TrialSiteNews

FDA's forced hand drops Pfizer's Bombshell Safety Document

SoniaElijah
December 14, 2021

16 Comments

By Sonia Elijah

The highly confidential Pfizer documents, which have been synonymous with the extreme lack of transparency revealed by the actions of pivotal governmental agencies, over the past 20 months, lead critics of the official narrative to demand "show us the data," is finally being revealed–well sort of, the first few hundred redacted pages out of a trove of 451,000.

What led to the disclosure?

The crack in Pfizer and the Food and Drug Administration (FDA) iron dome-style data safeguarding, arrived in the form of a Freedom of Information Act (FOIA) release with the request filed on August 27, 2021, to access all the Pfizer documentation that the FDA had relied on to authorize the Pfizer-BioNTech Covid-19 vaccine for emergency use authorization. An agency that has received a FOIA request is required to '*determine within 20 business days after the receipt of any such request whether to comply with such request,*' as set out by the 1967 FOIA law. It took the FDA though three months to release the first 91 redacted pages, on November 20.

The FOIA request was issued by a group of over 30 scientists and academics who filed a civil action lawsuit against the agency because they failed to fully comply with the request, since less than 1% of the documentation was released and with the FDA taking the position that all the data would be shared by 2076. Subsequently, the governmental agency had the audacity to push the date back even further to 2096. This was due to their recent disclosure of the existence of thousands of

additional pages, totaling 451,000 versus the originally stated 320,000 pages. However, the rate at which the FDA is willing to release the documentation has not changed and remains at 500 pages a month. It's worth noting that it took the FDA only 108 days to review all of Pfizer's documentation before authorizing the Pfizer BNT162B2 vaccine for emergency authorization use on December 1, 2020.

The scientists, public health officials, and academics, led by Dr. Peter McCullough, formed the plaintiff group, PHMPT (Public Health and Medical Professionals for Transparency), and are being represented by the law firm of Aaron Siri, of Siri & Glimstad LLP.

In an exclusive interview with *Trial Site News*, Aaron Siri, managing partner of the firm, who has extensive civil litigation experience, stated:

"The court has not ordered a single page to be produced yet. For the most part, when our firm submits a FOIA request, they [the agency] will produce documents but the FDA wants to do it at a pace that's incredibly slow, not commensurate with the needs of the request. The fight is not

whether they'll produce it-they'll produce it. The fight is how long it will take and then the fight once we get it will be the redactions they put in."

When I asked him whether FOIA requests will be made to obtain Moderna and Janssen's (a subsidiary of Johnson and Johnson) documentation supplied to the FDA to secure emergency use authorization, he responded:

"You can't make a request until a vaccine has been licensed. Authorization for emergency use is not the same as licensure or approval. The Pfizer vaccine is the only vaccine that's been licensed/approved as "safe and effective" according to the FDA on August 23rd 2021."

Details about the case and the relevant court documents can be found on Aaron Siri's blog, *Injecting Freedom*.

The first several hundred pages of the newly released Pfizer documents were shared on the PHMPT's website.

The focus of this investigative report centers on the 38-page document, entitled, "*Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) received through 28 February 2021*." The report was prepared by Pfizer, between the time of December 1,

2020, through February 28, 2021. The adverse events reports originate in the United States, United Kingdom, Italy, Germany, France, Portugal, Spain, and '*56 other countries.*'

It's interesting to note that the artifact represents an amended analysis provided by Pfizer, a response to their failings associated with the incomplete submittal of a safety data package to the FDA, which the agency commented on. A reference is made to the FDA's March 9th request to Pfizer *'We are most interested in a cumulative analysis of post-authorization safety data to support your future BLA submission.* ***Please submit*** *an integrated analysis of your cumulative post-authorization safety data, including U.S. and foreign post-authorization experience, in your upcoming BLA submission.* ***Please include a cumulative analysis of the Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified*** *in your Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). Please also include distribution data and an analysis of the most common adverse events. In addition, please submit your updated Pharmacovigilance Plan with your BLA submission.'*

The many unknowns

In the short three-month period in which the data was *'reported spontaneously to Pfizer,'* 42,086 cases were recorded with 158,893 events. According to the data, one can interpret that the average person (case) would have suffered from just under four symptoms (events). Particularly troubling, the FDA opted to protect Pfizer's interests by redacting the total number of doses to **(b) (4),** hindering the ability to calculate the incidence rates and provide a meaningful analysis of the data. Another deeply concerning fact centers on important limitations cited by Pfizer: 'the *magnitude of underreporting is unknown.' In relation to this topic, investigators leading* a prominent Harvard study conducted from 2007-2010, discovered that 'less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the FDA.' Assuming this math is correct, we can conclude that the 42,086 cases represent a staggeringly underreported amount.

Other significant 'unknowns' peppered throughout Pfizer's analysis are:

- 2990 cases where the gender is unknown
- 6876 cases where the age is unknown
- 9440 cases where the outcomes are unknown

Another anomaly that stands out is that for case outcomes, Pfizer has chosen to include those recovering from adverse events in the same category with those recovered, under the label, '*Recovered/Recovering'*. This move alone seems questionable.

The large numbers of spontaneous adverse event reports

Alarmingly, the analysis makes note of the fact that there has been such a large volume of adverse events, classified as 'serious cases' in that short period of time, that Pfizer has had to take on more full-time employees and make significant technology changes to cope with the processing of the voluminous reports while also meeting regulatory reporting timelines. As recorded in the document:

'Due to the ***large numbers of spontaneous adverse event reports*** *received for the product, the MAH has prioritized the processing of serious cases, to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity.'* The report went on to state how Pfizer has dealt with these large numbers of adverse event reports. '*Pfizer has also taken multiple actions to help alleviate the large increase of adverse event reports. This includes* ***significant technology enhancements****, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded additional b4 full-time employees (FTEs)..'*

(*b4 is a redacted term)

The 1228 Deaths

Within Pfizer's self-generated document, a serious red flag surfaces: 1228 people were recorded to have died within three months after taking the vaccine, while no record accounts for the gender of the study participants who died. This data, which has significant safety implications, was known to Pfizer by end of February, yet on April 12, Dr. Mace Rothenberg, former Pfizer Chief Medical Officer, when talking to the *Washington Journal* about the development of the Pfizer vaccine said "I can tell you that no corners were cut" and "there have been **no deaths** that have occurred directly as a result of the vaccine alone." Those defending the safety of the Pfizer vaccine have raised the argument that 'correlation does not imply causation, in which two events occurring together does not establish a cause-and-effect relationship.'

Page 10 of the Pfizer analysis presents an important identified risk of anaphylaxis with nine reported fatalities. Four out of the nine occurred on the same day the individuals were vaccinated (see below).

b There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated.

Pfizer emphasized that these individuals had underlying medical conditions, but for all four of them to die on the same day that they were received the vaccine, suggests potential vaccinal death causality.

In Table 7 of pages 16-17, 1403 cases of Cardiovascular AESIs (Adverse Event of Specific Interest) were reported and segmented by the following: Arrhythmia; Cardiac Failure*; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia*.

The relevant event onset latency ranged from less than 24 hours to 21 days. This means that relevant events occurred from any time less than 24 hours up to 21 days of receiving the vaccine, with a **median of less than 24 hours.** 136 relevant event outcomes were fatal. Therefore, 50% of these relevant outcomes (including deaths) occurred less than 24 hours after receiving the vaccine. This points again to vaccine death causality.

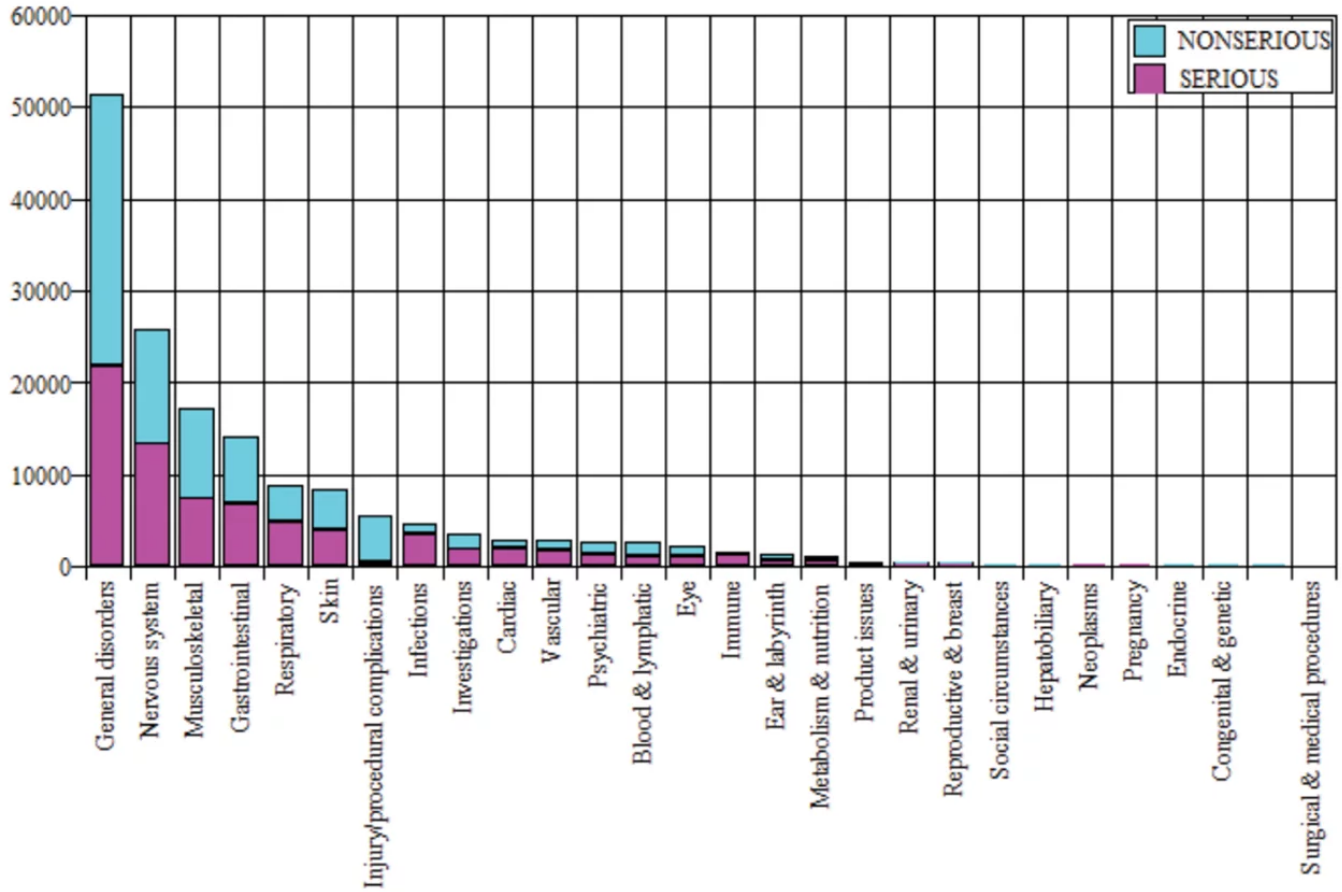
Yet, Pfizer somehow concludes: *'This cumulative case review does not raise any new safety issues. Surveillance will continue.'*

When looking at the category *'Immune-mediated/Autoimmune AESIs',* 1050 cases were reported, with just over three times more females affected than males- there were 12 fatal outcomes. The median of the relevant event onset latency was less than 24 hours, which again suggests vaccine death causality.

The seriousness of the cases

Looking at the graph below, a significant portion of cases are reported as serious compared to non-serious with the highest number of serious cases in the 'general disorders' category. A serious case is one that is medically significant resulting in either hospitalization or that has a life-threatening consequence or death. It's interesting to note that for cardiac, immune, vascular, and infections, serious cases dominate and for immune cases, all are classified as serious.

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness



Women were x3 times more affected by adverse events from the vaccine.

Across the board, in every category of AESI (adverse events of special interest), women were generally three times more adversely affected than men. However, nowhere was this as pronounced as in the case of anaphylaxis (a potentially life-threatening allergic reaction), where women were over eight times more affected. Out of the 1002 anaphylaxis cases reported meeting the Brighton Collaboration level of 1-4 (level 1 being the highest level of diagnostic certainty of anaphylaxis) 876 females were affected compared to 106 males. Women were also significantly more affected by cardiovascular events; 1076 females were reported as cases compared to 291 males. The statistically significant data reveals the real possibility of gender-specific vaccine safety risks.

Yet nowhere in Pfizer's analysis does the company comment on this data, but instead confidently reasserts, *'the cumulative case review does not raise any new safety issues.'*

The missing information

Also noteworthy, the data associated with the *'Use in pregnancy and lactation'* were somehow excluded in the original analysis submitted to the FDA. In the amended version, 413 adverse cases are reported with 84 classified as serious.

Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each).

It's alarming that Pfizer makes the assertion that '*there were no safety signals that emerged from the review of these cases of use in pregnancy and while breastfeeding.*' The data contained in the heavily redacted document appears to contradict this upbeat assessment.

In *pediatric* individuals < 12 years of age, which was originally missing from Pfizer's analysis, 34 cases were reported with 24 categorized as serious. The fact young children were administered the Pfizer vaccine raises concern since emergency use authorization was not awarded to the company to administer to the pediatric population at that time. Moreover, the age range raised considerable alarm given its '*from 2 months to 9 years.*' The report lacks data on how many children in total were administered the vaccine, hence, there is no way of calculating incidence rates to extrapolate a meaningful analysis.

A sample list of the known AESIs in Pfizer's cumulative analysis.

Blood and lymphatic system disorders: Lymphadenopathy

Cardiovascular events: acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia

Gastrointestinal disorders

General disorders and administration site conditions

Infection and infestations

Musculoskeletal and connective tissue disorders: Arthralgia; Arthritis; Arthritis bacterial; Chronic fatigue syndrome; Polyarthritis; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis

Nervous system disorders

Respiratory, thoracic, and mediastinal disorders: Lower respiratory tract infections; respiratory failures, Viral lower respiratory tract infections; acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary hemorrhage; Respiratory disorder; Severe acute respiratory syndrome

Skin and subcutaneous tissue disorders

Anaphylaxis

Vaccine-Associated enhanced Disease (VAED) including Vaccine-associated enhanced respiratory disease (VAERD).

COVID-19

Facial paralysis

Immune-Mediated/Autoimmune disorders

Neurological (including demyelination): Convulsions; Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy

Pregnancy-Related: Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labor; Stillbirth; Uterine rupture; Vasa praevia

Renal: Acute kidney injury, renal failure

Thromboembolic events: Embolism and thrombosis; Stroke AESIs, Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism

It's worth comparing the list above with the list below accessed via the FDA's website under the document 'Pfizer-BioNTech fact sheet for recipients and caregivers', revised as of Dec 9, 2021. It's evident to see that many of the serious and life-threatening side effects have not been included, even though Pfizer's cumulative analysis of post-authorization adverse event reports was produced for the FDA on April 30, 2021.

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting in association with injection of the vaccine

Conclusion

While this author strives to remain as objective and unbiased as humanly possible, a thorough review of this one report suggests that the FDA and Pfizer have appeared to conceal the full extent of the Pfizer-BioNTech vaccine side effects from the public. If this assumption is in fact true, then the 'Gold Standard' regulatory agency and the prestigious multinational pharmaceutical company have thrown the entire concept of informed consent out the window.

It's also a travesty that months later, the FDA dragged its feet and released this important safety document based on adverse event case reports under FOIA law. Case reports play an important role in pharmacovigilance. The recognition of the link between thalidomide given to mothers and malformations in their babies was triggered by a case report.

Perhaps even more devastating—and a mockery of the whole point of advanced regulatory systems meant to ensure public safety–would be if the FDA wins the ongoing dispute to delay information release, then the public must wait another 75 years to access all the data, which by then will be far too late.

Related

VAERS Scandal Interview: Deborah Conrad, Physician Assistant, Exposes Potential Massive Covid-Fraud

BioNTech and Pfizer Share Promising Preliminary Results for COVID-19 Investigational Vaccine Product BNT162 Under "Project Lightspeed"

The BMJ's Damaging Report on Parts of Pfizer's COVID Vaccine Trial

Explore Further

Global Health And The Politics Of Catastrophe - Who will save us from the WHO and its new world order?

TrialSite News' COVID-19 Pfizer-BioNTech Vaccine Investigation Reaches Australian Media Interview

The BMJ to Facebook—Stop Censoring Us and Shut Down Your Incompetent Fact-Checkers

Categories: News

Tagged: Coronavirus, COVID-19, Pfizer-BioNTech, SARS-CoV-2, Vaccine

SoniaElijah

Responses

You must be logged in to post a comment.

Jasmina0430

December 18, 2021

Thank you! I'm so sick of the correlation argument. If I went to the doctor and said I was severely sick and my stomach is messed up beyond belief along with other issues. He would ask me what I ate last night. If I said Kroger or gas station Sushi, he'd conclude I most likely had food poisoning. In no other area of medicine do they say causation doesn't equal correlation. Yet since the 90s, they have applied this nonsense statement ONLY when it pertains to their precious vaccines. Why is that?! Really? I think not! They will do and say everything to protect their profits.

Log in to Reply

Theoriginallisa

December 19, 2021

Amen!

Log in to Reply

GoodComrade

December 19, 2021

Correlation does not equate causation is a true statement in general. In the instance of a proposed product (such as a COVID vaccine) seeking FDA approval, however, the standard assumption is an adverse event is attributed to the product until and unless proven otherwise.

Log in to Reply

Lyuba

December 17, 2021

None of such revelations reach the masses and the majority believes every word of the narrative and marketing campaign for Covid vaccines and booster shots is gaining strength.

Log in to Reply

HardNews

December 17, 2021

So sad for those who cannot research for themselves. This is intentional – or they would have stopped with the huge number of deaths and SAEs.

Log in to Reply

Dr Carver

December 16, 2021

Excellent article! Please keep up the amazing work.

Log in to Reply

jimn

December 14, 2021

It looks to me that a key word is missing from the last sentence in the paragraph beginning: “Due to the large numbers of spontaneous adverse event reports…”. Comparing it to the original, the last sentence should read:
“… To date, Pfizer has onboarded approximately [REDACTED] additional full-time employees (FTEs)…”.

Otherwise an excellent article.

Log in to Reply

Gabiroach2

December 14, 2021

Objectively, this situation is fucked up.

Log in to Reply

Theoriginallisa

December 17, 2021

Hahaha!!! EXACTLY!

Log in to Reply

Theoriginallisa

December 19, 2021

Hahaha!!! That gets me every time!

Log in to Reply

Vicknaird

December 14, 2021

In a rational world this would be more than sufficient to rescind the EUA, convene grand juries and place an order for lumber and rope.

Log in to Reply

jacquelynsauriol

December 16, 2021

I think I would have a group of volunteer citizens simply use rubber bullets to execute the PharmaGov folks. It's macabre, but since they are a non lethal weapon, it would be more like an old fashioned stoning. Quick deaths for them are too nice.

Log in to Reply

AngorAnimi

December 17, 2021

That would be a waste of bullets – what we should do is put them in separate cages and determine the LD100 for their vaccines.

Log in to Reply

Emilee

December 17, 2021

Put them in the public stocks until the last document is released. If they want out sooner, release the docs.

Log in to Reply

Theoriginallisa

December 17, 2021

Godspeed!

Log in to Reply

TheRealRestoreInc.

December 14, 2021

Great report, Sonia.

Log in to Reply

FREE TO READ WITHOUT PAYING

Articles you can share with friends

An Open Letter to Dr. Grace Lee, CDC ACIP Chairperson on Transparency

THE COSTS OF INOCULATING CHILDREN AGAINST COVID-19 FAR OUTWEIGH THE BENEFITS

The Original Antigenic Sin: COVID-19 Vaccination and Sub-Optimal Initial Immune Priming Deranges the Antibody- Cytotoxic T cell Immune Response

Don’t Vaccinate Kids: Urgent Message From Doctors’ Summit

For the public record: Critical questions FDA must address about vaccine safety

This list will be updated frequently

RECENT DISCUSSIONS

What is typical recovering time frame?

Vaccine Efficacy in Israel, Sweden vs. Ivermectin , Natural Immunity in Nigeria

Ivertmectin Details

Ziverdo Kit – Anti Viral Medicine To Cure Covid-19

NYC Covid Mandate

IVM vs. Omicron Variant: Testimonials

Best way to prevent vaccine side effects (before taking the jab)?

I-RECOVER protocol to treat post-vaccine inflammatory syndromes

READ MORE ABOUT...

Alzheimer Australia Autoimmune Disease Breast Cancer Cancer Cardiovascular Challenging Results China Clinical Research Clinical Trials CNS Coronavirus COVID-19 Dementia Dermatology Diabetes Digital Health Digital Media FDA Gene Therapy Immunotherapy

India Investigator Content Investor Watch: Ivermectin Leading Pharma Leading Sites mRNA Neurology NIH Oncology Patient Recruitment Pfizer Pharma Watch Positive Results Price Watch Research SARS-CoV-2 Site Challenges Site Success Site Watch UK Vaccination Vaccine Vaccines

GROUPS

Newest **Active** Popular

Vaccine Side Effects

active 1 hour, 40 minutes ago

Covid-19 Early Treatments

active 9 hours, 44 minutes ago

Ivermektin SK & CZ

active 2 days, 13 hours ago

Decentralized Clinical Trials

active 3 days, 3 hours ago

Fibromyalgia

active 6 days, 20 hours ago

MORE

TrialSiteNews

Not you? Click here to reset

Latest news in your inbox

Once per day - no spam - we promise.

Email*

bdmesq@gmail.com

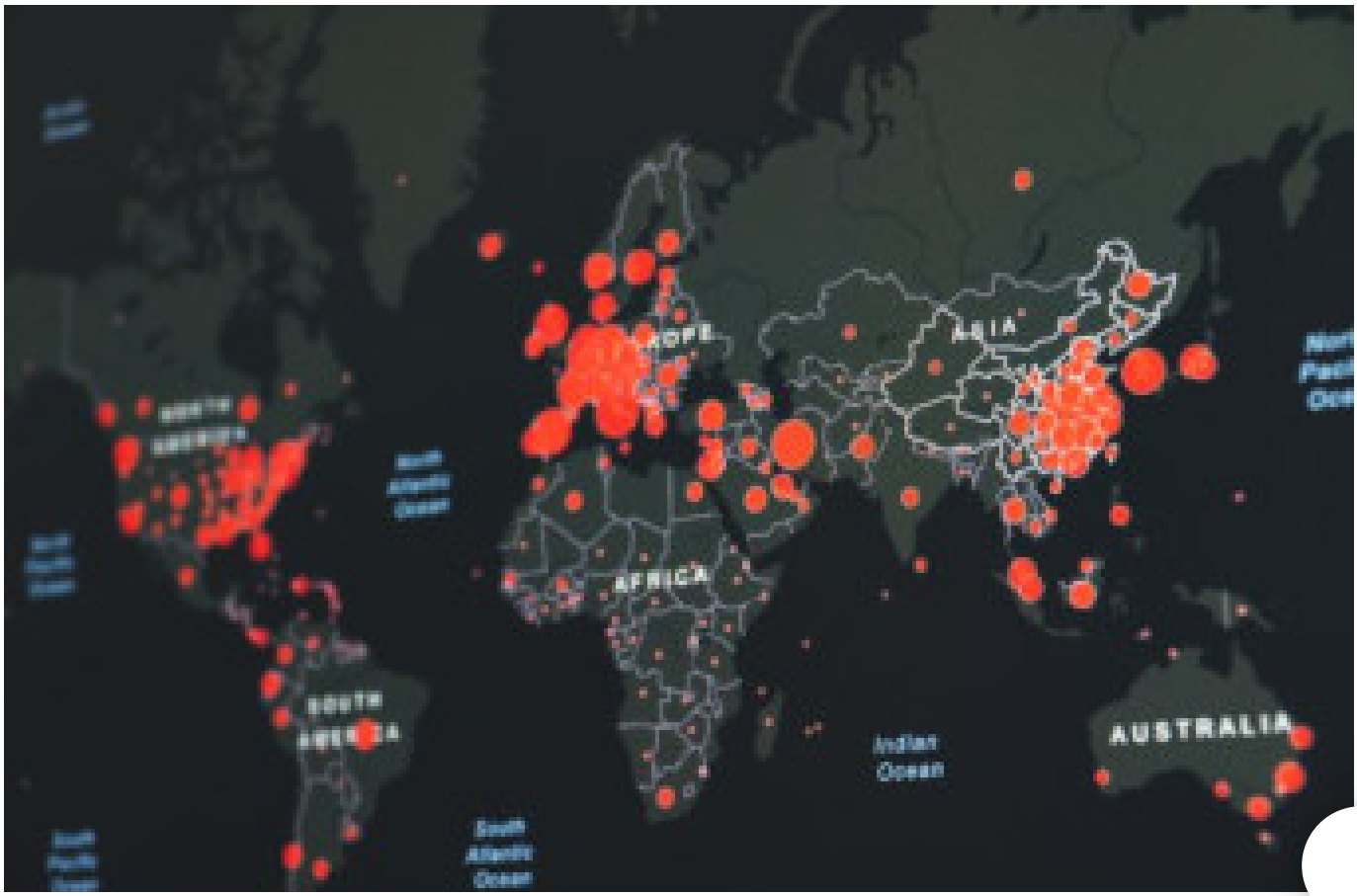
First name

Last name

Subscribe

Further Reading

Bioethics of Experimental COVID Vaccine Deployment under EUA: It's time we stop and look at what's going down.



Global Health And The Politics Of Catastrophe - Who will save us from the WHO and its

new world order?

Write for us - we are expanding our list of external authors

Joe Rogan Learns about Early COVID-19 Treatment & A lot More from Dr. Peter McCullough

Canadian Doctor of 15 Years Relieved of His Duties After Prescribing Ivermectin

UPCOMING TOWNHALLS

No posts found.