

## ABSTRACT

### An Analysis of the Ethics in the Role of Government in Vaccination Distribution and Regulation as a Response to Vaccine Refusal Resurgence

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Vaccinations play a vital role in the health and well-being of communities and individuals alike. With a rise of vaccine refusal in recent decades, societies globally are seeing spikes of disease that had been seemingly eradicated in those areas. This thesis looks at the role that government plays in regulating and implementing vaccinations, while also outlining potential methods to discourage vaccine refusal and misinformation about vaccinations. It also discusses the ethical implications of vaccinations, both of governmental mandates and of individuals who choose to forgo vaccination for themselves or make that decision for their children, looking at the public health decisions from philosophical perspectives including utilitarianism, social contract theory, liberal cosmopolitanism, and others. In a pandemic era, vaccines and vaccine mandates continue to have a prevalent role in public health policy and this thesis attempts to address various angles to navigate the issue.

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AN ANALYSIS OF THE ETHICS IN THE ROLE OF GOVERNMENT IN  
VACCINATION DISTRIBUTION AND REGULATION AS A RESPONSE TO  
VACCINE REFUSAL RESURGENCE

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## DEDICATION

I would like to dedicate this project to my parents, Dr. Kyle and Mrs. Amy Reese. Thank you for always prioritizing my education and encouraging me in every step of life. Without your love and support, I would not be the student or person that I am today.

## CHAPTER ONE

### The Creation of Vaccinations and the Inception of Vaccine Refusal

The government has a responsibility to “promote the general welfare” of each citizen by promoting advancements in medicine and protecting those most vulnerable; it has a duty to educate, facilitate, promote, and invest in the creation and distribution of vaccinations and immunizations to allow for a safe environment and for the greatest good of public health. Many modern public health issues result from controversy over debates of personal agency versus societal structure.

Preventative medicine is not something that is new to public health, though Louis Pasteur is credited with the creation of modern immunology. The beginnings of his works were focused on epidemics in silkworms, and as he progressed, he began to find answers that had previously been a complete mystery. For example, bacteria were then thought to be a causative agent of disease leading to the discovery and application of vaccinations. Through experimental trials with chickens, rabbits, and cattle, Pasteur was able to observe a range of disease virulence. The most success that Pasteur had experienced was in the use of the first vaccinations, protecting against rabies. An extension of his research with rabies in rabbits, Pasteur saved the life of a boy infected with rabies via a rabid dog bite. Following this, “an investigation revealed mortality of about 40% among 320

unvaccinated patients bitten by rabid animals. After vaccination, mortality fell to 0.5%,” and thus the first form of vaccinations had shown preventative results.”<sup>1</sup>

The World Health Organization established the Global Vaccine Action plan in 2010 at the start of the decade “to help realize the vision of the Decade of Vaccines, that all individuals and communities enjoy lives free from vaccine preventable diseases.”<sup>2</sup> It focused on the disease elimination of poliomyelitis, maternal and neonatal tetanus, and measles and rubella/congenital rubella syndrome. While also monitoring fluctuations of vaccine administration against these diseases, the WHO presented on vaccine safety, concluding “[a]dverse events following immunization (AEFI) case reporting rates were stable or marginally decreased in most of the regions over the past year.”<sup>3</sup> These data do however make conclusions about immunizations regionally and internationally, not specifically the United States.

Vaccines can provide a wide array of protection of infection caused by bacterial, parasitic, and viral pathogens in which the severity of their effects can be wide ranging. Some of the diseases vaccinated against include smallpox, measles, mumps and rubella, diphtheria, pertussis, tetanus, yellow fever, and poliomyelitis. Passive vaccination, as previously mentioned through the example of Louis Pasteur introducing antibodies to an already infected boy, is administered to people who have already been infected with a

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<sup>1</sup> P. Berche, “Louis Pasteur, from Crystals of Life to Vaccination,” *Clinical Microbiology and Infection* 18, no. s5 (2012): 1–6, <https://doi.org/10.1111/j.1469-0691.2012.03945.x>.

<sup>2</sup> “Global Vaccine Action Plan,” accessed March 23, 2021, <https://www.who.int/teams/immunization-vaccines-and-biologicals/strategies/global-vaccine-action-plan>.

<sup>3</sup> “Global Vaccine Action Plan.”



disease. In contrast, “the active vaccination approach, vaccines stimulate the immune system to produce either specific humoral (antibodies) and cellular immune responses, or both.”<sup>4</sup> The process of vaccination creates a memory in the immune system that can later be activated to provide a defense response, preventing infection or illness. Vaccines have key components approved by the CDC: “preservatives (to prevent contamination), adjuvants (to help boost the body’s response to the vaccine), stabilizers (to keep the vaccine effective after manufacture), residual cell culture materials (to grow enough of the virus or bacteria to make the vaccine), residual inactivating ingredients (to kill viruses or inactivate toxins during the manufacturing process), residual antibiotics (to prevent contamination by bacteria during the vaccine manufacturing process).”<sup>5</sup> Vaccines must first be approved by the FDA after a thorough safety and toxicity evaluation and then undergo approval by the CDC before they can be administered in the United States. And then following initial usage, the vaccines are monitored closely by the CDC to make further recommendations.

The CDC also makes recommendations for infants and children, providing a schedule alongside the Advisory Committee on Immunization Practices, which is approved by the American Academy of Pediatrics. It is recommended that at birth one dose of HepB is administered and again prior to two months. It is recommended that at two months, one dose of RV, DTaP, Hib, PCV13, and IPV is administered, and another

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<sup>4</sup> Olivia Olson, Corinne Berry, and Nirbhay Kumar, “Addressing Parental Vaccine Hesitancy towards Childhood Vaccines in the United States: A Systematic Literature Review of Communication Interventions and Strategies,” *Vaccines* 8, no. 4 (December 2020): 590, <https://doi.org/10.3390/vaccines8040590>.

<sup>5</sup> Olson, Berry, and Kumar.

dose at four months. At six months, repeated doses of RV, DTaP, Hib, PCV13 are administered. At twelve months, HepB, Hib, PCV13, IPV, as well as MMR and Varicella are administered. And then at eighteen months, DTaP, HepA, and the beginning of the yearly Influenza vaccine is administered.<sup>6</sup>

With the outline provided by the CDC and generally encouraged by pediatricians, parents still remain vaccine hesitant despite the safety measures and testing results presented. In the clinical setting, The Parent Attitudes about Childhood Vaccines (PACV) survey tool, created by the University of Washington School of Medicine, is used to assess the parents' view of vaccines and could potentially be used to alter those views in order to promote vaccine administration. Some examples of questions surveyed include: "How concerned are you that any one of the childhood shots might not be safe?" Or "If you had another infant today, would you want him/her to get all the recommended shots?" Or "All things considered, how much do you trust your child's doctor?"<sup>7</sup> Through assessment of the efficacy of the tool, the PACV can be used to measure vaccine hesitancy and it potentially has a place within the clinical setting and the potential to be used as a surveillance tool in public health.<sup>8</sup>

Vaccine hesitancy, which the World Health Organization defines as "the reluctance or refusal to vaccinate despite the availability of vaccines – threatens to reverse progress made in tackling vaccine-preventable diseases," was listed as one of the

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<sup>6</sup> Olson, Berry, and Kumar.

<sup>7</sup> Douglas J Opel, "The Parent Attitudes about Childhood Vaccines (PACV) Survey Tool," n.d., 26.

<sup>8</sup> Opel.

“Ten Threats to Global Health in 2019.”<sup>9</sup> Vaccines are extremely cost effective and have shown statistical improvements internationally. Lack of vaccinations can be the result of many social and medical factors such as lack of access and availability, but where the issues are beginning to arise are in countries that previously saw very limited numbers of cases, but they are now seeing a resurgence in diseases which had almost been eliminated.<sup>10</sup> There are other causes of vaccine hesitancy including “religious beliefs, distrust of big pharma, and worries about side effects and whether a child’s immune system will cope.”<sup>11</sup> But the decision to vaccinate— or not to vaccinate— children is given as a responsibility to the parents. Many decisions to not vaccinate children are in response to the belief that many vaccines are unsafe for children, with much of this disinformation being shared and received via social media.

Vaccine hesitancy can be seen at significant levels in the United States: as of March 2020, “more than one-third of U.S. children between the ages of 19 and 35 months were not following the recommended early childhood immunization schedule [... and...] approximately 1 in 4 parents reported serious concerns towards vaccinating their children.”<sup>12</sup> So, what is the cause of this increase of distrust and apprehension? Vaccines have provided large successes with the “elimination of polio in the Americas and

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<sup>9</sup> “Ten Health Issues WHO Will Tackle This Year,” accessed March 23, 2021, <https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019>.

<sup>10</sup> “Ten Health Issues WHO Will Tackle This Year.”

<sup>11</sup> “The Rise of Vaccine Hesitancy,” The Nuffield Council on Bioethics, accessed March 23, 2021, <https://www.nuffieldbioethics.org/blog/the-rise-of-vaccine-hesitancy>.

<sup>12</sup> Olson, Berry, and Kumar, “Addressing Parental Vaccine Hesitancy towards Childhood Vaccines in the United States.”

eradication of smallpox worldwide.”<sup>13</sup> In 2000, measles was virtually eliminated from the United States, though as vaccination rates have continued to decrease over the last two decades, an increase of cases have been seen within unvaccinated communities. The significance of the measles also is because of the high level of contagiousness. Peak cases have been seen in following outbreaks of measles in 2008 (64 cases), in 2014 (667 cases), in 2018 (375 cases), and peaking in 2019 (1,282 cases) which are all largely the effect of the rise in vaccine hesitancy in the United States.<sup>14</sup>

The “Report of the SAGE Working Group of Vaccine Hesitancy” outlines determinants of vaccine hesitancy into three isolated groups: contextual influences, individual and group influences, and vaccine/vaccination-specific issues. Contextual influences can largely be contributed to cultural and social perceptions of the region. Currently, significant influences in this category include social media and its lobbies one way or the other. Individual and group influences rely on personal experience and emotional pains of the individual or group. The vaccine/vaccine-specific issues are much more epidemiologically focused and rely mostly on the public health and clinical aspects of the vaccines such as administration and efficacy.<sup>15</sup>

Many people who are vaccine hesitant act as a response to information or experiences that they have seen or witnessed. Information and education is important when addressing vaccine hesitancy, though random factual information has been proven

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<sup>13</sup> Olson, Berry, and Kumar.

<sup>14</sup> Olson, Berry, and Kumar.

<sup>15</sup> “Report of the SAGE Working Group of Vaccine Hesitancy” (World Health Organization, November 14, 2014).

much less effective than a tailored materials approach. When tested, information was far more effective in altering individual's views of vaccines when race, vaccine-related concerns, patients' past experiences, and when the child's name was used directly. Also, the belief in conspiracy theories, whether merit-based or not, was not likely to be changed if the accurate information was presented *after* the theory had already been absorbed; in other words, the conspiracy theory must be debunked prior to ever being introduced to the parent or patient.<sup>16</sup>

Other aspects of vaccine hesitancy are not due to misinformation, but rather complacency. An increase of childhood immunization re-uptake can see an increase of 9% to 55% if there is a parental reminder system implemented or a childhood vaccine calendar presented to the parents. When addressing parents who are vaccine hesitant, research has shown an added level of importance to address "health care providers, family members, teachers, and community members/neighborhood coalitions who were core influencers of vaccine-hesitant parents" which can be especially effective in educating first time parents about vaccinating their children.<sup>17</sup> And while information is important, the current level of information given to parents of children in need of immunization is insufficient, and depending on where the parents exist on the vaccine-hesitancy spectrum depends on the amount of information and the specificity or aspects of vaccine knowledge they are interested in receiving. It is important that all of these distinctions are taken into consideration by health care providers. An aspect often left out

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<sup>16</sup> Olson, Berry, and Kumar, "Addressing Parental Vaccine Hesitancy towards Childhood Vaccines in the United States."

<sup>17</sup> Olson, Berry, and Kumar.

of vaccine information, but an aspect that is now being promoted are the details regarding the diseases that these vaccinations prevent. Many diseases have been eradicated and have skipped generations. This is a medical and public health success, though this causes a distancing from the emotional and horrific effects that these diseases left on previous generations that led to the efforts of their eradication in the first place. Because of the efficacy of these vaccinations, first-hand experience with these diseases has been removed which has made the need for the immunizations appear not as necessary to some patients as in the past.<sup>18</sup>

A source of some of the mistrust in vaccines originated from an article published in a 1998 issue of *The Lancet*. Andrew Wakefield and colleagues claimed that there were “environmental triggers” that lead to “developmental regression in a group of previously normal children.”<sup>19</sup> They reported findings claiming that the exposure identified was the measles, mumps, and rubella (MMR) vaccine and a behavioral diagnosis of autism or autism spectrum disorder. In 2010, the article was retracted for causes of manipulation of the test subjects because “the children that Wakefield studied were carefully selected and some of Wakefield’s research was funded by lawyers acting for parents who were involved in lawsuits against vaccine manufacturers.”<sup>20</sup> The size of the sample was also

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<sup>18</sup> Olson, Berry, and Kumar.

<sup>19</sup> A. J. Wakefield et al., “RETRACTED: Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children,” *The Lancet* 351, no. 9103 (February 28, 1998): 637–41, [https://doi.org/10.1016/S0140-6736\(97\)11096-0](https://doi.org/10.1016/S0140-6736(97)11096-0).

<sup>20</sup> Laura Eggertson, “Lancet Retracts 12-Year-Old Article Linking Autism to MMR Vaccines,” *CMAJ: Canadian Medical Association Journal* 182, no. 4 (March 9, 2010): E199–200, <https://doi.org/10.1503/cmaj.109-3179>.

questioned and an inability to replicate the results and conclusions found in Wakefield's study. The popularity of this article surged as parents of autistic children sought answers to the causes of their child's disorder. As a result of a new fear of these vaccines, parents stopped vaccinating their children, which became a growing health concern as measles outbreaks could be seen internationally. Despite the retraction of this article, its popularity remains, and many parents still are hesitant to vaccinate their kids because of the fear instilled by Wakefield.<sup>21</sup>

The importance of vaccine distribution and implementation can be seen through the eradication and significant infrequency of many once prevalent diseases. With an increase in vaccine refusal, a new public health problem has arisen. A solution is needed to address the parents who are choosing to forego vaccines and to educate them on the necessity for their child's safety and the well-being of the community. The most effective method of education is up for debate. The conversation amongst health care providers must not be solely informational, but also an emotional one. Research has shown that "the majority of interventions to combat vaccine hesitancy have been educational and focused on a "knowledge-deficit" approach, assuming that vaccine-hesitant individuals will change their mind if given proper information. However, research concludes that vaccine hesitancy is more complex, involving emotional, cognitive, cultural, spiritual, social, and political factors. Research has also shown that it matters which message techniques are used, and which messengers deliver the vaccine information."<sup>22</sup>

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<sup>21</sup> Eggertson.

<sup>22</sup> Olson, Berry, and Kumar, "Addressing Parental Vaccine Hesitancy towards Childhood Vaccines in the United States."

The role of government and if or what the policy should be has been debated since the rise of vaccine refusal and resurgence of many previously eradicated diseases. The debate is one of public health, politics, and ethics and can be reviewed to establish the safest environment for the health and safety of the masses.



## CHAPTER TWO

### The Role of Policy in Vaccinations

“Preventative methods for disease and infection have been prevalent as early as the year 1000 AD.<sup>23</sup> But as the modern medical era has advanced, discrepancies over the necessity, effectiveness, and reliability of vaccinations have arose. While some people claim personal choice and refrain from having themselves or their children vaccinated during different stages of life, it is the responsibility of the government to protect the common good and the general welfare of the country and its people by making vaccinations mandatory for all people.

While vaccines may appear to be a relatively modern addition to the medical field, in 1813 the National Vaccine Agency was created under President James Madison. In the early 1800s, the invention of the cowpox vaccine led to the smallpox vaccine, which shortly thereafter, became mandatory in Massachusetts. Rapid progress and advancements of the smallpox vaccine, and others, were made in each decade following, and by 1963, in order for students to attend public school in 20 states, they were required to have been vaccinated. By the mid-twentieth century, vaccines were developed to immunize people from: “typhoid (1899), cholera (1911), diphtheria (1914), tuberculosis (1921), tetanus (1924),... polio (1955), measles (1963), mumps (1967), and rubella (1969).”<sup>24</sup> While some questioned, and continue to question the constitutionality of

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<sup>23</sup> CDC, “How Vaccines Work,” Centers for Disease Control and Prevention, June 16, 2020, <https://www.cdc.gov/vaccines/parents/why-vaccinate/vaccine-decision.html>.

<sup>24</sup> CDC.

vaccination mandates, *Jacobson v. Massachusetts* previously has ruled that it is “the power of state government to take specific action to protect the public’s health and the Constitution’s protection of personal liberty.”<sup>25</sup> The mandate that the Supreme Court ruled on in 1905 was put in place in response to the smallpox outbreak that was occurring during the time devastating thousands. Vaccination mandates like these resulted in the eradication of smallpox in 1980 which is the ultimate goal of vaccinations. Other diseases, like polio, have been eliminated. The eradication of a disease is the complete extinction of it when it is no longer found globally, while elimination of a disease refers to when a disease is no longer present in a specific region, for example the United States.<sup>26</sup> Vaccinations like IPV and OPV are specifically meant to defend against the polio virus; however, the virus is not yet eradicated, and while no cases have originated in the United States since the 1970s, polio is still a threat to those in the Western hemisphere as it can still be brought into the country through travelers and visitors and spread. Vaccines not only advance the protection of health and the eradication of global viruses, but they also help people in the day-to-day remain healthy, preventing them from the yearly influenza virus, for example.

Vaccines, when injected, introduce the body to a mild infection, but rather than making the recipient ill, they allow the immune system to formulate a response and build up a defense against it, preventing an infection in the future. The typical vaccination

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<sup>25</sup> Wendy K. Mariner, George J. Annas, and Leonard H. Glantz, “Jacobson v Massachusetts: It’s Not Your Great-Great-Grandfather’s Public Health Law,” *American Journal of Public Health* 95, no. 4 (April 2005): 581–90, <https://doi.org/10.2105/AJPH.2004.055160>.

<sup>26</sup> CDC, “How Vaccines Work.”

helps the body to defend itself against 14 varying diseases. The shot itself, contains key ingredients to function: antigens (the key ingredient) that aids in developing immunity, preservatives, adjuvants to assist in the body's response, stabilizers, "residual cell culture materials" like egg protein for virus growth, "residual inactivating ingredients" like formaldehyde that disinfect during manufacturing, and residual antibiotics that prevent contamination of the virus."<sup>27,28</sup> These serums together within the vaccine are effective in preventing disease and provide a method to keep both children and adults healthy.

"Recently, the largest avoidance of vaccinations has been a result of the supposed effects on children's behavior and the potential risk that is thought to accompany vaccines. As vaccinations have become more widespread and continually used, research continues, ensuring the best and safest result. In 2003, the FDA took extra precautionary measures in removing thimerosal from all vaccinations strictly as a precaution, which can be noted is missing from the aforementioned ingredients. However, while some believed this ingredient could lead to behavioral problems, there was insufficient evidence to support that this thimerosal results in any side effects. The removal of it and the removal process were agreed upon and overseen by the American Academy of Pediatrics and the US Public Health Service.<sup>29</sup> Opposition also claims that the possibility of immediate side effects of vaccines is another reason they themselves, or their children, are not vaccinated. These can include redness and irritability of the injection site or could even lead to an allergic reaction; however, both of these are easily resolved. Refusing

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<sup>27</sup> CDC.

<sup>28</sup> Hannah Reese, "Government: Vaccinations," November 10, 2016.

<sup>29</sup> CDC, "How Vaccines Work."

vaccination for a life-threatening virus because of the fear of irritation can be illogical and pose a much larger threat on the health of the patient. The immunity from life threatening diseases that vaccinations provide, far outweigh the mild risks involved in receiving vaccinations that have been scientifically researched and tested for decades.

Each state within the United States has agreed upon its own vaccine policy for requirement for students entering both public and private day care and all schooling that follows; however, that does not imply that every student attending those institutions has been vaccinated. As each state varies on their exemptions for vaccination, each and every one has medical exemptions while some go as far as implementing religious and philosophical exemptions as well.<sup>30</sup> While this may seem to be the compromise made between lawmakers and abiding citizens, it ultimately affects and harms the children who have been vaccinated with the possibility of being exposed to these preventable diseases and viruses, inside the building where they should be and feel the most protected. That ultimately affects the safety, health, and well-being of each student that interacts with one who has not been immunized. Some make their decision based on the idea of injecting unnatural substances into the body, because they have heard that they are not “natural.” In fact, they are made and produced for people because their bodies cannot defend against the diseases alone. Parents’ decision to vaccinate their children—or not—remains at the basis of the vaccination debate, but at what point does the right to refuse immunity become more important than the threat of health and promised protection on other people?

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<sup>30</sup> “State Vaccination Requirements | CDC,” March 11, 2019, <https://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html>.

Another group of people who are highly cynical of the vaccination process are pregnant women, as they should be when making a health decision that effects two lives. Vaccinations are not discouraged for expecting women. In fact, there are some vaccines that are encouraged for women to get to protect them and their child. For example, the influenza virus can be extremely dangerous for mothers-to-be to become infected with during her pregnancy; however, there are vaccinations that should not be administered and are very clearly outlined by medical professionals as they can harm the fetus: this would include vaccinations for Measles, Mumps, and Rubella (MMR), for example.<sup>31</sup> While there are very clear guidelines expressing which vaccinations expecting women should avoid, there are some vaccinations that could be life-saving to a woman and her child and could fight and prevent illness and infection. It is important that women, as well as their children, vaccinate themselves to prevent the detrimental effects that can occur without the defense created by vaccinations.”<sup>32</sup>

There are many debated and contested methods for addressing people who are faced with making the decision to vaccinate themselves or their children. “Addressing Parental Vaccine Hesitancy Towards Childhood Vaccines in the United States” assesses the effective and ineffective methods in addressing patients with this decision. It was concluded that multiple methods must be used for effectiveness (getting the parent to vaccinate), and that individual methods by themselves lack effectiveness in changing people’s minds. The most important aspect of these conversations by health care

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<sup>31</sup> “Pregnancy Guidelines and Recommendations by Vaccine | CDC,” January 13, 2021, <https://www.cdc.gov/vaccines/pregnancy/hcp-toolkit/guidelines.html>.

<sup>32</sup> Reese, “Government: Vaccinations.”

providers were the “message-framing techniques.” It is necessary to approach the topic with “storytelling with the use of gists, emotive anecdotes, and imagery... and] science-based messaging” that primarily used laymen’s terms rather than clinical terminology.<sup>33</sup>

Timing, as well as vocabulary is also critically important in the effectiveness of the vaccine messaging. It is recommended to begin talking about the vaccination plan with future parents in early stages of pregnancy and continuing the conversation through postnatal appointments. With early and open conversations between health care providers and parents, it also builds trust between them, which also increases success in the vaccination of children. As previously mentioned, the “message-framing techniques,” or the methods in which the information is presented, are statistically effective as well. This includes what information is given, but also addressing why they are hesitant about vaccines and informing them about their misconceptions. Another important aspect that must be considered are the values that are important to the patient.

In the area of vaccine education, development must be made on educational tools for communication. Plain language must be used while also maintaining “content, word choice and style, use of numbers, organization, layout and design, and use of visual aids.”<sup>34</sup> Anecdotes and the provider of information should also be carefully selected with the intention to encourage the critical thinking of parents when making medical decisions for their children and ensuring they can navigate misinformation about their child’s health. Studies also have shown that there is certain messaging that is ineffective in

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<sup>33</sup> Olson, Berry, and Kumar, “Addressing Parental Vaccine Hesitancy towards Childhood Vaccines in the United States.”

<sup>34</sup> Olson, Berry, and Kumar.

persuading parents to vaccinate their children. The use of “heavy statistical and numerical messaging, fear-based messaging, and messaging that attempted to correct or debunk commonly held myths and misconceptions” were not sufficient in educating parents about the usefulness of vaccinations or enough to convince them to vaccinate their children.<sup>35</sup> When discussing benefits of vaccinations, it is important to not only address the safety it adds to the community, but also the safety vaccinations provide to the child.<sup>36</sup>

“At all stages in life, whether newborn or senior citizen, vaccinations are critical in preventing viruses and diseases that threaten the longevity of life. The lack of vaccinated young people within the United States today are threatening the general welfare of its citizens when they choose to opt out of immunizations. They not only [expose] themselves to the possibility of infection, but can reintroduce eliminated diseases back into hemispheres of the world. Starting with grade school and children all the way through schooling to adults in the workplace, people are faced with the decision to be vaccinated and schools and businesses are faced with the decision to enforce vaccinations to protect their environments. Through a long history, beginning back in 1000 AD with Chinese techniques, vaccinations have been changed, developed, tested, researched, and tested again to provide the most beneficial results for the recipients. With shots being combined and removed from the typical vaccination lists, doctors and

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<sup>35</sup> Olson, Berry, and Kumar.

<sup>36</sup> Olson, Berry, and Kumar.

scientists alike are working together to make immunizations the most practical, safe, and efficient as they can.”<sup>37</sup>

The need of vaccinations and the role of government was exposed at the beginning of 2020 when the United States became affected by the Covid-19 pandemic. There became an immediate need for the research, creation, and distribution of a vaccine to lessen the spread and wreckage caused by SARS-CoV-2. The Department of Health and Human Services, the Department of Defense, and the private sector all joined forces to create Operation Warp Speed (OWS) on May 15, 2020 “to accelerate control of the Covid-19 pandemic by advancing development, manufacturing, and distribution of vaccines, therapeutics, and diagnostics.”<sup>38</sup> The ultimate goal of OWS was to provide a vaccination approved by the FDA for use in the United States; there was a need that had not been needed for vaccinations previously and the establishment of OWS “partnership grew out of an acknowledged need to fundamentally restructure the way the U.S. government typically supports product development and vaccine distribution.”<sup>39</sup> The research and development of OWS was established using integration of various national organizations with varying expertise including the NIH, ASPR, CDC, BARDA, and the DOD. To combat West African Ebola in 2014, vaccination development flew into action utilizing 12 months to successfully navigate phase 1 to phase 3.<sup>40</sup> OWS was hoping to

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<sup>37</sup> Reese, “Government: Vaccinations.”

<sup>38</sup> Moncef Slaoui and Matthew Hepburn, “Developing Safe and Effective Covid Vaccines — Operation Warp Speed’s Strategy and Approach,” *New England Journal of Medicine* 383, no. 18 (October 29, 2020): 1701–3, <https://doi.org/10.1056/NEJMp2027405>.

<sup>39</sup> Slaoui and Hepburn.

<sup>40</sup> Slaoui and Hepburn.



create a vaccination ready for distribution in an even shorter time frame. The criteria for the vaccine, in order to ensure the safest and fastest results possible, required that one of four types of vaccine platforms be utilized: mRNA, replication-defective live-vector, recombinant-subunit-adjuvanted protein, or attenuated replicating live-vector platforms.<sup>41</sup>

As the world is experiencing a pandemic that has not been seen in one hundred years, *Jacobson v. Massachusetts* is once again being revisited by those in the public health sector. It still remains the precedent for many laws that involve mandatory vaccinations, however, many begin to question the extent that this decision should have on public health issues and whether or not it should begin and end with vaccinations. According to James Colgrove (2005), the decision of *Jacobson* was consistent with and was what to be expected from a decision regarding public health in the beginning of the 20th century. Many “compulsory measures have been used to constrain personal liberty for the sake of protecting the public health” and vaccinations are just one of those ways where the safety of the society took precedent over the decision of the individual.<sup>42</sup>

*Jacobson v. Massachusetts* has been revisited once again during the COVID-19 pandemic. With the creation and distribution of safe and effective vaccines against SARS-CoV-2, the discussion of mandates has arisen. While the vaccine has 95% efficacy, herd immunity can only be reached if about 80% of the population decides to get the vaccine, so the possibility of requirements may be thought to be needed by some

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<sup>41</sup> Slaoui and Hepburn.

<sup>42</sup> James Colgrove and Ronald Bayer, “Manifold Restraints: Liberty, Public Health, and the Legacy of *Jacobson v Massachusetts*,” *American Journal of Public Health* 95, no. 4 (April 1, 2005): 571–76, <https://doi.org/10.2105/AJPH.2004.055145>.

to achieve this goal. There are various levels of mandates including state, business, health care, secondary or postsecondary education. Many businesses and schools are requiring vaccination in order to reintroduce in person attendance, especially in places where people are in close quarters for extended periods of time. Many experts say during this current state of the pandemic, vaccinations are the best attempt to reach a level of normalcy. In an article for JAMA, the results of mandates can have varying effects.<sup>43</sup> If there is a mandate for vaccinations, it “signal[s] clear policy support... which can also increase resources for vaccine infrastructure.”<sup>44</sup> Mandates however can have the opposite effect with the public, as they can deter people from getting the vaccine and increase resentment or distrust. The greatest problem with mandates, despite the positive effects they have on communities, is that they “fundamentally alter this dynamic [inform decision-making, respecting individual choice] by overriding personal autonomy.”<sup>45</sup> Gostin et al. (2020) conclude that vaccinations and governmental roles in vaccinations are vital to their success in reaching herd immunity, however, mandates can sometimes have the opposite effect than their intended effect with the perception of the general public.<sup>46</sup> It is necessary to provide accurate information about the vaccines and show the benefits that they could have to return society into pre-pandemic life.

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<sup>43</sup> Lawrence O. Gostin, Daniel A. Salmon, and Heidi J. Larson, “Mandating COVID-19 Vaccines,” *JAMA* 325, no. 6 (February 9, 2021): 532–33, <https://doi.org/10.1001/jama.2020.26553>.

<sup>44</sup> Gostin, Salmon, and Larson.

<sup>45</sup> Gostin, Salmon, and Larson.

<sup>46</sup> Gostin, Salmon, and Larson.

Vaccinations play a vital role in the health of communities all over the world. While many aims of vaccination campaigns focus on encouraging and educating parents to vaccinate their children, the COVID-19 pandemic has introduced a new aspect of vaccines that focuses on the immunization of adults. The misinformation of vaccinations about vaccines like MMR are affecting the public's view on the COVID-19 vaccines and increasing a level of mistrust in scientific findings. Policy implemented for community health does not provide black and white answers for each public health crisis that is introduced to society. However, it is necessary that the policy focuses on protecting the well-being of communities while allowing individuals to maintain a level of autonomy to make their own decisions for themselves without hurting those around them.

## CHAPTER THREE

### The Role of Ethics

“Parents have a duty to protect their children, some believe that in order to do that they must immunize their children to protect them from contagious diseases, while other parents feel it is their responsibility to refrain from vaccinating their children for protection. The debate over required immunization of children and adults in the classroom and the workplace remains an issue that involves medical science but is also supported by educated ethicists. The decision of parents to vaccinate their children is one that affects everyone who comes into contact with them; therefore, it is not an isolated decision. Immunizations protect and prevent people over the entire continent from diseases that have been eradicated, and also prevent the re-introduction of diseases in places where it is no longer found. Parents have a responsibility to their own children to protect them and to maintain their health. Vaccinations have been proven successful through immense medical research, as well as proven necessary through global ethics conversations that understand the threat a single un-immunized person can have to those around him. By dispelling the rumors of the supposed effects of immunizations and making it a requirement of schools for the students to be vaccinated, children will be better protected from diseases and each other.”

*Social Contract Theory.* “As citizens of the United States, there are certain individual rights that the citizen must forfeit in order to receive safety and protection in return. Thomas Hobbes’ social contract theory states that in order for there to be a civil

society, there must be social cooperation and compromises made.<sup>47</sup> In the example of immunizations, if one or even a select few amount of people did not get immunized, it would not result in significant damage to the society. However, if everyone assumed everyone else were being vaccinated, and no one in fact was, it would be detrimental to their health, society's health, and the survival of the population (take the smallpox epidemic as an example). Since vaccinating and immunizing began, diseases have been eradicated globally and eliminated regionally; yet, through misinformation and doubts about the effectiveness of vaccines, diseases once no longer found have been reintroduced to regions.

While vaccines can be expensive to some, the ends justify the means. In order to make something in healthcare, like vaccines, mandatory for people, there must be affordable ways to pay for them. Many insurance policies, however, do in fact cover the price of vaccines.<sup>48</sup> There are also many clinics that will provide vaccinations for people for free or at a reduced cost. Additionally, if one weighs the cost of a vaccine versus the cost of an illness—prescriptions, doctors' appointments, time off of work/out of school—a vaccine of a preventable disease would be the more financially and emotionally beneficial option. Money, while being a necessary aspect of the vaccine decision, should not prevent proper vaccinations of individuals.

Each state within the United States has agreed upon its own vaccine policy for requirement for students entering both public and private day care and all schooling that

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<sup>47</sup> "Social Contract Theory," accessed April 10, 2021, [https://www.csus.edu/indiv/g/gaskilld/business\\_computer\\_ethics/sct.htm](https://www.csus.edu/indiv/g/gaskilld/business_computer_ethics/sct.htm).

<sup>48</sup> "Vaccine Basics - Paying for Vaccines," accessed April 10, 2021, <https://vaccineinformation.org/health-coverage-vaccines/>.

follows; however, that does not imply that every student attending those institutions has been vaccinated. As each state varies on their exemptions for vaccination, each and every one has medical exemptions while some go as far as implementing religious and philosophical exemptions as well.<sup>49</sup> While this may seem to be the compromise made between lawmakers and abiding citizens, it ultimately affects and harms the children who have been vaccinated with the possibility of being exposed to these preventable diseases and viruses, inside the building where they should be and feel the most protected. That ultimately affects the safety, health, and well-being of each student that interacts with one who has not been immunized. It is crucial to consider those who medically cannot be vaccinated due to situations of autoimmune and inflammatory diseases. Not only can they not physically protect themselves from diseases, but they are much more susceptible with their weakened immune system. So, while those who vaccinate themselves greatly decrease their chance of ever becoming infected with specific diseases, those who choose not to put those who desire to, but cannot, at a greater risk. There are certain instances in which people and the court should decide together to abstain from vaccinations, but these should be given less frequently than they currently are and only in instances where the health and survival of the recipient is at risk.

*Utilitarianism.* While John Locke believed that each and every person deserves a set of rights that should not be taken away, the right to not vaccinate children infringes upon other peoples' right to be protected. John Stuart Mill advocates the greatest

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<sup>49</sup> "State Vaccination Requirements | CDC."

happiness principle: to ‘seek the greatest good for the greatest number.’”<sup>50</sup>

Utilitarianism is a core moral framework of global health in making decisions and implementing policies and recommendations. “In the same way, it is not the well-being of the individual that should be assessed, but instead the well-being of the group as a whole—in this case, the United States, or even the entire continent. The repercussions have been noted and researched, and the benefits outweigh the disadvantages. The eradication of diseases and the prevention of diseases outweighs the individual cases of infection through vaccination. The proposition of the connection between autism and vaccinations lacks any current scientific evidence and it is just as likely for the daily diet is the result of heightened autism rates. With the lack of support of many of the accusations of the effects of vaccinations, Mill’s support stands, as saving thousands of lives from polio, tuberculosis, smallpox, etc., outweighs the possibility of disabilities later on in life for a select few individuals.”<sup>52</sup>

According to utilitarianism, decisions of global health like implementing vaccination policy and distribution would weigh the benefits of vaccinations as well as cost-effectiveness that “mitigate the most death and disability...per dollar spent.”<sup>53</sup> Utilitarianism while focusing on the health of the masses—which would support the

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<sup>50</sup> “John Stuart Mill,” accessed April 10, 2021, <https://www.utilitarianism.com/jsmill.htm>.

<sup>51</sup> Hannah Reese, “The Ethics of Immunizations,” April 27, 2017.

<sup>52</sup> Reese.

<sup>53</sup> Paul Farmer and Jim Yong Kim, *Reimagining Global Health: An Introduction* (University of California Press, 2013), 250.

distribution of a large number of vaccinations and immunizations—does not always include the best method for individual autonomy. This moral theory also could result in “policies...stepping on the rights of minorities in favor of the majority interest.”<sup>54</sup> While this may be the case, if decisions are made while also self-reflecting and analyzing all of the effects, utilitarianism could also provide a framework that promotes equity in healthcare. If vaccinations are generally administered throughout the country and to all children who are able to receive them, then there would be equal protection against preventable diseases.

*Liberal Cosmopolitanism.* Another moral framework for public health that is applied to vaccinations is liberal cosmopolitanism. This is “the idea that all human beings, regardless of their political affiliation, do (or at least can) belong to a single community, and that this community should be cultivated.”<sup>55</sup> There are examples of places that have implemented policies that require employees to be vaccinated, including vaccinations for common as the simple flu, and now COVID-19. Most employees in the healthcare industry are required to have their vaccinations up to date, and that includes students and interns in hospitals. Yet at the same time, visitors can come in without those vaccinations and put those with a weakened immune system at risk, as well as introducing themselves to a world of infection and disease that they are not protected from. In contrast, places like day care that are infested with bacteria from children provide an atmosphere for infection to thrive and spread immensely, especially without immunized children.

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<sup>54</sup> Farmer and Kim, 247.

<sup>55</sup> Farmer and Kim, 251.



“The topic of immunizations targets every aspect of people’s lives from the financial to the medical and the ethical. At this day in age, research has been thorough and extensive in terms of hoping to understand the short term and long term effects of vaccines as well as their efficiency and effectiveness. Vaccines have been proven crucial to the health of general populations. There is always the outside threat of being introduced to diseases that have previously been eliminated in regions for decades. The risk is not worth the threat of the infection or the spreading of diseases that people have forgotten for years. Every child who attends school is introduced to students whose parents have made a decision. And the terrifying thought is that the parent who chooses not to vaccinate their child has also made a decision for every other parent of the students. There are always exemptions for people who should not be vaccinated: people whose bodies cannot simply handle the introduction of an infection to build up the needed antibodies. However, those same students who cannot protect themselves by choice, may also be unavailable to protect themselves from others who have made a choice not to vaccinate themselves, and can introduce a potentially fatal disease to someone who cannot fight it.”<sup>56</sup>

Public health also analyzes decisions based on individual human rights. It is a belief that “everyone should have access to decent health services by virtue of being human.”<sup>57</sup> Human rights also bring up the problem of equal access to these preventable forms of healthcare, including vaccinations.

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<sup>56</sup> Reese, “The Ethics of Immunizations.”

<sup>57</sup> Farmer and Kim, 263.

Vaccinations help provide a longevity of life for all stages of life. Mill's idea of protecting and providing happiness for the greatest number of people applies to the debate of vaccinations. It is crucial that restrictions are made within schools. Not only will this protect the health of the mass of students, but it will also help prevent and stop the rise of eradicated diseases that have been reoccurring since vaccinations have decreased. Awareness of the actuality of the benefits of vaccinations must be more frequently shared and the rumors and stereotypes of what accompany them must be dispelled. Vaccines and immunizations are put in place to protect and benefit the general welfare of all people.

## CHAPTER FOUR

### Conclusions

While vaccination creation and distribution have been prevalent in modern medicine for over a century, there remains progress to be made. With an increase in vaccine refusal, the resurgence of diseases that once were seemingly absent from communities in the United States is occurring at alarming rates. And with the presence of the COVID-19 pandemic, vaccines are necessary now more than ever to return to and maintain a pre-pandemic way of life. While vaccines are important for the individual, their implementation must be efficient and widespread at an attempt to reach herd immunity. The herd immunity threshold for SARS-CoV-2 is estimated through experimentation to be about 50-64% of a population, however this number is not static and can be very difficult to estimate exactly.<sup>58</sup> Vaccinations are important to continue to keep cases of many preventable diseases at low levels to reduce morbidity and mortality in communities.

While government policy and advocacy can be seen in varying different ways through mandates and voluntary methods, the most effective, practical, and achievable tactic at the present is to address the problem of misinformation. This misinformation, as well as lack of information, contributes to mistrust of medical professionals and governmental role in healthcare. Trust can be rebuilt in a clinical setting, one-on-one with parents and physicians, or through campaigns to provide more information to those who

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<sup>58</sup> “Vaccination Is the Only Acceptable Path to Herd Immunity | Elsevier Enhanced Reader,” accessed April 9, 2021, <https://doi.org/10.1016/j.medj.2020.12.004>.

are unaware of the many benefits that vaccines contribute to communities and individuals. An article from JAMA written by Eric Perakslis (2019) encourages the use of cybersecurity to limit and remove the misinformation spread via social media and other platforms.<sup>59</sup> Another area of online misinformation is found on parenting blogs. In a study, 25% of information found on these blogs relating to vaccines included inaccurate details relating to health.<sup>60</sup> Also, many comments and information are emotionally driven; the study cites that emotionally driven language does not generally lead to accurate or unbiased information. This information can help clinicians tailor their conversation to parents who are unsure about the realities of vaccinations depending on where they receive their information or opinions.

Policy for vaccinations does not have black and white solutions. Ethics and various moral frameworks can be utilized when analyzing the best way for healthcare policy to move forward while also increasing safety and health of the general population. Many philosophies like utilitarianism, social contract theory, liberal cosmopolitanism and more can be reviewed as the topic is approached, though none of these theories alone can successfully provide all of the solutions for each problem. There are many variables to account for and many scenarios within the debate. While exemptions for vaccinations on a philosophical and medical basis may be granted and may have validity for some, they

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<sup>59</sup> Eric Perakslis and Robert M. Califf, “Employ Cybersecurity Techniques Against the Threat of Medical Misinformation,” *JAMA* 322, no. 3 (July 16, 2019): 207–8, <https://doi.org/10.1001/jama.2019.6857>.

<sup>60</sup> Marina C. Jenkins and Megan A. Moreno, “Vaccination Discussion among Parents on Social Media: A Content Analysis of Comments on Parenting Blogs,” *Journal of Health Communication* 25, no. 3 (March 3, 2020): 232–42, <https://doi.org/10.1080/10810730.2020.1737761>.

can be used by others as a means to avoid vaccination in general. Medical exemptions are important for many and thus these people rely on the vaccination of others in order to protect their health and safety. Individual autonomy though allows for control over one's own person and to make medical decisions for themselves.

However, deciding to vaccinate or to forgo vaccination is not a decision from which anyone is exempt. The decision to be vaccinated or not has consequences for the individual and the community. In public spaces, everyone is at risk of illness without control of who may be around. Schools at the primary, secondary, and postsecondary levels all have different protocols as to which vaccines are required or if any vaccines are required. To enter primary school, though requirements vary per state, the chickenpox, MMR, polio, and diphtheria, tetanus and pertussis vaccines are necessary to enroll into school.<sup>61</sup> For most postsecondary institutions, the meningitis vaccine is required before the student is able to begin classes. This puts every parent (and consequently their children) and young adult in a position to decide to vaccinate themselves or elect to be homeschooled. While the requirement for education has remained for many years, the discussion in the workplace is increasing with prevalence of COVID-19. Many workplaces have not previously required vaccines in order to be in the office or factory; however, with the spread of SARS-CoV-2, many workplaces are requiring it before they will allow employees to return to in-person work. Some businesses and companies have previously required yearly vaccinations for influenza and under law they are allowed to

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<sup>61</sup> CDC, "CDC's Interactive Vaccine Guide for Families," Centers for Disease Control and Prevention, November 1, 2016, <https://www.cdc.gov/vaccines/growing/index.html>.

do so; however, with the pandemic, many more are likely to require a COVID-19 vaccine than have required vaccines before.

With the prevalence of infectious disease today and the ability of medical advancements to combat them, vaccination and other methods of prevention are likely to surge in coming months and years. The rollout of the COVID-19 vaccine is likely to have many effects on the implementation and requirements of other previously implemented vaccinations and on future vaccinations. There are many questions and problems that persist in the attempt to eliminate preventable diseases, especially infectious diseases. This thesis has looked at the current state of governmental policy in the United States, both with childhood and adulthood vaccinations. It has also attempted to broadly address ethical and philosophical perspectives that could prove beneficial when seeking solutions for effective and safe outcomes.

As governments, organizations, and individuals alike continue to make decisions about vaccination, the primary focus should follow the framework of utilitarianism, protecting the greatest number of people. Vaccinations are thoroughly tested prior to rollout and their safety continuously questioned and observed. Individuals should not be able to forgo vaccination simply because of carelessness or a lack of information. However, it is clear that there is a significant misinformation and mistrust problem within the healthcare system regarding vaccinations. This problem too must be addressed. Clinicians must be intentional about the message-framing techniques they use to present information to their patients, as previously mentioned in Chapter 2. With all of the knowledge and understanding that is present about vaccinations, it is the duty of the healthcare system to provide the masses with the information and feel confident enough

to protect themselves—rather than leaving themselves and others at risk when unvaccinated.

Another important influencer against vaccine refusal is the government. They must show support for the research and testing of vaccinations. The greater the infrastructure for vaccination distribution and research, the more resources will be available to provide information and a sense of well-being and safety to its recipients. While maintaining an individual's autonomy, it is also important that the role of individual freedoms comes with the expectation that those freedoms are limited within a functioning society and structure. An individual may choose what they eat or what they do not eat as an individual freedom (as those choices do not have a significant effect on the individuals around them), however, the decision to not be vaccinated can have detrimental effects on individuals in society who are unable to be vaccinated due to severe medical conditions. In this case, the “individual freedom” of one individual to not be vaccinated impedes another individual's freedom to be protected by their government. It is for examples like these that the utilitarian approach is generally the most sufficient and ethical framework when addressing vaccinations.

While the government and individuals both have a responsibility to the safety of themselves and to others, organizations—public and private alike—have a large responsibility to health and safety as well. In a time of a global pandemic, the discussion of contagion and vaccines are extremely prevalent within the workplace, companies, and higher education though hopefully these discussions do not stop when the pandemic is over. Preventable diseases have been around for centuries and there is still an opportunity to protect ourselves and fight against them. Meningitis vaccines have always been

required for first year college students throughout the United States. The COVID-19 vaccine should also be required as the vaccine becomes more prevalent, especially in high contact areas like college campuses and office buildings. The polarization of vaccinations is impeding the ability to “require” them, however if organizations come to a joint decision, eventually the concept of mandatory vaccines could become the expected social practice, protecting one another from preventable disease.

Vaccines are (and will remain) a problem for the past, present, and future. The creation, distribution, assessment, and reassessment of vaccines will remain a necessary part of the well-being and functioning of society. What once was seen as a miracle technique, saving lives from diseases that were ravaging communities and families are now being criticized as “unnatural” and “unnecessary.” With a re-focus of government, healthcare, and individuals onto the actual problem—harmful and fatal (and preventable) diseases—and away from the villainization of a scientific and medical tool that can protect individuals of all ages, there is the opportunity to decrease the prevalence of vaccine refusal and increase the prevalence of scientific literacy and immunological protection for individuals. It is vital to regain the public’s trust and acceptance of vaccinations, but the safety and health of the general public is the top priority.



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