NOTICE TO CEASE AND DESIST MANDATE

TIME SENSITIVE DOCUMENT ESTOPPEL CONDITIONS APPLY

From:

_____
_____
_____

To:

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_____

OFFICE FOUND

Within the universal maxim of law 'notice to agent is notice to principal and notice to principal is notice to agent'. All addressed parties Jointly and Severally as well as their Successors, Nominees and assigns.

Notice Your Business is in serious violation of multiple federal state and local laws including the gross violation of human rights. You must immediately cease and desist all Covid-19 vaccine mandates and requirements. Covid-19 vaccines MUST be entirely optional for all patrons and employees. All policy must reflect Covid-19 vaccines are entirely optional and up to the individual.

You are required to get this notice to the CEO of the corporation so they will be made aware that the corporation must IMMEDIATELY alter policy to reflect that **Covid-19 vaccines** are entirely optional. YOU CAN NO LONGER MANDATE Covid-19 vaccination.

My findings raise significant concerns, both medically and legally, of the current mandate of the EUA Covid-19 Pfizer vaccine policy in place. You are in direct violation of Federal law by mandating a vaccine that is not FDA approved.

21 U.S.C. § 360bbb-3 - U.S. Code - Unannotated Title 21. Food and Drugs § 360bbb-3. Authorization for medical products for use in emergencies

(e) Conditions of authorization

(1) Unapproved product

(A) Required conditions

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

FDA Pfizer authorization (Comirnaty): Key points to consider and discuss.

These points are an aggregate of many minds, including Dr. Robert Malone.

23 Aug 2021

General talking points

- Why mandates if herd immunity isn't possible?
- What happens 8 months after boosters?
- What's the plan for the next variant?
- Why we're messing with vaccine injury liability if the vaccines are safe and effective?

There are now TWO LEGALLY distinct (Pfizer vs. BioNTech), but otherwise identical products, based on two FDA letters, as well as a press release. The analysis of these FDA products below is preliminary and subject to change.

Letter to Pfizer

https://www.fda.gov/media/150386/download

- DOES NOT GIVE FULL APPROVAL
- Extends EUA to allow supply of current Pfizer under EUA because limited supply of BioNTech version.
- "The products are legally distinct with certain differences that do not impact safety or effectiveness. (page 2, Pfizer letter)

o here FDA quietly admits that the licensed Pfizer vaccine and the authorized Pfizer vaccine are identical with regard to safety/efficacy, but they are "legally distinct." That's code for one has manufacturer liability, while the other doesn't. It is also code for "we don't want to impose a mandate on the EUA product cause it is illegal, but we can probably get away with a mandate on the licensed product."

o page 12 AA (Conditions with Respect to Use of Licensed Product). This tells you

that yes, we licensed the vaccine, but...there is a lot of the old vaccine out there, actually "a significant amount" and this amount will be considered an EUA and will continue to be used.

o Now, why would they do that? Why specify that identical versions of the product will be legally different? Because they need the license to impose the mandates. But they need the EUA to evade liability.

o Along with the license comes liability for the manufacturer. (While all EUA products were given a liability shield.)

o Unfortunately, our federal governments would prefer us to be without recourse if we are injured, rather than have Pfizer defend its product in court.

So, the feds want us to THINK the vaccine we are receiving is licensed, which will make people submit because they think it can now be mandated, but instead we are almost certain to receive the EUA vials instead, to save Pfizer's behind.

Yes, a stingy CICP injury program exists, but **it has not paid out for a single COVID vaccine injury yet.**

• Warning about myocarditis and pericarditis

Letter to BioNTech (COMIRNATY): (signed by Mary Malarkey) – MARKET AUTHORIZES BLA(APPROVAL)

https://www.fda.gov/media/151710/download

• For "active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older."

• Analysis of […] adverse events reported […] not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

• 13 Post marketing studies required

  o Pediatric (3 studies) < 6m to <15 y

  o Myocarditis and pericarditis (6 studies), with UP TO 5 years follow up

  o Pregnancy – teratology (1 study)

  o Dose levels, VA, effectiveness in Kaiser system (3 studies)

• The FDA bypassed/disregarded the normal advisory committee and public comment process for this license. See p2 "We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion."

Press release

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

• "On August 23, 2021, FDA approved the biologics license application (BLA) submitted by BioNTech Manufacturing GmbH for COMIRNATY (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.

• **The efficacy claims are based on outdated data**. The press release indicates that the basis of the efficacy claims was as quoted below. However, those data are outdated, and captured with strains of virus (Alpha, Beta) that are no longer predominant. The efficacy claims are therefore invalid – it is quite clear that the vaccine is much less effective in preventing infection by the currently circulating strain (Delta)

  o "Specifically, in the FDA's review for approval, the agency analyzed effectiveness data from approximately 20,000 vaccine and 20,000 placebo recipients ages 16 and older who did not have evidence of the COVID-19 virus infection within a week of receiving the second dose. The safety of Comirnaty was evaluated in approximately 22,000 people who received the vaccine and 22,000 people who received a placebo 16 years of age and older."

  o "Based on results from the clinical trial, the vaccine was 91% effective in preventing COVID-19 disease."

  o "More than half of the clinical trial participants were followed for safety outcomes for at least four months after the second dose. Overall, approximately 12,000 recipients have been followed for at least 6 months."

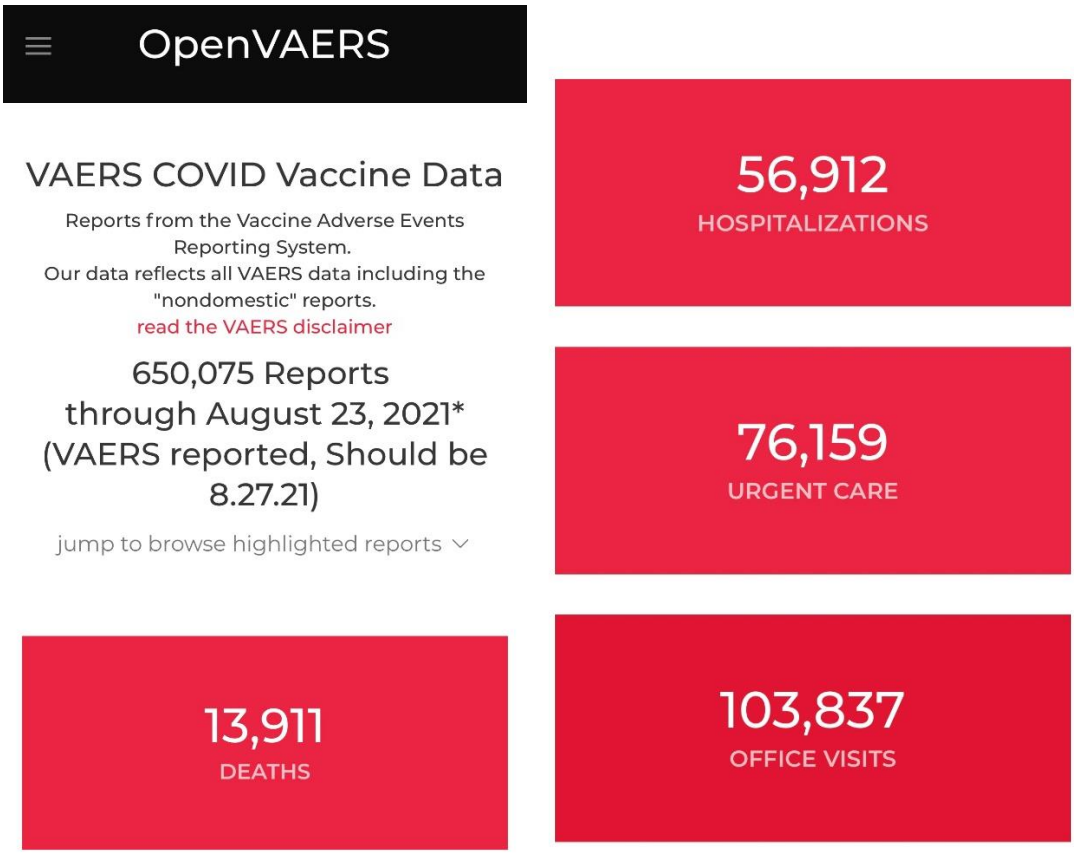
- “The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle or joint pain, chills, and fever. The vaccine is effective in preventing COVID-19 and potentially serious outcomes including hospitalization and death.”

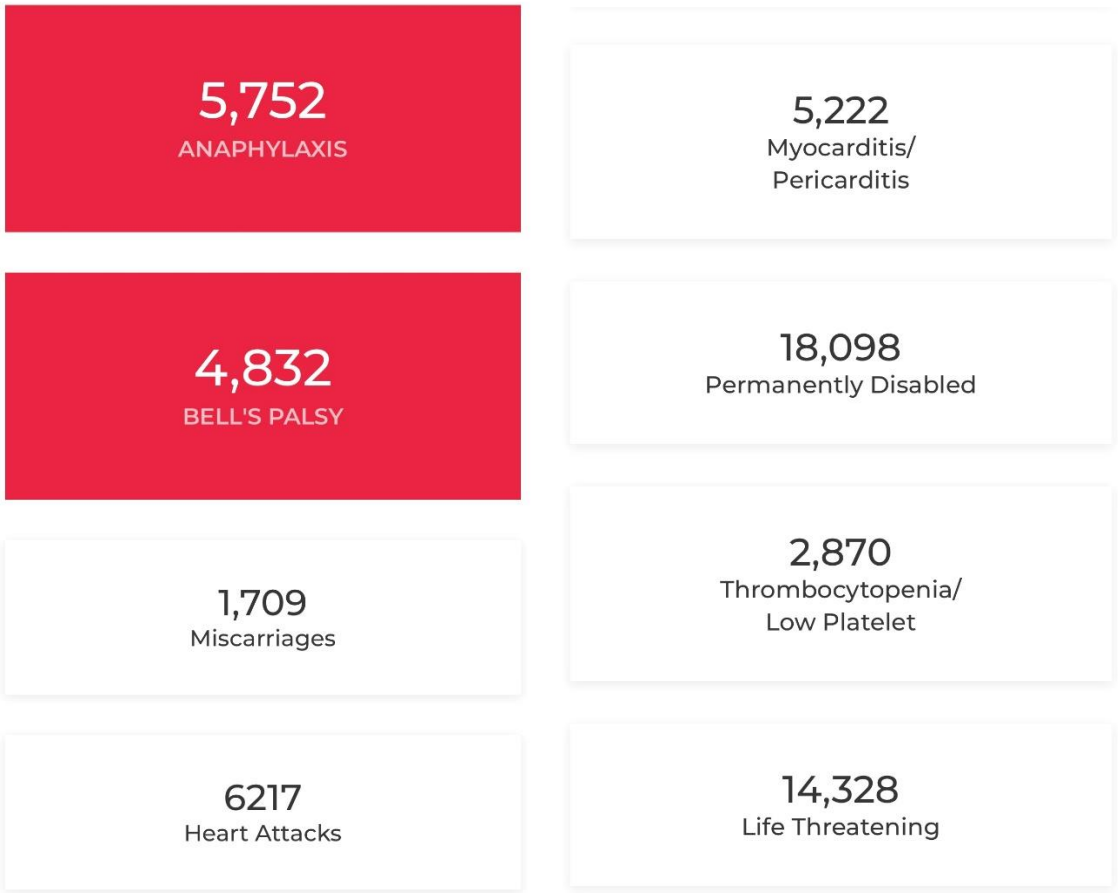
• **The decision is premature. Regarding the risks of myocarditis and pericarditis**. Per CDC, those risks are still being assessed and may be at least 2.5 times higher than previously known. FDA does not have access to the new assessment as it has not been completed.

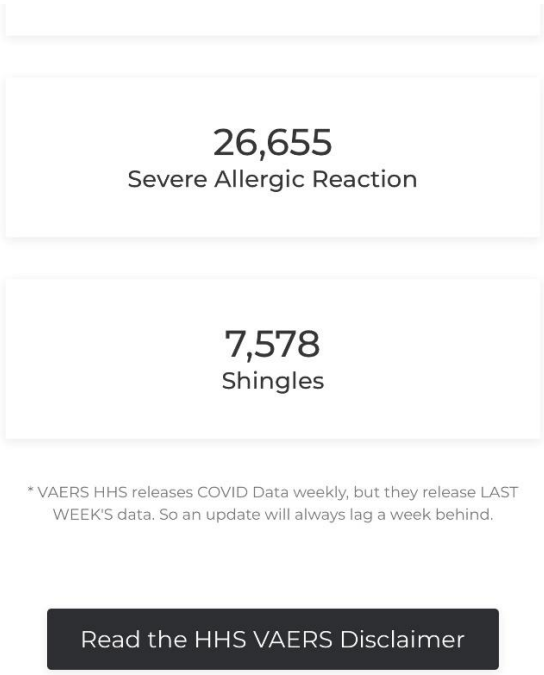
- “the FDA conducted a rigorous evaluation of the post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine and has determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes.”

- **FDA ongoing safety data monitoring is inadequate.** Yet the FDA indicates otherwise.
    - o “The FDA and Centers for Disease Control and Prevention have monitoring systems in place to ensure that any safety concerns continue to be identified and evaluated in a timely manner. In addition, the FDA is requiring the company to conduct post marketing studies to further assess the risks of myocarditis and pericarditis following vaccination with Comirnaty.”
    - o In its letter to BioNTech, the FDA states “" We have determined that an analysis of spontaneous post marketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis. Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.”
    - o The first sentence says that VAERS will be incapable of assessing known serious risk
    - o The second sentence says that the other pharmacovigilance systems that by law FDA employs (supposedly about 20 different databases when they were bragging about them last October) are similarly incapable of assessing known serious risk

https://www.openvaers.com/covid-data




5,752
ANAPHYLAXIS
5,222
Myocarditis/
Pericarditis
4,832
BELL'S PALSY
18,098
Permanently Disabled
1,709
Miscarriages
2,870
Thrombocytopenia/
Low Platelet
6217
Heart Attacks
14,328
Life Threatening



Covid-19 vaccines <u>MUST</u> be entirely optional for all patrons and employees in The Republic of America.

You have 7 days to comply.

In addition, this shall serve as a pre-suit letter demanding that you provide written assurance within 7 days that you will cease and desist.

If you do not comply with this cease-and-desist letter within the aforementioned time-period then a lawsuit may be filed in the proper jurisdiction seeking monetary damages as well as pursuing all available legal remedies.

Dated this _____ day of _____, 20___.

Sincerely,

_____