ETHICS AND PUBLIC POLICY CENTER

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Public Comment of David Gortler, Pharma.D. FCCP., Fellow, Ethics and Public Policy Center—Vaccines and Related Biological Products Advisory Committee (VRBPAC); Notice of Meeting; Establishment of a Public Docket; Request for Comments, Docket No. FDA-2022-N-0895

My name is Dr. David Gortler. I am a pharmacologist, pharmacist, and an FDA and health care policy oversight fellow and FDA reform advocate at the Ethics and Public Policy Center think tank in Washington, DC. I was a professor of pharmacology and biotechnology at the Yale University School of Medicine, where I also served as a faculty appointee to the Yale University Bioethics Center. While at Yale, I was recruited by the FDA where I became a medical officer who was later appointed as senior advisor to the FDA commissioner for drug safety, FDA science policy, and FDA regulatory affairs.

I am responding to a request for comments by the Food and Drug Administration (FDA) announcing a public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss an Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID-19 in individuals 18 years of age and older.[1]

The Novavax vaccine should not be granted an EUA.

It is clear is that there is an increase in adverse events, especially cardiovascular-related events, following existing Covid vaccines/boosters. Based on available evidence, there is no reason to think the Novavax vaccine will be any different. Indeed, the FDA review of the Novavax vaccine acknowledged the vaccine carried the possible risk of causing heart inflammation, particularly in young males similar to those of the Pfizer, Moderna, and AstraZeneca mRNA vaccines.

The FDA's VAERS database for Covid-19 vaccines shows a long and impersonal number of cardiovascular-related events in young healthy people specifically.[2] The United States alone has accumulated a list of over 800,000 reports of adverse events, with even more adverse events reported worldwide. To date, there are tens of thousands of reports of heart attack/myocarditis/ pericarditis in the U.S. alone.[3] Moreover, these thousands of cases are well known to represent

[1] 87 Fed. Reg. 32423, https://www.federalregister.gov/documents/2022/05/31/2022-11668/vaccines-and-related-biological-products-advisory-committee-notice-of-meeting-establishment-of-a.
[2] *COVID Vaccine Data*. (2022). OpenVAERS. https://openvaers.com/covid-data.
[3] *Id.*

only 1–10% of the adverse events that occur in actuality.[4] In short, the sheer number of cases—something we've never seen before—is cause for alarm to drug safety experts like myself.

Myocarditis and pericarditis used to be considered rare conditions. They are defined as inflammation of the heart muscle or layers of the pericardial sac, respectively. Both conditions cause easily recognizable ECG changes and have nonspecific symptoms that include shortness of breath and chest pain. They can easily be diagnosed clinically with echocardiograms and can easily be treated by pharmacology.

These cardiovascular adverse events were warned about in the FDA medical review of the Pfizer application, and the FDA receives new reports on cardiovascular adverse events on a daily basis. The FDA's medical officer review, which was the basis for approving the Pfizer vaccine, notes that "clinically important serious adverse reactions [were] anaphylaxis and myocarditis/ pericarditis."[5]

But the problem is patients are not being adequately warned or monitored for cardiovascular symptoms. Pfizer should already have placed a warning on the label. Pfizer, Moderna, and AstraZeneca should have already volunteered to warn all their patients about potentially deadly cardiovascular adverse events, as well as other adverse events trending upward in VAERS that are associated with COVID vaccine and booster administration. *At a minimum*, any Novavax vaccine should have a warning informing the public about the risk of potential serious and deadly cardiovascular adverse events.

Because Pfizer and Moderna's cardiovascular and other adverse events were not taken seriously enough by the FDA to warrant more substantial labeling warnings, Covid-19 adverse events have become a major source of morbidity and mortality.

The FDA further wants to grant an Emergency Use Authorization (EUA) to the Novavax vaccine, prior to its full clinical approval, which appears to have at least the same cardiovascular risk as COVID-19 vaccines.

In its meeting, the FDA's vaccine advisory committee members will vote on the question: "Based on the totality of scientific evidence available, do the benefits of the Novavax COVID-19 Vaccine when administered as a two-dose series outweigh its risks for use in individuals 18 years of age and older?"

The answer to the question should be "no."

Novavax's vaccine, called NVX-CoV2373, is given as two doses three weeks apart for the primary vaccination series, but the FDA did describe events of myocarditis and pericarditis

[4] Electronic Support for Public Health - Vaccine Adverse Event Reporting System (ESP:VAERS) | Digital Healthcare Research. (2010). Agency for Healthcare Research and Quality. https://digital.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system.
[5] Wollersheim, S., & Schwartz, A. (n.d.). Wayback Machine. Retrieved June 6, 2022, from https://web.archive.org/web/20210918205409/https:/www.fda.gov/media/152256/download.

associated with the Novavax.[6] This is in spite of the fact that Novavax, along with all drug manufacturers made their best effort to only recruit health volunteers to enter their vaccine trials. While the number of reports were few, the real-word incidence of cardiovascular risk and all other adverse events presented in the Novavax briefing document is likely substantially greater. Novavax's Nuvaxovid COVID-19 vaccine does not appear to offer any safety advantage to existing mRNA vaccines.[7]

It appears that this vaccine has the same risks as other vaccines, which may be inherent to the spike proteins generated by the mRNA technology, despite the Novavax vaccine being a protein subunit vaccine. Protein subunit vaccines only contain attenuated antigenic parts such as proteins, polysaccharides or peptides necessary to elucidate an immune/antigenic response.

Like the Pfizer, Moderna, and Astra-Zeneca vaccines, the risk for myocarditis is greatest with young, healthy males. Despite the rather clear pattern, Novavax officials stated that "we believe there is insufficient evidence to establish a causal relationship."

Other adverse events reported (*not* including minor adverse event reports such as pain at the injection site, fatigue, headache and muscle ache) with Novavax appear to follow the same unacceptable safety profile associated with other vaccines. Despite that Novavax officials have stated that "We believe our vaccine offers a differentiated option." But that differentiation while certainly applying to a development mechanistic effect, does not appear to translate to a safety or clinical effect.

There are two central questions that seem to have been ignored by the FDA.

The first question is whether a vaccination, especially approved through the EUA process, is needed at all. We are no longer deeply embedded in the throes of the pandemic. In addition to that, there is a well-established low risk of serious COVID complications in with the existing dominant variants and the availability of therapeutics with known safety records, mask-wearing, and social distancing as alternate protective measures. On top of that, we have seen a crumbling efficacy plus clear problems with safety from all other COVID-19 vaccines.[8] If the Nuvaxovid vaccine is somehow better, Novavax needs to scientifically prove it via clinical trials before widely advocating for administering it to patients nationwide.

The second question is regarding vaccination for anyone (and everyone), as we are approaching heard immunity from the wild-type COVID-19 strain. Giving the original vaccine for COVID-19 is akin to giving the flu vaccine from 2020 for the new strain of vaccine in 2022. On top of that, most people around the world have already acquired natural immunity through previous

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[6] *U.S. FDA flags risk of heart inflammation after Novavax COVID vaccine*. (2022). MSN. https://www.msn.com/en-us/news/us/us-fda-staff-says-novavax-vaccine-lowers-covid-risk/ar-AAY2BD5.

[7] FDA. (2022). *Vaccines and Related Biological Products Advisory Committee Meeting June 7, 2022*. https://www.fda.gov/media/158912/download.

[8] News Clips. (2021b). *Video Clowns Fauci et al Over Rapidly Devolving Narrative on "Vaccine" Effectiveness*. Rumble. https://rumble.com/vnprrw-video-clowns-fauci-et-al-over-rapidly-devolving-narrative-on-vaccine-effect.html.

infections,[9] and therefore do not need any COVID-19 vaccinations. This is especially true in light of the findings of the recent 30,000 person study sponsored by Moderna and Anthony Fauci's National Institute of Allergy and Infectious Disease (NIAID),[10] which shows that natural immunity is superior to immunity given by vaccines.[11]

In conclusion, the Novavax vaccine should not be granted an EUA because there is no emergency necessitating the emergency approval process and the vaccine trials show evidence of serious risk of heart inflammation.

[9] Gortler, D. (2022, May 1). *Sin, original sin, original antigenic sin and COVID-19 natural immunity*. The Christian Post. https://www.christianpost.com/voices/sin-original-sin-original-antigenic-sin-and-covid-19-immunity.html.
[10] Follmann, D. (2022, January 1). *Anti-nucleocapsid antibodies following SARS-CoV-2 infection in the blinded phase of the mRNA-1273 Covid-19 vaccine efficacy clinical trial*. medRxiv. https://www.medrxiv.org/content/10.1101/2022.04.18.22271936v1.
[11] Piper, G. (2022, May 24). *Fauci's researchers find better antibody response from natural immunity than Moderna vaccine*. Just The News. https://justthenews.com/government/federal-agencies/faucis-researchers-find-better-antibody-response-natural-immunity.