March 2, 2023

Delegate Joseline Peña-Melnyk Chair House Health and Government Operations Committee

RE: House Bill 699: State and Local Government - Proof of Vaccination for Employees and Applicants for Employment- Prohibition (Vaccination by Choice Act)

Position: Favorable with Amendment

Dear Chair Peña-Melnyk and Members of the Committee:

Thank you for the opportunity to voice my strong support for this bill with the amendment that applies to state of Maryland universities.

I'm Peter Doshi. For identification purposes, I am on the faculty at the University of Maryland School of Pharmacy and an editor at the medical journal, *The BMJ*. I have no relevant financial conflicts of interest and my comments are my own, not those of the University of Maryland or *The BMJ*.

About me and my scholarship on this topic

Briefly, let me share a few words about myself and my scholarship on the topics of vaccines, public health policy, and pandemics: I hold a PhD from MIT, and I am an Associate Professor (with tenure) in the Department of Practice, Sciences, and Health Outcomes Research at the University of Maryland School of Pharmacy.¹ I teach a required course in the PharmD curriculum, "Medical Evidence," which trains students in skills necessary to critically appraise the scientific literature. I research the drug and vaccine approval process, how the risks and benefits of medical products are communicated, and how to improve the credibility and accuracy of evidence synthesis and biomedical publications. At the University of Maryland, I lead the RIAT Support Center which aims to accelerate the correction of the scientific record of clinical trials by making clinical trial publications more accurate and more complete, addressing these problems of publication bias and reporting bias.² I have received national recognition for my work on clinical trial data transparency.³

¹ <u>https://faculty.rx.umaryland.edu/pdoshi/</u>

² <u>https://restoringtrials.org/</u>

³ https://www.nytimes.com/2013/06/30/business/breaking-the-seal-on-drug-research.html

My credentials related to the topics of vaccines, public health policy and pandemics are that I have studied influenza policy since around 2004. I have dozens of peer reviewed publications on the topic, and my PhD dissertation is on the topic of CDC and WHO influenza and pandemic control policies (primarily vaccines).

Since 2020, I have written and spoken on many occasions on the topic of covid.⁴ This includes lay media commentaries in the *New York Times, Washington Post, Baltimore Sun, Scientific American*, and *STAT*, as well as scholarly writing for *The BMJ* and testimony at multiple FDA Advisory Committee meetings regarding covid-19 vaccines. I am the senior author of a peer-reviewed research paper on serious adverse events following mRNA covid-19 vaccination, published in a leading vaccinology journal, *Vaccine*.⁵

My opinion on the bill

I support this bill with the amendment that applies to State of Maryland universities. In general, I oppose mandating medical interventions. I think they are incompatible with the duty of informed consent, a fundamental principle in medical ethics. Among medical interventions, vaccine mandates in particular have a long legacy of being socially corrosive and eroding public trust, irrespective of their impact on health metrics. I think the United States can learn much from the United Kingdom, Denmark, and Japan, where there are high overall vaccination rates without any general mandate for any vaccines.

With respect to covid, and separate from the reasons set forth in the above paragraph, there are at least four distinct, additional reasons why I think covid vaccine mandates in particular cannot stand. I regard each of these four reasons, on their own, to constitute sufficient reason to reject mandates. For those who have been of the conviction that the circumstances in 2021 and onwards justified mandates, I implore you to consider these four points.

- Wrong product. The mandate was and is based on a critical assumption that the available products (Pfizer, Moderna, and J&J covid-19 vaccines) stop the transmission of SARS-CoV-2. But this assumption was never properly tested or proven and it is now widely accepted that these products do not halt transmission.⁶
- 2. Wrong target. There is no practical means of exempting from the mandate those people who have already experienced a SARS-CoV-2 infection. It is essential to exclude people with past infections because this is a population in which there is strong reason to predict the average harms will outweigh the average benefits. On average, harms will outweigh benefits because natural immunity affords strong protection against severe disease, thus even a highly effective vaccine cannot substantially improve that

 ⁴ See <u>https://faculty.rx.umaryland.edu/pdoshi/#publications</u> for a list of 47 such publications/speaking events.
⁵ Fraiman J, Erviti J, Jones M, Greenland S, Whelan P, Kaplan RM, Doshi P. Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. Vaccine. 2022 Sep 22;40(40):5798-5805. https://doi.org/10.1016/j.vaccine.2022.08.036. Epub 2022 Aug 31. PMID: 36055877; PMCID: PMC9428332.
⁶ For many details and citations supporting this point, see pages 2-4 of https://downloads.regulations.gov/FDA-2023-P-0360-0001/attachment_1.pdf

protection, as the risk of severe complications following a SARS-CoV-2 infection is very low for the vast majority of those who have been previously infected. On the flip side, however, adverse events following mRNA vaccination are common, and multiple surveys indicate that the adverse event profile in those with past infections is worse than it is among those who are SARS-CoV-2 naïve.⁷ Serious adverse events also appear to be far more common than generally appreciated. In the Pfizer trial, for example, we found that there was one additional serious adverse event for every 555 vaccinated individuals.⁸ The number of people with past SARS-CoV-2 infections was substantial at the time mandates were put into place at the University of Maryland, but no matter the number of people affected, the important point is that these people could not be excluded from a mandate. This is because there do not exist accurate tests for determining who is already immune. Antibody tests cannot detect all past infections. We therefore have never had an adequate means of excluding a population of people from the mandate in whom we can predict harms will outweigh benefits, and thus the mandate can't stand.

- 3. Wrong context. Covid vaccine mandates have always been socially unacceptable in American society. Separate from the effects a mandate might have on parameters such as covid cases, hospitalizations, or deaths, mandates also have effects on the social fabric of our society—and I would argue that mandates have helped exacerbate social divisions. Though unintended, this is a profoundly negative consequence, and any policy decision must consider both intended as well as unintended consequences. People who feel coerced will understandably feel angry, resentful, and lose trust in the system. Mandates have also enabled "vax-or-mask" type policies which segregate and stratify people into vaccinated vs. unvaccinated. Such policies are socially divisive, and should not be part of any society that values civility, inclusivity, diversity, and social justice.
- 4. No data. There must be full and immediate public access to data for any mandated product. But for covid vaccines, complete data is not publicly available. For example, if you are interested in analyzing the data for Pfizer's phase 3 vaccine trial, you will have to wait until February 2025 before you can even request it from the company.⁹ (Pfizer has indicated that it will not begin entertaining requests for trial data until 24 months after the primary study completion date, which is listed on ClinicalTrials.gov as 10 February 2023.¹⁰)

⁷ Menni et al. Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID Symptom Study app in the UK: a prospective observational study. Lancet Infect Dis. 2021 Jul;21(7):939-949. <u>https://doi.org/10.1016/S1473-3099(21)00224-3</u>. Epub 2021 Apr 27. PMID: 33930320; Mathioudakis et al. Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: A Vaccine Recipient Survey. Life (Basel). 2021 Mar 17;11(3):249. https://doi.org/10.3390/life11030249. PMID: 33803014.

⁸ See Table 2 of Fraiman J, Erviti J, Jones M, Greenland S, Whelan P, Kaplan RM, Doshi P. Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. Vaccine. 2022 Sep 22;40(40):5798-5805. <u>https://doi.org/10.1016/j.vaccine.2022.08.036</u>. Epub 2022 Aug 31. PMID: 36055877; PMCID: PMC9428332.

⁹ Doshi P, Godlee F, Abbasi K. Covid-19 vaccines and treatments: we must have raw data, now. BMJ. 2022 Jan 19;376:o102. <u>https://doi.org/10.1136/bmj.o102</u>. Erratum in: BMJ. 2022 Jan 24;376:o189. PMID: 35045956. ¹⁰ https://clinicaltrials.gov/ct2/show/NCT04368728

The illusion of a consensus among scientists

My message for the Maryland House of Delegates is to please not assume you know what scientists in academia think about this topic unless you have asked them for their views and offered them a chance to speak off-the-record. (Speaking off the record is important in order for them to be frank, without fear of the consequences of 'misspeaking.')

The mandate at the University of Maryland was instituted by University System of Maryland to improve the "safety of our people, our campuses, our communities."¹¹ Whether or not the mandate achieved that goal is an important question but not the point I wish to focus on here—my point here is that the stated purpose of the mandate was to improve public safety. As such, the implementation of a mandate creates an environment in which voicing support for the mandate is construed as believing in the goal of improving public safety and voicing concern about a mandate is construed as showing a disregard for public safety.

Voicing concerns about the mandate can thus become viewed as acts of disobedience—the dissenter is questioning authority, and in doing so, jeopardizing public safety—even if the dissenter harbors no such ill intentions. The real and perceived negative consequences of freely sharing one's views are thus strong incentives to stay silent.

I personally know many clinicians and academics who have self-censored for exactly these reasons. They guard their thoughts, ensuring that their academic colleagues do not know what they actually think.

When this is not just an isolated individual, but a phenomena across entire campuses, it has some very deleterious downstream effects. When the voices of those with doubts cannot be heard around water coolers, in meetings, symposia, and in the press, this has the effect of rarifying the discourse, leaving it dominated by those who voice opinions largely in agreement with policies like mandates and producing a misleading appearance of "scientific consensus."

It is worth remembering that mandates in academic institutions did not follow a conscious deliberation among academic faculty who debated the pros and cons. It was mandated without any broad deliberation among academic faculty, even on campuses full of professionals and researchers in the biomedical sciences. Even to this day, despite the magnitude of impact mandates have on livelihoods, I am unaware of any university that has hosted a major forum to debate the wisdom of the policies implemented.

I implore you to not assume there is a scientific consensus about covid-19 vaccine mandates without first figuring out how to accurately assess what people actually think. I believe there is a diversity of opinions over this matter among the relevant specialists, that should be taken into consideration.

¹¹ https://www.usmd.edu/newsroom/news/2154

Data have not been sufficiently assessed by independent researchers

I have been assessing evidence on covid-19 vaccines—particularly the clinical trials—as closely as I possibly can for the past 2.5 years. One might hope, given the effort to vaccinate the planet, that the great majority of biomedical scientists would similarly devote a significant amount of their attention to independently scrutinizing all the evidence they possibly can.

My observation, however, is that a surprisingly small number of academics (a very small minority) have independently scrutinized the data. As an anecdote to illustrate the point, last November I noticed, for the key Moderna phase 3 clinical trial, that a vital study document was missing. It was listed in the journal article, but if one looked carefully at the time, the 125-page original trial protocol was not there. I notified the journal editors. Two days later, they posted the 125-page document.¹²

This is a critical study document – a trial cannot occur without a study protocol. But if two years after the file was supposed to be available, I was the first person to notice this and bring it to the journal's attention, I submit to you that we have a real problem: there is not a vast safety net of people out there scrutinizing every detail, ensuring that everything is trustworthy. Far from it. I submit that the more likely scenario is that we are seeing a continuation of a long legacy of the classic problems of under and mis-reporting that go uncorrected in large part because too few people are aware of the scope and depth of the data requiring critical scrutiny.

Instead of a scenario where thousands of people are independently pouring over every detail, it seems to me that we have a situation in which the vast majority of researchers with adequate expertise to independently review the evidence have not done so. And even if they wanted to do so, the necessary complete data has not yet been made available (see point #4 above). They, like ordinary Americans, are relying on somebody else to have done the work. But it cannot be in the best interests of the public that we are left to just trust "in the system" with an unverifiable hope that the right decisions will be made.

Sincerely, Peter Doshi, PhD[†] Associate Professor Department of Practice, Sciences, and Health Outcomes Research University of Maryland School of Pharmacy Baltimore, Maryland [†] My organizational affiliation is included for identification purposes only.

¹² <u>https://youtu.be/xPUiHrflJos?t=1940</u> (see video at 32:20 minute mark)