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LETTER TO THE EDITOR

Lock the Doors: The Myocarditis Disaster and a call for the broad examination of the CDC and FDA

Karl David Jablonowski¹, Brian Hooker¹

Children's Health Defense

*brian.hooker@childrenshealthdefense.org

Summary

“Lock the doors.” uttered by LeRoy Cain, the flight director of STS-107, meant the complete loss of Space Shuttle Columbia. Locking the doors initiated the protocol to preserve data and logs for the impending investigation. Some hard lessons were learned from the Space Shuttle Challenger disaster 17 years earlier, one of which was that the National Aeronautics and Space Administration (NASA) should not be put in a position to investigate itself. The interagency Columbia Accident Investigation Board (CAIB) was formed to learn what we could from the fate of Columbia. Had NASA been the investigating agency, given the culture, it is possible the concluding cause would have been a random event such as bird strike after takeoff or micrometeoroid in orbit. “We are convinced that the management practices overseeing the Space Shuttle Program were as much a cause of the accident as the foam that struck the left wing.”¹ Those management practices point to lock-stepping, where dissenting opinions are discouraged or suppressed. NASA’s opinion was that foam is safe. When Bob Page, chair of NASA’s Intercenter Photo Working Group, saw foam strike the wing he raised an alarm that the heat shield may be compromised. He and two members of the Debris Assessment Team made a total of three requests to the Department of Defense (DoD) to obtain high-resolution images of Columbia’s left wing. A request that, by all accounts, the DoD was willing and able to fulfill. Those requests were subsequently canceled by the shuttle program managers. The CAIB report went on to say, “[t]he Board was also influenced by discussions with members of Congress, who suggested that this nation needed a broad examination of NASA’s Human Space Flight Program, rather than just an investigation into what physical fault caused Columbia to break up during re-entry.” There are two vitally important lessons we have learned from NASA. The first is that a government agency should not be able to investigate itself. The second is that lock-stepping is lethal.

The most advanced population health surveillance in the United States couldn’t find a single healthy child who died of COVID-19. Zero is a powerful number. Zero is also the number of vaccines that impart superior immunity over that of natural immunity. If we could choose one feature that the emergent 5th endemic cold virus could have, it would unequivocally be a minimal effect on children – safeguarding our future and allowing the progression of natural immunity.

There is nothing mild about pediatric myocarditis. Even with the best medical management, 1/3rd of all patients never completely recovers, and will live with dilated cardiomyopathy. If untreated, 80% of children will develop chronic heart disease. These children are subject to a high risk of sudden death and may require an urgent heart transplant².

Before 2021:

Vaccine-induced myocarditis is a known phenomenon. In 2015 Engler, et al. found a 200-times increase above background rates of myocarditis associated with the smallpox vaccine³. Neither clinical trial for Moderna⁴ nor Pfizer⁵ mentioned myocarditis, so on December 11th, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the COVID-19 mRNA vaccine.

Documents⁶ obtained by Informed Consent Action Network's Freedom of Information Act request reveals on September 17th, 2020, Pfizer submitted a toxicity study to the FDA showing statistically significant enlargement of hearts in male rats 17-days after injection of BNT162b2. Under the exact same conditions, enlargement was not observed in female rats.

January:

The first documentation linking myocarditis to the vaccine originates in a DoD study⁷ detailing 23 service personnel of the US Army, Navy, and Air Force starting in January 2021 (published June 29th). Early that same month, on January 8th, Brook Jackson filed a False Claims Act Complaint, Jackson v. Pfizer⁸, implicating Pfizer's clinical trial was compromised.

February:

The Diaz et al. study⁹ period begins in February and finds 20 novel cases of myocarditis in a study published on August 4th. February 1st the Jerusalem Post published an article¹⁰ detailing a 19-year-old contracting myocarditis immediately post-vaccination (Jaffe-Hoffman). The week of February 19th – VAERS receives enough serious adverse event reports implicating myocarditis causally connected to the COVID-19 vaccine in young males with greater than 95% confidence – the typical threshold beyond reasonable doubt¹¹. By February 28th Pfizer received reports of adverse events, implicating 5 different versions of myocarditis (autoimmune myocarditis; immune-mediated myocarditis; Lupus myocarditis; myocarditis; myocarditis post infection) which are appended to the list of adverse events of special interest¹². Pfizer files this report, 'Cumulative analysis of post-authorization adverse event reports of PF-07302048 (BNT162B2) received through 28-Feb-2021' on April 30th. Also on February 28th, Dr. Roe Singer, Deputy Director, Division of Epidemiology, Israel Ministry of Health contacts the Centers for Disease Control and Prevention (CDC) stating "From the Israel vaccine adverse event

monitoring team: We are seeing a large number of myocarditis and pericarditis cases in young individuals soon after Pfizer COVID-19 vaccine. We would like to discuss the issue with a relevant expert at CDC."¹³

April:

In April and May, the Marshall et al. study¹⁴ details 7 case studies of myocarditis patients, published June 4th. The week of April 2nd - VAERS receives enough serious adverse event reports implicating a causal connection between the COVID-19 vaccine and myocarditis in young males with greater than 99.9% confidence. The week of April 23rd - VAERS receives enough serious adverse event reports implicating a causal connection between the COVID-19 vaccine and myocarditis in young males with greater than 99.99% confidence – the bar for highest scientific scrutiny. On April 26th the Israel Health Ministry initiated an investigation into myocarditis¹⁵. Later on April 26th, McClatchy publishes an article by Michael Wilner, wherein the CDC and FDA independently deny any 'safety signals for myocarditis'¹⁶. On April 27th Garcia et al. published a myocarditis case study in a letter to the editor of *Revista Española de Cardiología (English Edition)*¹⁷.

May:

The act of incompetence or negligence – for which our children would be right to not forget nor forgive – occurred on May 10th when the FDA expanded the EUA for the 14 million Americans ages 12, 13, 14, and 15 years old. In lockstep, the CDC approved and recommended the vaccine two days later. On May 17th the Advisory Committee on Immunization Practices (ACIP) COVID-19 Vaccine Safety Technical (VaST) Work Group session "included several presentations on myocarditis following mRNA vaccines, from the Department of Defense (DoD), the Vaccine Adverse Event Reporting System (VAERS), and Vaccine Safety Datalink (VSD)." The CDC has declined to provide supporting material. On May 18th Albert et al. published a myocarditis case report in *Radiology Case Reports*¹⁸. On May 27th the CDC website added 'Myocarditis and Pericarditis following mRNA COVID-19 Vaccination' including the statement "Since April 2021, there have been increased reports to the Vaccine Adverse Event Reporting System (VAERS) of cases of inflammation of the heart...".

June:

On June 16th Rosner et al. published a study of 7 myocarditis cases¹⁹, and Larson et al. published a study of 8 myocarditis cases²⁰. On June 23rd – presiding over

their own oversight - ACIP heard evidence and accepted the risk-benefit balance of myocarditis in children and the COVID-19 vaccines.

Vigilance delayed; vigilance denied:

The VAERS program is a poor implementation of a vital component of pharmacology, surveillance. As a passive, volunteer-based surveillance system VAERS was perhaps a good idea in 1986 with 1986 technology. In its current form it fails the National Childhood Vaccine Injury Act in spirit, if not in law. The CDC undercuts VAERS when it's convenient to do so. In a Lancet - Infectious Disease article²¹, when evaluating VAERS death reports from the COVID-19 vaccine, the CDC writes "[t]his pattern might represent reporting bias because the likelihood to report a serious adverse event might increase when it occurs in close temporal proximity to vaccination." All VAERS is a collection of adverse events in close temporal proximity to vaccination. The CDC does not view the system as a pharmacovigilance surveillance system, but a collection of 'reporting bias'. The authors then go on to describe in detail six symptoms with no scientific or medical concern: injection-site pain; fatigue; headache; myalgia; chills; joint pain. If all six presented in 100% of recipients of the vaccine the FDA would still approve it and the CDC would still recommend it. Scientists were not the intended audience of the poorly written paper. It was written to influence policy, and two months after publication, was cited by ACIP's VaST Work Group as supporting the claim "No unusual clustering of causes of death associated with U.S. authorized COVID-19 vaccines." VAERS was not conceived of by the agencies charged with the nation's pharmaceutical safety. It was mandated by an act of Congress after public outrage of vaccine injury. Today it exists solely to placate that public into a false sense of security that government agencies are maintaining pharmaceutical vigilance.

Conflict of Interest:

"We declare no competing interests" was written in the aforementioned CDC publication in the Lancet - Infectious Disease. The authors were 14 members of the CDC COVID-19 Response team, writing about VAERS and v-safe (both administered by the CDC), monitoring the Pfizer and Moderna (both financially entangled with the CDC) vaccines (both recommended

by the CDC). A conflict of interest exists when one interest (e.g. employment, duty, financial, reputation, etc.) is in conflict with another interest (e.g. publishing an unbiased research article).

Safe only means one thing:

The CDC/FDA messaging surrounding vaccinations is clear - it is still ringing in our ears. Safe means 'devoid of harm', which a vaccine is not. Clean drinking water is safe. You can drink it; give it to your children; give it to your dog; pour it on your plants. A vaccine is not 'safe'.

Informed consent:

"Governments are instituted among Men, deriving their just powers from the consent of the governed"²² is a necessary concept in any representative government. The power resides in the people, and from their collective consent imbue that power into a government. That consent must be informed, which means the government must not deceive the governed (in today's environment that is a preposterously naive requirement), or there is no representation. The democracy experiment will fail if we cannot right our wrongs and learn from our mistakes. Though there is a pointed truth in "the government you elect is the government you deserve", vaccine injured children are not what Thomas Jefferson had in mind.

The call:

The authors simply call for a broad examination of the CDC and the FDA.

The prospective findings:

Lack of trust in public health agencies is the number one public health threat...the onus is not on Americans to trust the authorities, but on the authorities to BE trustworthy.

The communication practices of the CDC/FDA are framed such that 'in the interest of public health' is as untouchable and unquestionable as 'an interest of national security' without the security clearance. Those communications have been socially engineered to fearmonger and turn neighbor against neighbor.

Does a conspiracy exist (an agreement to deprive one or more people of their rights)? Do the conditions exist for a conspiracy to emerge? Do the patent royalties received by regulatory agencies affect the behavior of that regulatory agency? What percentage of

regulatory employees go on to employment at the companies they regulated? What percentage of regulatory employees return as lobbyists? What safeguards are in place to ENSURE there was no conflict of interests? Are those safeguards circumventable?

Do large government agencies inevitably self-organize into a structure that is counter to their mission? If so, are there safeguards to prevent this corruptive force?

The CAIB report strengthened NASA and gave the world a template for healthy necessary scrutiny of a

government agency. The CDC/FDA and the United States will be all the better for such an inquiry.

Conclusion:

The true toll may never be known of the criminally incompetent, criminally negligent, or criminally orchestrated myocarditis disaster in our children. The time has long since past, but it is never too late, to 'lock the doors' and broadly examine the CDC and FDA.

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