FDA COVID-19 Update on Vaccines
Data reveals questions on efficacy

The 170th meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) was held on April 6th.

https://www.youtube.com/watch?v=laaL0_xKmmA

"The committee will meet in open session to discuss considerations for use of COVID-19 vaccine booster doses and the process for COVID-19 vaccine strain selection to address current and emerging variants"

The FDA now recommends a second booster dose of Pfizer or Moderna for older and immunocompromised individuals at 4-month intervals. Even though the FDA recognizes there is a reduced efficacy in the vaccines over time, it still maintains its view that boosters are necessary.

During the meeting Dr. Peter Marks, Director for Biologics Evaluation and Research, suggested that boosting every 4-6 weeks is not sustainable and that people are exhausted and fed-up with vaccinations.

The day's presentation included a Public Hearing Session. There were many presenters objecting to continuing vaccine EUA authorizations, especially for children. Jessica Rose, Ph.D, an expert on the U.S. Vaccine Adverse Effects Reporting System (VAERS), presented her slides showing the number of adverse events and reported deaths (specifically myocarditis) in children and recommended a no vote to vaccinating children.

Another expert was David Wiseman, PhD, presenting 22 slides revealing that vaccine efficacy of the mRNA products wanes significantly after the first four months. In fact, vaccine effectiveness after two doses or a booster, immunity wanes from 60% effective to 20%. Shockingly the data also reveals that with the third (booster) dose vaccine efficacy drops *below zero.* What this means is that with increasing doses the vaccines make a person '*more'* susceptible to contracting COVID. We can now categorically say the benefit of boosting is getting smaller and smaller.

Dr. Wiseman also presented slides showing all-cause mortality *increased* following vaccine inoculations. In 23 countries in Europe data has revealed there were *more deaths from all causes* following vaccine booster doses. We are now giving people multiple exposures to these products. Why hasn't this knowledge been available to the public and why are we not having a national discussion on this?

During the committee's presentation there were no discussions of VAERS reported vaccine injuries. However, 10 presenters were among the vaccine injured sharing their horrific stories of significant injuries following the vaccinations. All of them had signed up for the vaccines thinking they were doing their part. Not one of their stories was

acknowledged by the committee. It was as if they didn't exist. The committee just moved on with little discussion of vaccine safety.

The consensus among those experts presenting during the public hearing session was that an Emergency Use Authorization for children is premature given there is not sufficient safety data and authorizing vaccinations for children will do more harm than good.

At the end of the day the committee cast its vote on the question, "Based on the totality of scientific evidence available, do the benefits of the Pfizer-BioNTech COVID-19 Vaccine when administered as a 2-dose series (10 ug each dose, 3 weeks apart) outweigh its risk for use in children 5-11 years of age? The vote was 17 yes, 1 abstain.

It was apparent the committee did not take into account any of the scientific data presented by the experts during the public hearing session.

Other discussions by the committee during the day included:

- There were too many considerations and all these will take time and additional data before there is clarity on whether it is wise to keep developing vaccines for emerging variants.

- Sars-Cov-2 variants have not appeared in a predictable seasonal pattern. The virus mutates 2.5 time faster than the flu. How can vaccine development keep pace with emerging variants?

- Immunogenicity and effectiveness data indicate that current COVID-19 vaccines provide insufficient protection against circulating variant viruses.

- Should we really continue with vaccinating? Maybe we should concentrate on developing therapeutics, such as antivirals.

- More data on antibody levels is needed in people who have recovered from COVID. (The latest batch of Pfizer documents confirm acquired immunity is as effective as the vaccine at preventing severe illness).

- More safety and efficacy studies are needed.

Given the vast amount of scientific data presented during the meeting, the public will now have to consider what is best in agreeing to further boosters. Of utmost importance, however, is a parent's decision on whether to vaccinate their children and decide for themselves if the benefits outweigh the risks. It is clear we are lacking long-term safety data on the mRNA products when it comes to vaccinating children. From the data presented to the committee, 2-dose vaccine efficacy wanes rapidly, additional boosting has negative efficacy, and all-cause mortality increases with additional dosing.

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