

March 27, 2019

To: California Legislators

Re: SB 276 (Pan) as amended on 3/25/19 – Immunizations: medical exemptions; Elimination of physicians' right to determine medical exemptions to vaccination for their patients

Position: OPPOSE

We at Physicians for Informed Consent (PIC), on behalf of our California members, oppose SB 276 as amended by Pan, as it is both unscientific and unethical.

PIC is a nationally recognized 501(c)(3) nonprofit organization representing hundreds of doctors, as well as scientists and attorneys, whose mission is to safeguard informed consent in vaccination. In addition, our Coalition for Informed Consent consists of over 150 member organizations which represent millions of Americans.

SB 276 is unscientific because:

• SB 277-mandated vaccines have not yet been proven to be less risky than the diseases they are designed to prevent.

For example, the chance of dying from measles is 1 in 10,000, based on U.S. data from the prevaccine era. However, the risk of dying or being permanently disabled by the measles, mumps, and rubella (MMR) vaccine has not been proven to be less than 1 in 10,000. This makes mandating the MMR vaccine unscientific and unethical. See attached Measles Disease Information Statement (DIS), Vaccine Risk Statement (VRS), and Immunocompromised Schoolchildren Risk Group Information Statement (RGIS).

In addition, in 2017, we reported in *The BMJ* that every year an estimated 5,700 U.S. children (approximately 1 in 640) suffer febrile seizures from the first dose of the MMR vaccine—which is five times more than the number of febrile seizures expected from measles. This amounts to 57,000 febrile seizures over the past 10 years due to the MMR vaccine alone. As 5% of children with a history of febrile seizures progress to epilepsy, a debilitating and life-threatening chronic condition, the estimated number of children whose epilepsy is due to the MMR vaccine in the past 10 years is 2,850. Furthermore, the risk of seizure from MMR in siblings of children with a history of febrile seizures is 1 in 252, and the risk of seizure from MMR in children with a personal history of febrile seizures is 1 in 51. <sup>2</sup>

- Promotes medical bullying by governmental agents and obstructs parents from being able to
  protect their children from the potential risk of vaccine injuries (i.e., it violates the principle of
  informed consent/informed refusal).
- Thwarts doctors from being able to protect their patients' health through personalized vaccine recommendations based on infectious disease risks and individualized vaccine-injury risks, and instead promotes an outdated one-size-fits-all governmental vaccine schedule which is not based on new medical discoveries.
- Subjects the health of California's children to the mercy of a State Public Health Officer with whom they don't have a patient-doctor relationship.

Finally, the National Childhood Vaccine Injury Act (NCVIA) of 1986 was created by Congress as a remedy to mounting vaccine injury lawsuits. Since then, it has not been effectively possible to sue vaccine manufacturers or physicians for vaccine injuries and instead the Vaccine Injury Compensation Program (VICP) has cumulatively awarded about \$4,000,000,000 for severe vaccine injury cases or deaths—to only a small fraction of the VICP petitioners who apply within the two- or three-year statute of limitations. Consequently, it is mostly families whose children have suffered uncompensated vaccine injuries and the doctors who care for them (including many of PIC's M.D. and D.O. members) who have a heightened awareness of the risks vaccines pose to the health of some American children and the diligence required to provide informed consent in an environment that is effectively immune from the tort system, civil litigation, and publicity.

For these reasons, we oppose SB 276 on both scientific and ethical grounds.

We are here to assist you in these highly technical matters and hope you will not allow bad science to violate the ethics of informed consent.

Sincerely,

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

1 Miller S. Re: The unofficial vaccine educators: are CDC funded non-profits sufficiently independent? *BMJ.* 2017;359:j5104. https://www.bmj.com/content/359/bmj.j5104/rr-13.

2 Vestergaard M, Hviid A, Madsen KM, et al. MMR vaccination and febrile seizures: evaluation of susceptible subgroups and long-term prognosis. *JAMA*. 2004 Jul 21;292(3):351-7. https://www.ncbi.nlm.nih.gov/pubmed/15265850.

Enclosed: Measles Disease Information Statement (DIS), Vaccine Risk Statement (VRS), and Immunocompromised Schoolchildren Risk Group Information Statement (RGIS)

### **MEASLES**

#### What Parents Need to Know





Available in Spanish at / Disponible en español en physiciansforinformedconsent.org/measles



#### 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.9
- 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>
- 6 to 22 in 1,000,000 or 0.0006-0.0022% of cases result in subacute sclerosing panencephalitis (SSPE).<sup>11</sup>

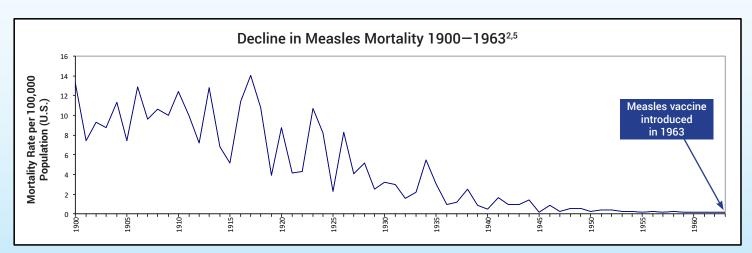


Figure 1: Measles death declined 98% from 1900 to 1963, before the measles vaccine was introduced.



## 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 A12
- Immune globulin (available for immunocompromised patients, such as those on chemotherapy)<sup>13</sup>



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>13</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

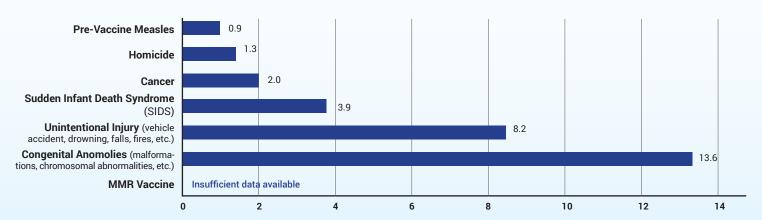
as a reduced risk of atopic diseases such as hay fever, eczema and asthma.<sup>14-18</sup> In addition, measles infections are associated with a lower risk of mortality from cardiovascular disease in adulthood.<sup>19</sup> Moreover, infants born to mothers who have had naturally acquired measles are protected from measles via maternal immunity longer than infants born to vaccinated mothers.<sup>20</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. 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." 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). 22, 23

#### 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.

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)

Is It Safer Than Measles?



Available in Spanish at / Disponible en español en physiciansforinformedconsent.org/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.1 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.3



The Centers for Disease Control and Prevention (CDC) states that serious allergic reactions to the vaccine occur in about one in a million doses.1 However, other severe side effects include deafness, long-term seizures, coma, lowered consciousness, permanent brain damage, and death.1 While the CDC states that these side effects are rare, the precise numbers are unknown. 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."4





#### 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.5 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.6 The CDC states, "VAERS receives reports for only a small fraction of actual adverse events."7 Indeed, as few as 1% of serious side effects from medical products are reported to passive surveillance systems,8 and as few as 1.6% of MMR-related seizures are reported to VAERS.9 In addition, VAERS reports are not proof that a side effect occurred, as the system is not designed to thoroughly investigate all cases. 10 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 smallusually 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."6 Since measles is fatal in about 1 in 10,000 cases and results in permanent injury in about 1 in 80,000 cases,3 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.4

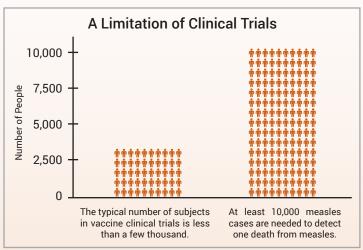


Figure 1: There are not enough subjects in clinical trials to prove that the MMR vaccine poses less risk than measles.



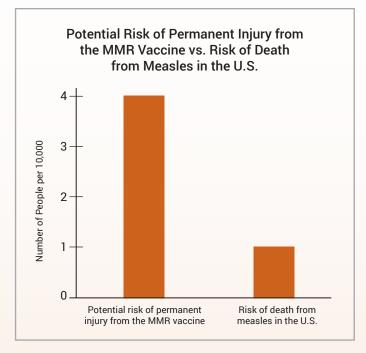
## 5. HOW ACCURATE ARE EPIDEMIOLOGICAL STUDIES OF THE MMR VACCINE?

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.11 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.

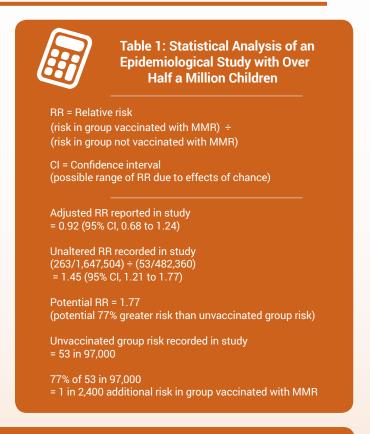


## 6. IS THE MMR VACCINE SAFER THAN MEASLES?

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 preand post-marketing, are largely inadequate."12 Because permanent sequalae (aftereffects) from measles, especially in individuals with normal levels of vitamin A, are so rare,3 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.



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

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

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# Vaccines: What About Immunocompromised Schoolchildren?





Available in Spanish at / Disponible en español en physiciansforinformedconsent.org/ immunocompromised-schoolchildren



## 1. WHAT DOES IT MEAN TO BE IMMUNOCOMPROMISED?

Immunocompromised children have weakened immune systems that prevent them from optimally fighting infections on their own. Consequently, they may be at increased risk of complications from infectious diseases and require additional precautions and treatments.



## 2. CAN IMMUNOCOMPROMISED CHILDREN ATTEND SCHOOL?

Severely immunocompromised children are too vulnerable to be in public places and cannot attend school. However, children who are not severely immunocompromised can attend school with the approval of their doctor.



Severely immunocompromised children cannot attend school because they are too vulnerable to be in public places.



## 3. CAN IMMUNOCOMPROMISED SCHOOLCHILDREN BE VACCINATED?

Immunocompromised schoolchildren have the option to receive all the vaccines licensed for children in the United States, except for the live virus vaccines (such as vaccines targeting measles, mumps, rubella, or varicella infections). Although vaccination often results in protective levels of antibodies in immunocompromised children, clinical vaccine safety trials typically exclude immunocompromised subjects. In addition, vaccines have not been

evaluated for their potential to cause cancer, genetic mutations or impaired fertility in the general or immunocompromised population.<sup>8</sup> Due to these limitations, it is not known whether the benefit of vaccinating an immunocompromised child outweighs the risk of vaccine injury to that child.



## 4. DOES THE VACCINATION STATUS OF OTHER SCHOOLCHILDREN POSE A SIGNIFICANT RISK TO IMMUNOCOMPROMISED SCHOOLCHILDREN?

The vaccination status of other schoolchildren does not pose a significant risk to immuno-compromised schoolchildren for the following reasons (Table 1):

- Some vaccines cannot prevent the spread of the bacteria or viruses they target.
- Not all infectious diseases are contagious.
- · Some infectious diseases are not spread in schools.
- Some infectious diseases rarely cause complications in immunocompromised schoolchildren.
- Immune globulin (plasma containing antibodies) is available for immunocompromised children exposed to certain infectious diseases.



Immunocompromised schoolchildren are not put at significant risk by the vaccination status of other schoolchildren.

## Table 1: Why the Vaccination Status of Other Schoolchildren Is Not a Significant Risk to Immunocompromised Schoolchildren



Some vaccines cannot prevent the spread of the bacteria or viruses they target.

Children vaccinated with the diphtheria, tetanus, and pertussis (whooping cough) vaccine (DTaP) or the inactivated polio vaccine (IPV) can still be infected with diphtheria-causing bacteria, pertussis bacteria, or poliovirus and spread them to others, even with mild or no symptoms of their own.<sup>9-11</sup> The influenza vaccines (TIV and LAIV) have not been observed to significantly reduce the spread of influenza.<sup>12,13</sup>



Not all infectious diseases are contagious.

Tetanus is not a communicable disease; that is, it cannot spread from person to person under any circumstances.<sup>14</sup>



Some infectious diseases are not spread in schools.

Hepatitis B is not spread by kissing, hugging, holding hands, coughing, sneezing, or sharing eating utensils, 15 and the main routes of hepatitis B transmission (sexual contact, injection drug use, or being born to an infected mother) 16 do not occur in school. Human papillomavirus (HPV) is sexually transmitted and is therefore not spread in school. 17 Haemophilus influenzae type b (Hib) is spread among children younger than school age, mostly of ages 3 and younger. 18



Some infectious diseases rarely cause complications in immunocompromised schoolchildren.

Fatal cases of mumps are very rare in schoolchildren (1 mumps death per 100,000 mumps cases),<sup>19</sup> and immunocompromised children have been observed to recover just as well from mumps as the general population.<sup>20</sup> The greatest risks of pertussis and rubella are to infants and unborn babies, and being immunocompromised has not been observed to be a significant risk factor for complications of pertussis or rubella in schoolchildren.<sup>21</sup>



Immune globulin (plasma containing antibodies) is available for immunocompromised children exposed to certain infectious diseases.

Immune globulin (IG) is available for the prevention of severe symptoms in immuno-compromised children exposed to measles or rubella (IG does not provide protection for fetuses of expectant mothers infected with rubella). Varicella-zoster immune globulin (VIG) is available for the prevention of severe symptoms in immunocompromised children exposed to varicella (chickenpox). Hepatitis B immune globulin (HBIG) and tetanus immune globulin (TIG) are also available for immunocompromised children.

All references are available at physiciansforinformedconsent.org/immunocompromised-schoolchildren.

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

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