GlobalResearch
Center for Research on Globalization

US FDA Willfully Blind on the Safety of COVID-19 Vaccination

How Our Regulatory Agency Got Out of the Way from the Beginning

By Dr. Peter McCullough
Global Research, November 18, 2022
Courageous Discourse

Region: USA
Theme: Science and Medicine

***

When the US HHS invoked the Emergency Use Authorization and the Department of Defense offered COVID-19 vaccination to be administered by the US FDA and CDC, it was clear the FDA was going to play no role in stopping the vaccination freight train that was about to steamroll America.

A recent paper from Dr. Maryanne Demasi points out that the FDA "checked-out" early in the COVID-19 pandemic:[i]

> *"Regulatory documents show that only nine out of 153 Pfizer trial sites were subject to FDA inspection before licensing the mRNA vaccine. Similarly, only 10 out of 99 Moderna trial sites and five of 73 remdesivir trial sites were inspected. Now, facing a backlog of site inspections, experts have criticized the FDA's oversight of clinical trials, describing it as "grossly inadequate."*

They say the problem, which predated covid-19, is not limited to a lack of inspections but also includes failing to notify the public or scientific journals when violations are identified—effectively keeping scientific misconduct from the medical establishment. The FDA is "endangering public health" by not being candid about violations that are uncovered during clinical trial site inspections, says David Gortler, a pharmacist and pharmacologist who worked as an FDA medical reviewer between 2007 and 2011 and was then appointed as a senior adviser to the FDA commissioner in 2019-21."

FEATURE

Check for updates

Sydney, Australia
maryannedemasi@hotmail.com
Cite this as: *BMJ* 2022;379:o2628
http://dx.doi.org/10.1136/bmj.o2628
Published: 16 November 2022

BMJ INVESTIGATION

COURAGEOUS DISCOURSE

FDA oversight of clinical trials is "grossly inadequate," say experts

Covid-19 vaccines and drugs were developed at "warp speed" and now experts are concerned that the US Food and Drug Administration inspected too few clinical trial sites. **Maryanne Demasi** reports

Maryanne Demasi *investigative journalist*

On 25 September 2020, the US Food and Drug Administration (FDA) received a complaint by Brook Jackson who had been working for Ventavia Research Group, a Texas based company hired to run clinical trials for Pfizer's covid-19 mRNA vaccine. Jackson, a regional director, had witnessed problems at three trial sites she was overseeing and complained to an FDA inspector about a range of problems including falsified data, unblinded patients, and inadequately trained vaccinators who were slow to follow up on adverse events. "I thought that the FDA was going to swoop in and take care of everything. What I was reporting was so important," Jackson told *The BMJ*. The FDA did not, however, inspect the trial sites in question.

intended for millions of people. "The drug companies took appropriate measures to keep staff safe, which is exactly what the FDA could and should have done," said Gortler.

A former staffer in the FDA's Office of Criminal Investigations was also concerned about the agency's failure to fully tackle Jackson's complaint about falsified data in Pfizer's mRNA vaccine trial. In an email dated March 2021, they wrote, "Having worked at the FDA, I see it as surprising, for many reasons, that the agency turned a blind eye . . . They likely feared the criticism they undoubtedly would have received for holding up a vaccine (which they knew they would eventually approve anyway) at the expense of untold lives lost."

BMJ: first published as 10.1136/bmj.o2628 on 16 November 2022.

Demasi goes on to point out the FDA suspended inspections and despite having vast resources, does not utilize their discretionary budget to protect Americans from product safety threats. "With a total budget of $6.1bn in 2021, he [Gortler] suggests the agency needs to be leaner and more efficient, with employees interested in improving public health." "The bottom line is that the FDA has over 18,000 full time employees, more than any other drug regulatory agency by far, so it could have retrained and retooled anybody to tackle the need for increased inspections," he says. "Half of its budget, about $3bn, is discretionary, which means it could have hired contractors, retirees, or repurpose existing workers. It chose not to. The FDA was just yawning its way through the pandemic. The entire agency is broken." "The lack of full transparency and data sharing does not allow physicians and other medical scientists to confirm the data independently and make comprehensive risk-benefit assessments," continues Gortler, who is now a fellow at the Ethics and Public Policy Center thinktank in Washington DC."

The most egregious example of FDA malfeasance is the intent to withhold release of the Pfizer regulatory dossier on its COVID-19 vaccine for 55 years knowing it contained reports of 1223 deaths shortly after administration of their vaccine. In a continued set of historic blunders, the FDA approved the COVID-19 bivalent vaccines with no randomized trials powered for clinical outcomes with Omicron, and no information on safety. I believe Drs Demasi and Gortler are correct, the FDA is broken beyond repair, officials and staff involved in malfeasance should be named as targets in federal investigations since so many lives have been impacted by their malfeasance.

If you find "Courageous Discourse" enjoyable and useful to your endeavors, please subscribe as a paying or founder member to support our efforts in helping you engage in these discussions with family, friends, and your extended circles.

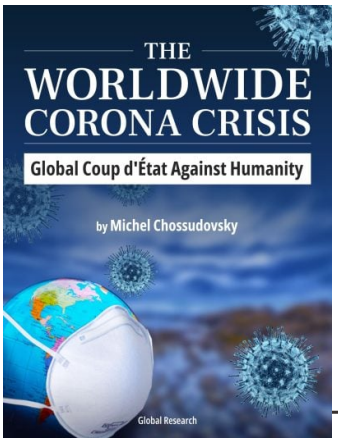
*

Note to readers: Please click the share buttons above. Follow us on Instagram and Twitter and subscribe to our Telegram Channel. Feel free to repost and share widely Global Research articles.

Note

[i] Demasi M. FDA oversight of clinical trials is “grossly inadequate,” say experts BMJ 2022; 379 doi: https://doi.org/10.1136/bmj.o2628 (Published 16 November 2022) Cite this as: BMJ 2022;379:o2628

Featured image is from NOQ Report



The Worldwide Corona Crisis, Global Coup d’Etat Against Humanity

by Michel Chossudovsky

Michel Chossudovsky reviews in detail how this insidious project “destroys people’s lives”. He provides a comprehensive analysis of everything you need to know about the “pandemic” — from the medical dimensions to the economic and social repercussions, political underpinnings, and mental and psychological impacts.

“My objective as an author is to inform people worldwide and refute the official narrative which has been used as a justification to destabilize the economic and social fabric of entire countries, followed by the imposition of the “deadly” COVID-19 “vaccine”. This crisis affects humanity in its entirety: almost 8 billion people. We stand in solidarity with our fellow human beings and our children worldwide. Truth is a powerful instrument.”

ISBN: 978-0-9879389-3-0, Year: 2022, PDF Ebook, Pages: 164, 15 Chapters

~~Price: $11.50~~ Get yours for FREE! Click here to download.

We encourage you to support the eBook project by making a donation through Global Research’s DonorBox “Worldwide Corona Crisis” Campaign Page.

The original source of this article is Courageous Discourse

Comment on Global Research Articles on our Facebook page

Become a Member of Global Research

Articles by: Dr. Peter McCullough