FDA ignored evidence of Autoimmune Disease & Vaccine-Associated Enhanced Disease in the Confidential Pfizer Documents

expose-news.com/2022/06/16/fda-ignored-evidence-vaed-in-pfizer-docs/

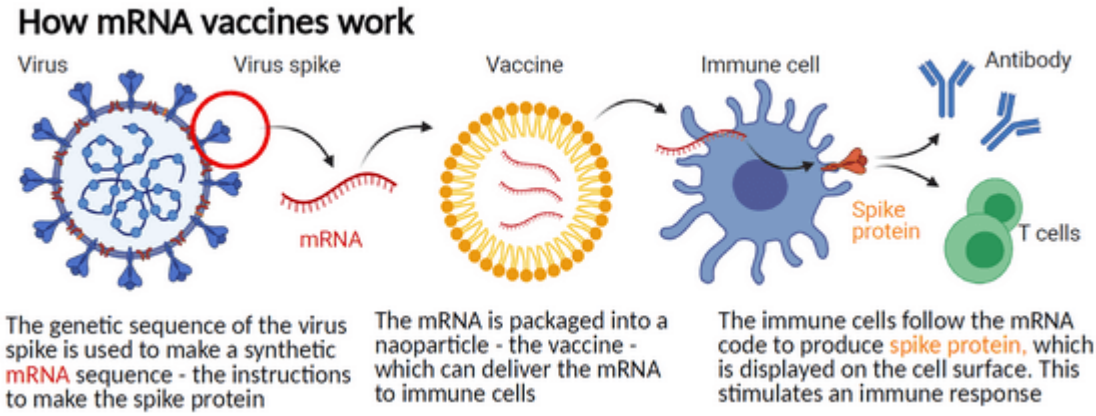
By The Exposé June 16, 2022



U.S. Food & Drug Administration ignored evidence of Autoimmune Disease & Vaccine-Associated Enhanced Disease in the Confidential Pfizer Documents

The confidential Pfizer documents, that the U.S. Food and Drug Administration (FDA) has been forced to publish by court order, reveal that Pfizer presented evidence of Covid-19 vaccine recipients suffering auto-immune disease and Vaccine-Associated Enhanced Disease as adverse events, but the FDA chose to ignore it.

The Pfizer Covid-19 injection uses a technology that prior to the end of December 2020, had never before been authorised for use in Humans. It is known as mRNA.



And there's a pretty good reason as to why it had never been authorised for use in Humans. During animal trials for SARS and MERS, it had the opposite of its intended effect and actually worsened disease by inducing antibody-dependent enhancement.

Eighteen months after the administration of the injections in the trials, all the animals had died.

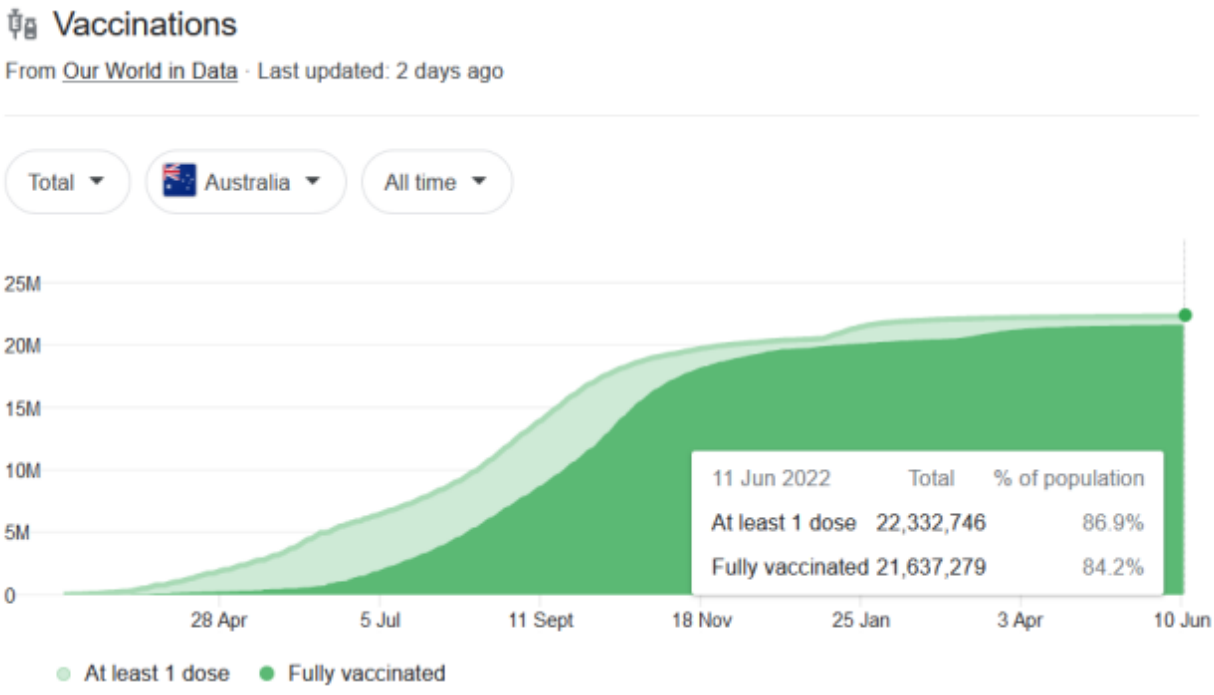
Yet, despite this, the Pfizer jab was granted emergency-use authorisation all around the world and administered to millions.

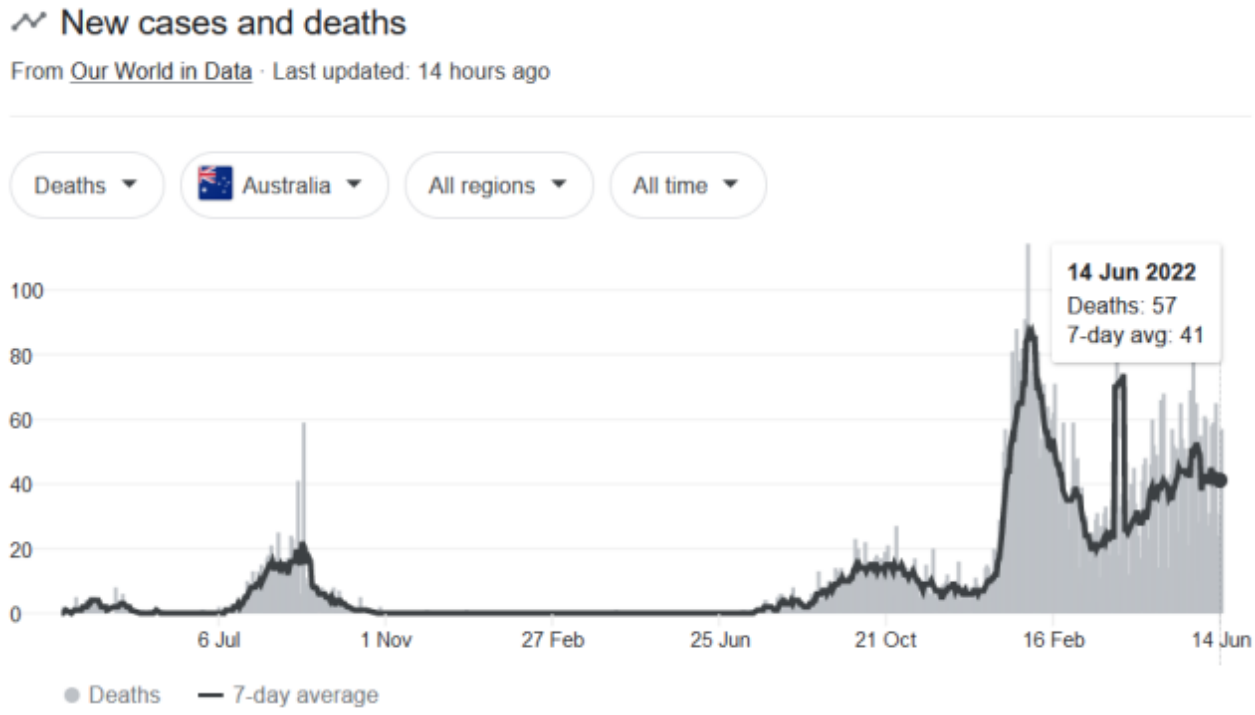
Why?

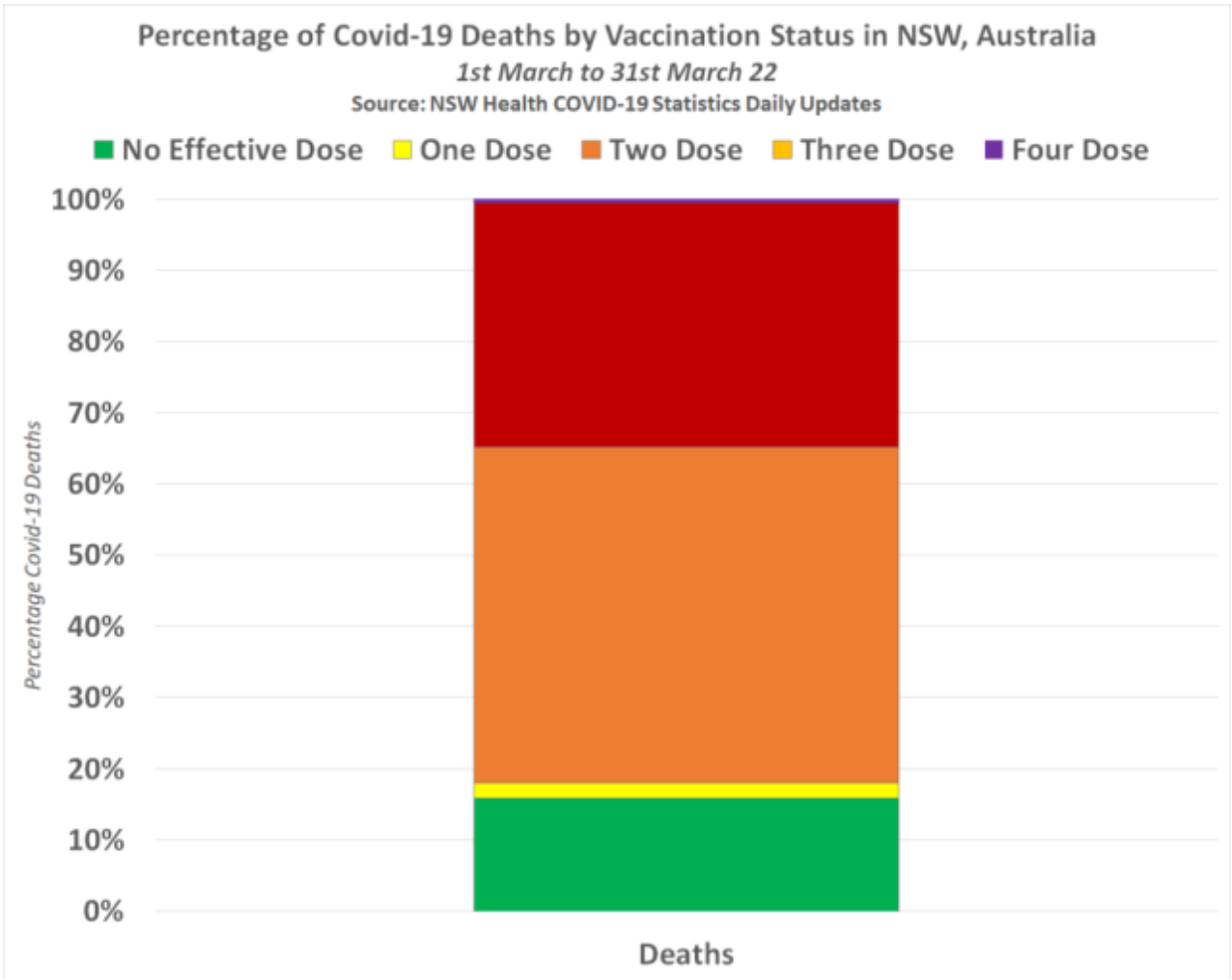
Well apparently, it was to protect people against a disease that statistically kills less than 0.2% of those it infects, the vast majority being elderly, vulnerable and having existing underlying conditions.

But even there it has failed.

Take Australia for example. As of June 2022, nearly 90% of Australia is considered fully vaccinated, yet the country is currently riding the largest wave of Covid-19 deaths since March 2022. And according to data from March 2022, at least 4 in every 5 of those deaths are among the fully vaccinated.







This data not only suggests that the Covid-19 injections don't work, it actually suggests the Covid-19 injections make recipients worse, just like the same technology did during animal trials for a vaccine against SARS and MERS.

But data forcibly published by the U.S. Food and Drug Administration (FDA) reveals all of this could have been avoided if only they'd actually bothered to read the documents submitted by Pfizer.

The FDA attempted to delay the release of Pfizer's COVID-19 vaccine safety data for 75 years despite approving the injection after only 108 days of safety review on December 11th, 2020.

But in early January 2022, Federal Judge Mark Pittman ordered them to release 55,000 pages per month. They released 12,000 pages by the end of January.

Since then, PHMPT has posted all of the documents on its website. The latest drop happened on June 1st 2022.

One of the documents contained in the data dump is 'reissue_5.3.6 postmarketing experience.pdf'. Page 11 of the confidential document contains data on important potential risks, with one of these being Vaccine-Associated Enhanced Disease (V-AED).

BNT162b2
5.3.6 Cumulati

Table 5.

Topic
Important Potential Risk
Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)

Source

What is V-AED?

Vaccine-associated enhanced disease (V-AED) occurs when an individual who has received a vaccine, develops a more severe presentation of that disease when subsequently exposed to that virus, compared with when infection occurs without prior vaccination.

Disease enhancement has previously been associated with dengue virus infection and was previously observed in humans with inactivated whole-virus vaccines against respiratory syncytial virus (RSV) and measles virus in the 1960s.

Previous animal trials of experimental vaccines against SARS-CoV-1 and MERS-CoV have also been shown to induce a more serious disease when subsequently exposed to the virus.

Pfizer Fraud

It can be difficult to distinguish between vaccine failure (also known as breakthrough disease) and V-AED. Identification of a case of VAED requires the recognition that a clinical presentation is different, atypical, modified or more severe in comparison to the natural disease presentation.

And Pfizer made sure to use that fact to their advantage, claiming not of the cases of potential V-AED identified could be definitely considered to be V-AED.

> Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD.

But as the real-world data now shows, Pfizer were most likely committing fraud, and it wouldn't be the first time, and we doubt it will be the last.

One example being in 2009, when Pfizer paid "$2.3 billion in the largest health care fraud settlement in the history of the Department of Justice. for "mis-promoting" medicine Neurontin for uses not approved by medical regulators, and paying "kickbacks" to compliant doctors



This article is more than **12 years old**

Pfizer drug breach ends in biggest US crime fine

- **Record lawsuit punishes misbranding of painkiller**
- **Whistleblower told of 'sales that risked lives'**

Source – The Guardian

Vaccine-Associated Enhanced Disease

Here's what Pfizer revealed to the FDA in regard to Vaccine-Associated Enhanced Disease in full –

Table 5. Important Potential Risk

Topic	Description
Important Potential Risk	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)	No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue. The search criteria utilised to identify potential cases of VAED for this report includes PTs indicating a lack of effect of the vaccine and PTs potentially indicative of severe or atypical COVID-19[a]. Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 138 cases [0.33% of the total PM dataset], reporting 317 potentially relevant events were retrieved: Country of incidence: UK (71), US (25), Germany (14), France, Italy, Mexico, Spain, (4 each), Denmark (3); the remaining 9 cases originated from 9 different countries; Cases Seriousness: 138; Seriousness criteria for the total 138 cases: Medically significant (71, of which 8 also serious for disability), Hospitalization required (non-fatal/non-life threatening) (16, of which 1 also serious for disability), Life threatening (13, of which 7 were also serious for hospitalization), Death (38). Gender: Females (73), Males (57), Unknown (8); Age (n=132) ranged from 21 to 100 years (mean = 57.2 years, median = 59.5); Case outcome: fatal (38), resolved/resolving (26), not resolved (65), resolved with sequelae (1), unknown (8); Of the 317 relevant events, the most frequently reported PTs (≥2%) were: Drug ineffective (135), Dyspnoea (53), Diarrhoea (30), COVID-19 pneumonia (23), Vomiting (20), Respiratory failure (8), and Seizure (7). Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD. In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue.

Source – Page 11

Pfizer writes in the description section that –

> 'an expected rate of VAED is difficult to establish so a meaningful observed / expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue'.

Considering the fact this document was approved on 30th April 2021, and based on data on adverse reactions received up to 28th Feb 2021, this sentence should concern even the most loyal pharmaceutical worshippers.

In the UK the Pfizer jab was granted emergency use authorisation on the 8th Dec 20, and the first injection was administered the following day. By April 2021, 5 months later, Pfizer was admitting that it did not have a clue if its Covid-19 injections caused VAED, and that they will only know once they have more data.

This confirms in black and white that the general public has been taking part in possibly the largest experiment ever conducted, and it's an experiment that has made a select few extremely rich.

Pfizer continues in the description section to state –

> 'Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 138 cases [0.33% of the total PM dataset], reporting 317 potentially relevant events were retrieved.'

What Pfizer is admitting here is that up to 28th Feb 21, 138 people had reported adverse events that were markers of Vaccine-Associated Enhanced Disease.

According to Pfizer those 138 cases reporting 317 VAED relevant events included –

- 71 incidents in the UK;
- 25 incidents in the USA;
- 14 incidents in Germany;
- 16 incidents in France, Italy, Mexico & Spain (4 each);
- 3 incidents in Denmark;
- and 9 incidents from 9 different countries

Of the 138 cases, 71 were deemed 'medically significant' of which 8 were left with serious disabilities Non-fatal / non-life-threatening hospitalisation was required for 16 cases of which 1 was left with serious disabilities. 17 cases were deemed life-threatening of which 7 were deemed serious for hospitalisation, and 38 cases resulted in death.

At the time of the report which was based on data submitted up to the end of February 2021, apart from the 38 cases that were known to have resulted in death at the time, just a further 26 cases were listed as resolved, with 65 not resolved, 1 not resolved with sequelae, and 8 with unknown outcomes.

Pfizer go on to state in the confidential document that –

> 'Of the 317 relevant events, the most frequently reported PTs (≥2%) were: Drug ineffective (135), Dyspnoea (53), Diarrhoea (30), COVID-19 pneumonia (23), Vomiting (20), Respiratory failure (8), and Seizure (7).'

Pfizer concludes in its document that –

> 'VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death.'

This seems to be an admittance from Pfizer that its vaccine isn't very good at protecting recipients of its experimental It's important to remember that these injections do not prevent infection or transmission, they are only supposed to protect against hospitalisation and death. Therefore, with 75 of the 101 confirmed Covid-19 cases being severe (69%), this seems to be an admittance from Pfizer that its vaccine isn't very good at actually doing that.

Pfizer finishes by stating that –

> 'In this review of subjects with COVID-19 following vaccination, based on the current evidence,
> **VAED/VAERD remains a theoretical risk for the vaccine**. Surveillance will continue.'

Here we have Pfizer admitting that Vaccine-Associated Enhanced Disease is a theoretical risk associated with its experimental Covid-19 gene therapy, which has been injected into the arms of hundreds of millions of people around the world several times since December 2020.

There are no appropriate words that could possibly convey how unbelievably stupid and dangerous the decision to give this injection to millions of people, including children was and still is.

Autoimmune Disease

Unfortunately, the FDA also chose to ignore the evidence presented by Pfizer of autoimmune disease being suffered as adverse events to its Covid-19 injection.

Page 20 of the reissue_5.3.6 postmarketing experience.pdf document contains details surrounding adverse events reported relating to immune-mediated/autoimmune diseases.

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.
Immune-Mediated/Autoimmune AESIs *Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity*	• Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed; • Country of incidence (>10 cases): UK (267), US (257), Italy (70), France and Germany (69 each), Mexico (36), Sweden (35), Spain (32), Greece (31), Israel (21), Denmark (18), Portugal (17), Austria and Czech Republic (16 each), Canada (12), Finland (10). The remaining 74 cases were from 24 different countries. • Subjects' gender (n=682): female (526), male (156). • Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2). • Number of relevant events: 1077, of which 780 serious, 297 non-serious. • Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each); • Relevant event onset latency (n = 807): Range from <24 hours to 30 days, median <24 hours. • Relevant event outcome[l]: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

Source – Page 20

According to Pfizer, of the 42,086 trial participants, 1,050 reported suffering autoimmune disease, of which 760 were medically confirmed.

Just 196 of these cases were among the elderly, with the vast majority (746) among adults, and a further 2 among adolescents.

780 of these autoimmune disease cases were considered serious, whilst 297 were considered non-serious.

The most frequently reported events included hypersensitivity, neuropathy peripheral, pericarditis, myocarditis, and autoimmune disorder and Raynaud's phenomenon among many others.

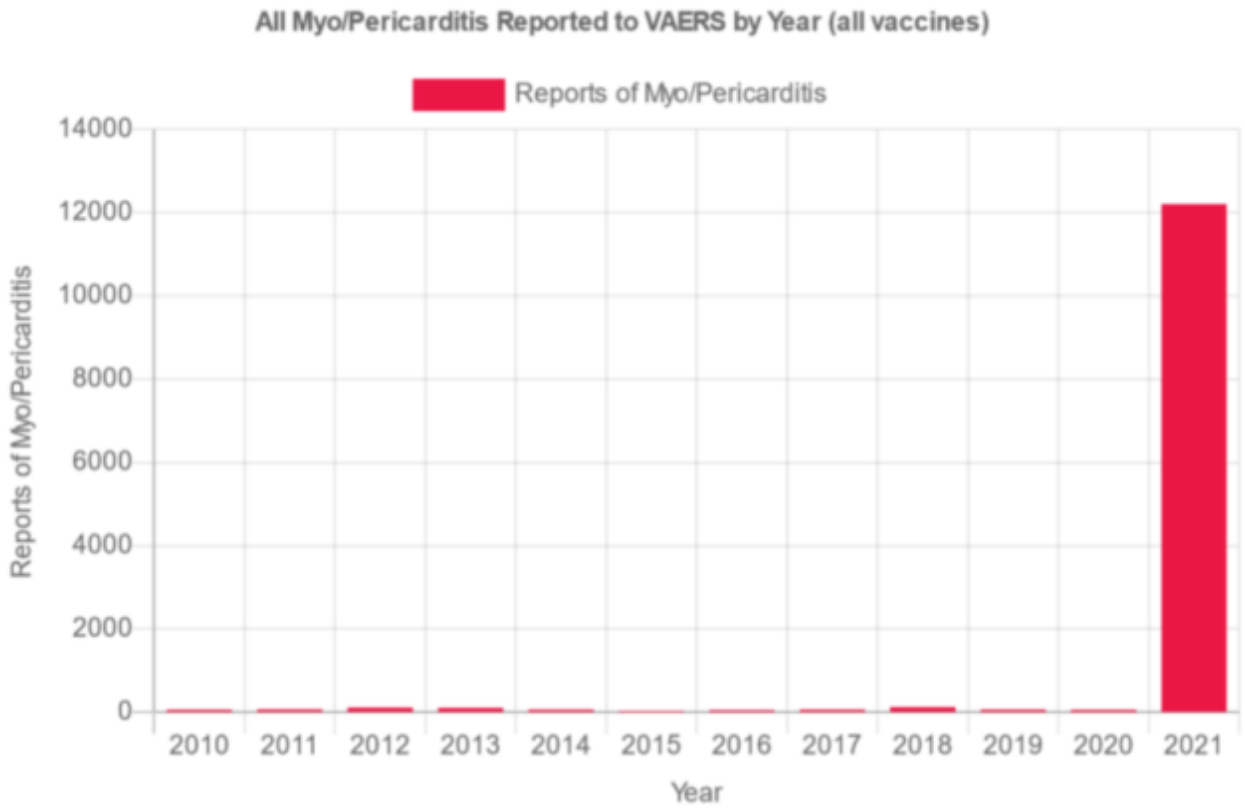
This shows that back in April 2021, medicine regulators were fully aware of the risk of suffering myocarditis and pericarditis. As of June 2022, these are two of the only side effects of Covid-19 vaccination that medicine regulators have admitted can occur, proving how common the side effects are.

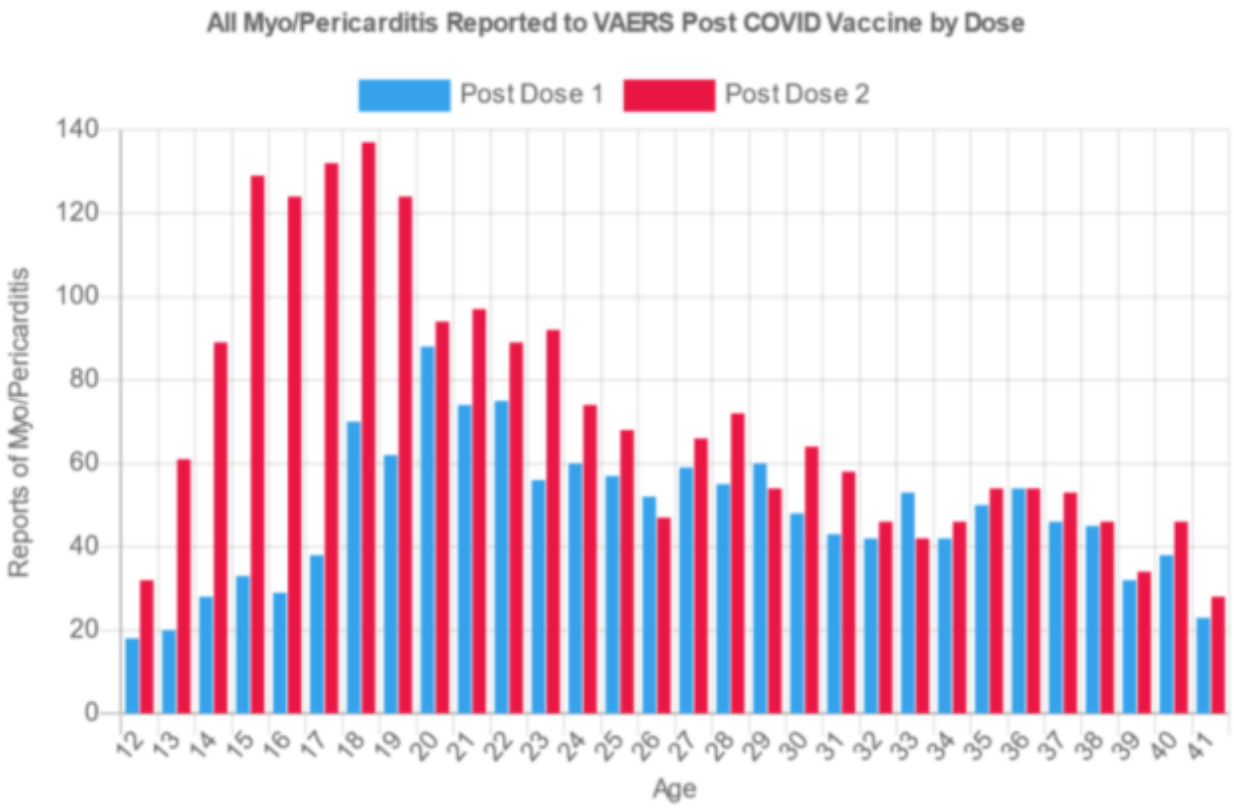
Questionably, Pfizer concluded in their submitted document that –

> “This cumulative case review does not raise new safety issues. Surveillance will continue.”

This is a statement Pfizer would live to regret at least when it comes to myocarditis and pericarditis.

Here’s how both autoimmune diseases have affected people in the USA according to the Vaccine Adverse Event Reporting System (VAERS), where just 1-10% of adverse reactions are actually reported –





Incompetent or Criminal?

The FDA attempted to delay the publication of the confidential Pfizer documents for 75 years, and they fought hard to do so in various courts.

Thankfully, they failed.

Those documents reveal that Pfizer made the FDA aware of hundreds of potential cases of Vaccine-Associated Enhanced Disease, and thousands of potential cases of autoimmune disease as a result of Covid-19 vaccination.

They also reveal that Pfizer attempted to play it down, as they would if they were trying to get their product on the market.

But we now know, thanks to real-world data, that Vaccine-Associated Enhanced Disease is most likely occurring around the world, with the current state of Covid-19 in Australia, where nearly 90% of the population are fully vaccinated, being just one example.

We also know, thanks to real-world data and medicine regulators admitting it, that at the very least, tens of thousands of people are suffering myocarditis and/or pericarditis as a result of Covid-19 vaccination, with the autoimmune conditions mainly affecting the young.

The question is whether the FDA, and other medicine regulators around the world, actually bothered to read the submitted Pfizer documents, proving them to be incompetent if they didn’t, or whether they read them and chose to ignore the evidence of V-AED and Autoimmune Disease as a consequence of Covid-19 vaccination, which would prove them to be criminals.

Subscribe now to make sure you receive the latest uncensored news in your inbox…

The Expose is now censored by Google, Facebook, Twitter & PayPal. So we need your help to ensure We can continue to bring you the facts the mainstream refuse to…

We're not funded by the Government to publish lies & propaganda on their behalf like the mainstream media.

Instead, we rely solely on our support. So please support us in our efforts to bring you honest, reliable, investigative journalism today. It's secure, quick and easy…

Just choose your preferred method to show your support below support











Send Bitcoin

The Expose Bitcoin Wallet Address –
3KpsgfuEX6v7w83aVN4b1dfCZTzas7Kt74

Send Monero

Follow Daily Expose on Telegram

Follow us on gab

FOLLOW US ON GETTR

Subscribe to our Newsletter

Letter to the Editor: Weather Modification in Worcestershire and Smelly Chemtrails Over Exmoor
Covid Pandemic Truths: NIH Website Filters Out Top Search Results For “Covid What Is the Truth”
The Men Who Made Klaus Schwab and The World Economic Forum
Monkeypox? – U.S. Gov. Data proves Covid-19 Vaccines increase risk of suffering Shingles by at least 4925%

Follow Daily Expose on Telegram