VACCINES & OUR HEALTH – WHAT DO YOU NEED TO KNOW?

A LOOK AT THE INTERSECTION OF RELIGION, LAW AND VACCINES





Vaccines & Our Health – What do you need to know? A look at the Intersection of Religion, Law and Vaccines¹

Vaccinations² were first introduced in the United States in the late 18th century to inoculate people against the highly contagious smallpox virus. Not surprisingly, the new treatment was met with suspicion, uncertainty and apprehension—even though it proved successful in protecting people from the deadly virus.

Today, vaccines are safer and more effective than when they were first introduced. Yet, many people remain skeptical or have religious or philosophical objections to taking them. They often rely on exemptions in state laws that permit them to refuse otherwise mandated vaccinations.

As we confront the COVID-19 pandemic and look to new vaccines to allow us to get back to "normal," questions about the veracity and safety of vaccines simmer beneath the surface. We therefore offer this overview of vaccine controversies in the United States over the years, including a summary of currently mandated vaccines, their purpose, history, value—and their critical role in keeping us safe. We hope that you will find this paper helpful, and that it adds to your religio-cultural understanding of a critical issue facing all of us.

¹ Vaccines and Our Health – What do you need to know? is presented solely as an informational overview and is not intended as a substitute for professional medical advice, diagnosis, or treatment. Always seek the advice of your physician or other qualified health provider with any questions you may have regarding vaccinations or any other medical issue or condition. Never disregard professional medical advice or delay in seeking it because of something you have read here or on the Tanenbaum Website. If you think you may have a medical emergency, call your doctor, go to the emergency department, or call 911 immediately.

The terms vaccination, inoculation and immunization are often confused. Vaccination and inoculation refer to the process of giving someone their vaccine (often, but not always, through a shot). After receiving a vaccine or developing antibodies because a person had a disease, the person generally becomes immune. Being immunized means that your body's immune system has developed antibodies and you have become "immune" from the getting the disease. Duda, RN, K. (2020, June 9). What Is the Difference Between Immunization and Vaccination?. In Verywell Health . Retrieved from https://www.verywellhealth.com/the-difference-between-immunization-and-vaccination-4140251

Why are vaccinations important?

Vaccines are one of the best tools we have for limiting the spread of many diseases. There are four key ways that vaccines protect us and help to preserve public health:

- *Disease Control:* Widespread use of vaccinations can eradicate diseases on a global scale, eliminate diseases in localized communities, and help control and reduce mortality rates, chronic ill health, and complications that result from the disease.
- Herd Immunity: Herd immunity occurs when a large percentage of the population (called the "threshold proportion" of the community) becomes immune to the disease (through vaccination or previous infection). This makes the spread of the disease from person to person unlikely and provides protection for the whole community.
- Protecting Unvaccinated Populations: While vaccines are highly safe and effective, there
 are some people who should not be vaccinated for medical reasons because they have
 compromised immune systems or allergies to the vaccine's ingredients. When a majority
 of people get vaccinated, it slows or stops the spread of the disease and protects
 vulnerable populations.
- Prevention of Related Diseases: Sometimes, vaccines can protect people against other diseases related to the target disease. For example, the human papillomavirus virus (HPV) can cause precancerous cervical lesions and, ultimately, cervical cancer. When the HPV vaccine is used, it helps prevent these lesions from developing and significantly decreases the chance the patient will develop cervical cancer.

Every ten years, the Department of Health and Human Services (HHS) sets goals for improving our national health in the ensuing decade. In 2020, HHS adopted *Healthy People 2030*. Its vision is for "a society in which all people can achieve their full potential for health and well-being across the lifespan." This includes the appropriate use of vaccines, which provide protection and help ensure that people do not get preventable diseases.^{iv}



What vaccinations are required?

The Centers for Disease Control and Prevention (CDC) publish recommended child and adult vaccination schedules that specify which vaccinations most people should get and when they should receive them. Following the schedules ensures that patients will have comprehensive and effective immunity from disease. For 2020, the schedules listed 15 vaccines for children and young adults (from birth to 18 years old) and 13 vaccines for adults ages 19 and older (some of these vaccines require additional doses and/or boosters for immunization).

For more information about the vaccines on the 2020 immunization schedules, how the diseases they prevent spread, and the rationale for each of the vaccines, see Appendix A.

Where can you get vaccinated?

Start with your doctor, if you have a provider you see regularly. But if not, many established vaccines are still readily accessible and can be obtained through federally funded health centers. In addition, many adult vaccines are available at pharmacies. For travel, there are often required travel vaccinations, which can also be provided at travel medical clinics. The different vaccines are given in different ways (for example, by shots in muscles and under the skin either subcutaneous or intradermal, orally and into the nose). The method that is recommended for any particular vaccine is the one that provides the best protection with the fewest side effects.



How did vaccines become controversial?3

The value of vaccines came to be widely accepted, but in the early 1980's new controversies began to erupt in the U.S. after a 1982 NBC documentary aired, focusing on the risks of the "whooping cough" vaccine (i.e., the DPT vaccine - diphtheria, pertussis, tetanus).

The show was widely criticized by medical experts. They objected to the way it emphasized possible unsubstantiated risks from the vaccine (brain damage, epilepsy, and intellectual disability and other developmental issues) but ignored the vaccine's benefits of nearly wiping out whooping cough and related risks of getting it (death, brain damage, severe lung disease). Even though subsequent research established that there is no correlation between the vaccination and brain damage, the spreading concerns about the vaccine spawned a powerful anti-vaccine organization now known as the National Vaccine Information Center.

Subsequent events further fueled mistrust in vaccines. The MMR shot (measles, mumps, rubella) was inaccurately characterized by a researcher as potentially damaging the brain and causing autism, while an ingredient in many vaccines was also suspected of causing autism.

Though widespread research disproved both of these notions (and the researcher for the MMR shot was stripped of his medical license), the association of vaccines with risk became more widespread and new theories emerged including that too many vaccines at the same time period can overwhelm and weaken the immune system (there is no scientific evidence to support this).

Fake news and social media troll farms, often run by foreign governments, still use these false facts to sow mistrust and conspiracy theories.

There is a price to be paid for the increased suspicion of vaccines. Since the 1990s, there has been an increase in diseases that vaccines can prevent – including diseases that were once believed to be eliminated and/or controlled. One example, was an outbreak of measles at Disneyland that sickened 131 people, hospitalized 20% of them, and spread to six states. This was serious, because measles can cause inflammation of the brain in 1 of every 1,000 cases and can be fatal; it accounts for more than 100,000 deaths each year. For more information about the vaccine controversies see Appendix B.

Within the past few decades, the anti-vaccine movement has gained momentum including in certain communities around the United States. In this resource, we have chosen not to refer to people who object to vaccines as anti-vaxers, who are often associated with this movement, because we do not want to misrepresent or homogenize the beliefs and practices of the different groups who object to vaccines. Instead, we have opted to more closely examine the reasons and/or concerns a person or group may have when it comes to receiving certain vaccines.

What are some concerns about vaccines?

Concern: Distrust of large pharmaceutical companies seen as driven by financial incentives and therefore not trustworthy.

The Facts: Vaccines usually do not make money for pharmaceutical companies. In most cases, pharmaceutical companies make their money through manufacturing drugs that treat or mitigate symptoms from those diseases.

Concern: Distrust of government (in part for past wrongdoing) and of institutions monitoring vaccines' side-effects.

The Facts: There are four primary safety activities conducted by the CDC.

- Vaccine Adverse Event Reporting System (VAERS): National vaccine safety surveillance program co-sponsored by the FDA and the CDC that collects and analyzes information from reports of adverse events that occur after U.S. licensed vaccines are administered.
- Vaccine Safety Datalink: A collaboration between the CDC and numerous other health care organizations that allows for ongoing monitoring and searches of vaccine-related data.
- Clinical Immunization Safety Assessment (CISA) Project: A partnership between the CDC and several medical centers that conduct clinical research on vaccine-associated health risks in certain groups of people.
- Emergency Preparedness for Vaccine Safety: In the event of a disease outbreak in which a mass vaccination campaign is needed, CDC activates emergency preparedness activities to ensure that vaccines are and remain safe.



Concern: Worry about side effects/complications.

The Facts: Extreme/severe side effects are *extremely* rare when taking a vaccine, averaging less than 1 out of a million doses.^x

In 1998, a rotavirus vaccine was licensed and recommended for routine use in children. Fifteen reports came into VAERS of a rare intestinal blockage occurring after administration of the vaccine. When this was investigated, it was determined that children who received the vaccine experienced a higher rate of intussusception (when the lining of an intestine swells and slips into another part of the intestine^{xi}) than children who didn't receive the vaccine. The RotaShield vaccine was then pulled off the market because 1 in 10,000 children experienced a serious side effect. This example is often used to illustrate that there are high standards for safety when it comes to vaccines, and that the systems are in place to ensure that potential side effects are identified proactively.

Concern: There are too many vaccines are given at once:

The Facts: Trillions of bacteria live on our body at any given time. Each single bacterium has between 2,000 and 6,000 immunological components. The total number of immunological components contained in all 14 vaccines that children get in their first few years of life is 150.xii

Concern: Vaccines contain harmful ingredients:

The Facts: Dozens of studies have established that the theories over supposedly harmful ingredients are groundless. (See history of vaccine controversy and Appendix B.) Many contents in vaccines (such as mercury, aluminum, etc.) exist in nature or daily life in a variety of ways (e.g., breast milk contains 15 times the amount of Mercury that exists in a vaccine^{xiii} and we often ingest much larger amounts than the microscopic amounts that exist in a vaccine.^{xiv})

Concern: Vaccines cause autism and a number of other illnesses:

The Facts: This is not the case. Not only has all reliable research established that this is not accurate, but the doctor who first promoted the idea was thoroughly discredited and lost his medical license due to falsified facts, fraud, and unprofessional conduct. (See history of vaccine controversy and Appendix B.)



What are religious concerns about vaccines?4

Most religions and faith-based groups that have issued public stances agree that vaccines are important because they maintain public health. Despite institutional acceptance of vaccines, some people still hold religious reservations about the use of certain vaccines.

There is great diversity within all religions including how individuals believe and practice their faith. The information in this section may not apply to all people within a tradition. As a health practitioner, it is important to ascertain what a particular person may believe and practice. Likewise, religious people who have questions about taking vaccines based on their religion should consult with their personal spiritual leader.

Catholicism: Some vaccines, such as varicella (chickenpox), rubella (R in MMR vaccine), hepatitis A, and certain preparations of the rabies vaccine, were initially developed from laboratory cell lines that were derived from aborted fetuses (the vaccines themselves contain no fetal cells).*^{vv}

- The National Catholic Bioethics Center summarizes the Church's official position: While Church members should seek alternatives to vaccines using cell lines derived from aborted fetuses, when available, "[o]ne is morally free to use the vaccine regardless of its historical association with abortion. The reason is that the risk to public health, if one chooses not to vaccinate, outweighs the legitimate concern about the origins of the vaccine. This is especially important for parents, who have a moral obligation to protect the life and health of their children and those around them."xvi
- In December 2020, the Vatican clarified that, with respect to COVID-19 vaccines, it is morally acceptable to take the vaccines derived from fetal cell lines (i.e., research and production), when alternatives are not available and public/individual health is at risk.xvii At this time, the Pfizer and Moderna vaccines, both approved in the U.S., were not manufactured using fetal cell linesxviii but the Johnson & Johnson vaccine, also approved, was.xix



Christian Science: Christian Scientists have no formal policy against vaccines, but generally rely on prayer and spiritual practices centered on the teachings of Jesus Christ for healing. Their faith holds that medical interventions, which can include vaccines, are unnecessary. For this reason – and not because of a church doctrine, fear of vaccines, or indifference to societal well-being – church members often seek religious accommodation from vaccination when it's available. An ethic of their faith calls on Christian Scientists to be law abiding and to respect the rights of others. This may include getting vaccinated if the needs of the wider community call for doing so.⁵

The following faith healing denominations have a theological objection(s) to vaccinations⁶:

- Faith Tabernacle
- · Church of the First Born
- Faith Assembly
- End Time Ministries^{xx}

⁵ An official statement on vaccinations and public health by the Christian Science church is available at "A Christian Science Perspective on Vaccination and Public Health," which can be viewed here.

Outbreaks of measles have occurred among Orthodox Jewish communities in New York City and Rockland County, most notably in 2019. These measles outbreaks were attributed to misinformation campaigns led by the secular, anti-vaccine group PEACH (Parents Advocating and Educating for Children's Health) and not to the community's religious beliefs. Belluz, J. (2019, April 10). New York's Orthodox Jewish community is battling measles outbreaks. Vaccine deniers are to blame. Vox.

Both **Judaism** and **Islam** direct adherents not to eat pork and take similar approaches to vaccines that include porcine gelatin.^{xxi}

- Muslims permit porcine gelatin in vaccines because there is a medical necessity and all life is considered sacred.⁷ However, if a non-porcine alternative is readily available and will protect health and life, it should be taken.
- Under Jewish law, the highest obligation is to preserve life and, according to most Jewish authorities, that includes taking life-saving vaccinations even when they include porcine gelatin to preserve one's own health and the health of the broader community. If there is a vegan alternative, it is preferred but not required.

Although many **Hindu**, **Buddhist**, **Jain**, and **Sikh** adherents abstain from eating meat based on their religious and/or philosophical precepts that one should do no harm, degrees of abstention vary. If a vaccine contains animal byproducts, some may refuse it and seek a vegetarian or vegan alternative. Generally, these traditions view personal choice and duty as linked so that an individual's decision regarding a vaccine is often made with consideration of one's obligation to contribute to a greater good. In the case of vaccines, this could involve weighing the harm incurred in the creation of a vaccine against the harm to society from refusing to take the vaccine.

The current list of vaccines in the United States that contain porcine gelatin follows: Live, attenuated influenza (Flumist); measles, mumps, rubella (MMR II); measles, mumps, rubella, varicella (ProQuad); rabies (Rabavert); typhoid oral (Vivotif); varicella (Varivax); yellow fever (Y-F Vax).xxii

Is it legal to require children to be vaccinated before attending school?

Yes, with some exceptions.

Over 150 years ago, Massachusetts became the first state to require vaccinations for schoolchildren. And by 1981, student vaccinations were mandated in all 50 states. The courts—including the U.S. Supreme Court—have upheld these laws while also providing guidance on exemptions. In so doing, they have defined the current parameters for vaccines and exemptions based on a number of key principles:

- There are limits to our Constitutional rights. To preserve the common good including public
 health, limits can be imposed on our freedoms. In *Jacobson v. Massachusetts* (1905), the U.S.
 Supreme Court stated: "the liberties secured by the Constitution ... [do] not import an absolute
 right in each person to be ... wholly freed from restraint. There are manifold restraints to which
 every person is necessarily subject for the common good."
- A state must have a compelling reason for limiting the free exercise of religion. This core
 principle is set forth in a U.S. Supreme Court case overturning denial of unemployment
 insurance to a woman who turned down a job offer that required her to violate her religion and
 work on her Sabbath. More recently, this principle was reaffirmed in a case in which the Court
 struck down stringent limitations placed on the number of people allowed to attend houses of
 worship during the COVID-19 public health crisis.

⁷ Over 20 years ago, 112 leading Islamic scholars publicly determined that ingesting porcine gelatin in medicines for reasons of health was permitted under Islamic law (Sharia) McNeil Jr., D. G. (2019, April 26). Religious Objections to the Measles Vaccine? Get the Shots, Faith Leaders Say. New York Times.



- Many states recognize religious objections to vaccinations, though a number of states (beginning with California) repealed their religious exemptions to protect school children and preserve herd immunity. The right to refuse an exemption for vaccinations has been upheld by courts that have considered the question. Though *Jacobson* was a vaccination case, it was a 14th Amendment liberty interest case that did not involve claims of religious exemptions or free exercise. The issue of whether the free exercise clause of the 1st Amendment allows a person to opt out of compulsory vaccination laws has not gone to the U.S. Supreme Court at the time of this writing.
- When states permit exemptions from vaccinations required before attending school, there may be consequences for the student. For example, if there is an outbreak of an infectious disease, like measles, the child may be asked to stay home and not go to school.

Given the current COVID-19 pandemic, we can predict that the issue of exemptions including religious exemptions may not be fully settled, as yet.

For more detailed information about vaccines and the law, see Appendix C.

What if people object to being vaccinated? How do they legally opt-out?

Every state has laws providing one or more ways people can be exempted from getting a vaccine because they're worried about vaccines, refuse them, or delay getting them, contrary to the CDC Schedule.

Exemptions vary from state to state and can be classified as "easy," "medium," or "hard" to obtain.

There are currently three types of exemptions recognized in the U.S.:

- Medical Objections: Patients who receive medical exemptions usually have immune system
 disorders or severe allergies to the vaccine or components of it.xxiii All 50 states allow
 vaccination exemptions for medical reasons.xxiv
- Religious Objections: Religious objections are generally linked to the core beliefs of the patient or guardians of the patient.*** They are recognized in 44 states and the District of Columbia.
- Philosophical Objections: Philosophical exemption is an umbrella term covering exemptions for a variety of beliefs and practices that affect how the patient or their guardians understand and approach vaccinations.xxvi Fifteen states recognize philosophical exemptions.

The CDC maintains a database of the types of exemptions in each of the 50 states and the District of Columbia. While all the states recognize medical exemptions, most also allow other exemptions (five do not). This database can be helpful for determining the rules in your state.

Data suggests that people claim exemptions depending on what is available in their state. For example, religious exemptions are more frequently sought in states that do not recognize philosophical exemptions. The rates of patients seeking exemptions in states that allow philosophical exemptions are 2.5 times higher than in states that only permit religious exemptions.**

Given the impact of the exemptions on herd immunity, some states have clarified that "philosophical" arguments may not be used as a basis for granting a religious exemption. Other states are reevaluating their religious exemption laws.

For more details about opting out of vaccines see Appendix D.

How are vaccines approved and implemented?

There are two organizations that are responsible for overseeing the approval and use of vaccines in the United States – The Food and Drug Administration (FDA) and the CDC.

The FDA is a federal agency within the Department of Health and Human Services. It is charged with protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. XXIX Vaccines, like all products regulated by the FDA, undergo a rigorous review to ensure their safety, effectiveness, purity and potency. XXXX

The FDA licenses and oversees testing of new drugs and vaccines. In general, once a new vaccine is approved for clinical testing, it goes through three phases of testing, each involving more subjects. If the tests are successful and the FDA approves the vaccine, it can then go to market and be distributed nationwide. The FDA continues to monitor the manufacturing process and the side effects even once a vaccine is released to the general public.



The CDC is another federal agency within the Department of Health and Human Services that monitors vaccines once they have been distributed. Its primary goal is to protect public health through the control and prevention of disease. It therefore focuses on infectious diseases, food borne pathogens, environmental health, occupational safety and health, promoting health, preventing injury, and providing educational activities designed to improve national health. Once vaccines have been licensed by the FDA, the CDC oversees the long-term safety of vaccines by monitoring and recording side effects.

For more detailed information on the approval of vaccines and getting the vaccine in use, see Appendix E.

Final Thoughts

In closing, it is important to note that this resource is being presented at a time when people around the world are struggling with the COVID-19 pandemic and information on the emerging vaccines to fight the pandemic is evolving daily. The information provided here is current as of January 2021 and does not include the most up-to-date information on COVID-19 vaccine recommendations. Accordingly, this resource is not intended to substitute for the recommendations of health professionals. For more information about current vaccine recommendations, please consult your local health institutions and care providers.



Appendix A

Vaccine Immunization Schedules

(Birth to 15 months):

Hepatitis B: A virus that attacks the liver and can cause liver damage and liver cancer.

CONTAGIOUSNESS: Exposure to even minute quantities of blood from an infected person can cause hepatitis B. If 10 susceptible people live in a house with one person who is infected with hepatitis B, 4 of 10 people will likely become infected.

RATIONALE FOR VACCINE: Every year in the U.S., about 5,000 people die from hepatitis B. One in 20 people living in the U.S. has been infected with hepatitis B, and two million of these are chronically infected.

Rotavirus: A virus that causes severe diarrhea.

CONTAGIOUSNESS: Highly contagious through hands, toys and surfaces contaminated with an infected person's feces.

RATIONALE FOR VACCINE: As many as 55,000 children were hospitalized each year due to rotavirus infection prior to the use of the vaccine.

• **Diphtheria:** A bacterial illness that releases a toxin making it difficult for children to breathe and swallow. Also attacks the heart, kidneys and nerves.

CONTAGIOUSNESS: Passed by coughing and sneezing. If 10 susceptible people are exposed to one infected person, about 7 to 10 people will become infected.

RATIONALE FOR VACCINE: Diphtheria was a common cause of death in the 1920s; the vaccine was implemented in the 1940s and virtually eliminated the disease.

• **Tetanus:** A disease caused by a bacterium that makes a toxin. The toxin triggers muscle spasms that can interfere with breathing, cause suffocation, and damage the heart.

CONTAGIOUSNESS: Caused by the spores of the Clostridium tetani bacterium in soil entering a wound.**xxi

RATIONALE FOR VACCINE: Given that children are often prone to injury (cuts and scrapes), immunization is considered important.

• **Pertussis:** A bacterial illness, also known as 'whooping cough.' Makes children cough uncontrollably and unable to catch their breath; they make a "whooping" sound when they attempt to breathe in against a windpipe severely narrowed by mucus.

CONTAGIOUSNESS: Spreads through coughing and sneezing. If 10 susceptible people are exposed to one person who has pertussis, all 10 people will typically become infected.

RATIONALE FOR VACCINE: It is particularly severe and even deadly for infants who are too young to be vaccinated (vaccination by others protects them). Half of infants under 1 who get pertussis are hospitalized; 1 or 2 in every 100 hospitalized infants die.

Haemophilus influenzae type b #1 (Hib): A bacteria that infects the lining of the brain causing
meningitis, which can lead to coma and death or if children survive, leave them permanently
paralyzed, deaf, blind or mentally impaired. It usually affects children under the age of five, but
can affect adults with certain comorbidities.

CONTAGIOUSNESS: Spreads through coughing and sneezing. If 10 susceptible children (under 4) are exposed to a person infected with Hib, up to 1 of 10 children will become infected.

RATIONALE FOR VACCINE: Before introduction of the vaccine, 25,000 children were affected every year. Half of people with Hib develop meningitis, and 4 in 100 of those infected die.

Pneumococcus: A bacteria that causes meningitis, bloodstream infections and Pneumonia.
 When the respiratory tract is compromised with an infection like Influenza, the bacteria invades the lungs, bloodstream or spinal cord.

CONTAGIOUSNESS: In 1 in 4 people, the pneumococcal bacterium lines the surface of the nose and throat.

RATIONALE FOR VACCINE: Before the vaccine, every year, pneumococcus caused about 700 cases of meningitis, 17,000 cases of bloodstream infections, and 71,000 cases of Pneumonia. Due to overuse of antibiotics, certain strains of pneumococcus are now highly resistant to most antibiotics.

Polio: A virus that infects the brain and spinal cord, and can cause paralysis.

CONTAGIOUSNESS: Spread through the stool of an infected person. When 10 people are exposed to an infected person, all 10 will become infected. One or 2 will become paralyzed.

RATIONALE FOR VACCINE: Polio leads to paralysis in 1 in 75 cases in adults and 1 in 1,000 cases in children. While it has been eliminated in the U.S., it has not been eradicated in other parts of the world.

• **Influenza:** A virus that infects the nose, throat, windpipe and lungs, often called the flu (though it is not the same as the traditional stomach flu).

CONTAGIOUSNESS: Transmitted through coughing and sneezing. If 10 susceptible people are exposed to someone who has influenza, 3 of 10 will typically become infected.

RATIONALE FOR VACCINE: The H1NI virus (swine flu) was contracted by 59 million Americans in 2009-2010; 265,000 were hospitalized, and 12,000 people died.

• Measles: A viral infection that cause high fever, body rash and diarrhea.

CONTAGIOUSNESS: One of the most contagious illnesses. If 10 susceptible people are in an elevator with one person infected with measles virus, all 10 people will likely become infected.

RATIONALE FOR VACCINE: A resurgence of measles in 2019 led to 1,282 cases across the United States, the highest recorded since 1992. One in 1,000 children with measles die, and 1 in 1,000 develop encephalitis, which can lead to deafness or intellectual disability.

Mumps: A virus that causes swelling in the salivary glands below the ear, giving people a
chipmunk-like appearance. A cause of viral meningitis in children and orchitis in men.xxxii

CONTAGIOUSNESS: Transmitted through coughing, sneezing or contact with saliva. If 10 susceptible people are exposed to one person infected with mumps, about 6 of 10 people will become infected.

RATIONALE FOR VACCINE: Mumps can cause permanent deafness, sterility in men, and stillbirth in pregnant women.

 Rubella: A viral infection also known as German measles that causes a rash in the face, swelling glands behind the ear and fever. Has much more severe impact on unborn children causing blindness, deafness, heart defects in infants whose mothers were infected during pregnancy.

CONTAGIOUSNESS: Spread through coughing and sneezing. If 10 susceptible people are exposed to one person infected with rubella, about 7 of 10 people will become infected.

RATIONALE FOR VACCINE: Before the vaccine, as many as 20,000 babies were born every year with birth defects caused by rubella.

 Chickenpox (Varicella): A highly infectious disease that causes an itchy rash and small fluidfilled blisters.

CONTAGIOUSNESS: Spreads through coughing, sneezing, physical contact with blisters or virus particles from blisters sprayed into the air. If 10 susceptible people are exposed to one infected person, 9 of 10 people will typically become infected.

RATIONALE FOR VACCINE: Before the licensing of the varicella vaccine, there were approximately 4 million cases, 100-150 deaths, and more than 11,000 hospitalizations a year from chickenpox. Most of the people who died were healthy before they got chickenpox. The vaccine vastly reduced the number of people who die from chicken pox, though some deaths do occur. One in 50 women infected during pregnancy will deliver children with birth defects.

Hepatitis A: A virus that attacks the liver (A strain).

CONTAGIOUSNESS: Fecal-oral transmission, or getting something into your mouth (such as through food or by touching) that has been contaminated.

RATIONALE FOR VACCINE: Every year about 8,500 people in the U.S. contract hepatitis A and 50 people die.

• **Meningococcal:** A highly contagious bacterium that can cause death within hours of infection.

CONTAGIOUSNESS: Spreads through intimate contact such as kissing or sharing food. One in every 20 people exposed to the virus will be infected.

RATIONALE FOR VACCINES: There are two separate vaccines that protect against five types of meningococcal bacteria (A,C,W, Y and B). Four of 10 people infected die.

(15 months to 18 years):

- Adhere to recommended vaccinations listed on the birth to 18 years schedule and maintain immunity by getting the booster shots recommended by the CDC.
- Human papillomavirus (HPV): A sexually transmitted infection that can cause diseases such a
 genital warts and cancer.

CONTAGIOUSNESS: Sexually transmitted.

RATIONALE FOR VACCINE: HPV is the most common sexually transmitted infection that can often lead to certain types of cancers. The vaccine protects against nine strains of the virus.

(Adults):

- Adhere to recommended vaccinations listed on the birth to 18 years schedule and maintain immunity by getting the booster shots recommended by the CDC.
- Hepatitis B (HBV): Virus that attacks the liver (B strain).

CONTAGIOUSNESS: Spread through contact with infected bodily fluids.

RATIONALE FOR VACCINE: Approximately 3000 people in the U.S. contract HBV each year. Globally, HBV is the most common type of blood-borne infection. Infection can be fatal, often leading to cirrhosis or liver cancer.

• Shingles (Varicella-Zoster): A reactivation of the chickenpox virus that causes a painful rash.

CONTAGIOUSNESS: Anyone who previously had the chickenpox virus is at risk of having it reactivated.

RATIONALE FOR VACCINE: People become more susceptible to reactivation as they age. Although the virus is not often fatal, it is very painful. Approximately one million people get shingles each year in the U.S.

Appendix B

Evolution of Modern Vaccine Controversies in U.S.

- 1982: NBC put out a one-hour documentary called *DPT: diphtheria, pertussis, tetanus Vaccine Roulette*. The theory presented was that the pertussis vaccine was causing permanent brain damage, epilepsy and intellectual disability and other developmental issues.*xxiii,xxxiv
 - The NBC documentary was aired even though the pertussis vaccine, which was introduced in the 1940s, had significantly reduced infection rate from 175,000 cases per year in the United States to fewer than 5,000 cases per year by the 1970s.xxx
 - The advocacy group, Dissatisfied Parents Together (now called the National Vaccine Information Center), was born out of a concern around the DPT vaccine.xxxvi It has

since emerged as what journalist Michael Specter of The New Yorker describes as "the most powerful anti-vaccine organization in America, [...whose] relationship with the U.S. government consists almost entirely of opposing federal efforts aimed at vaccinating children.xxxvii"

- Extensive research ultimately found no connection between the DPT vaccine and brain damage. The research was from studies in over 12,000 peer reviewed articles that were assessed by the Institute of Medicine, a committee appointed by Congress and charged with reviewing reported adverse effects.xxxviii
- 1998: Andrew Wakefield published a paper in the British journal *Lancet* on a study of 12 children
 that showed that the MMR shot (measles, mumps, rubella) altered immune systems causing
 intestinal problems, which ultimately damage the brain and cause autism.xxxix
 - o Dozens of extensive epidemiological studies, in multiple countries, studying hundreds of thousands of children, found that Wakefield's research was meritless.xl
 - The Lancet retracted the paper.xii
 - o 10 of Wakefield's 13 co-authors formally withdrew their names from the paper.xiii
 - In 2010, Andrew Wakefield was stripped of his medical license due to falsified facts, fraud, and unprofessional conduct, including that his research was partially paid for by lawyers for parents seeking to sue vaccine makers for damages.xiii
- 1999: the American Academy of Pediatrics and the Public Health Service recommended the immediate removal of thimerosal (an ethyl mercury) from all vaccines given to young infants as a *precautionary* directive. *Iiv Thimerosal had been in vaccines since the 1930s to prevent contamination of the vaccine that can otherwise occur and cause life-threatening conditions. Thimerosal was removed from all vaccines (flu vaccines are available in thimerosal-containing and thimerosal-free versions). However, confusion about the reasons for its removal led to unsubstantiated claims that thimerosal caused autism. *Iv
 - The actual reason thimerosal was removed from vaccines: As more vaccines were identified and added, scientists became concerned by the cumulative amount of *ethyl* mercury in the infant immunization schedule potentially exceeding the recommended threshold set by the United States government for *methyl* mercury.
 - Ultimately, studies found that ethyl mercury and methyl mercury operate very differently the half-life of ethyl mercury is shorter and ethyl mercury is excreted in the gut rather than accumulating in the blood like methyl mercury.
 - Four epidemiological studies were done to investigate any associations between neurobehavioral disorders (autism) and vaccines containing thimerosal (ethyl mercury). No links were found.xlvi
- 2000 to present: When studies of MMR vaccines and thimerosal-containing vaccines failed to show an association with autism, alternative theories emerged, suggesting that too many vaccines administered at once overwhelm the immune system or even weaken it.
 - Science establishes that this theory is fallacious: Trillions of bacteria live on our body at any given time. Each single bacterium has between 2,000 and 6,000 immunological

components. The total number of immunological components contained in all 14 vaccines that children get in their first few years of life is 150.xivii

- Concomitant "use" studies: Every time a new vaccine is recommended to be added to
 the vaccine schedule for children, the FDA requires the company to prove that the new
 vaccine doesn't interfere with the safety or immune efficacy of the existing vaccines and
 vice versa.
- 1990s to the present: The number of outbreaks of vaccine preventable illnesses has increased, including diseases once thought to be eliminated or at least controlled. Examples are:
 - 2013: A pertussis (whooping cough) outbreak infected 9,000 people in California.xiviii
 The outbreak was caused by a significant percentage of unvaccinated children, who contracted and spread the disease.
 - 2015: A measles outbreak at Disneyland in California sickened 131 people and spread to six U.S. States. One-fifth of these cases required hospitalization.

While this may seem like a small number compared to the overall population of California and the U.S as a whole, health officials see this as one of several incidents illustrating a disturbing trend. Increasingly, they are seeing the reemergence of diseases previously controlled by vaccines.

Measles is highly contagious (e.g., A girl infected with measles went to a church picnic in Indiana of about 500 people. Of those 500 people, 35 were unvaccinated and 31 of them or approximately 89% got the measles.) Measles can also cause complications, like encephalitis (inflammation of the brain) in 1 of every 1000 cases.xiix

Appendix C

Vaccinations and Legal Exemptions: Timeline

- 1855: Massachusetts passed the first U.S. law making vaccinations mandatory for schoolchildren. An additional 10 states followed suit.
- 1890: In 1890, the California Supreme Court *Abeel v. Clark*, 24 P. 383 (Cal. 1890), upheld the state's vaccination requirement as a prerequisite for school attendance, finding that the mandate was within the power of the state.
- 1904: In *In the Matter of Viemeister*, 72 N.E. 97 (N.Y. 1904), the New York Court of Appeals upheld the state's power to require vaccinations as a prerequisite for attending public school.
- 1905: U.S. Supreme Court ruling in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), upheld mandatory smallpox vaccination programs that authorized local boards of health to require vaccinations in order to preserve the public health and found them to be constitutional.
 - "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" (197 U.S. at 26).

- 1922: U.S. Supreme Court ruling in *Zucht v. King*, 260 U.S. 174 (1922), upheld the constitutionality of childhood vaccination requirements for school attendance.
 - "These ordinances confer not arbitrary power, but only that broad discretion required for the protection of the public health." (260 U.S. at 177)
- 1944: Prince v. Massachusetts, 321 U.S. 158 (1944):
 - "The family itself is not beyond regulation in the public interest... 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." (321 U.S. at 166)
- 1959 and following: In Board Educ. Mountain Lakes v. Maas, 152 A. 2d 394, 405-09 (N.J. Super. Ct. App. Div. 1959), a New Jersey court held that the absence of an existing emergency did not mean the state could not implement preventive measures through compulsory vaccination; holding otherwise would have destroyed the state's ability to use prevention as a methodology for combating disease. In subsequent cases, other courts have similarly concluded that states have the power to enact preventive mandates even when disease does not pose a clear and present danger.
- By 1963: 20 states, the District of Columbia and Puerto Rico had similar vaccine mandates to Massachusetts for school children with varying levels of enforcement.
- 1963: In Sherbert v. Verner, 374 U.S. 398 (1963), U.S. Supreme Court established that state laws must serve a compelling state interest before they can burden the free exercise of a person's religion. This ruling was reinforced by the 1993 passing of the federal Religious Freedom Restoration Act (RFRA), 42 U.S.C. § 2000bb through 42 U.S.C. § 2000bb-4.
- By 1981: All 50 states had laws mandating vaccinations for students' first entering school.
- After 1981: Numerous state and federal courts addressed vaccination-related questions.
 For example,
 - In a number of cases, state and federal courts have held or recognized that a child may be excused from otherwise mandatory state or local vaccinations based on their parents' religious beliefs. See, e.g., Hanzel v. Arter, 625 F. Supp. 1259, 30 Ed. Law Rep. 347 (S.D. Ohio 1985) (applying Ohio law); Department of Health v. Curry, 722 So. 2d 874, 131 Ed. Law Rep. 870 (Fla. Dist. Ct. App. 1st Dist. 1998); Syska v. Montgomery County Bd. of Ed., 45 Md. App. 626, 415 A.2d 301 (1980); Bowden v. Iona Grammar School, 284 A.D.2d 357, 726 N.Y.S.2d 685, 154 Ed. Law Rep. 921 (2d Dep't 2001).
 - A New York state court held that a city school district could not eliminate, discontinue, or suspend its school health program, which provided examinations and immunizations for school children. *Liebowitz v. Dinkins*, 176 A.D.2d 666, 575 N.Y.S.2d 827, 70 Ed. Law Rep. 1196 (1st Dep't 1991).
 - A Nebraska court held that an unimmunized student at public school can be asked to stay home from school, when the school has confirmed the presence of a dangerous and communicable disease. The presence of the unimmunized student presents a clear threat to that child's physical safety, and also to the other students at the school. *Maack v. School Dist. of Lincoln*, 241 Neb. 847, 491 N.W.2d 341, 78 Ed. Law Rep. 1038 (1992).
 - In Berg v. Glen Cove City School Dist., 853 F. Supp. 651, 92 Ed. Law Rep. 850 (E.D. N.Y. 1994) (applying New York law), a federal court found that the exception from school immunization requirements for those who oppose immunization based on their religious

beliefs, does not apply to persons who object based on medical or moral considerations, scientific and secular theories, or philosophical and personal beliefs.

- January 2015: Philips v. City of New York, 775 F.3d 538 (2d Cir. 2015). Families whose children were religiously exempt from being vaccinated sued New York City for barring their children from attending school during an outbreak of measles. The court stated that New York's mandatory vaccine law does not violate families' constitutional due process, equal protection or religious freedom rights. In doing so, the *Philips* court relied in part on the unpublished 4th Circuit decision in *Workman v. Mingo County School District*, 419 Fed.Appx. 348, 268 Ed.Law Rep. 744, 2011 WL 1042330 (4th Cir.), cert. denied, 565 U.S. 1036 (2011), where a mother sued a school district claiming that the vaccination requirement violated her First Amendment right to the free exercise of religion. The Phillips court relied on the portion of *Workman* that had stated: "It has been settled law for many years that claims of religious freedom must give way in the face of the compelling interest of society in fighting the spread of contagious diseases through mandatory inoculation programs." *Workman*, 419 Fed.Appx. at 354 (quoting *Sherr v. Northport–East Northport Union Free Sch. Dist.*, 672 F.Supp. 81, 88 (E.D.N.Y.1987)); accord Phillips, 775 F.3d at 543 (citing *Workman*).
- July 2015: California passes a law that eliminated both personal and religious vaccine exemptions for children entering school (effective July 1, 2016).
- 2016: In Whitlow v. California, 203 F. Supp. 3d 1079, 1092 (S.D. Cal. 2016), a federal district court relying on Jacobson held that states need not provide religious or conscientious exemptions to mandatory vaccination requirements, noting that the U.S. Supreme Court in Jacobson was, over one-hundred years ago, "unwilling to hold it to be an element in the liberty secured by the Constitution of the United States that ... a minority of persons residing in any community ... should have the power to dominate the majority when supported ... by the authority of the state acting in good faith for all."
- 2018: In Brown v. Smith, 235 Cal. Rptr.3d 218, 224, 356 Ed.Law Rep. 353 (Ct. App. 2018), a California appeals court upheld the state's repeal of the right to receive a waiver from immunization based on religion. The court recognized that vaccination is the best scientific means to lessen the spread of disease. Accordingly, the court held that it was within the power of the legislature to enact a vaccination law to ensure that herd immunity is maintained, and that such an act did not abridge constitutionally protected freedom of religion. Brown further recognized that states could require all students to be vaccinated and could repeal waivers that it had previously established. The court concluded that "the right of education, fundamental as it may be, is not more sacred than any of the other fundamental rights that have readily given way to a state's interest in protecting the health and safety of its citizens, and particularly school children."
- 2019: Maine and New York state eliminated religious exemptions after measles outbreaks. Washington state eliminated personal/philosophical exemptions for MMR vaccine for children who attend school or day care. III
- November 25, 2020: The United States Supreme Court, in Roman Catholic Diocese Of Brooklyn, New York v. Andrew M. Cuomo, Governor Of New York, 592 U. S. ____ (2020), determined that a state must have a compelling reason for imposing stringent numerical limitations on people attending houses of worship during a public health crisis, because such limitations curtail the free exercise of religion. Though not specifically related to vaccines, this matter is worth noting. A majority of the justices believed that, because the limitations impinged on the free

exercise of religion and were more restrictive than limits imposed in some secular settings, such governmental orders must satisfy "strict scrutiny" (define?) and be "narrowly tailored" to serve a "compelling" state interest.

In a strongly-worded concurrence addressing how such an assessment should be applied, Justice Neil Gorsuch endorsed an expansive reading of religious rights and a shrinking reading of the police power reflected in *Jacobson v. Massachusetts*, 197 U. S. 11 (1905). Given that *Jacobson* is a core precedent on vaccines that assessed the neutrality of a state rule under the much lower rational basis test, this raises the question how future challenges to vaccine requirements and exemptions will be treated. Central to assessing such future vaccine cases will be whether the vaccine mandate or rules at issue allow any exemptions, especially non-religious ones that will allow religious groups to claim unequal treatment and seek consideration of their rights to religious freedom and observance.

See also, South Bay United Pentecostal Church v. Newsom, 592 U.S. __ (Feb. 5, 2021) No. 20A136 (20-746G), 2021 WL 406258 (here, the United States Supreme Court addressed a similar situation in California and authorized the churches bringing the lawsuit to operate at 25% capacity rather than not at all, while still restricting singing and chanting).

Appendix D

What if people object to being vaccinated? How do they legally opt-out?

"Vaccine Hesitancy" is a term used to describe anyone who is concerned about vaccinations, refuses to receive them, or delays getting them as recommended by the CDC schedule. According to a 2020 Gallup poll, many Americans believe in vaccines, but significant numbers also have concerns and may object.

- 84% of respondents in the U.S. say vaccinating children is important (down from 94% in 2001).
- 86% say vaccines are not more dangerous than the diseases they prevent.
- 45% of Americans say vaccinations do not cause autism.

There are three rationales for refusing mandated vaccinations that are legally recognized in different states. Exemptions vary from state to state and can be classified as "easy", "medium", or "hard" to obtain. Data shows that in states where it is considered easier to obtain a nonmedical exemption, more people applied for and obtained nonmedical exemptions.

- Medical Objections: Patients who receive medical exemptions usually have immune system disorders or severe allergies to the vaccine or components of the vaccine.[™]
 - All states allow vaccination exemptions for medical reasons.
- Religious Objections: Religious objections are generally linked to the core beliefs of the patient or guardians of the patient. Religious exemptions are permitted in 44 states and the District of Columbia.
 - Religious exemptions are sought more often in states that do not permit philosophical exemptions.

According to the Cornell Legal Institute, "Strict Scrutiny" is a form of judicial review that courts use to determine the constitutionality of certain laws. It is often used when a plaintiff sues the government for discrimination. In order to pass strict scrutiny, the law must further "a compelling government interest", while being narrowly tailored to achieve that interest (Strict Scrutiny (n.d.). In Legal Information Institute.

- For example, California recognizes both religious and philosophical exemptions. In 2012, it reported 14,921 philosophical exemptions and no religious exemptions. On the other hand, Illinois, which only recognizes religious exemptions reported 8,082 religious exemptions. Ixii
- Philosophical Objections: Philosophical exemption is an umbrella term covering exemptions
 for a variety of beliefs and practices that affect how the patient or their guardians understand
 and approach vaccinations. |xiii
 - Fifteen states allow an exemption based on philosophical beliefs or personal concerns.
 They include: Arizona, Arkansas, Colorado, Idaho, Louisiana, Michigan, Minnesota, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Texas, Utah, Wisconsin.
 - Opt-out rates by patients seeking exemptions in states that allow philosophical exemptions are 2.5 times higher than the rates in states that only permit religious exemptions. |xiv
 - o In Colorado, which allows both religious and personal belief exemptions, only 82 percent of children had received both of the recommended doses of the mumps, measles, rubella vaccine for the 2013-14 school year, while in Mississippi, which allows only medical exemptions, 99.7 percent had gotten both doses.

The CDC maintains a <u>database</u> of the rules for all 50 states that one may consult. To highlight a few items:

- All 50 states allow medical exemptions for situations where a child may be allergic or have a compromised immune system.
- Only medical exemptions: California, Maine, Mississippi, New York, and West Virginia.
- There is wide variation among the states in how vaccination exemptions are administered.
 Many states specify that "philosophical" arguments must not be cited as a basis for granting a religious exemption. Many states are also reevaluating their religious exemption laws.

Appendix E

How are vaccines approved and implemented?

- Process of approving a new vaccine:
 - The FDA's Center for Biologics Evaluation and Research (CBER) oversees the testing and licensing of new drugs and vaccines in the United States.
 - Vaccine testing and licensing processes are very similar to drug approval processes. The company testing and manufacturing the vaccine must submit an Investigational New Drug (IND) application.
 - The application is evaluated and if it is deemed safe and effective in animal testing trials, then the company is approved to begin clinical trials with human subjects.
 - The clinical trials typically go through three phases, gradually increasing the number of subjects and then distinguishing between certain characteristics (race, age, sex) so results, safety, and side effects can be monitored.

- If the company successfully completes the phases of the clinical trials they are then able to submit a Biologics License Application (BLA) which is then reviewed by an FDA team consisting of microbiologists, medical officers, chemists, and biostatisticians.
- If approved, the company is then allowed to market and transport vaccines over state lines to distribute widely. The FDA continues to monitor this process and side effects are still recorded and tracked once the vaccine has been given to the general population.
- Process of recommending/approving a vaccine in the CDC: Within the CDC there is a
 committee called the Advisory Committee on Immunization Practices (ACIP) that is tasked
 with reviewing and recommending new vaccines for the general public. The committee is
 comprised of medical and public health experts. Their recommendations are then sent to the
 CDC Director for approval.
- Process for requiring vaccination: ACIP is also responsible for setting the vaccination schedules for children and adults. This committee meets every three years to review the schedule and make changes according to new research or needs. The CDC implements the schedule based on ACIP's recommendations. The children's schedule is also reviewed and approved by the American Academy of Pediatrics (AAP), American Academy of Family Physicians (AAFP), American College of Obstetricians and Gynecologists. The adult's schedule is also approved by the American Academy of Family Physicians (AAFP), American College of Obstetricians and Gynecologists, the American College of Physicians, and the American College of Nurse-Midwives.

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