Ohio House of Representatives
Health Committee

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Testimony by
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Chair Lipps, Vice Chair Holmes, ranking member Russo, and members of the Ohio House Health Committee, thank you for the opportunity to provide opponent testimony on Substitute House Bill 248. My name is Patrick Plues and I am the Vice President, State Government Relations, at the Biotechnology Innovation Organization (BIO). BIO and our members oppose this bill due to the broad-reaching negative impacts this bill would have on public health. In this testimony, we discuss vaccine development, safety, and value to public health.

BIO is the world's largest trade organization representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 countries. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products. BIO's membership includes developers and manufacturers of vaccines, therapeutics, diagnostics, and medical countermeasures against emerging infectious diseases, pandemic pathogens, and other health security threats. As the leading biotech trade association, BIO is working to help accelerate R&D of biotech solutions to the current pandemic, help patients weather the storm of the pandemic, and enhance US preparedness for future public health emergencies.

The health, social, and economic impacts of the COVID-19 pandemic are a reminder of the importance of preventing infectious disease through vaccination. Vaccines are our best protection against infectious diseases. We are fortunate to be able to prevent more than 20 diseases through the use of vaccines.[1] In general, vaccination has led to decreases in the number of cases of more than 90% for many significant infectious diseases such as polio, measles, mumps, and pertussis.[2] Individual and collective protection against these infectious diseases depends upon community immunity and high vaccination rates.

[1] Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/index.html
[2] Roush SW, Murphy TV, Vaccine-Preventable Disease Table Working Group. Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States. JAMA 2007;298(18):2155-2163. https://jamanetwork.com/journals/jama/fullarticle/209448

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Vaccinations are lifesaving and cost-saving. In addition to the human toll, outbreaks of infectious diseases have high economic costs. Analyses of recent measles outbreaks found that response costs ranged from $68,000 to deal with two unrelated measles cases in Colorado (July 2016-January 2017)[3] to more than $3 million for the total direct and indirect costs of a 4-month outbreak in Clark County, WA in 2019.[4]

Substitute House Bill 248

Under the guise of putting safeguards in place for COVID-19 vaccines, Sub. H.B. 248 would upend existing vaccine policies in Ohio which have protected us against infectious diseases that have been well-controlled for many years. This legislation would limit the ability of the public health community to implement vaccine requirements for school entry and daycare, would make it harder for employers to ensure the safety of their employees, and would hamper future outbreak response efforts. Public health authorities, schools, and employers should not be limited in their ability to implement evidence-based policies. Employers should have the flexibility to implement policies to protect their employees and patrons. Schools must have all public health and disease mitigation tools at their disposal to ensure safe environments for students and staff.

Ohio already allows for personal belief exemptions from vaccination requirements, respecting individual choice and making Sub. H.B. 248 unnecessary. There is no reason to reverse longstanding evidence-based vaccine policy when vaccination exemptions are available under current law.

Additionally, as a secondary result of the pandemic, routine vaccination rates have dropped among children, adolescents, and adults nationally.[5,6] Sub. H.B. 248 would potentially put all requirements for any vaccine at risk. As we return to our pre-pandemic routines, policies that support strong vaccination policies are needed to maintain high immunization rates to avert outbreaks of other infectious diseases such as measles, pertussis, meningitis, and influenza on top of COVID-19.

COVID-19 Vaccine Development

When a novel coronavirus emerged in late 2019, no products existed to treat or prevent this disease. In December 2020, the first COVID-19 vaccine was approved for use in the United States, and just six months later, more than 141 million people are fully vaccinated. While we are still learning more about these vaccines, the COVID-19 vaccines in use in the United States have been proven to be safe and effective through rigorous clinical trials.

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[3] Marx GE, Chase J, Jasperse J, et al. Public Health Economic Burden Associated with Two Single Measles Case Investigations — Colorado, 2016–2017. MMWR Morb Mortal Wkly Rep 2017;66:1272–1275. DOI: http://dx.doi.org/10.15585/mmwr.mm6646a3

[4] Pike J, Melnick A, Gastanaduy PA, et al. Societal Costs of a Measles Outbreak. Pediatrics 2021;147(4)e2020027037. DOI: https://doi.org/10.1542/peds.2020-027037.

[5] Santoli JM, Lindley MC, DeSilva MB, et al. Effects of the COVID-19 Pandemic on Routine Pediatric Vaccine Ordering and Administration — United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:591–593. DOI: http://dx.doi.org/10.15585/mmwr.mm6919e2

[6] Trost A, Young J, Donthi S, Becker L. How COVID-19 Has Impacted US Adolescent and Adult Vaccine Utilization. Avalere Health. 1 Feb. 2021. https://avalere.com/insights/how-covid-19-has-impacted-us-adolescent-and-adult-vaccine-utilization

Our industry is devoting our expertise, resources, and capabilities to identify science-based solutions and medical treatments to combat this threat. These efforts have encompassed unparalleled collaboration and cooperation between industry, academia, non-governmental organizations, and governments around the world.

In this effort, COVID-19 vaccines have been held to the highest scientific and regulatory standards. Authorization or approval by the FDA represents the gold standard in scientific and regulatory rigor; before the FDA issues an approval or authorization, vaccines are tested for safety and efficacy in tens of thousands of people. In addition, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) assesses the clinical data to make evidence-based recommendations for use in the most appropriate populations. Ongoing evaluation of COVID-19 vaccines continues post-authorization through FDA safety surveillance activities.

Clinical trials for COVID-19 vaccines reflect those same rigorous standards. These trials are enrolling *as many or more trial participants* than other vaccines and going through the *same steps for approval* (in a condensed timeframe) to help ensure the data on safety and efficacy are robust. Phase 3 studies are being conducted using clinical trial designs that also represent the gold standard in vaccines R&D – randomized, placebo-controlled, event-based trials. Last Fall, before any vaccine was under review, the FDA provided guidance on the use of Emergency Use Authorizations (EUAs) that show high scientific standards are being upheld.

Additional information on COVID-19 vaccine development, including answers to frequently asked questions about COVID-19 vaccines, is available at COVID Vaccines Facts (www.covidvaccinefacts.org).

Vaccine Safety

Serious vaccine side effects are extremely rare – estimated to be approximately 1 per 1 million vaccines administered[7] – no medical intervention is without risk. In the United States, there are numerous, robust systems that monitor vaccine safety.

As with all vaccines, ongoing monitoring of safety and efficacy will continue as long as the COVID-19 vaccine is in use. While the authorized and late-stage vaccines are highly safe and effective, we will be learning more about the vaccines as they are used in broader populations. COVID-19 vaccines will be monitored for safety signals using existing systems as well as new systems established specifically for COVID.

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) & FDA. Anyone (providers, manufacturers, & vaccine recipients) may report information about adverse events that occur after administration of vaccines. It is important to note that once a VAERS report is made, FDA and CDC investigate whether there is a causal link between the vaccine and the alleged side effect.

[7] Health Resources and Services Administration. Data & Statistics. 1 June 2021. https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/data-statistics-report.pdf

One new safety monitoring system developed specifically for COVID-19 vaccines is CDC's v-safe text-based monitoring. When vaccinated, individuals will receive information about how they can register for v-safe. Enrolling in v-safe will prompt periodic check-ins asking about side effects. Reports made via text that show more severe side effects will result in CDC follow-up and reporting to VAERS, if appropriate.

In April 2021, the FDA and CDC review of reported cases of a rare type of blood clot following vaccination with the Johnson & Johnson vaccine showed that the safety monitoring system works. Six cases of this rare side effect out of more than 7 million vaccine recipients initiated a process during which CDC ACIP publicly reviewed data and revisited the vaccine recommendation. While the continued use of this vaccine was upheld, ACIP advocated for vaccine programs to ensure choice in which vaccine individuals receive, and additional information on the side effect was offered for providers and the public so that individuals can make an informed choice.

Conclusion

We are already seeing the positive impact of COVID-19 vaccines. Real-world data has shown that COVID-19 vaccination has reduced cases and hospitalizations. In the US, since January 2021, COVID-19 cases have fallen from a peak of more than 179,000 new cases per day to less than 15,000 new cases daily. A study of Cleveland Clinic patients found that 99.75% of patients hospitalized with COVID-19 between January 1-April 13, 2021 were not vaccinated,[8] demonstrating that vaccines are effective at keeping people healthy and out of the hospital. We must not risk this progress in fighting the pandemic by implementing policies like Sub. H.B. 248.

More importantly, we must not abandon evidence-based vaccine policies that have been effective in controlling infectious diseases for decades.

The biotechnology industry is committed to bringing safe and effective vaccines, therapeutics, and diagnostics across the finish line for people in Ohio, the United States, and around the world. BIO and our members urge the Committee to vote no on HB 248.

Thank you again for the opportunity to provide testimony. BIO and our members stand ready to serve as a resource for the Committee.

[8] Gonzalez O. Study: Over 99% of hospitalized COVID-19 patients were not vaccinated. Axios, 11 May 2021. https://www.axios.com/study-hospitalized-coronavirus-patients-unvaccinated-7ed34f63-fd1d-437c-b4b7-0c1dd3600a15.html?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiospm&stream=top