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How Can Pennsylvania Protect Itself From Its Own Measles Outbreak?

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How Can Pennsylvania Protect Itself From Its Own Measles Outbreak?

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[Editor's note: this article and the preceding article are intended to be read in tandem as a point-counterpoint.]

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ABSTRACT

When a response to inaccurate information strives to be an informative exercise of its own, it is difficult to balance the desire to respond point by point to mischaracterized, misleading, or untrue information, with the need to simply offer a complete picture of facts. This article is a response to Abigail Wenger's article regarding vaccinations. To reply to each mischaracterization or inaccuracy in turn means this response loses its own informative intent and becomes simply a rebuttal. However, to ignore mischaracterizations and inaccuracies is to risk the reader's acceptance of those points as true. Through illustrative examples in the United States and around the world, the authors will discuss six foundational and important concepts related

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to vaccination: 1) vaccination laws—history, why they matter, and effects; 2) authority to mandate—federal case law, Pennsylvania law; 3) exemptions—Pennsylvania and other states, recent changes, effect of exemptions on immunization and disease rates; 4) misinformation and its effects; 5) vaccine safety; and 6) informed consent. Within each topic, we will address some specific inaccuracies in Wenger's piece, where possible and appropriate. Presenting facts supported by credible evidence will provide its own rebuttal of Wenger's assertions. We note, however, that Wenger has multiple instances where information is mischaracterized, misleading, and sometimes simply untrue. Where appropriate, the authors will recognize and attempt to correct that information.

I. INTRODUCTION

Is statutory reform of vaccination exemption necessary in Pennsylvania? Yes, it definitely is. Pennsylvania is among only 18 states that allow parents to avoid vaccination requirements for school entry based on a philosophical objection to vaccines. Every state, plus Washington D.C., provides a medical exemption to school immunization requirements. 45 states allow a religious exemption. Among the 18 states that also provide a philosophical exemption, Pennsylvania's may be the most lax and easiest to claim. During this time of increased reported measles cases, a disease which less than two decades ago the Centers for Disease Control (CDC) declared "eliminated" within the U.S., Pennsylvania should follow the lead of many other states and strengthen its vaccination laws, review current exemptions and potentially remove some.

If anything, this process should be strengthened to inform parents about what can happen not just to their child, but to entire communities should the parent forego vaccination for non-medical reasons.

Most Americans have never witnessed the realities of smallpox, measles, polio, and other serious infectious diseases. We live in a time when the question of whether to vaccinate a child is a privilege. Throughout much of world history, the ability to prevent disease was only a dream. Since development of the smallpox vaccine in the late 1700s, scientists and the medical community have found and developed vaccines for numerous diseases. While some individuals are medically unable to be vaccinated because of a fragile or compromised immune system or severe allergy to a vaccine ingredient, most people can and should be vaccinated to protect not only themselves, but their communities, from severe and potentially fatal diseases. Vaccination is about more than personal (or parental) autonomy, it involves recognition of the need to contribute to the health and safety of one's community. This understanding has been recognized by legislatures and courts throughout the country, and, most notably, time and again by the U.S. Supreme Court.

This article argues for stronger and more strongly enforced vaccination laws in Pennsylvania. It does so by giving a brief history of vaccination laws in this country and some European countries, including why and when laws came about, and the effect of vaccination laws on the communities impacted. We will highlight what has happened in Europe, the U.S., and, most tragically at present, Samoa. Next, the article will illustrate the legal analysis providing states authority to direct individuals to act in specific ways, particularly to mandate vaccination for school attendance, and why this is important for the health and safety of communities. It will explain the state of the law in Pennsylvania and compare it to other states, specifically, what

other states have done or are attempting to do in response to increases in preventable diseases in places they either never existed or had been eradicated. The article will address state exemptions to immunization requirements. It will discuss the relationship between increased and easier to obtain exemptions and increased rates of vaccine preventable diseases. The article will show how misinformation about vaccination negatively impacts communities. It will offer scientific and medical explanations of vaccines and vaccine safety: what they are, what they can do, and what they do not do. Finally, the article will clarify what informed consent does and does not mean and what it requires of physicians before medical interventions. We know vaccination is safe, it saves lives, and it ensures the health and safety of entire communities. Continued and reliable vaccination is vital to every community, and this article will explain why that is so and what can happen in communities when misinformation and fear take hold.

II. HISTORY OF VACCINATION LAWS, WHY THEY EXIST

In a 1999 report detailing great public health achievements of the 20th century, the CDC declared vaccination among the top ten.[3] Even among other public health evolutions recognized to dramatically affect the spread of infectious diseases and death during childhood—public hygiene, antibiotics, and vaccination—"vaccination has been singularly effective in preventing diseases for which there is no effective therapy."[4] Vaccination "has resulted in the eradication of smallpox; elimination of poliomyelitis in the Americas; and control of measles, rubella, tetanus, diphtheria, Haemophilus influenza type b, and other infectious diseases in the United States and other parts of the world."[5]

Edward Jenner published his discovery of a vaccination for smallpox in 1798. Before Jenner's vaccine became widely available, 85-95% of the population endured the disease.[6] "Few reached adult life without having suffered its effects."[7] Throughout Europe, smallpox decimated communities during the 18th and 19th centuries, with an estimated 400,000 people dying every year from smallpox alone.[8] In London, smallpox affected an estimated 10,000 people per year during the 18th century.[9]

In 1809, Massachusetts enacted the first state law mandating vaccinations.[10] In 1853, Britain became the first country with mandatory vaccination laws, requiring babies to be vaccinated against smallpox.[11] Two years later, Massachusetts enacted school vaccination requirements.[12]

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3. *Ten Great Public Health Achievements – United States, 1900-1999*, 48 Ctrs. For Disease Control & Prevention Morbidity & Mortality Wkly. Rep. 241, 241 (1999), https://www.cdc.gov/mmwr/preview/mmwrhtml/00056796.htm.

4. Michael J. Rieder and Joan L. Robinson, *'Nosodes' are no substitute for vaccines*, 20 Pediatrics & Child Health 219, 219 (2015).

5. Ctrs. For Disease Control & Prevention, *supra* note 1, at 241.

6. Med. Soc'y. of the State of Pa., Vaccination: A Message From the Medical Society of the State of Pennsylvania (1908).

7. *Id.*

8. *Id.*

9. *Id.*

10. Kevin M. Malone & Alan R. Hinman, *Vaccination Mandates. The Public Health Imperative and Individual Rights*, in Law in Public Health Practice 338, 346 (Richard A. Goodman et al. eds., 2d ed. 2007).

11. Christal Cammock and Jennifer Baumn, *Vaccination Law 101: A Guide for Children's Lawyers*, American Bar Association (July 2, 2009), https://www.americanbar.org/groups/litigation/committees/childrens-rights/articles/2019/summer2019-vaccination-law-101-a-guide-for-childrens-lawyers/.

12. *Id.*

Compulsory vaccination laws went into effect in Germany in 1874, and between 1875 and 1886 the average yearly mortality rate due to smallpox fell to 1.91 out of 100,000. Compare that to Austria, where vaccination laws were much laxer, and the mortality rate due to smallpox increased to between 39.28 and 94.79 per 100,000. By 1897, Germany saw five cases of smallpox out of a population of 54 million.[13] By the early 20th century, the smallpox epidemic in Germany had ended.

In 1963, the first measles vaccine was approved,[14] and by the mid-1970s, states began enacting school vaccination laws. Two jurisdictions, Alaska and Los Angeles in California, illustrate the dramatic effect vaccination laws had in the eventual decline of measles rates in this country. Alaska started enforcement in 1976. "[O]n the announced day of [vaccination] enforcement, 7,418 of 89,109 [students] (8.3%) failed to provide proof of vaccination and were excluded from school. One month later, fewer than 51 students were still excluded. *No further cases of measles occurred.* In 1977, [i]n Los Angeles, approximately 50,000 of 1,400,000 students (4%) were excluded; most were back in school within a few days, and the number of measles cases dropped precipitously."[15] Immediately after vaccination mandates went into effect, states with vaccination laws for measles had incident rates 40-51% lower than states without mandatory laws.[16]

III. VACCINATION LAWS MATTER—EFFECTS OF VACCINATION AND NON-VACCINATION

Globally, prior to widespread immunizations, measles was one of the primary causes of childhood death, causing an estimated 2.6 million deaths annually.[17] Worldwide eradication campaigns in the 1970s cut the number of deaths to less than one million.[18] A second campaign begun in 2000 further reduced the number of worldwide measles deaths to just under 100,000,[19] more than a 95% reduction.[20] In the U.S., prior to wide availability of the vaccine, up to four million people every year contracted measles.[21] By 2000, "the U.S. had the highest immunization coverage and the lowest rates of vaccine-preventable disease ever documented,"[22] and by 2004, only 37 people were reported to have contracted measles.[23]

In the wake of this dramatic result, the last decade has seen the number of individuals, including parents on behalf of their children, who refuse vaccinations increase in the U.S. and worldwide.[24] The World Health Organization (WHO) reports 13% of parents worldwide have chosen not to vaccinate their children.[25]

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13. Med. Soc'y. of the State of Pa., *supra* note 4.
14. Cammock and Baumn, *supra* note 9.
15. Malone and Hinman, *supra* note 8, at 344 (emphasis added).
16. *Id*.
17. *GBD Results Tool*, Institute For Health Metrics and Evaluation, http://ghdx.healthdata.org/gbd-results-tool?params=gbd-api-2017-permalink/2b57f63c15fce3a393f7661aea4c7a3a (last visited Jan. 27, 2020).
18. *Id*.
19. *Id*. (internal citations omitted).
20. Peter Hotez, *America and Europe's New Normal: The Return of Vaccine-Preventable Diseases*, 85 Pediatr Res 912, 912 (2019), https://www.nature.com/articles/s41390-019-0354-3.
21. Cammock and Baumn, *supra* note 9.
22. Erin Flanagan-Klygis, *School Vaccination Law: Personal Exemptions From Mandatory Vaccination Requirements Ensure Peaceful Coexistence Between Personal Autonomy and Social Responsibility*, 5 Virtual Mentor 11 (2003), https://doi.org10.1001/virtualmentor.2003.5.11.pfor1-0311 (internal citations omitted).
23. Cammock and Baumn, *supra* note 9.
24. *Social Medicine: The Effect of Social Media on the Anti-Vaccine Movement*, Infectious Disease Advisor, https://www.infectiousdiseaseadvisor.com/home/topics/prevention/social-medicine-the-effect-of-social-media-on-the-anti-vaccine-movement/ (last visited January 27, 2020).
25. *Id*.

In 2000, with so few reported measles cases in the U.S., the WHO declared measles to be eliminated in the U.S., and by 2016 to be eliminated in the Western Hemisphere. With just over 5,000 cases in all of Europe in 2016, the WHO European Region reported that measles reached its lowest point. Global elimination was in sight.[26] Then, in an 11-month period between April 2017 and March 2018, over 4,000 new measles cases were reported in Europe.[27] By November 2018, over 53,000 measles cases were reported in Europe resulting in 40 deaths.[28] Most cases appeared in Italy, Romania, and Greece and primarily among unvaccinated individuals.[29] The Ukraine saw 29,464 new measles cases.[30] By the end of October 2018, England alone had 913 measles cases. Most cases occurred in teenagers and young adults who had never been vaccinated against measles as children.[31] To those studying vaccination confidence around the world, this measles outbreak across Europe was predictable. A 2016 study measuring levels of confidence in vaccine safety found Europeans to be the most skeptical.[32] The previously positive trend of lowered, almost eliminated disease incidence has largely been reversed. In each of the countries seeing outbreaks, immunization rates have decreased.

The U.S., while not experiencing the same dramatic numbers as Europe, is witnessing an increase in reported measles cases. From 2017 to 2018, outbreaks occurred in Minnesota (over 50 cases reported and linked to anti-vaccine rhetoric),[33] New York, New Jersey, Kansas, and Missouri, with a total of 220 measles cases in 2018 alone.[34] Most of those affected by outbreaks were unvaccinated.[35]

In what is perhaps one of the most tragic and illustrative examples of what can happen without proper vaccination, Samoa is currently suffering from an alarming measles outbreak, including extremely high numbers of deaths. As of December 11, 2019, 4,995 measles cases had been recorded, and 72 people, mostly young children, had died.[36] In a two-week period, between November 27 and December 11, the number of reported cases more than doubled and 40 additional people died.[37] In a single 24-hour period in November 2019, 243 new cases were reported to health officials.[38] "Children under five account for half of cases" and "more than 90% of those recently admitted to hospitals were children."[39] Even more tragic, among those who died, 40% were babies under one year and thus too young to be vacci-

26. Hotez, *supra* note 19, at 912 (internal citations omitted).
27. Arthur L. Caplan et al., *Science in the fight to uphold the rights of children*, 16 PLoS Biol. (2018), https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.3000010 (internal citations omitted).
28. Hotez, *supra* note 19, at 912.
29. Caplan et al., *supra* note 26 (internal citations omitted).
30. Heidi J. Larson, *The State of Vaccine Confidence*, 392 The Lancet 224 (2018), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)32608-4/fulltext (internal citations omitted).
31. *Id*. (internal citations omitted).
32. *Id*. (internal citations omitted)
33. Gerard Gallagher, *Minnesota Measles Outbreak Linked to Anti-Vaccine Rhetoric Hits 50 Cases*, Healio, https://www.healio.com/infectious-disease/vaccine-preventable-diseases/news/online/%7Bc13b1e00-3187-40c0-b81b-61d05f6e7b62%7D/minnesota-measles-outbreak-linked-to-anti-vaccine-rhetoric-hits-50-cases (last visited January 27, 2020).
34. Hotez, *supra* note 19, at 912 (internal citations omitted).
35. *Id*.
36. Katherine Gibney, *Measles In Samoa: How a Small Island Nation Found Itself In the Grips of an Outbreak Disaster*, Conversation, https://theconversation.com/measles-in-samoa-how-a-small-island-nation-found-itself-in-the-grips-of-an-outbreak-disaster-128467 (last visited January 27, 2020).
37. Ben Guarino et al., *Deadly Measles Outbreak Hits Children in Samoa After Anti-Vaccine Fears*, Washington Post (Nov. 27, 2019), https://www.washingtonpost.com/health/2019/11/26/deadly-measles-outbreak-hits-children-samoa-after-anti-vaccine-fears/.
38. *Id*.
39. *Id*.

nated, while almost 90% were children less than five.[40] In late November 2019, the country took the drastic steps of closing schools nationwide and banning children under 17 from public gatherings.[41]

Not only does this show the effects of measles on an unvaccinated population, but also what happens when misinformation spreads and confidence in vaccine safety is compromised. By 2018, the vaccination rate in Samoa for children one year and less had fallen from 76% in 2012 to 31%.[42] This decline resulted from at least two identifiable factors. One is the death of two children in July 2018 after they received an MMR vaccination.[43] The deaths were later determined to have resulted from human error, the vaccines were mixed with muscle relaxant rather than water, but the damage to vaccine confidence had been done by the time the true cause of death was determined.[44] Second is a culture of anti-vaccine sentiment fostered by advocacy groups using hashtags such as #makinginformedchoices and #investigatebeforeyouvaccinate.[45] Through social media, these groups perpetuated "false rumours that hospitals were using faulty or expired vaccines and, as in other countries, repeated the debunked claim that immunisation is linked to autism."[46] A now arrested anti-vaccination advocate claimed that "1000mg vit C sodium ascorbate taken dissolved in 1/4 cup water every 3 hours" would cure measles cases.[47] An anti-vaccine seminar, titled "Making Informed Choices," scheduled for June 2019 was cancelled after Samoan health officials, including the Health Ministry's director general, pressured planners to cancel.[48]

It was not until after a full government shutdown and a door-to-door vaccination campaign from December 5-6 that the number of new cases appearing daily began to slow.[49] Officials report that the vaccination campaign resulted in an estimated 93% of the population now being vaccinated. To stop the outbreak entirely, over 95% of children six months to four years old must be vaccinated.[50]

IV. STATE AUTHORITY TO MANDATE VACCINATION

The U.S. has a strong culture of individualism. Freedom of personal expression, religion, and choice are among the most revered rights Americans hold. At the same time, we live in a society that depends on interrelationships and connections with others to ensure success. We depend on proper behavior from those around us for our own safety and well-being. To function, we must believe we will be safe in public settings. Questions regarding vaccination mandates have forced federal and state courts to balance individual freedoms with public responsibility. From the first case examining this issue, the conclusion has been that a state's obligation to ensure the health and safety of its citizens outweighs an individual's right to refuse vaccination.

40. Gibney, *supra* note 36.
41. Guarino, *supra* note 37.
42. *Id*.
43. *Id*.
44. *Id*.
45. *Id*.
46. *The anti-vax movement causes an epidemic in Samoa*, ECONOMIST, Dec. 5, 2019, https://www.economist.com/asia/2019/12/05/the-anti-vax-movement-causes-an-epidemic-in-samoa.
47. Arturo Garcia, *Anti-Vaxxer Arrested in Samoa Boasted of American Support via Social Media*, Disinformation, Reporting, TRUTHORFICTION.COM, Dec. 6, 2019, https://www.truthorfiction.com/edwin-tamasese-samoa-facebook-anti-vaxxer/.
48. Guarino, *supra* note 36.
49. Gibney, *supra* note 35.
50. *Id*.

The U.S. Supreme Court first addressed this issue in *Jacobson* v. *Massachusetts*, in 1905 and declared "the liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good. On any other basis organized society could not exist with safety to its members."[51]

Even in recognition of a guarantee of religious freedom, or a later identified right to family privacy, courts consistently recognize the obligation to protect public health and take necessary measures to do so. *Jacobson* upheld the right of states to compel vaccination and the ability of states to use their police power to do so, without violating an individual's liberty rights under the Fourteenth Amendment.[52] The Court specifically rejected the idea of a personal choice exemption, stating that to do otherwise "would practically strip the legislative department of its function to . . . care for the public health and the public safety when endangered by epidemics of disease."[53]

The Court spoke to the depth of authority of the state's police power in 1922 in *Zucht* v. *King* when it clarified that states have authority to mandate and direct behavior not just in *response* to an outbreak, but to *prevent* one.[54] The Court specifically stated, "these ordinances confer not arbitrary power, but only that broad discretion required for the protection of the public health."[55]

State courts have responded similarly. In 1987, the Arizona Court of Appeals "rejected the argument that an individual's right to education would trump the state's need to protect against the spread of infectious diseases short of confirmed cases of measles in the particular school."[56] The court decided the state's exclusion of unvaccinated children from school in the face of a risk for the spread of measles was appropriate.[57]

The U.S. Supreme Court has also based this authority to mandate vaccination on the doctrine of *parens patriae* which was summarized by the Court in 1944 in *Prince* v. *Massachusetts* when it stated:

> "[n]either rights of religion nor rights of parenthood are beyond limitation. Acting to guard the general interest in youth's well being, the state as *parens patriae* may restrict the parent's control by requiring school attendance, regulating or prohibiting the child's labor, and in many other ways. Its authority is not nullified merely because the parent grounds his claim to control the child's course of conduct on religion or conscience. Thus, he cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds. The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death."[58]

Two additional U.S. Supreme Court cases, *Wisconsin* v. *Yoder* (1972) and *Sherbert* v. *Verner* (1963), offer insight into the Court's thinking on the doctrine.[59] Dicta in both cases reference *Jacobson* and *Prince* indicating states have a compelling interest to mandate vaccination of children using *parens patriae* and police powers to ensure

51. *Jacobson* v. *Massachusetts*, 197 U.S. 11, 26 (1905).
52. Malone and Hinman, *supra* note 8, at 346 (citing *Jacobson*, 197 U.S. at 25).
53. *Jacobson*, 197 U.S. at 37.
54. *Zucht* v. *King*, 260 U.S 174, 177 (1922).
55. *Id*.
56. Malone and Hinman, *supra* note 8, at 347 (citing *Maricopa County Health Department* v. *Harmon*, 750 P.2d 1364, 1369 (1987).
57. *Maricopa County Health Department*, 750 P.2d at 1370.
58. *Prince* v. *Massachusetts*, 321 U.S. 158, 166-7 (1944).
59. *Wisconsin* v. *Yoder*, 406 U.S. 205, 215 (1972); *Sherbert* v. *Verner*, 374 U.S. 398, 403 (1963).

the health of community and children.[60] The *Yoder* decision further states "the very concept of ordered liberty precludes allowing every person to make his own standards on matters of conduct in which the society as a whole has important interests."[61]

Interestingly, the *Yoder* Court goes even further in its assertion of the state's vast authority to protect public health with a reference to an Arizona Supreme Court case which held "no First Amendment right existed to a religious exemption given the state's compelling interest in mandating vaccination under its police power to protect the public health."[62] The *Yoder* Court uses that language in dicta and seems to imply even a religious exemption to mandatory vaccination is not constitutionally protected thus reinforcing the Court's strong belief in governmental authority to mandate vaccinations.[63]

V. STATE LAWS AND EXEMPTIONS

A. Pennsylvania

Like all states, Pennsylvania requires children entering school be vaccinated against several communicable diseases. This requirement is found in the Pennsylvania Code section addressing Health and Safety, specifically disease prevention, and school health. The regulation directs schools and school administrators to "ascertain the immunization status of a child prior to admission to school or continued attendance at school."[64] The section explains the "requirements under which admission or continued attendance is permitted" for situations in which a child has *not* received immunizations.[65] One such situation is "upon submission of information sufficient for an exemption under §23.84."[66] Section 23.84, Exemption from Immunization, offers two possible exemptions to the requirement that children be immunized: a medical exemption, when "immunization may be detrimental to the health of the child,"[67] and a religious exemption that states "children need not be immunized if the parent, guardian, or emancipated child objects in writing to the immunization on religious grounds *or on the basis of a strong moral or ethical conviction similar to a religious belief*."[68] As such, the regulation functionally also allows philosophical exemptions. The writing the regulation references is a form on which a parent or guardian need only fill in name, address, phone, grade, date of birth, and then sign and check a box indicating the child is exempt from immunizations because of a religious, moral, or ethical conviction.[69] Thus, the process by which a parent's child can be excused from the vaccination requirement is to fill out a form with five pieces of information, sign the form, and check a box. There is no requirement for medical documentation, a statement from a religious leader, or even a statement by the parent or guardian about why s/he objects.

B. Other States

Pennsylvania is one of only 18 states currently allowing for a philosophical exemption in addition to a religious exemption. 45 states and Washington, D.C. grant

60. Malone and Hinman, *supra* note 8, at 350.
61. *Yoder*, 406 U.S. at 216.
62. *Wright* v. *DeWitt School District*, 238 Ark. at 913, 385 S.W.2d at 648.
63. Malone and Hinman, *supra* note 8, at 350.
64. 28 Pa. Code §23.85 (2019).
65. *Id*. (emphasis added).
66. *Id*.
67. 28 Pa. Code §23.84 (2019).
68. *Id*. (emphasis added).
69. *Id*.

religious exemptions.[70] Only three states have neither a religious nor philosophical exemption: California,[71] Mississippi,[72] and West Virginia.[73] Of note, it was the Mississippi Supreme Court that removed the religious exemption in that state in 1979.[74] In *Brown* v. *Stone*, the Court stated "the religious exemption that appeared in the Mississippi school vaccination statute . . . violated the Equal Protection Clause of the Fourteenth Amendment because it would 'require the great body of school children to be vaccinated and at the same time expose them to the hazard of associating in school with children exempted under the religious exemption who had not been immunized.'"[75]

Since 2015, eleven states have passed legislation tightening allowances for religious or philosophical exemptions to immunizations.[76] In 2015, California and Vermont removed exemptions for philosophical reasons, and California's statute limited exemptions to be only medical exemptions.[77] In 2019 alone, three states enacted legislation removing personal and/or religious exemptions for public schools, private schools, and/or day care centers.[78] Washington, Maine, and New York all removed sections of their laws allowing exemptions based on personal and/or religious beliefs.[79] Across the country, and in response to localized outbreaks of diseases, states have recognized that low vaccination rates in a community are serious, and often fatal. Limiting or tightening exemptions is one important way to increase vaccination rates among school-age children.[80]

C. Exemptions

School immunization requirements have resulted in substantial increases in immunization rates among school-aged children and significant reductions in vaccine-preventable disease incidence and associated outbreaks. However, to optimize the ability of these requirements to prevent and control the spread of vaccine-preventable disease, the architecture and stringency of enforcement is important.

Multiple studies show the relationship between the ease of claiming an exemption, the number of exemptions claimed, the number of unvaccinated children, and, ultimately, the number of cases of preventable diseases. As expected, and as the studies noted below illustrate, states offering more exemptions with easier exemption processes and less enforcement see more parents claiming an exemption. Those states have higher rates of unvaccinated children and thus higher rates of preventable diseases.

The A*merican Journal of Public Health* published a 2001 study that found:

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70. *States With Religious and Philosophical Exemptions From School Immunization Requirements*, Nat'l Conference of State Legislatures (June 2019), https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx.
71. Cal. Health & Safety Code §120325 *et seq*. (West Supp. 2016).
72. Miss. Code Ann. §41-23-37 (2017).
73. W.Va. Code §16-3-4 (LexisNexis 2017).
74. *Brown* v. *Stone*, 378 So. 2d 218 (Miss. 1979).
75. *Id*. at 223.
76. Malone and Hinman, *supra* note 8, at 350.
77. *States With Religious and Philosophical Exemptions From School Immunization Requirements*, Nat'l Conference of State Legislatures (June 2019), https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx.
78. *Id*.
79. N.Y. Pub. Health Law §2164 (2019).
80. Erik Skinner, *State Vaccination Policies: Requirements and Exemptions for Entering School*. 25 NCSL Legisbrief 1 (2017).

> an inverse correlation between the complexity of the exemption process and the proportion of exemptions filed. None of the 19 states with the highest level of complexity in gaining exemptions [for example, notarization of exemption form, required vaccine education] had more than 1% of students exempted compared with 5 of 15 states with the simplest exemption procedure. In these latter states, less effort was required to claim a nonmedical exemption than to fulfill the vaccination requirement.[81]

A 2000 study published in the *Journal of the American Medical Association* looked at data from Colorado, the state with the "highest percentage of unvaccinated children due to personal," medical, religious, and philosophical exemptions. The data showed that:

> unvaccinated children 3-18 years old were 22 times more likely to acquire measles and 6 times more likely acquire pertussis than immunized children. In children 3-10 years old, the risks were 60-fold greater for acquiring measles and 16-fold greater for pertussis. Rates of disease in vaccinated children exposed to exemptors increased as well.[82]

This study confirmed the serious risks vaccine refusal poses not just to unvaccinated individuals but to the health of entire communities.

Minimizing vaccine exemption rates has important public health implications, and state policy plays an important role in determining the ease with which individuals can claim an exemption.[83] The exemptions Pennsylvania allows and the process to claim an exemption are among the easiest in the country. Observing what has happened around the country in recent years, Pennsylvania can expect to see higher rates of vaccine-preventable diseases, not just among unvaccinated children, but even among those who have been vaccinated. Easy vaccine exemption requirements have dire consequences for the entire population.

Recent evidence also shows vaccination has health benefits beyond prevention of the infection targeted by the vaccine. Specifically, measles vaccines not only prevent measles but also reduce the risk for other infectious diseases.[84] This is because measles infection results in immunosuppression through B and T lymphocyte depletion that persists even after the measles infection has resolved. Studies have

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81. Malone and Hinman, *supra* note 8, at 355 (citing J.S. Rota et al., *Processes for Obtaining Nonmedical Exemptions to State Immunization Laws*. 91 Am J Public Health 645 (2001)).

82. Flanagan-Klygis, *supra* note 21.

83. Robert Bednarczyk et al., *Current Landscape of Nonmedical Vaccination Exemptions in the United States: impact of policy changes*, 18 Expert Rev. Vaccines 175 (2019), https://doi: 10.1080/14760584.2019.1562344. *See also*: Saad B. Omer et al., *Nonmedical Exemptions to School Immunization Requirements: Secular Trends and Association of State Policies with Pertussis Incidence*, 296 J. of Am. Med. Ass'n 1757 (2006); Saad B. Omer et al., *Geographic Clustering of Nonmedical Exemptions to School Immunization Requirements and Association with Geographic Clustering of Pertussis*, 168 Am. J. Epidemiology 1389 (2008), https://doi: 10.1093/aje/kwn263; Carlin Aloe et al., *Geospatial Analysis of Nonmedical Vaccine Exemptions and Pertussis Outbreaks*, 114 Proc. Natl. Acad. Sci. USA 1389 (2008), https://doi.10.1073/pnas.1700240114; Varun K. Phadke et al., *Association Between Vaccine Refusal and Vaccine-Preventable Disease in the United States: Review of Measles and Pertussis*, 315 J. of Am. Med. Ass'n 1149 (2016), https://doi: 10.1001/jama.2016.1353; Saad B. Omer et al., *Trends in Kindergarten Rates of Vaccine Exemption and State-Level Policy, 2011-2016*, 5 Open F. Infectious Diseases (2018), https://doi:10.1093/ofid/ofx244; Jacqueline K. Olive et al., *The State of the Antivaccine Movement in the United States: A Focused Examination of Nonmedical Exemptions in States and Counties*, 15 PLoS Med. e1002578 (2018), https://doi: 10.1371/journal.pmed.1002578.

84. *See* Kartini Gadroen et al., *Impact and Longevity of Measles-Associated Immune Suppression: A Matched Cohort Study Using Data From the THIN General Practice Database in the UK*, 8 BMJ Open e021465 (2018), https://bmjopen.bmj.com/content/8/11/e021465; Hayley R. Ashbaugh et al., *Association of Previous Measles Infection With Markers of Acute Infectious Disease Among 0- to 59-Month-Old Children in the Democratic Republic of the Congo*, 8 J. Pediatric Infectious Diseases Soc. 531 (2018), https://doi.org/10.1093/jpids/piy099.

shown an increased likelihood of signs of non-measles acute infection among children with a history of prior measles infection compared to children without a history of measles. Measles vaccination has therefore been associated with a reduction in all-cause childhood mortality among young children less than 5 years old. This point is important to highlight in consideration of the allegation from Wenger, et al., that high immunization rates are associated with increased infant mortality. This supposed association is inaccurate, is not supported by evidence, and mischaracterizes the complexity of factors such as maternal obesity, maternal smoking and poverty that do influence infant mortality rates.[85] In fact, vaccination is a key prevention strategy to reduce morbidity and mortality among infants. Introduction of routine immunization has resulted in significant decreases in illness and death due to vaccine-preventable diseases such as *Haemophilus influenza*, pneumococcus, varicella and measles, while polio is nearly eradicated. Many countries around the world have high immunization rates and better infant mortality rates. It is more important to examine what happens to vaccine-preventable disease incidence when immunization rates decline.

VI. MISINFORMATION AND VACCINE HESITANCY

Exemption requests, and thus lower immunization rates, in many communities are symptoms of rising "vaccine hesitancy." Vaccine hesitancy has been present since the first requirements for smallpox vaccination in the 19th century, and reasons for hesitancy then and now have many parallels. Hesitancy is largely related to beliefs about freedom of choice, as well as vaccine safety concerns and questions about the need for vaccines to prevent disease. It is certainly valid to have questions about vaccines. Vaccinology is not a standard part of science curricula, so many people, when faced with decisions about vaccination, may not know how vaccines are produced or why certain vaccines are recommended at certain times. The field of vaccinology has evolved over time, and we are now challenged by an expanding, rapidly changing immunization schedule that protects against diseases many parents have not experienced, along with willful dissemination of misinformation designed to undermine confidence in vaccines and their scientific foundation.

Misinformation has been characterized as a public health threat because it is highly accessible and has the potential to induce fear, but it can also be difficult to recognize. One particularly concerning, but impactful, form of misinformation is bad science.[86] Andrew Wakefield's publication alleging MMR vaccines may cause autism is a good example of the far-reaching impact of bad science. Wakefield's paper was found to be fraudulent but was published in a respected journal before its retraction. Even though a large body of literature has demonstrated vaccines are not associated with autism, the belief has persisted, fueling vaccine refusal associated with current measles outbreaks. Another feature of misinformation is its widespread propagation through social media amplifying antivaccine allegations, giving them false equivalence. Many allegations use scientific language to gain credibility or present flawed or biased studies. It is important to evaluate the information being

85. *See* Lindsay S. Womack et al., *Urban-Rural Infant Mortality Disparities by Race and Ethnicity and Cause of Death*, 58 Am. J. Prev. Med. 254 (2019), https://doi.org/10.1016/j.amepre.2019.09.010; Erin Clements et al., *Underlying Causes and Distribution of Infant Mortality in a Statewide Assessment From 2005-2016 by Infant, Maternal and Neighborhood Characteristics*, 102 R.I. Med. J. 15 (2019).

86. *See* Heidi J. Larson, *The Biggest Pandemic Risk? Viral Misinformation*, 562 Nature 309 (2018); Bert Baumgaertner et al., *The Influence of Political Ideology and Trust on Willingness to Vaccinate*, 13 PLoS One e0191728 (2018).

used as a resource or as evidence, including source and tone. Many websites and media reports may rely upon anecdotes rather than scientific studies. Even when scientific studies are cited, they may not all be reliable. Generally, scientific studies use statistics to look for significant associations between intervention (i.e. vaccination) and outcome. To do this well, a study should be peer-reviewed, have a comparison group, consider other factors that might bias an association and have results that can be supported by other studies.[87]

VII. VACCINE SAFETY

Vaccines work by prompting an immune response that produces antibodies specific to the bacteria or viruses targeted by a particular vaccine. If the body is exposed to these bacteria or viruses in the future, it already has the antibodies it needs to provide protection against infection. Importantly, vaccines prompt an immune response without causing disease or illness. The idea that vaccines stimulate the immune system can be a source of concern, especially since current recommended immunization schedules call for the receipt of multiple vaccines at the same time. Because vaccines stimulate an immune response, individuals may experience symptoms such as fever, arm swelling, or redness. These are signs the vaccine is working, and there is no evidence that this immune response suppresses the ability to respond to other infections, induces autoimmunity or results in long-term health outcomes.[88] Recent studies have specifically examined whether exposure to vaccines among infants and children is associated with significant changes to their immune system, a higher risk for non-vaccine targeted infections or adverse neuropsychological outcomes. Immune response from natural infection would be far more robust and, as evidenced by the immunosuppressive impact of natural measles infection, longer lasting. Natural infection also comes at a high cost. To suggest otherwise underplays the potential risks of a "short-term" virus. Many viral and bacterial illnesses are self-limited, but short-term infections can result in long-term problems and death. People die of influenza every year despite antiviral medications. People die of meningococcal disease or lose their limbs despite antibiotics.

Some may have concerns about other ingredients included in vaccines such as adjuvants like aluminum or inactivating agents like formaldehyde. Vaccines include such ingredients because they are necessary to keep vaccines safe and help vaccines

87. *Evaluating Information: What You Should Know,* Children's Hosp. Phila. (2017), https://media.chop.edu/data/files/pdfs/vaccine-education-center-evaluating-info-qa.pdf.

88. Jason M. Glanz et al., *Association Between Estimated Cumulative Vaccine Antigen Exposure Through the First 23 Months of Life and Non-Vaccine-Targeted Infections From 24 through 47 Months of Age*, 319 J. of Am. Med. Ass'n 906 (2018); Ashley M. Sherrid et al., *Lack of Broad Functional Differences in Immunity in Fully Vaccinated vs. Unvaccinated Children*, 81 Pediatric Res. 601 (2017); Anders Hviid et al., *Childhood Vaccination and Nontargeted Infectious Disease Hospitalization*, 294 J. of Am. Med. Ass'n 699 (2005); Rohan Ameratunga et al., *Evidence Refuting the Existence of Autoimmune/Autoinflammatory Syndrome Induced by Adjuvants (ASIA)*, 5 J Allergy & Clinical Immunology: in Practice 1551 (2017); Mia Topsøe Mailand et al., *Vaccines and Multiple Sclerosis: A Systematic Review*, 264 J. Neurology 1035 (2017); Annette Langer-Gould et al., *Vaccines and Risk of Multiple Sclerosis and Other Central Nervous System Demyelinating Diseases*, 71 J. of Am. Med. Ass'n 1506 (2014); Serkan Ozakbas et al., *Development of Multiple Sclerosis After Vaccination Against Hepatitis B: A Study Based on Human Leucocyte Antigen Haplotypes*, 68 Tissue Antigens 235 (2006); Thomas Verstraeten et al., *Analysis of Adverse Events of Potential Autoimmune Aetiology in a Large Integrated Safety Database of AS04 Adjuvanted Vaccines*, 26 Vaccine 6630 (2008); Shahed Iqbal et al., *Number of Antigens in Early Childhood Vaccines and Neuropsychological Outcomes at Age 7-10 Years*, 22 Pharmacoepidemiology & Drug Safety 1263 (2013); Frank DeStefano et al., *Increasing Exposure to Antibody-Stimulating Proteins and Polysaccharides in Vaccines Is Not Associated with Risk of Autism*, 163 J Pediatrics 161 (2018); Michael J. Smith et al., *On-time Vaccine Receipt in the First Year Does Not Adversely Affect Neuropsychological Outcomes*, 125 Pediatrics 1134 (2010).

work better. These ingredients are compounds we encounter every day through the foods we eat or exposure to our natural environment. They are present in such small amounts in vaccines, even from multiple vaccines given at the same time, that exposure does not lead to any toxicity. In fact, we already have heavy metals like aluminum in our bloodstream, and vaccines do not increase our natural levels.[89]

Every part of vaccine development and recommendation formation is done with safety of individuals and community first and foremost in mind. Because vaccines are given when individuals are healthy, the requirements to establish safety are higher than for any other pharmaceutical product. All medical interventions, including vaccines, have risks, but those risks are defined, and a vaccine will not be approved if any potential risks outweigh benefits. Vaccine safety is a rigorous part of development that continues after licensure, supported by a robust active and passive surveillance system. Schedules are designed to optimize safety and effectiveness, and, most importantly, provide coverage when individuals are at their highest risk of contracting vaccine-preventable diseases. Precautions and contraindications are designed to minimize and avoid potential risks. It is irresponsible to suggest that safety is not a consideration for those who develop and recommend vaccines. There is no benefit to recommend something that adversely affects the long-term health of a community.

VIII. INFORMED CONSENT

No single person can know and understand the depth of medical conditions, interventions, symptoms, treatments, and/or consequences. Therefore, one of the tenets of American medicine is that patients and/or their guardians be informed about the medical condition or diagnosis being addressed, what suggested intervention involves, and risks and benefits of all possible medical treatments, including non-treatment.[90] The American Medical Association requires this communication to be in a form understandable to the patient and/or guardian and to include information on treatment alternatives.[91] The requirement for physicians to obtain informed consent prior to vaccination already exists; and the CDC prepares—and physicians are required to provide—vaccination information statements (VIS) for every vaccine, even each vaccine dose in a multi-dose series, provided in this country.[92]

The information provided in VISs regards *medical* information. "Each VIS contains a brief description of the disease as well as risks and benefits of the vaccine."[93] Most VISs "dedicate almost half of their information to detailing risks of the vaccines and providing information to parents on how to report negative vaccine reactions to the National Vaccine Injury Compensation Program."[94] Parents should be informed of recommendations being made for their children. Parents should be

89. Mateusz P. Karwowski et al., *Blood and Hair Aluminum Levels, Vaccine History, and Early Infant Development: A Cross-Sectional Study*, 18 Acad. Pediatrics 161 (2018); Robert J. Mitkus et al., *Updated Aluminum Pharmacokinetics Following Infant Exposures Through Diet and Vaccination*, 29 Vaccine 538 (2011); Robert J. Mitkus et al., *Pharmacokinetic Modeling as an Approach to Assessing the Safety of Residual Formaldehyde in Infant Vaccines*, 31 Vaccine 2738 (2013); Jorgen Stassijns et al., *A Systematic Review and Meta-Analysis On the Safety of Newly Adjuvanted Vaccines Among Children*, 34 Vaccine 714 (2016).

90. *Informed Consent*, Ama-assn.org, https://www.ama-assn.org/delivering-care/ethics/informed-consent (last visited Jan. 27, 2020).

91. *Id*.

92. *Id*.

93. Ctrs. for Disease Control & Prevention, History of Vaccine Safety, https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html (last visited Jan. 27, 2020).

94. Olivia Benecke et al., 6 Global Pediatric Health 1 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6657116/.

able to ask questions and have their concerns heard and answered, but parents must receive accurate and credible information based upon facts. To present anything besides vaccination as an effective alternative to preventing disease would be false, would not be *medical* information, and could cause harm to individuals and entire communities.

Homeopathic therapy, known as "nosodes" (from Greek *nosos*, meaning disease), has been increasingly identified by anti-vaccine advocates as an alternative to routine vaccines.[95] Nosodes are "biological preparations" and are a "specific category of homeopathic treatment."[96] The idea of nosodes as a therapy developed in the mid-1700s. Despite the process being around for over 200 years, there is very little "evidence in the medical literature for either the efficacy or safety of nosodes, which have not been well studied for the prevention of any infectious disease in humans."[97] Given that limited information is known regarding the effectiveness or safety of nosodes, it would be foolish indeed for physicians to offer homeopathic therapy as a legitimate alternative to vaccination.

While some vaccine-preventable diseases may be treated after acquisition of the disease, no intervention prevents infection as does vaccination. Treatment does not prevent having to experience the disease and its symptoms. While treatment may reduce morbidity and mortality, it is at the cost of serious illness and suffering. Vitamin A for measles is the only recommended treatment and can only help mitigate symptoms; it is not a cure. Antibiotic use for other vaccine-preventable diseases has potential sequelae as well, such as side effects and, more importantly, resistance. Some infectious diseases have few available treatments left due to resistance for which prevention through vaccination is especially important. For many vaccine preventable diseases, no treatment beyond supportive care is available.

While informed consent is necessary and vital for parents learning about vaccination, the suggestion that current mandates are not enough, or that information on alternatives be part of the conversation is faulty. Vaccination is a standard of care, recommended under tenets of the Hippocratic Oath: nonmaleficence and beneficence. The benefits of vaccination far outweigh any possible risks for individuals and communities, and the risks of not vaccinating far outweigh any possible benefits.

IX. CONCLUSION

This article argues that Pennsylvania law should be strengthened to limit the type and number of exemptions allowed for vaccine mandates. It is in response to a suggestion that Pennsylvania law does not protect the rights of parents during the vaccination process. However, what is clear about Pennsylvania vaccination law is that it does not adequately protect the safety of Pennsylvania citizens. Federal and state courts have repeatedly concluded that state power to protect the health and safety of citizens outweighs any personal right to forego vaccines. The process Wenger proposes, allowing parents an exemption from vaccination requirements by giving informed consent to their physician, is, in fact, stricter than current Pennsylvania law. Currently, exemption forms require no written statement from physicians, religious leaders, or parents. It simply requires a box to be checked. Informed consent to medical interventions is necessary, but parents need not be informed about un-

95. Rieder and Robinson, *supra* note 2, at 219.
96. *Id.*
97. *Id.*

proven methods of protecting children from diseases.[98] Physicians already must inform parents of possible negative effects of vaccines, along with serious and long-term consequences of the diseases vaccines protect against. If anything, this process should be strengthened to inform parents about what can happen not just to their child, but to entire communities should the parent forego vaccination for nonmedical reasons. Parents must have accurate and reliable information when learning about vaccination, especially with the proliferation of misinformation from wide-ranging sources. As professionals, it is especially imperative that physicians apply due diligence in ensuring the accuracy of their statements.

Pennsylvania would be well served to move in the direction of California, Vermont, Washington, Maine, and New York to remove at least philosophical and moral exemptions, if not all nonmedical exemptions. At a minimum, Pennsylvania exemption forms should be required to be signed in the presence of a notary. Adding such a requirement will result in parents' serious consideration and assumption of more responsibility for a request to exempt their children from vaccination requirements.

Because of the current broad exemption policy and lax enforcement of school immunization requirements, Pennsylvania is at serious risk of an outbreak of infectious diseases, such as measles or pertussis. Parents have a right to protect the health of their child and to ask questions about vaccines. However, no legitimate debate exists regarding the safety and efficacy of vaccines in this country. That issue has long been resolved, and evidence is clear that vaccines are not only safe, but necessary, to the continued health and safety of communities. The debate, if anything, is how to ensure all individuals who are not medically compromised receive them. This should be the focus of lawmakers.

98. *See W.B.* v. *Crossroads Academy*, 2019 WL 6257963 (WD Mo.), 2019 WL 206718 (WD Mo.) (parents have no right to require state not to advocate the benefits of vaccination on approved consent form).