

Pantazatos, Spiro P.

From: Pantazatos, Spiro P.
Sent: Friday, August 26, 2022 12:25 AM
To: Racaniello, Vincent R.
Subject: RE: Help us ensure CU does not mandate another booster

Dear Vincent,

I agree that is also an issue. In terms of safety, the FDA's own risk-benefit analysis strongly suggests the booster poses more risk to males 16-19. Below I paste my own summary of the FDA's memo to recommend the 3rd booster in this age group. Please let me know if you think I missed something in my analysis. The full document is worth a close read.

Best regards,
Spiro

1. The FDA's recommendation to administer a single homologous Pfizer booster dose to individuals 16 to 17 years of age was based on a risk-benefit assessment (conducted by Pfizer) and also discussed data from Pfizer's placebo-controlled booster clinical trial which include 78 individuals ages 16-17 yrs old (out of 10,125 total in in the trial)¹. Even with only ~39 participants in the booster arm, 1 case of myopericarditis was observed, while 2 cases of symptomatic COVID-19 (neither resulting in hospitalization) occurred in the placebo arm in this age group. In their risk-benefit analysis, Pfizer predicted that boosters would prevent 29-69 COVID-associated hospitalizations per 1M booster doses which would come at a cost of 11-54 and 23-69 myopericarditis cases per 1M booster doses in 16-17 and 16-19 yr age groups, respectively (see Table 1 on pg 7 of the memorandum). There are several important things to note about the risk-benefit assessment. First, 'COVID-associated hospitalizations' is not a good comparison with myocarditis cases because 'COVID-associated hospitalizations' need not be *due* to COVID². Second, Pfizer's own analysis suggested boosters would prevent as many 'COVID-associated hospitalizations' as myocarditis events following boosters. Third, Pfizer's myocarditis incidence rates used for their risk-benefit assessments are for the 2nd dose (not booster), and the risk is underreported since it is based on passive surveillance (VAERS). Most importantly, Marks goes on to note that Pfizer's estimates of myocarditis risk post 2nd-dose in 16-17 year old males is about 6-7x lower than the risk estimated by the FDA's own analysis of the Optum healthcare claims database (200 cases 1M). In other words, the letter presents data suggesting boosters will cause 6-7x more cases of myocarditis (many or most which result in hospitalizations) than a 'best case scenario' estimate of hospitalizations prevented in males 16-17 yrs old (assuming Pfizer's assumptions about effectiveness against hospitalizations were accurate), and yet still recommended the booster for this age group.

Endnotes

1. <https://www.fda.gov/media/154869/download>
2. https://gis.cdc.gov/grasp/COVIDNet/Documents/320393-A_COVID-NET_cumulative-geo2.pdf

From: Racaniello, Vincent R. <vrr1@cumc.columbia.edu>
Sent: Wednesday, August 24, 2022 6:53 AM

To: Pantazatos, Spiro P. <spp2101@cumc.columbia.edu>
Subject: Re: Help us ensure CU does not mandate another booster

Why do you think the booster poses more risk than getting COVID-19 itself? That is not the issue; rather it is that we do not know if the booster will provide any benefit.

It's best if you go ahead with your email without my signature as we are clearly on different pages.

Vincent

From: "Pantazatos, Spiro P." <spp2101@cumc.columbia.edu>
Date: Tuesday, August 23, 2022 at 9:25 PM
To: "Racaniello, Vincent R." <vrr1@cumc.columbia.edu>
Subject: RE: Help us ensure CU does not mandate another booster

Thanks for your response. I'm not sure I follow the logical behind the example you give. Would you be able to expand more on why you think the mandates are "ethical"?

While I would agree that it is "legal" for Columbia to mandate an FDA-approved product, I don't see how it can be "ethical" if the product poses more risks than benefits to the population, and those risks are not divulged to give true informed consent (i.e. the CU FAQ on vaccine safety does not mention myocarditis riskin young males with the Pfizer and Moderna vaccines, only stroke risk from the Janssen vaccine in women under 50).

About 4,500 FDA approved products are recalled each year (<https://www.drugwatch.com/fda/recalls/>) so just because a product is FDA-approved does not mean it is sufficiently safe. But even if the COVID vaccines were perfectly safe, mandating them essentially amounts to discrimination on the basis of innate biological characteristics, which is unethical as argued in <https://jme.bmj.com/content/48/4/240>

Vaccine mandates also restrict "people's access to work, education, public transport and social life based on COVID-19 vaccination status" and "impinges on human rights, promotes stigma and social polarisation, and adversely affects health and well-being." as argued in <https://pubmed.ncbi.nlm.nih.gov/35618306/>

Kind regards,
Spiro

From: Racaniello, Vincent R. <vrr1@cumc.columbia.edu>
Sent: Monday, August 22, 2022 9:32 AM
To: Pantazatos, Spiro P. <spp2101@cumc.columbia.edu>
Subject: Re: Help us ensure CU does not mandate another booster

Before you add my name to any email I need to see the exact text of what will be sent out. For example, you cannot say that mandating the vaccine is 'unethical'. Columbia is a private institution and that can mandate an FDA-approved vaccine. Before you make such proclamations you should check your facts.

Vincent

From: "Pantazatos, Spiro P." <spp2101@cumc.columbia.edu>
Date: Sunday, August 21, 2022 at 2:00 PM
To: "Racaniello, Vincent R." <vrr1@cumc.columbia.edu>

Cc: [REDACTED]
Subject: RE: Help us ensure CU does not mandate another booster

Dear Vincent,

Thank you for signing the petition, and for bringing my awareness to your blog/podcast, I greatly appreciate it. I will aim to include and cite it in the letter this week.

Unfortunately, I was unaware of your efforts until just now as I'm not a trained virologist. I have been approaching the issue from the side of statistics applied to publicly available data in order to calculate accurate and reliable adverse event incidence rates to aid in risk-benefit assessment across age groups. So in this sense, the issue is up my alley since much of my previous training and research experience is in health and clinical informatics, biomedical data science as well as evidence synthesis/integration.

That said, I agree that my official title/affiliation does not make it immediately apparent what skills/authority I bring to the issue.

With your permission, can I include your names and signatures in my emails to CU members going forward? It definitely adds special weight behind the effort. I have just begun the email campaign (Outlook is not well suited for mass emails and I can only send them out in batches of 500). I may also reach out to Dr. Scully for his permission to include his signature in the emails as well since he is an MD with clinical experience in infectious diseases division and co-chairs the infection control committee at NYP (he signed the petition and also gave some feedback on the letter).

Kind regards,

Spiro

From: Racaniello, Vincent R. <vrr1@cumc.columbia.edu>
Sent: Friday, August 19, 2022 8:34 AM
To: Pantazatos, Spiro P. <spp2101@cumc.columbia.edu>
Cc: [REDACTED]
Subject: Re: Help us ensure CU does not mandate another booster

Hello Spiro,

I have been a professor of microbiology & immunology at CUMC since 1982, working on viruses. Since 1982 I have been publishing the weekly podcast 'This Week in Virology' which in the past 2 years has mainly focused on the COVID-19 pandemic. We have been constantly arguing against the need for a booster beyond the first (which did in fact expand antibody neutralization to include all variants up to Omicron).

I agree that an Omicron specific booster is not needed. We discussed this issue with Paul Offit who is a vaccinologist at U Penn; there is no evidence that such a booster will be beneficial. Please see his episode:

<https://www.microbe.tv/twiv/twiv-917/>

While I agree that Columbia should not mandate an Omicron booster in the fall, and I will sign your petition, I do not feel that this initiative carries so much weight when delivered by a clinical neurologist. I do not mean to impugn your skills but throughout this pandemic, problems have continually arisen by individuals not 'staying in their lane'.

You should have known about our communication work in this area and reached out to me to co-sign your email.

I am copying my virology colleague Dr. Amy Rosenfeld on this email. She shares these views on boosters.

My stance on this matter has been clear to the public for months.

Vincent

Vincent Racaniello, Ph.D. | Higgins Professor
Department of Microbiology & Immunology
Columbia University, New York

virology.ws | microbe.tv

From: "Pantazatos, Spiro P." <spp2101@cumc.columbia.edu>

Date: Friday, August 19, 2022 at 2:34 AM

Subject: Help us ensure CU does not mandate another booster

Dear colleague,

An [omicron specific booster](#) will be [rolled out this fall](#), carrying with it the possibility that it may be mandated by CU in late fall or winter.

[Available empirical evidence](#) shows that neither the current nor imminently available COVID vaccines and boosters will prevent transmission, are unnecessary in people with prior infection, and their risk-benefit is unfavorable for the large majority of CU members facing the mandates, such as young adults who are at extremely low risk from the virus (i.e. $\leq 0.006\%$ infection fatality rate following exposure to wild type/delta strain for ages under 25 yrs).

If you would like to learn more about why the mandates are a bad idea (and unethical), please see this Google docs [letter](#) that includes over 100 citations with up-to-date science and supporting data.

If you agree that we do not need any more COVID vaccine or booster mandates, please sign our [online petition using this Google form](#).

The letter was delivered to the President's Office on August 1st and includes a link to the online version which serves as a living document. Please leave a comment on the letter or reply to this email if you have any feedback or suggestions, or if you believe the mandates are a good idea (but please read the [letter](#) first).

If you believe CU needs to change course on its COVID vaccine policies, please help us send this message to CU leadership by [signing the Google forms petition](#).

Much appreciation in advance for your time and attention to this important matter.

Kindest regards,
Spiro

Spiro Pantazatos, PhD
Assistant Professor of Clinical Neurobiology

