

Exhibit 431

Report 11: Pfizer Vaccine-FDA Fails to Mention Risk of Heart Damage in Teens

<https://dailyclout.io/pfizer-vaccine-fda-fails-to-mention-risk-of-heart-damage-in-teens/>

Report on their findings of 35 cases of myocarditis in children within one week after receiving the second dose of the Pfizer mRNA vaccine.

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Pfizer Documents Analysis



Pfizer Reports

Report 11: Pfizer Vaccine – FDA Fails to Mention Risk of Heart Damage in Teens

April 7, 2022 • by Dr. Chris Flowers

BOMBSHELL: FDA MUST HAVE KNOWN THAT MYOCARDITIS IN TEENS WAS A RISK WHEN THEY ISSUED THE EMERGENCY USE AUTHORIZATION THAT DID NOT MENTION IT.

In a paper published in pre-print last week (25th March, 2022) in the Journal of Pediatrics

[https://www.jpeds.com/article/S0022-3476\(22\)00282-7/fulltext#%20](https://www.jpeds.com/article/S0022-3476(22)00282-7/fulltext#%20)

[https://www.jpeds.com/article/S0022-3476\(22\)00282-7/fulltext#](https://www.jpeds.com/article/S0022-3476(22)00282-7/fulltext#)

Shauer et al. from the Seattle Children’s Hospital at the University of Washington:

Report on their findings of 35 cases of myocarditis in children within one week after receiving the second dose of the Pfizer mRNA vaccine.

They present the evolution of changes on Cardiac MRI (Magnetic Resonance Imaging)

1) Myopericarditis has emerged as an important adverse event following COVID-19 mRNA vaccination, particularly in adolescents. This affects both the lining of the heart (pericardium) and the cardiac muscle (myocardium) itself.

[Ref: Gargano JW, Wallace M, Hadler SC, Langley G, Su JR, Oster ME, et al. Morbidity and Mortality Weekly Report Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices-United States, June 2021

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8312754/>

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The report acknowledged the risks of myocarditis post vaccine, but still recommended vaccination to everyone.

This initial report, established the serious problem of myopericarditis in adolescents following MRNA vaccination was published in June 2021.

June 2021 was one month AFTER the FDA received the priority review for an EUA for 16 yrs and older to receive the mRNA vaccine.

125742_S1_M1_priority-review-request-1 (released March 24, 2022)

BNT162b2
1.2 Request for Priority Review



REQUEST FOR PRIORITY REVIEW

COVID-19 Vaccine (BNT162, PF-07302048)

BLA 125742

MAY 2021

CONFIDENTIAL
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FDA-CBER-2021-5683-0013748

2) This timeline raises grave questions about what the FDA knew and when they knew it, since the results of this paper would have been 'peer reviewed' some

months BEFORE the May 2021 publication took place.

That is, the risk of heart damage to teenagers would have been part of the medical knowledge base BEFORE the emergency use authorization for teenagers was issued by the FDA in June 2021.

The finding of heart damage in teenagers, thus, would have been available to the FDA at the time of the May 2021 EUA application.

The FDA did not disclose the risk of these harms to the general public at that time.

3) The Emergency Use Authorization itself in May 2021 does NOT mention any risk of myocarditis in adolescents, even though the 16+ age group was being filed for in this EUA.

An FDA committee reviews and then grants the EUA. The FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to discuss newly available data for the currently available COVID-19 vaccines

We [the volunteers in the Pfizer WarRoom documents review group Team 3] have not seen any discussions of the issues [of myopericarditis] by the FDA approvals committee as they are not available to the public.

There is no press release from the FDA about the approval of the May 2021 EUA application, but in an August 2021 press release

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine> (<https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>)

the FDA report that myocarditis is a known side effect and a warning is in the data sheet of the newly authorized commercial vaccine (Comirnaty).

See below from press release.

Thus it appears that the Food and Drug Administration should or must have known about elevated risk of heart damage to teenagers in a peer-reviewed publication, and failed to disclose it to the public when announcing the Emergency Use Authorization. (We don't actually have any data on this) This is an educated assumption only.

Due to the lack of disclosure by the FDA, of the known harms, the parents who chose to have their teenagers vaccinated with mRNA vaccines, therefore, could not have made use of fully informed consent. That was remedied a few months later in the data sheet of the commercial (Comirnaty) vaccine, as described in the press release above.

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