



May 22, 2018

HB559: Change school immunization requirements

Position: Oppose

Dear Ohio Legislators,

On both ethical and scientific grounds, and on behalf of our Ohio members, we at Physicians for Informed Consent (PIC) oppose House Bill 559, as introduced by Representative Anne Gonzales and Representative Al Landis, as it adds bureaucracy and extra medical costs that thwart the informed consent process.

PIC is a nationally-recognized 501(c)(3) nonprofit organization of physicians, scientists, and attorneys, whose mission is to safeguard informed consent in vaccination. In addition, our Coalition for Informed Consent consists of more than one hundred U.S. and international organizations. We at PIC believe that mandating vaccination for school attendance, or making the existing vaccine exemption process more difficult, is a form of state coercion that negates the medical ethic of informed consent.

As sovereign individuals living in the United States have the right to bodily integrity, they correspondingly have the right to refuse medical procedures, including vaccination, for themselves or their children—without undue discrimination, duress, or hardship. The National Childhood Vaccine Injury Act (42 U.S.C. §300aa-26) already mandates all healthcare providers in the United States to provide current vaccine information materials produced by the Centers for Disease Control and Prevention (CDC) to a child's parent or guardian prior to the administration of each dose of a vaccine, usually at well-baby visits or other pediatric appointments.

HB559 would subject the residents of the state of Ohio, who have already received federally-mandated vaccine information and chosen to exercise their right to refuse some or all vaccines at the time when they were offered by their pediatrician (i.e. informed refusal), to incur extra medical costs and loss of time due to a state-mandated doctor's appointment that is not medically-indicated. HB559 contradicts medical ethics as it sanctions government intervention into the informed consent/informed refusal process and intrudes into the doctor-patient relationship.

Thwarting the well-established procedure for exercising vaccine exemptions with additional state-imposed bureaucracy and extra cost to the parent, especially when the necessary measures for protecting public health are already in place (e.g. excluding vaccine-exempt children from school during an outbreak), is not only coercive and medically unethical, but also not evidence-based. To make a scientifically justifiable and medically ethical public health policy, it is imperative that the risk of death or permanent injury due to a vaccine is adequately researched and compared with that of the corresponding disease, as we will briefly outline below for measles.

In the U.S., measles is generally a benign, short-term viral infection, and rare untoward consequences can readily be prevented through vitamin A supplementation. In the late 1950s and early 1960s, right before the measles mass vaccination program was introduced in 1963, the case-fatality rate for measles was 1 in 10,000 or 0.01%. This means that 99.99% of children fully recovered from measles, and that the risk of

dying from measles in the U.S. was very small, even in the pre-vaccine era.

As we describe in more detail in the enclosed Measles Disease Information Statement (DIS) and Vaccine Risk Statement (VRS), it has *not* been proven that the risk of dying or suffering permanent injury from the measles, mumps, and rubella (MMR) vaccine is less than 1 in 10,000. Therefore, one cannot claim that it is safer to receive the MMR vaccine than it is to have measles.

Furthermore, PIC recently reported in the scientific journal *The BMJ* that every year an estimated 5,700 U.S. children suffer febrile seizures from the first dose of the MMR vaccine—which is five times more than the number of seizures expected from measles. This amounts to 57,000 febrile seizures over the past 10 years due to the MMR vaccine alone. And, as five percent of children with febrile seizures progress to epilepsy, the estimated number of children developing epilepsy due to the MMR vaccine, in the past 10 years, is 2,850.

In addition, we found that the Vaccine Adverse Event Reporting System (VAERS) receives only about 90 annual reports of seizures following the first dose of MMR—that's only 1.6% of the 5,700 MMR-vaccine seizures that occur each year. We contend that VAERS, as a passive surveillance system, does not adequately capture vaccine side effects and that serious side effects, including permanent neurological harm and death from MMR and other vaccines, may similarly be underreported.

We have focused this letter on measles and the MMR vaccine; however, there are other vaccines for which the risk of serious harm or death has not been proven to be less than that of the corresponding disease. Should you wish to learn more about these vaccines and infectious diseases, we would be happy to discuss them with you.

In conclusion, thwarting the existing exemption procedure to mandatory vaccination for school attendance in Ohio violates the medical ethic of informed consent and overlooks the tenable risk of severe vaccine injury, including permanent harm and death. We at PIC strongly oppose HB559 and urge you to see its harm to your constituents.

Sincerely,



Shira Miller, M.D.  
President  
Physicians for Informed Consent

Enclosed: Measles Disease Information Statement (DIS) and Vaccine Risk Statement (VRS)

# MEASLES

## What Parents Need to Know



### 1. WHAT IS MEASLES?

Measles is a self-limiting childhood viral infection.

- Measles symptoms include a prodromal (initial) phase of cough, runny nose, eye irritation and fever, followed by a generalized rash on days 4–10 of the illness.<sup>1</sup>
- Measles is contagious during the prodromal phase and for 3-4 days after rash onset.<sup>1</sup>
- Most measles cases are benign and not reported to public health departments.<sup>2</sup>
- Before the measles mass vaccination program was introduced, nearly everyone contracted measles and obtained lifetime immunity by age 15.<sup>1</sup>
- In rare situations, measles can cause brain damage and death.<sup>3,4</sup>

Centers for Disease Control and Prevention (CDC) publishes measles case-fatality rates based on reported cases. However, nearly 90% of measles cases are benign and not reported to the CDC.<sup>2</sup> Calculating case-fatality rates based on reported cases (that constitute only 10% of all cases) results in a case-fatality rate that is 10 times higher than what it actually is in the general population. Data analysis herein is based on total measles cases (both reported and unreported).



### 2. WHAT ARE THE RISKS?

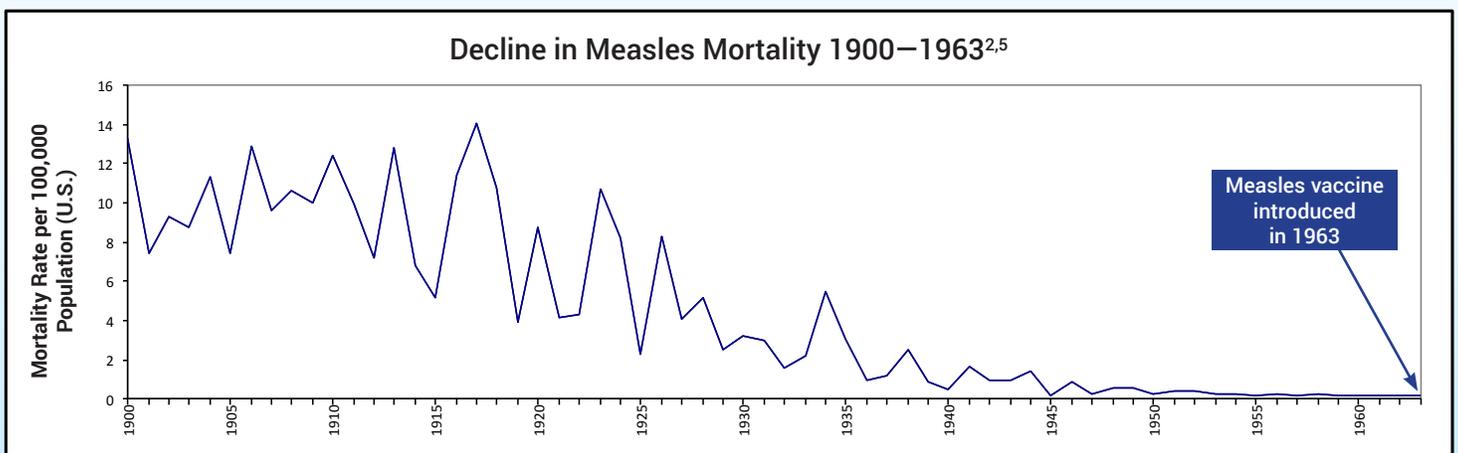
In the modern era, it is rare to suffer permanent disability or death from measles in the United States.

Between 1900 and 1963, the mortality rate of measles dropped from 13.3 per 100,000 to 0.2 per 100,000 in the population, due to advancements in living conditions, nutrition, and health care—a 98% decline (Fig. 1).<sup>2,5</sup>

Malnutrition, especially vitamin A deficiency, is a primary cause of about 90,000 measles deaths annually in underdeveloped nations.<sup>6</sup> In the U.S. and other developed countries, 75–92% of hospitalized measles cases are low in vitamin A.<sup>7,8</sup>

Research studies and national tracking of measles have documented the following:

- 1 in 10,000 or 0.01% of measles cases are fatal.<sup>3</sup>
- 3 to 3.5 in 10,000 or 0.03–0.035% of measles cases result in seizure.<sup>9</sup>
- 1 in 20,000 or 0.005% of measles cases result in measles encephalitis.<sup>4</sup>
- 1 in 80,000 or 0.00125% of cases result in permanent disability from measles encephalitis.<sup>4</sup>
- 7 in 1,000 or 0.7% of cases are hospitalized.<sup>10</sup>



**Figure 1:** Measles death declined 98% from 1900 to 1963, before the measles vaccine was introduced.



### 3. WHAT TREATMENTS ARE AVAILABLE FOR MEASLES?

Because measles resolves on its own in almost all cases, usually only supportive treatment is necessary. As such, treatment options include the following:

- Rest
- Hydration
- High-dose vitamin A<sup>11</sup>
- Immune globulin (available for immunocompromised patients, such as those on chemotherapy)<sup>12</sup>



#### Vitamin A

The World Health Organization (WHO) recommends that serious measles cases be treated with high-dose vitamin A, 50,000–200,000 IU, orally on two consecutive days.<sup>12</sup>



### 4. ARE THERE ANY BENEFITS FROM GETTING MEASLES?

There are studies that suggest a link between naturally acquired measles infection and a reduced risk of Hodgkin’s and non-Hodgkin’s lymphomas, as well

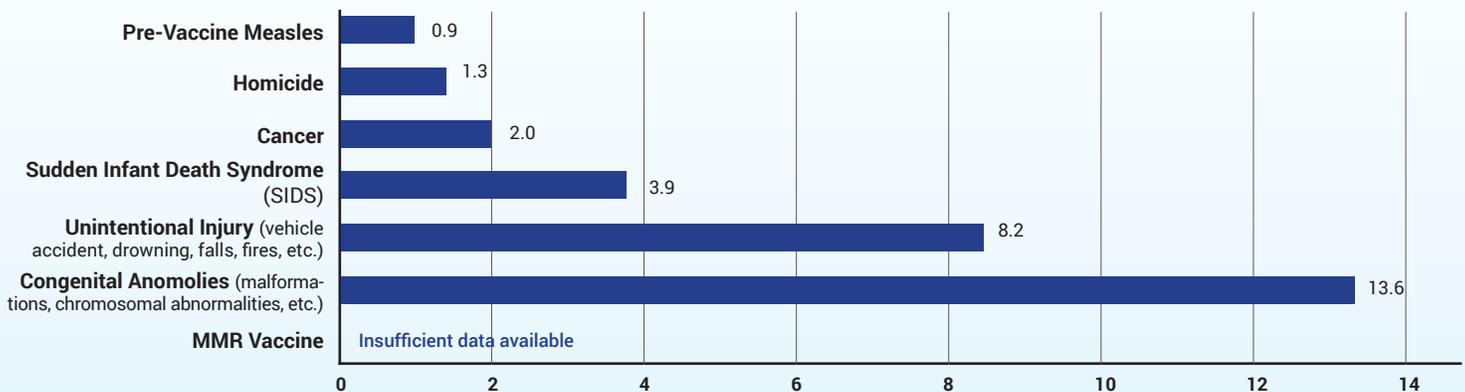
as a reduced risk of atopic diseases such as hay fever, eczema and asthma.<sup>13-17</sup> In addition, measles infections are associated with a lower risk of mortality from cardiovascular disease in adulthood.<sup>18</sup> Moreover, infants born to mothers who have had naturally acquired measles are protected from measles via maternal immunity longer than infants born to vaccinated mothers.<sup>19</sup>



### 5. WHAT ABOUT THE VACCINE FOR MEASLES?

The measles vaccine was introduced in the U.S. in 1963 and is now only available as a component of the measles, mumps, and rubella (MMR) vaccine. It has significantly reduced the incidence of measles; however, the vaccine is not capable of preventing all cases of measles, as failures have been reported.<sup>20</sup> The manufacturer’s package insert contains information about vaccine ingredients, adverse reactions, and vaccine evaluations. For example, “M-M-R II vaccine has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility.”<sup>21</sup> Furthermore, the risk of permanent injury and death from the MMR vaccine has not been proven to be less than that of measles (Fig. 2).<sup>22, 23</sup>

Measles Mortality vs. Leading Causes of Death in Children Under Age 10 (per 100,000 Population)<sup>22-25</sup>



**Figure 2:** This graph shows the measles death rate before the vaccine was introduced, when measles was a common childhood viral infection, and compares it to the leading causes of death in children under age 10 today. Hence, in the pre-vaccine era, the measles death rate per 100,000 was 0.9 for children under age 10. In 2015, the death rate per 100,000 for homicide was 1.3, followed by cancer (2.0), SIDS (3.9), unintentional injury (8.2), and congenital anomalies (13.6). The rate of death or permanent injury from the MMR vaccine is unknown because the research studies available are not able to measure it with sufficient accuracy.<sup>22, 23</sup>

All references and the Measles Vaccine Risk Statement (VRS) are available at [physiciansforinformedconsent.org/measles](http://physiciansforinformedconsent.org/measles).

These statements are intended for informational purposes only and should not be construed as personal medical advice.

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# MMR VACCINE (Measles, Mumps, and Rubella)



Available in Spanish at / Disponible en español en [physiciansforinformedconsent.org/measles](http://physiciansforinformedconsent.org/measles)

## Is It Safer Than Measles?



### 1. WHAT ARE SIDE EFFECTS OF THE MMR VACCINE?

Common side effects of the MMR vaccine include fever, mild rash, and swelling of glands in the cheeks or neck.<sup>1</sup> A more serious side effect is seizure, which occurs in about 1 in 640 children vaccinated with MMR<sup>2</sup>—about five times more often than seizure from measles infection.<sup>3</sup>

## H

Seizures from the MMR vaccine occur 5x more often than measles-related seizures.

The Centers for Disease Control and Prevention (CDC) states that serious allergic reactions to the vaccine occur in about one in a million doses.<sup>1</sup> However, other severe side effects include deafness, long-term seizures, coma, lowered consciousness, permanent brain damage, and death.<sup>1</sup> While the CDC states that these side effects are rare, the precise numbers are unknown.<sup>1</sup> Additionally, the manufacturer’s package insert states, “M-M-R II vaccine has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility.”<sup>4</sup>

No safety studies for:

Cancer

Genetic mutations

Impaired fertility



### 2. HOW ARE RISKS OF VACCINE SIDE EFFECTS MEASURED?

Methods to measure vaccine risks include surveillance systems, clinical studies, and epidemiological studies.



### 3. HOW ACCURATE IS SURVEILLANCE OF ADVERSE EVENTS FROM THE MMR VACCINE?

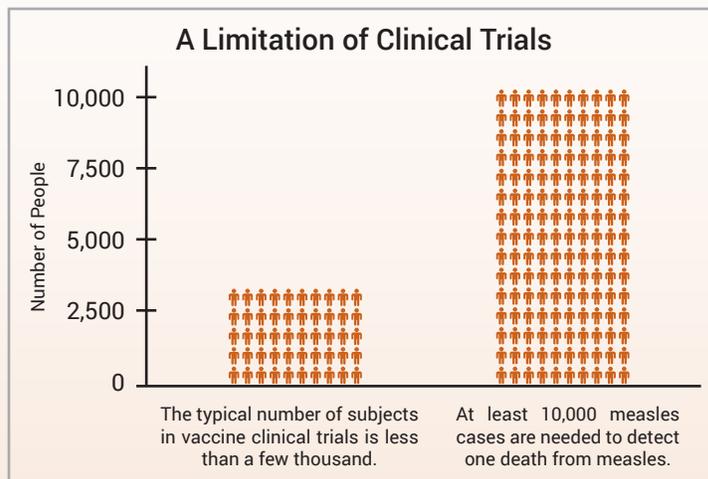
The government tracks reported cases of vaccine side effects through the Vaccine Adverse Event Reporting System (VAERS). Approximately 40 cases of death and

permanent injury from the MMR vaccine are reported to VAERS annually.<sup>5</sup> However, VAERS is a passive reporting system—authorities do not actively search for cases and do not actively remind doctors and the public to report cases. These limitations can lead to significant underreporting.<sup>6</sup> The CDC states, “VAERS receives reports for only a small fraction of actual adverse events.”<sup>7</sup> Indeed, as few as 1% of serious side effects from medical products are reported to passive surveillance systems,<sup>8</sup> and as few as 1.6% of MMR-related seizures are reported to VAERS.<sup>9</sup> In addition, VAERS reports are not proof that a side effect occurred, as the system is not designed to thoroughly investigate all cases.<sup>10</sup> As a result, VAERS does not provide an accurate count of MMR vaccine side effects.



### 4. HOW ACCURATE ARE CLINICAL TRIALS OF THE MMR VACCINE?

The CDC states, “Prelicensure trials are relatively small—usually limited to a few thousand subjects—and usually last no longer than a few years. Prelicensure trials usually do not have the ability to detect rare adverse events or adverse events with delayed onset.”<sup>6</sup> Since measles is fatal in about 1 in 10,000 cases and results in permanent injury in about 1 in 80,000 cases,<sup>3</sup> a few thousand subjects in clinical trials are not enough to prove that the MMR vaccine causes less death and permanent injury than measles (Fig. 1). In addition, the lack of adequate clinical trials of the MMR vaccine resulted in the manufacturer’s package insert data to be reliant on passive surveillance for rates of MMR-related neurological adverse reactions, permanent disability, and death.<sup>4</sup>



**Figure 1:** There are not enough subjects in clinical trials to prove that the MMR vaccine poses less risk than measles.



## 5. HOW ACCURATE ARE EPIDEMIOLOGICAL STUDIES OF THE MMR VACCINE?

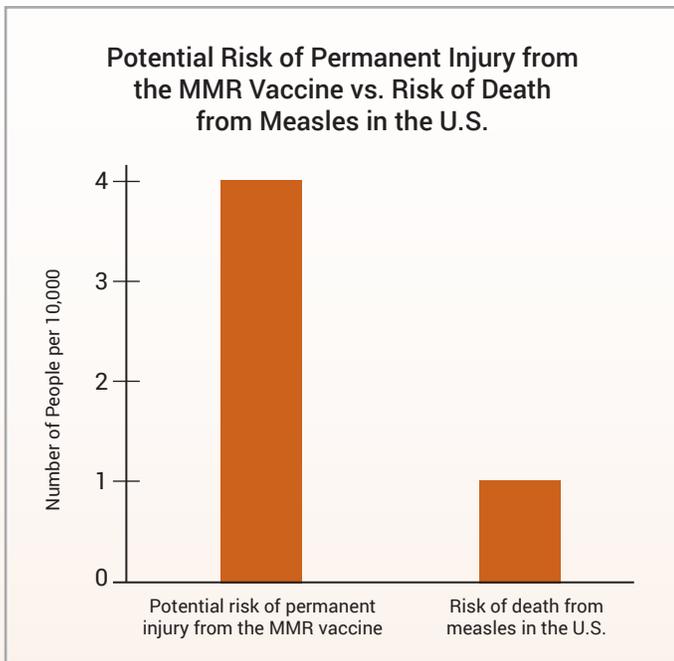
Epidemiological studies are hindered by the effects of chance and possible confounders—additional factors that could conceivably affect the groups being studied. For example, there is a well-known 2002 Danish study published in the *New England Journal of Medicine* involving about 537,000 children that looked for an association between the MMR vaccine and certain adverse events.<sup>11</sup> The raw data in the study was adjusted, in an attempt to account for potential confounders, and the study found no association between the MMR vaccine and the adverse events. However, because there is no evidence that the estimated confounders used to adjust the raw data were actually confounders, the study did not rule out the possibility that the MMR vaccine increases the risk of an adverse event that leads to permanent injury by up to 77%. Consequently, the study did not rule out the possibility that such adverse events might occur up to four times more often than death from measles: 1 in 2,400 compared to 1 in 10,000 (Fig. 2 and Table 1). The range of possibilities found in the study, between the adjusted data and the raw data, makes the result inconclusive; even large epidemiological studies are not

accurate enough to prove that the MMR vaccine causes less death or permanent injury than measles.



## 6. IS THE MMR VACCINE SAFER THAN MEASLES?

It has not been proven that the MMR vaccine is safer than measles. The vaccine package insert raises questions about safety testing for cancer, genetic mutations, and impaired fertility. Although VAERS tracks some adverse events, it is too inaccurate to measure against the risk of measles. Clinical trials do not have the ability to detect less common adverse reactions, and epidemiological studies are limited by the effects of chance and possible confounders. Safety studies of the MMR vaccine are particularly lacking in statistical power. A review of more than 60 MMR vaccine studies conducted for the Cochrane Library states, “The design and reporting of safety outcomes in MMR vaccine studies, both pre- and post-marketing, are largely inadequate.”<sup>12</sup> Because permanent sequelae (aftereffects) from measles, especially in individuals with normal levels of vitamin A, are so rare,<sup>3</sup> the level of accuracy of the research studies available is insufficient to prove that the vaccine causes less death or permanent injury than measles.



**Figure 2:** A 2002 Danish study did not rule out the possibility that the MMR vaccine can cause an adverse event leading to permanent injury four times more often than measles can be fatal.



**Table 1: Statistical Analysis of an Epidemiological Study with Over Half a Million Children**

RR = Relative risk  
 $(\text{risk in group vaccinated with MMR}) \div (\text{risk in group not vaccinated with MMR})$

CI = Confidence interval  
 (possible range of RR due to effects of chance)

Adjusted RR reported in study  
 = 0.92 (95% CI, 0.68 to 1.24)

Unaltered RR recorded in study  
 $(263/1,647,504) \div (53/482,360)$   
 = 1.45 (95% CI, 1.21 to 1.77)

Potential RR = 1.77  
 (potential 77% greater risk than unvaccinated group risk)

Unvaccinated group risk recorded in study  
 = 53 in 97,000

77% of 53 in 97,000  
 = 1 in 2,400 additional risk in group vaccinated with MMR

All references and the Measles Disease Information Statement (DIS) are available at [physiciansforinformedconsent.org/measles](http://physiciansforinformedconsent.org/measles).

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