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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; Notice of Meeting; Establishment of a Public Docket; Request for Comments, Docket No. FDA-2022-N-0904

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 write in response to the request for comments for public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) as it considers two topics: (1) amend the Emergency Use Authorization (EUA) of the Moderna COVID-19 mRNA vaccine to include the administration of a primary series to infants, children, and adolescents 6 months through 17 years of age; and (2) to amend the EUA of the Pfizer-BioNTech COVID-19 mRNA vaccine to include the administration of a primary series to infants and children 6 months through 4 years of age.¹

The Advisory Committee should not grant either COVID-19 vaccine EUA for children.

The FDA and its advisory panel have maintained a highly non-scientific and casual attitude toward approving a vaccine whose short- and long-term effects on children are unclear.

Before parents consent to vaccinate their children against COVID, basic medical ethics requires that they be informed of exactly how safe that vaccine is.

The lack of concern for vaccine safety for children was apparent from so-called “FDA experts” from the very beginning. Americans witnessed a shocking on-video admission by Dr. Eric Rubin, an advisory-committee member to the FDA, who stated during an official FDA hearing about the Pfizer COVID vaccine EUA in children five to eleven: “We’re never going to learn about how safe the vaccine is until we start giving it. That’s just the way it goes.”²

¹ 87 Fed. Reg. 32,420, <https://www.federalregister.gov/documents/2022/05/31/2022-11669/vaccines-and-related-biological-products-advisory-committee-notice-of-meeting-establishment-of-a>.

² Rubin, E. (2021). *Grabien on*. Twitter. <https://twitter.com/GrabienMedia/status/1453362914312835073>.

Obviously, Dr. Rubin does not understand anything about the FDA's review process for new vaccine approvals. That is *not* "the way it goes." Our children deserve better than that. He could have requested more safety studies or more safety vigilance at any time. Dr. Rubin's comment reveals that despite his Harvard and *New England Journal of Medicine* chief-editor pedigree and acumen, he does not understand the FDA's fundamental safety mission. Apparently, neither did the rest of the advisory committee, which followed Dr. Rubin's lead, possibly because of his auspicious titles. The only thing more unacceptable was the FDA's silence in failure to correct Dr. Rubin's outrageously incorrect and objectively false regulatory recommendation.

The FDA has duplicitously used its advisory panels validate decisions it had ostensibly already made (or been pressured to make) by repeatedly reminding its followers that they are not obligated to follow its advisory panel recommendations, as it suits its non-scientific narrative.³ This Committee should not fall prey to such pressures when making its recommendations.

The Committee should not implement the same poor regulatory standards used for other COVID vaccine approvals to push for endless vaccines for all of America's children.

Because the Biden administration is fond of using the FDA as cover for its medical mandates, it is all the more important that the FDA produce comprehensive and conclusive safety data for public review *before* approving the vaccines.

To that end, below is a list of COVID-19 vaccine safety shortcomings (that the FDA should have started addressing *years* ago):

- Genotoxicity (ability to damage DNA)⁴;
- Teratogenicity,⁵ (via bioaccumulation of vaccine spike proteins in women's ovaries)⁶;
- Oncogenicity (ability to cause tumors);
- The abundantly apparent cardiovascular risk following vaccination;⁷
- The potential for reduced fertility in men and women;⁸ and
- The clinical effects of spike proteins in donated/transfused blood.⁹

³ Office of the Commissioner. (2020, October 20). Advisory Committees Give FDA Critical Advice and the Public a Voice. U.S. Food and Drug Administration. <https://www.fda.gov/consumers/consumer-updates/advisory-committees-give-fda-critical-advice-and-public-voice>.

⁴ *Mutagenesis*, Volume 35, Issue 6, November 2020, Pages 509–510, <https://doi.org/10.1093/mutage/geaa028>

⁵ Moro PL, Cragan J, Lewis P, Sukumaran L. Major Birth Defects after Vaccination Reported to the Vaccine Adverse Event Reporting System (VAERS), 1990 to 2014. *Birth Defects Res.* 2017 Jul 17;109(13):1057-1062. doi: 10.1002/bdr2.23622. PMID: 28762675; PMCID: PMC6528469.

⁶ Wood, E. (2021, August 14). *Former Pfizer VP urges pregnant, childbearing age women not to get COVID vaccine; CDC disagrees*. The Christian Post. <https://www.christianpost.com/news/former-pfizer-vp-urges-pregnant-women-not-to-get-covid-vaccine.html>.

⁷ Gortler, D. (2022, February 4). *Vaccine Manufacturers, FDA Not Adequately Warning About Myocarditis Risks*. Ethics & Public Policy Center. <https://eppc.org/publication/fda-drug-safety-expert-dr-david-gortler-vaccine-manufacturers-fda-not-adequately-warning-about-myocarditis-risks/>.

⁸ Chen, F., Zhu, S., Dai, Z., Hao, L., Luan, C., Guo, Q., Meng, C., & Zhang, Y. (2021). Effects of COVID-19 and mRNA vaccines on human fertility. *Human Reproduction*, 37(1), 5–13. <https://doi.org/10.1093/humrep/deab238>

⁹ Arntsen, E. (2022, January 3). *COVID-19 can affect the blood. Its spike protein may be the culprit*. News @ Northeastern. <https://news.northeastern.edu/2021/02/08/covid-19-can-affect-the-blood-its-spike-protein-may-be-the-culprit/>.

It is imperative that these safety risks be fully evaluated *before* EUA is extended to children. The FDA should dedicate an independent Data Safety Monitoring Board to surveil all post-marketing trial adverse effects.¹⁰

The Committee must seriously consider the safety and efficacy concerns of currently approved COVID-19 vaccines.

There have been an unpresented 12 billion doses of the vaccine administered worldwide with over 800,000 adverse events reported in the USA alone.¹¹

Over time, we have seen crumbling efficacy rates,¹² and the FDA hasn't made a *single safety update* to the FDA's official labeling despite epidemiological findings detailing clear problems with both safety and efficacy.

As a drug safety expert, I find it alarming that according to even the left-leaning publication the International Business Times (which almost always supports FDA policies) the number of safety reports have been so overwhelming,¹³ it necessitated that Pfizer hire 2,400 new employees to specifically handle adverse event intake.¹⁴ That is unpresented for any drug and any manufacturer, by a longshot.

On top of that, the existing vaccine has been shown to be ineffective -- and it's not new news. For example, from December 1, 2021, through December 30, 2021—just a 30-day period—there were numerous news reports on the lack of effectiveness of the COVID vaccine/booster, including the following:

1. According to statistics from the Oregon Health Authority 622 Fully Vaccinated Oregon Residents Died Of COVID-19.¹⁵
2. Massachusetts reported nearly 14,000 new boosted/breakthrough cases in the week before Christmas.¹⁶

¹⁰ [Center for Biologics Evaluation and Research](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/establishment-and-operation-clinical-trial-data-monitoring-committees). (2021, December 3). *Establishment and Operation of Clinical Trial Data Monitoring Committees*. U.S. Food and Drug Administration. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/establishment-and-operation-clinical-trial-data-monitoring-committees>

¹¹ *Coronavirus (COVID-19)*. (2022, June 6). Google News. <https://news.google.com/covid19/map?hl=en-US&state=7&mid=%2Fm%2F02j71&gl=US&ceid=US%3Aen>; OpenVAERS. (2022). *COVID Vaccine Data*. <https://openvaers.com/covid-data>.

¹² News Clips. (2021). *Video Clowns Fauci et al Over Rapidly Devolving Narrative on "Vaccine" Effectiveness*. Rumble. <https://rumble.com/vnprw-video-clowns-fauci-et-al-over-rapidly-devolving-narrative-on-vaccine-effect.html>.

¹³ (2021, June 2). *International Business Times*. Media Bias/Fact Check. <https://mediabiasfactcheck.com/international-business-times/>.

¹⁴ Mishra, P. R. (2022, April 7). *Pfizer Hired 2,400 Staff to Manage Adverse Reaction to Its Covid-19 mRNA Vaccine, New Report Reveals*. International Business Times, Singapore Edition. <https://www.ibtimes.sg/pfizer-hired-2400-staff-manage-adverse-reaction-its-covid-19-mrna-vaccine-new-report-reveals-63829>.

¹⁵ Ong, D. (2021, December 17). *622 Fully Vaccinated Oregon Residents Died Of COVID-19; 64% Are White Americans*. International Business Times. <https://www.ibtimes.com/622-fully-vaccinated-oregon-residents-died-covid-19-64-are-white-americans-3359388>.

¹⁶ Benjamin Kail, bkail@masslive.com. (2021, December 21). *Despite rise in omicron, breakthrough COVID cases in Massachusetts last week amounted to about 43% compared t*. Masslive.

3. Most new COVID-19 cases in Denmark occur in people who are vaccinated or boosted – and that is true for both Omicron and earlier variants. More than 76 percent of non-Omicron COVID infections in Denmark are in vaccinated people, along with about 90 percent of Omicron infections.¹⁷
4. On December 10, Reuters and MSN had reported that most (79%) of the 43 COVID-19 cases caused by the Omicron variant identified in the United States so far were in people who were fully vaccinated, and a third of them had received a booster dose.¹⁸
5. On December 19, fully vaccinated and boosted Senators Elizabeth Warren and Cory Booker both tests positive for COVID-19.
6. On December 27, the U.S. set a single-day record of new COVID-19 infections, with 441,278 new cases, according to the Centers for Disease Control and Infection, despite many already having vaccines and boosters.¹⁹
7. New York City sets new infection record after record even though a whopping 85 percent of all New York City residents have received at least one injection as of October 2021.²⁰ On Dec. 26, 2021, 189,714 new cases of COVID-19 were reported. Of those, 54,828 (almost 30%) came from New York City.²¹
8. On December 29, new infection records were made in the United Kingdom where one in 35 people now infected across the country and one in 20 infected in London.²²
9. On December 30, the U.S. set a world record: 489,267 new COVID cases in 24 hours, the most of any country in the world.²³
10. On December 30, 2021, the Robert Koch Institute, a German federal government agency and research institute, reported that 95.58% of Omicron cases in Germans are among the fully vaccinated, while 4% are among the unvaccinated.²⁴

<https://www.masslive.com/coronavirus/2021/12/massachusetts-reports-13919-new-breakthrough-covid-cases-over-last-week-as-state-ramps-up-testing-deploys-national-guard-to-bolster-hospitals-and-ambulance-service.html>.

¹⁷ Grok, G. (2021, December 22). *Denmark: 76% of Non-Omicron COVID Infections and 90% of Omicron Infections are Vaccinated!* The Blue State Conservative. <https://thebluestateconservative.com/2021/12/22/denmark-76-of-non-omicron-covid-infections-and-90-of-omicron-infections-are-vaccinated/>.

¹⁸ Roy, M. (2021, December 10). *Most reported U.S. Omicron cases have hit the fully vaccinated - CDC.* Yahoo News. <https://news.yahoo.com/most-reported-u-omicron-cases-182642515.html>.

¹⁹ Weixel, N. (2021, December 28). *US sets daily COVID-19 infection record.* The Hill. <https://thehill.com/policy/healthcare/587552-us-sets-daily-covid-19-infection-record/>.

²⁰ ‘Super Majority’: 85% of NYC Adults Have Received at Least 1st Dose of COVID Vaccine. (2021, October 14). NBC New York. <https://www.nbcnewyork.com/news/local/super-majority-85-of-adults-in-nyc-have-received-at-least-1st-dose-of-covid-vaccine/3322972/>.

²¹ Margolis, M. (2021, December 27). *Nearly 30% of New COVID Cases in America Came From One City.* Pjmedia.Com. <https://pjmedia.com/news-and-politics/matt-margolis/2021/12/27/nearly-30-of-new-covid-cases-in-america-came-from-one-city-n1544735>.

²² Walker, A. (2021, December 29). *Covid cases: UK reports record 183,037 new daily infections as Omicron surge continues.* MSN. <https://www.msn.com/en-gb/news/world/covid-cases-uk-reports-record-183037-new-daily-infections-as-omicron-surge-continues/ar-AASfw6p>.

²³ U.S., M. S. (2021, December 31). *US hits record of nearly 500,000 Covid cases in 24 hours: Experts says US will see “viral blizzard.”* Mail Online. <https://www.dailymail.co.uk/health/article-10355849/US-hits-record-nearly-500-000-Covid-cases-24-hours-Experts-says-viral-blizzard.html>.

²⁴ RKI - Startseite. (2022, July 6). Robert Koch Institute. https://www.rki.de/DE/Home/homepage_node.html.

The Committee should not fall for the fallacy of “mild disease if vaccinated” v. “severe disease without vaccination.”

Data shows that it’s not just “boostered” people usually who have mild COVID-19 symptoms, it appears that with these new variants practically everyone regardless of vaccination status seems to have mild symptoms. This data should not be ignored.

The FDA’s director of the FDA’s Center for Biologics Evaluation and Research **stated he would not hold up approval for efficacy, even if it was lower than the 50% efficacy threshold of preventing severe disease, as required in official FDA guidelines.**²⁵ The FDA shouldn’t need the reminder that America’s young children are *not* drug-safety research volunteers and should not be subject to being forced to take objectively ineffective COVID-19 vaccines. Additionally, the FDA’s failure to *comprehensively* address safety concerns will only undermine its goal of mass vaccination of kids.

According to one analysis, four million doses must be administered to children, 5 to 11 years of age, to prevent a *single* ICU admission in this age group.²⁶ Assuming two doses per child, that means two million children must risk potentially serious side effects to prevent a single child from requiring intensive care due to COVID-19. The Joint Committee on Vaccination and Immunisation (JCVI) has stated:

vaccination of children aged 5 to 11 years who are not in a clinical risk group would prevent a relatively small number of hospitalizations or intensive care admissions. For a variant like Omicron, it would take around four million vaccine doses to two million children to prevent one admission to ICU. For less severe illnesses, 58,000 child vaccinations would prevent one-child hospitalization. Children admitted recently to hospital with COVID had an average length of stay of 1-2 days. The Omicron wave saw no more children in hospital than before Omicron hit the UK.²⁷

Another analysis shows the COVID jab increases children’s risk of dying from COVID infection. Children under 18 are also 51 times more likely to die from the vaccine than they are to die from COVID infection if not vaccinated.²⁸

In other words: there is no clinical or epidemiological justification for vaccination in this particular group.

²⁵ *Following Briefing, Clyburn Vows to Hold FDA to Its Commitment to Review Coronavirus Vaccines for Young Children as Expeditiously as Science Allows.* (2022, May 9). House Select Subcommittee on the Coronavirus Crisis. <https://coronavirus.house.gov/news/press-releases/following-briefing-clyburn-vows-hold-fda-its-commitment-review-coronavirus>.

²⁶ Jenkins, J. (2022, February 20). 4 million doses in children needed to prevent 1 ICU admission. Stats Jamie. <https://www.statsjamie.co.uk/4-million-doses-in-children-needed-to-prevent-1-icu-admission/>.

²⁷ J. Jenkins. (2022, February) “Four Million Doses In Children Needed To Prevent One ICU Admission” <https://www.statsjamie.co.uk/4-million-doses-in-children-needed-to-prevent-1-icu-admission/>.

²⁸ Dopp, K., & Seneff, S. (2022, February). *COVID-19 and All-Cause Mortality Data by Age Group Reveals Risk of COVID Vaccine-Induced Fatality is Equal to or Greater than the Risk of a COVID death for all Age Groups Under 80 Years Old as of 6 February 2022.* https://www.skirsch.com/covid/Seneff_costBenefit.pdf.

Other foreign officials are more forthcoming. It's "time to admit failure," stated Israel's Professor Ehud Qimron, head of the department of microbiology and immunology at Tel Aviv University:

Two years [later], you finally realize that a respiratory virus cannot be defeated and that any such attempt is doomed to fail. You do not admit it, because you have admitted almost no mistake in the last two years ... it is clear that you have failed miserably in almost all of your actions, and even the media is already having a hard time covering your shame.²⁹

While it's nice to see public health officials and other scientists in Israel unafraid to advocate for evidence-based findings, why aren't any of the career employees at the so-called "independent" federal public health agencies such as the CDC and NIH—and especially the FDA—speaking out now in support of irrefutable safety and efficacy findings? The FDA and the advisory committee members should consider and follow Professor Qimron's lead.

The Committee should find that infants, children, and adolescents never needed COVID-19 vaccines, and certainly not so now.

There are two central questions that this Committee should not ignore.

The first is whether vaccination of children *is even needed at all*. We are no longer deeply embedded in the throes of the pandemic. In addition, there is a well-established low risk of serious COVID complications in children without vaccination, especially when the original version of COVID-19 that the vaccine was developed for no longer responsible for 99% of the cases,³⁰ new variants being much less severe, and the widespread availability of therapeutics with known safety records, mask-wearing, and social distancing as alternate protective measures.

The second question is whether children who have naturally acquired immunity through previous infections should be vaccinated—something being totally omitted by the EUA.

Primary approval for young children is not the same as the *emergency* approval of COVID vaccines for adults in 2020. Children are physiologically distinct from adults (*i.e.*, they are not just smaller people). Since we do not have a full accounting of safety, especially long-term risks, in adults, it is inappropriate that to propose mass vaccination in children. The risk COVID-19 presents to children is minuscule.³¹ Multiple studies have detailed in no uncertain terms that it's hard to justify vaccinating the younger age group *at all* because severe disease and

²⁹ Charbonneau, D., PhD. (2022, January 14). 'Time to Admit Failure,' Leading Immunologist Tells Israel's Ministry of Health. Truth. Based. Media. <https://truthbasedmedia.com/2022/01/13/time-to-admit-failure-leading-immunologist-tells-israels-ministry-of-health/>.

³⁰ David Gortler (April 2022) If Monoclonal Antibody EUAs Are Being Revoked, Shouldn't COVID Vaccine Approvals Be as Well? <https://pjmedia.com/columns/davidgortler/2022/04/11/if-monoclonal-antibody-euas-are-being-revoked-shouldnt-covid-vaccine-approvals-be-as-well-n1588211>.

³¹ Wallace-Wells, D. (2021, July 12). *The Kids Are Alright*. Intelligencer. <https://nymag.com/intelligencer/2021/07/the-kids-were-safe-from-covid-the-whole-time.html>.

hospitalization are so rare.³² Yet the FDA’s homepage still pictures and advocates for young adolescents and little kids getting vaccinated despite their negligibly low risk.³³

At the same time, adverse events seem to disproportionately affect a younger population.³⁴

It breaks all FDA norms and practices for the FDA to leap into an EUA so blindly and ignore decades-old standards of making careful and objective findings, *especially* when we are talking about children. Leaving the bioethics argument and question of using our children as test subjects aside: Whatever happened to using hard clinical and scientific evidence as the basis for making decisions? What about the FDA physicians’ centuries-old sacrosanct vow of “doing no harm?”

As someone who has committed the past two decades of his life to drug epidemiology and drug safety and served as adviser to the former FDA commissioner on the same, I encourage the FDA to rely on its objective historical standard of drugs needing to be comprehensively tested for safety before recommending them. But what we’re seeing is the moral bankruptcy equivalent of what Ernest Hemingway once said about actual bankruptcy, which comes “gradually, then suddenly.” The FDA, White House, and media appear to be “all in” on endless COVID vaccinations for all regardless of objective risk/benefit assessments. The data be damned.³⁵

The FDA’s lack of drug-safety transparency and unrelenting push for seemingly unnecessary and apparently unsafe COVID-19 vaccines is nonsensical, as is the FDA panel’s abandonment of basic safety standards that have served the FDA well for nearly a century. It is time for the FDA advisory committee members to stop blindly listening to the federal agencies, the White House, and mainstream news narratives for advice on clinical pharmacology and use their credentials, start their research from scratch and examine the safety, efficacy, and natural immunity data themselves.

In summation: There is no emergency requiring the use of the truncated EUA approval process for COVID-19 vaccines for children. Infants, children, and adolescents all have a *decreased benefit* from COVID-19 vaccination, but a *greater safety risk*. Many have already had COVID and have the benefits of naturally acquired immunity. The Committee should follow the data not politics and reject the EUA proposals. Our children deserve no less.

³² Healy, M. (2021, October 30). *Analysis: Do we vaccinate kids if pandemic’s end is near?* Los Angeles Times. <https://www.latimes.com/science/story/2021-10-28/its-harder-to-justify-covid-vaccine-for-kids-if-pandemics-end-is-near>; Bendix, A. (2021, June 24). *The Delta variant may be making COVID-19 more common in kids — but severe infections are still rare*. Business Insider. <https://www.businessinsider.com/delta-variant-covid-risk-to-children-kids-2021-6?international=true&r=US&IR=T>.

³³ *FDA Home Webpage*. (2022). U.S. Food and Drug Administration.

<https://web.archive.org/web/20220320211847/http://web.archive.org/screenshot/https://www.fda.gov/>

³⁴ Gortler, D. (2022, May 3). *Why Aren’t The FDA And CDC Informing The Public About Documented Adverse Events After mRNA Injections?* The Federalist. <https://thefederalist.com/2022/03/25/why-arent-the-fda-and-cdc-informing-the-public-about-documented-adverse-events-after-mrna-injections/>; Gortler, D. (2022b, May 6). *CDC Tells New York Times It Hid Covid Data For Political Reasons*. The Federalist.

<https://thefederalist.com/2022/03/22/cdc-tells-new-york-times-it-hid-covid-data-for-political-reasons/>.

³⁵ MacMillan, C. (2022, May 20). *COVID-19 Vaccine Authorized For Kids Ages 5 to 11: What Parents Need to Know*. Yale Medicine. <https://www.yalemedicine.org/news/covid-vaccine-for-ages-5-to-11>.