020, the date of the United Kingdom's public rollout of Pfizer's COVID-19 experimental mRNA "vaccine" product and 2) **no pediatric dose of the Pfizer product was approved for use during that time frame.**

What dose(s) of Pfizer's mRNA "vaccine" was given to these children since no approved dose existed?

Important points from this report include:

- **A seven-year-old experienced a stroke.**
- **One child and one infant suffered facial paralysis.**
- **One infant had a kidney adverse event, either kidney injury or failure.**
- **Of the 34 adverse event cases, 24 (71%) were classified as serious.**
- **Predominantly female patients were affected** — at least 25 of 34 (73.5%) patients.
- Table 6 reports **34 cases of use in pediatric individuals**. However, **28 additional cases were excluded** because details such as height and weight were "not consistent with pediatric subjects."
- Ages ranged from **two months to nine years**, with **median 4.0 years**, which means **half the children were under four years of age**.
- 132 adverse events were reported in the 34 children – i.e., **an average of 3.88 AEs per child**.

Shockingly, Pfizer concluded:

"No new significant safety information was identified based on a review of these cases compared with the non-paediatric population."

Please read the disturbing, two-page report by the Post-Marketing Group (Team 1) below.



War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 6:
Review of 5.3.6 - Use in Pediatric Individuals < 12 years of age



Infants and children under 12 were injected with the Pfizer "vaccine" seven months before the product was approved for children.

The 5.3.6 document was compiled by Pfizer for the purpose of reporting adverse events to the FDA. The reporting period was during the first 90 days, starting December 1, 2020, after the COVID-19 "vaccine" rollout to the public. This experimental product was not approved for use in the < 12 years of age group at that time.

Who was responsible for administering this unapproved product to children? Did these children receive a full or a partial adult dose? Who decided how much to inject? Were the AEs in these children monitored long term? Were the results of final outcomes of this inappropriate administration utilized when the approval for this age group was considered? These questions are not answered in the 5.3.6 document.

In Pfizer's 5.3.6 document, Tables 3, 4, 5 and 6 present a summary of information the FDA requested from the Pfizer Pharmacovigilance Plan: "Please include a cumulative analysis of the Important Identified Risks, Important Potential Risks, and Areas of Important Missing Information identified in your Pharmacovigilance Plan, ..."

In response, Pfizer identified three categories of Safety Concerns in Table 3:

Table 3. Safety concerns

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and Lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf

Table 6. Description of Missing Information

Topic	Description
Missing Information	<p>Post Authorization Cases Evaluation (resubmitted to 28 Feb 2021)</p> <p>Total Number of Cases in the Reporting Period (N=2086)</p> <ul style="list-style-type: none"> In 4 cases (1 non-serious, 3 serious) Suggested lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (1), Headache (1), Vomiting (1), pain in extremity, Arthralgia, Diarrhoea, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discontinuation (1 each) <p>Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.</p>
Use in Pediatric Individuals <12 Years of Age	<p>Zelenko, pediatrics <12 years of age</p> <ul style="list-style-type: none"> Number of cases: 34 (7.1% of the total PA dataset), indicative of administration in pediatric subjects <12 years of age. Countries of residence: UK (29), US (1), Germany and Andorra (1 each) Case Terminations: Serious (2), Non-Serious (10). Gender: Females (23), Males (7), Unknown (2). Age (n=34) ranged from 3 months to 9 years; median = 3.7 years, median = 4.0. Case outcome: resolved/resolving (16), not resolved (13), and unknown (5). Of the 132 reported events, those reported more than once were as follows: Product administered to patient of inappropriate age (2), use Medication (none), Off label use (11), Pyrexia (9), Product use issue (3), Fatigue, Headache and Nausea (4 each), Vaccination site pain (5), Abnormal pain upon COVID-19, Facial paralysis, Lymphadenopathy, Malaise, Pruritus and Swelling (2 each). <p>Conclusion: No new significant safety information was identified based on a review of these cases compared with the non-pediatric population.</p>

https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf

The Pfizer COVID-19 "vaccine" was not approved for use in this age group until October 2021, when the FDA granted EUA authorization for (only) children aged 5 through 11 years. In Table 6, titled "Safety Concerns," the <12 age group appears under the "Missing Information" category.

Table 6 reports 34 cases of use in pediatric individuals. 28 additional cases were excluded because details such as height and weight were "not consistent with pediatric subjects." Pfizer did not supply further details of their pediatric parameters. Country of origin was predominantly UK (29), with an additional three from the U.S. and one each from Germany and Andorra.

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SOURCE:

https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf

5.3.6 AE REPORTING PERIOD:

"Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021."

ABBREVIATIONS:

5.3.6 : Pfizer source document

SOC : System Organ Class

AE : Adverse Event

AESI : Adverse Event of Special Interest

EUA : Emergency Use Authorization by FDA

PM : Post-Marketing

BNT162b2 : Pfizer's mRNA COVID-19 vaccine

SEQUELAE: an abnormal condition resulting from a previous disease, injury, or other trauma

AGE GROUPS defined in 5.3.6 (p. 25 footnote) :

- Adult 18 - 64
- Elderly ≥ 65
- Child 2 - 11
- Adolescent 12 - < 18
- Infant 1 – 23 months

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<https://dailyclout.io/wp-content/uploads/Post-Marketing-Team-Pediatrics-MicroReport.pdf> (<https://dailyclout.io/wp-content/uploads/Post-Marketing-Team-Pediatrics-MicroReport.pdf>)

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