Support of HB1171 - Labor and Employment - Maryland Employee Protection Plan for Vaccine Refusal

From: George Gallagher
1212 Barbud Lane
Annapolis, MD 21403
410-868-0005

To: Members of the Economic Matters Committee

As a biotechnology consultant for over 30 years, I am in strong support of HB1171 - Labor and Employment - Maryland Employee Protection Plan for Vaccine Refusal.

This is good, sound, and well-reasoned legislation. The legislation is consistent with HHS regulation 45 CFR 46.116(a).

Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care.

The FDA granted emergency use authorizations (EUAs) for the Pfizer/BioNTech and Moderna vaccines in December 2020, the clinical trials the FDA will rely upon to ultimately decide whether to license these vaccines are still underway and are designed to last for approximately two years to collect adequate data to establish if these vaccines are safe and effective enough for the FDA to license.

The abbreviated timelines for the emergency use applications and authorizations means there is much the FDA does not know about these products even as it authorizes them for emergency use, including their effectiveness against asymptomatic infection, death, and transmission of SARS-CoV-2, the virus that causes the disease.

EUAs are clear: Getting these vaccines is voluntary.

The same section of the Federal Food, Drug, and Cosmetic Act that authorizes the FDA to grant emergency use authorization also requires the secretary of Health and Human Services to "ensure that individuals to whom the product is administered are informed ... of the option to accept or refuse administration of the product."

Likewise, the FDA's guidance on emergency use authorization of medical products requires the FDA to "ensure that recipients are informed to the extent practicable given the applicable circumstances … That they have the option to accept or refuse the EUA product …"

Dr. Amanda Cohn, the executive secretary of the CDC's Advisory Committee on Immunization Practices, was asked if Covid-19 vaccination can be required, she responded that under an EUA, "vaccines are not allowed to be mandatory. So, early in this vaccination phase, individuals will have to be consented and they won't be able to be mandatory." Cohn later affirmed that this prohibition on requiring the vaccines applies to organizations, including hospitals. (https://www.fda.gov/media/143982/download)

The EUAs for both the Pfizer/BioNTech and Moderna vaccines require facts sheets to be given to vaccination providers and recipients. These fact sheets make clear that getting the vaccine is optional.

The key point to consider is that a significant number of adverse events have been reported for these emergency use authorized COVID vaccines. It is important to exercise caution and allow people the individual right to evaluate the potential risks.

As of Feb. 26, 2021, 1022 deaths, 4,174 emergency room admissions, 770 life threatening incidents - as subsets of 20,011 total adverse events – have been reported to the Centers for Disease Control and Prevention's (CDC) Vaccine Adverse Event Reporting System (VAERS) following COVID-19 vaccinations. The numbers reflect reports filed between December 2020 and February 26, 2021.

Best regards,

George Gallagher