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FDA Systematically Excluding Meaningful Scientific Input

The Vaccine Considerations Project will be holding the FDA to account during its presentation at the FDA Advisory Committee meeting on October 15th.

Live meeting on YouTube: https://youtu.be/c-H40GrvWz4

The Vaccine Considerations Project, will be one of only three presenters at 11am EST on October 15th, in the <u>Open Public Hearing Session of the FDA Advisory</u> <u>Committee's meeting</u> to address boosters for the Johnson & Johnson vaccine.

Jared Krupnick, the founder of the Vaccine Considerations Project has had enough of what he calls the FDA's disingenuous and shameful process for soliciting public input on critical decisions of national importance.

"Quite frankly, if each one of you had the personal and professional integrity that Dr. Gruber and Dr. Krause have demonstrated, you would all refuse to participate in a process that is looking more and more like a rubber stamp than a thoughtful, scientific consideration."

- excerpt from Krupnick's planned presentation to the FDA Advisory Committee on 10/15

Krupnick is referring to the two senior FDA leaders, Marion F Gruber, PhD and Philip R Krause, MD, who recently announced their sudden departure from the FDA, and subsequently were co-authors of an article critical of booster considerations within the United States. "Careful and public scrutiny of the evolving data will be needed to assure that decisions about boosting are informed by reliable science more than by politics." - <u>The Lancet</u>

"The FDA can't keep saying, 'Trust us because we follow the science,' when they consistently make a mockery of the scientific process, which is based on peer review," says Krupnick.

"Deadline to apply to present today - a week ago.

Deadline for slides and written comment submission - three days ago.

Public release of most of the data being considered today - two to three days ago.

Are any of you troubled by the fact that thousands of your colleagues across the country have been systematically and procedurally excluded from providing their meaningful input, not just for this meeting, but for meeting after meeting, for a year now, by unnecessarily tight scheduling that consistently has feedback deadlines nearly simultaneous to, or before data is released?" - excerpt from Krupnick's planned presentation to the FDA Advisory Committee

This will be Krupnick's third presentation to the FDA since he founded the Vaccine Considerations Project a year ago (<u>First Presentation - 12/10/20</u>; <u>Second</u> <u>Presentation - 2/26/21</u>).

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http://VaccineConsiderations.com



Mission - Help people make informed decisions and take effective actions by providing science-based, expert COVID-19 vaccine information.

The Vaccine Considerations Project has assembled a Team of graduate and undergraduate interns from across the country, working to help people make informed decisions and take effective actions by providing science-based, expert COVID-19 vaccine information.

One of the interns, James Rios, a Masters in Economics candidate from FIU, was one of only seven presenters at the 10/14 <u>FDA Advisory Committee meeting</u>.

Another intern, Katie MacQueen, a Masters of Public Health candidate from the Colorado School of Public Health, will share the Vaccine Considerations Project's 5-minute presentation time with Krupnick at the 10/15 meeting.