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 colleges and universities. My name is Linda Wastila. For purposes of identification, I am professor and Endowed Chair in Geriatric Pharmacotherapy in the Peter Lamy Center on Drug Therapy in Aging at the University of Maryland Baltimore School of Pharmacy<sup>1</sup>.

Today I wear two hats—the first, as a drug safety scientist, the second, as mother to two children who attended colleges in the University System of Maryland during the mandates. I have no financial conflicts of interest and my opinions are my own, not those of my employer.

## About Me

I specialize in analyzing large data bases to examine the intended and unintended consequences of pharmaceutical policies on vulnerable populations. I received my pharmacy and public health degrees from the University of North Carolina-Chapel, and my doctorate in social welfare policy from Brandeis University. Since coming to UMB in late 2001, I have authored over 100 peer-reviewed publications based on research funded by NIH, CMS, FDA, SAMHSA, the Maryland Department of Health, and others. In addition to teaching in the pharmacy and doctoral program, I have successfully mentored nearly a dozen doctoral students and, in 2016, received one of our campus' highest awards—Founder's Day Researcher of the Year.

My scholarship has focused on medication utilization and outcomes surrounding mental health and substance use disorder policy. Since 202, I have written and spoken on the topic of covid. These include letters and commentaries in the *Baltimore Sun*, the *British Medical Journal*, and various podcasts and substacks. As well, I have several peer-review publications on COVID policies in nursing homes. I have provided testimony to CDC and FDA Advisory Committee meetings regarding COVID-19 vaccines, participated in a hearing on Capitol Hill, and am signatory author on two Citizen Petitions presented to the Food and Drug Administration.

## My Opinion on the Bill

I fully support this bill with amendment. My reasons stem from multiple sources, including scientific evidence, philosophical and moral arguments, and deeply-held religious beliefs. Today, however, my rational for supporting this bill with amendment arise from the science around safety concerns of the vaccines, lack of access to safety data as violating informed consent of individuals coerced or otherwise pressured to take the vaccine through the guise of mandates, and my personal concerns as a parent.

<sup>&</sup>lt;sup>1</sup> <u>https://faculty.rx.umaryland.edu/lsimoni-wastila/</u>

#### The Impetus to Investigate

On April 23, 2021, my professional and personal lives were upended by a system-wide memorandum emailed to all faculty, staff, and students. The email noted that vaccination with then unapproved, emergency authorized COVID-19 products would be required to return to campus in the fall. There was no language in that email regarding the consequences of not complying, nor was there information on whether exceptions would be made, for medical and/or religious reasons.

I take my position as a scientist seriously. It is my job to ask questions—and seek answers. This questioning and seeking embody the scientific process. As a scientist, I was familiar with previous—and unsuccessful—applications of the vaccines' mRNA platform for products in development for HIV, cancer, and the common cold. As a scientist whose research focuses on drug safety, the mandated use of these experimental vaccines for ALL individuals involved in the USM chilled me. As a clinically-trained health professional, I also concluded the COVID-19 virus posed negligible risk to most populations, including college-aged students.

I also take my role as a parent seriously. As mother to two college students in the system, one of whom was chronically ill from tick-born diseases, the mandate petrified me. How could I assure the continuation of my children's college education without potentially endangering their safety? Emails to the Chancellor's office regarding clarifications to the policy and consequences if disregarded went unanswered. I received similar non-responses from my campus' HR department, as well as from the Towson offices. My children and I spent much of our summer panicked about our uncertain futures.

It wasn't until late July that my Human Resources department posted information on medical and religious exemptions. The process for submitting was onerous and directions vague. As well, there was no clarification by administration of what would happen if one failed to get vaccinated. By then, most of my colleagues and most of my students were fully vaccinated, many unwillingly, never aware of the possibility of requesting exemptions.

## The Quest for Answers

The lack of information and transparency from USM and state public health leadership on the vaccine mandate, coupled with the media- and reward- fueled vaccine roll-out, drove my decision to investigate the limited evidence to date on the efficacy and safety of the COVID-19 vaccines. I felt the regulatory process was rushed for the vaccines, which further raised my concern there was insufficient safety evidence, especially long-term safety. The trial data presented by the manufacturers to the FDA for Emergency Use Authorization focused only on short-term adverse events; there were no animal studies on longer-term harms.

With colleagues, I delved into the limited data. We uncovered information provided to other nations' regulatory agencies. Pivotal to me was information provided by Pfizer and Moderna to the Japanese regulatory agency (but not the US FDA) demonstrating wide biodistribution of the vaccine in rats to many organs of the body, including the brain, testes, ovaries, adrenals, and bone.<sup>2</sup> These data convinced me of the potential safety harms of the vaccines, especially in my children and young people, and furthered my resolve to fight the full approval of the COVID-19 vaccines. Full FDA approval of the EUA vaccines would essentially provide a foundation for state- and nation-wide mandates. Large-scale

<sup>&</sup>lt;sup>2</sup> https://www.pmda.go.jp/drugs/2021/P20210212001/672212000\_30300AMX00231\_I100\_2.pdf

mandates could result in massive safety concerns, including heart failure, strokes, clotting issues, infertility, and autoimmune issues.

On July 23, 2021, we submitted a Citizen Petition to the FDA requesting a pause on vaccine approval.<sup>3</sup> We received over 1,600 public comments on our petition; not a single comment disagreed with our request. On August 23, 2021, the FDA denied our petition. The same day FDA approved Pfizer's vaccine Comirnaty<sup>®</sup>. Since approval, mandates have proliferated in public and private sectors, with the FDA's 'safe and effective' seal of approval used as justification for discriminatory mandates.

## **Focus on Safety**

In the two years since Chancellor Perman mandated vaccination for USM employees and students, research has demonstrated both the lack of the vaccines' effectiveness in preventing infection and transmission, and the magnitude of adverse reactions associated with the mass immunization of the population. Indeed, much of this evidence has emerged from data provided by the vaccines' manufacturers themselves, as well as from the FDA and the CDC. I remain convinced the vaccines were not only ineffective but, more importantly, unsafe. In other words, the harms associated with the vaccines now outweigh their benefits for most populations. Sadly, most patients and many health care providers remain ignorant of the potential harms of the vaccines. A primary reason for this gap in knowledge is the lack of easily accessible information. A foundation of medical practice and ethics is informed consent. However, *without complete knowledge there cannot be informed consent.* 

On January 31, 2023, colleagues and I submitted a second citizen petition calling for current and accurate product labeling<sup>4</sup>. We also requested the creation of a Medication Guide and to communicate these labeling changes via a Dear Health Care Provider letter. We believe incomplete, inaccurate, and/or misleading labeling of medical products negatively impacts the health and safety of Americans, for if prescribers and vaccine administrators do not have accurate and current vaccine safety and effectiveness information, how can they provide informed consent to their patients?

## Vaccine Harms and College Students

The citizen petition details ten key points on vaccine effectiveness and safety. Briefly, I focus on two components of safety that are vitally important to college students, and which can affect their immediate health, as well as that of future generations: myocarditis and reproductive health.

<u>Myocarditis</u>: Current labeling provides no information on the frequency or myocarditis or pericarditis. Labels should contain a range of rates that have been reported in the literature and should stratify by risk factors, notably age and sex. Post-vaccine myocarditis incidence has been reported in many studies throughout the world, with risks ranging from 7/301 to 1/2700 in young people after receipt of a second vaccine dose (Pfizer). The FDA estimates increased myocarditis/pericarditis risk at 1/5000 among vaccinated males 16-17 years old.

<u>Reproductive Health</u>: Despite CDC, FDA, and professional societies such as the American Congress of Obstetricians and Gynecologists (ACOG) recommending all pregnant women to get vaccinated, at the time of EUA and full approval, pregnant women were excluded from the original clinical trials. In

<sup>&</sup>lt;sup>3</sup> <u>file:///C:/Users/Isimoniw/Downloads/FDA-2021-P-0786-0001\_attachment\_1%20(7).pdf</u>

<sup>&</sup>lt;sup>4</sup> <u>https://www.regulations.gov/document/FDA-2023-P-0360-0001</u>

February 2021, Pfizer began a clinical trial of pregnant women, originally intending to enroll 4,000 women, but enrollment was inexplicably stopped at the end of 2021 with only 349 participants. One year later, nothing has appeared in the literature: no publication, no preprint, no conference abstract.

Meanwhile, considerable research has emerged demonstrating the vaccines' association with reduced sperm concentration and motility in males, heavy menstrual bleeding and other menstrual irregularities in women, and detection of vaccine mRNA in breastmilk.

# Despite the evidence of these two significant and life-altering risks in young, healthy people, several University of Maryland campuses STILL require up-to-date vaccination for their students.

## The Mandate's Toll

The USM mandate has exerted significant physical and psychological tolls on my family. Because of my many often-public questions to administrators within my school and campus, I have been ostracized by colleagues and administration. A former supervisor told me I would never allowed to participate in a 'high profile' leadership position on campus. When approached to discuss concerns about the vaccines, colleagues have declined, with at least one noting "a meeting would not be productive." For me, the greatest personal toll of the mandates has been the systematic shut-down and discouragement of scientific discourse.

It is important to note that a sizable minority of students, employees, and faculty throughout the USM system do NOT support mandates. Due to job or educational security concerns, due to imminent promotion and/or tenure concerns, and due to fears of ostracism by peers, many did not speak out and many did feel coerced to receive vaccination. The personal and economic consequences were too high.

My children did not have optimal college experiences. They have had professors call them out due to their vaccination status, and have been refused other accommodations previously in place. The required continual testing was onerous and caused tremendous physical difficulty for one child, who had mobility issues due to Lyme disease. As a result, this child was late to classes due to inflexibility of scheduled, twice-weekly testing, and her grades were affected. The toll of continual testing and other mandate policies caused anxiety and depression to the extent she could not leave her apartment. When she missed one test, she was placed on academic probation and threatened with expulsion if she failed to test again. She withdrew from several of her classes that semester. Neither child endorses their schools to others, and both felt they endured college rather than thrived in a learning environment.

In conclusion, I fully support House Bill 699 with amendment. We must protect scientific discourse and medical autonomy in our educational system, and fully protect the safety and health of our children.

Sincerely,

Linda Wastila, BSPharm, MSPH, PhD\* Professor and Chair, Peter Lamy Center on Drug Therapy and Aging Department of Practicem Sciences, and Health Outcomes Research University of Maryland School of Pharmacy Baltimore, Maryland \*My organizational affiliation is included for identification purposes only