NEUTRALIZING THE CONVERSATION BETWEEN PHYSICIANS AND PATIENTS TO INCREASE VACCINATION RATES

BY

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LIST OF ABBREVIATIONS

- § 137: The Commonwealth of Massachusetts Statute Chapter 75 § 137
- AAP: American Association of Pediatrics
- ACIP: Advisory Committee on Immunization Practices
- ACOG: American College of Obstetrics and Gynecology
- CDC: Center for Disease Control and Prevention
- DTaP: Diptheria Pertussis and Tetanus.
- DPT: Diptheria-Pertussis-Tetanus
- EPA: Environmental Protection Agency
- HHS: U.S. Department of Health and Human Services
- HPV: Human Papilloma Virus
- MMR: Measles-Mumps-Rubella
- Model Act: Model State Emergency Health Powers Act
- National Childhood Vaccine Injury Act: NCVIA (referred to as the Vaccine Act on page XX of chapter One: Law & Policy)
- National Childhood Vaccine Injury Program: NCVIP
- Ob/Gyns: Obstetrician/Gynecologists
- OSM: Office of Special Masters. Alternatively known as the Vaccine Court.
- PANYC: Pediatric Association of New York City
- PCP: Primary Care Physician
- Vaccine Court: The Office of Special Masters
- VFC: Vaccine for Children Program
- VIS: Vaccine Information System
- VPD: Vaccine-preventable disease
- WHO: World Health Organization

ABSTRACT

This paper sets out to encourage an overhaul in how the vaccine topic is approached by physicians when interacting with patients. In an effort to bridge the gap between government public health interests and personal autonomy, this paper advocates changing informed consent practices to their initial intention, which was to protect patients from battery rather then protect physicians from liability. This paper advocates for prioritizing patient-centered care, even in public health measures and when the patient does not agree with the prescribed care method. In the same effort, this paper advocates starting the vaccine conversation early and having it often. This is accomplished by starting the conversation in the Ob/Gyns office and continuing it in small conversations throughout the pregnancy and in the pediatric well-child visits. This paper advocates for prioritizing patient-centered care, even in public health measures and when the patient does not agree with the prescribed care method.

INTRODUCTION

This thesis is to establish the ethical responsibilities of medical providers[1] to communicate with their patients[2] regarding vaccinations,[3] their benefits, and their potential consequences. The purpose of this thesis is to neutralize the public conversation around vaccines to one of scientifically proven facts, rather than one of opinions based on media portrayals, by creating an informative conversation based on mutual respect between physicians and patients. This communication is an attempt to bridge the gap between autonomous decision making for individual patients and government public health goals. The practical reason for changing the conversation is that by creating better relationships between patients and their physicians and a renewed sense of patient autonomy, vaccine rates will rise. The timing of this thesis is relevant because the number of outbreaks in the United States of almost forgotten diseases has increased drastically in the last 10-15 years, as opposed to the numbers between the 1950s-2000s.[4] The importance of this topic is finding the line where choosing to get vaccinated is a concern of personal health and when a group of individuals who are not vaccinated becomes a major concern of public health.

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[1] The terms "medical providers," "caregivers," "physicians," and "doctors" will be used interchangeably.

[2] The term "patients" applies to parents of patients, since these patients are not autonomous adults making decisions about their vaccinations.

[3] The terms "vaccination" and "immunization" have a note-worthy difference. A "vaccination" is when a vaccine is administered, usually by injection. An "immunization" is the stimulation of the immune system caused by the vaccine so that the immune system can recognize the disease and protect the body from future infection (Retrieved from http://www.nps.org.au/medicines/immune-system/vaccines-and-immunisation/for-individuals/questions-and-answers-about-vaccines/difference-between-vaccination-and-immunisation). While this distinction does not change the goals of this thesis, it is fundamental.

[4] (2015, October 8). *Pertussis Outbreak Trends.* Center for Disease Control and Prevention. Retrieved from http://www.cdc.gov/pertussis/outbreaks/trends.html

The communication discussion will include a new look into informed consent conversations when patients are making decisions regarding vaccinations. This thesis will examine how vaccine mandates and the tradition of paternalism in medicine have stripped patients of informed consent when it comes to vaccines, leaving them confused and defensive.

This thesis will focus on parents with children who are deciding whether to vaccinate their children, and thus focuses on pediatrics and vaccinations that are routinely given as part of children's healthcare. There are various reasons for this. One is that because children are not autonomous, their parents make their vaccine choices for them. Vaccines are unique in this way, as each child does not choose whether they are vaccinated. While some children are also subjected to other medical treatments at the choice of their parents, that varies based on each individual. Vaccines are the only medical treatment universally applied to children via their parents' decision-making. Another reason is that the recent measles,[5] mumps,[6] and whooping cough[7] outbreaks occurred in populations of children. Another reason is that the age of onset for autism, thought by some to be associated with the Measles-Mumps-Rubella vaccination (MMR), is approximately four years

[5] (2017, March 6). *Measles Cases and Outbreaks*. http://www.cdc.gov/measles/cases-outbreaks.html
[6] Szabo, L. (2014, December 15). *2014 was a bad year for mumps, a nearly forgotten virus.* Retrieved from http://www.usatoday.com/story/news/nation/2014/12/15/mumps-stages-comeback/20446743/
[7] (2015, October 8). *Pertussis Outbreak Trends.* Center for Disease Control and Prevention. Retrieved from http://www.cdc.gov/pertussis/outbreaks/trends.html

old.[8,9] There is no evidence that this association is based in science. This thesis posits that the misconception mainly comes from a now debunked study.

The specific types of vaccines are not particularly relevant, but the flu vaccine is specifically avoided because the nature of this vaccine is different from those administered to newborns and small babies. The flu vaccine is recommended annually to people of all ages, and its composition is different from that of typical vaccines that are only administered at certain points of an individual's life. Where examples of particular vaccines are necessary, this paper tends to focus on the HPV immunization for older children and MMR immunization for babies.

The reason for choosing the HPV immunization is that it is relatively new, especially to male recipients, making long-term side effects unknown. This immunization is currently under great debate because young women who received their Gardasil vaccine years ago when they were children are now reporting long-term adverse events through the Vaccine Adverse Effect Reporting System (VAERS).[10, 11]

The reasons for choosing the MMR immunization are (1) there have been increasing numbers of outbreaks in measles and mumps throughout the country

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[8] Bleicher, A. (2013, April 1). *Hunting for Autism's Earliest Clues.* Retrieved from https://www.autismspeaks.org/science/science-news/hunting-autisms-earliest-clues

[9] The origin of the Autism Scare is something that will be discussed later in this proposal and cited as a reason for the vaccine conversation becoming so polarized.

[10] Slade B.A., Leidel L., Vellozzi C., Woo E.J., Hua W., Sutherland A., Izurieta H.S., Ball R., Miller N., Braun M.M., Markowitz L.E., Iskander J. (2009). Postlicensure safety surveillance for quadrivalent human papillomavirus recombinant vaccine. *JAMA*, 302(7):750-7. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/19690307

[11] Most adverse events recognized by the vaccine injury table must occur within 72 hours of the administration. While these HPV claims may still be successful in the Vaccine Court, they will be harder to prove. The difference between on-table and off-table claims in the Vaccine Court is explained in Chapter One, Section II, Part B.

because of the decreasing number of children receiving the MMR vaccination, specifically in California;[12] (2) MMR is the vaccine most associated with causing autism, which contributed to the decreasing numbers of vaccinated children.[13] This faulty association[14] is what is often cited in the media frenzy over vaccines and thus, was the impetus for polarizing this topic.[15]

This thesis will be broken into four chapters. Chapter one will focus on vaccine law and policy. This will include a discussion of (1) state vaccine mandates and (2) the federal National Childhood Vaccine Injury Act.

Chapter One: Law & Policy

Chapter one will be a background explanation of the law and policies around vaccines. This chapter has two purposes; to show why the government has a public health interest in the population being immunized, and to explain the remedies made available by the government to the public in case of a vaccine-related injury. This includes the structure and process of obtaining these remedies.

This chapter will be broken down into two sections: state vaccine mandates and federal vaccine law. Section I will explore how states were given the power to implement mandatory vaccinations in an effort to protect the public health and safety. It will also provide a very basic explanation of how vaccines are paid for and by whom. Section II will explore will be a discussion of National Childhood Vaccine

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[12] (2017, March 6). *Measles Cases and Outbreaks*. http://www.cdc.gov/measles/cases-outbreaks.html

[13] (2015, November 2013). *Measles, Mumps, and Rubella (MMR) Vaccine Safety*. Retrieved from http://www.cdc.gov/vaccinesafety/vaccines/mmr-vaccine.html

[14] "Association" is not being used in a scientific or legal way. It is being used for its plain meaning of "a connection" and that people believe autism is a result of the MMR vaccines.

[15] Levs, J. (2015, February 4). The Unvaccinated by the Numbers. *CNN*. Retrieved from http://www.cnn.com/2015/02/03/health/the-unvaccinated/

Injury Act (NCVIA) and the National Childhood Vaccine Injury Compensation Fund. This will include why this Act was passed, its intended purpose, and how it can be practically applied by citizens. Subsection B will explain the Vaccine Injury Table, the Office of Special Masters (known as the "Vaccine Court"), and the Vaccine Court's role in assessing vaccine-related injury claims and awarding compensation.

Chapter Two: Media Portrayals of the Autism Scare & The Politicization of Vaccines

Chapter two will look at vaccination rates over the last 35 years. It will focus on the differences between the 1980s and early 1990s, the pre-autism-scare rates, and from the late 1990s until now, the post-autism-scare rates. The comparison of the statistics of vaccine rates and outbreak rates between these two periods will be used to show how vaccine rates have dropped and as a result, the outbreak rates have increased. This chapter will be broken into three sections. Section I will be a more complete background on the development of vaccines over the years, trends in society's perception of vaccines, and a discussion on herd immunity. Section II will will discuss Andrew Wakefield's fraudulent study, the discrediting of the study and Andrew Wakefield himself, and the media coverage of the entire debacle. This thesis purports that this quickly debunked connection between MMR and the rise in autism is the impetus for the polarization of opinions of all vaccines and creating a division between "anti-vaxxers"[16] and everyone else. Related to this, this chapter will look at the rising number of autism diagnoses around this time and the "autism

[16] The term "anti-vaxxer" is consistently put into quotations because it is somewhat of a misnomer. The term also includes those who are not entirely anti-vaccination, but interested in alternative vaccination schedules, partial vaccinations, or anyone who strays in any form from the childhood vaccination schedule.

scare" that contributed to the anti-vaccination movement that swept the nation through the media and through celebrity representatives. The stories will include both sides of the conversation, those that are pro-vaccination and various anti-vaccination arguments.

Section III gets deeper into the media's role in the vaccine discussion and the politicization of vaccines. The media is easily accessible to the public and in a powerful position that could be used to educate the public on the potential medical consequences of getting their children vaccinated, the public health detriments of choosing not to vaccine their children, and the balance between the two options. Instead, the media pushes headlines about the direst circumstances of a vaccinated child who suffered an injury or spreads fear of epidemics in communities with low vaccination rates. While these stories are based in true facts, they do not aid an informed decision. Instead, they promote extreme beliefs in a misinformed public. This is where medical caregivers are responsible for filling the gap via patient-centered care and informed consent. The media is not a focus of this thesis, however media stories will be used as one tool to depict the shift of opinion in our society.

The use of mass media in this thesis is to show how the public gets information. The media will be used to show where the general public stands on the topic and the battle between the "anti-vaxxers" and everyone else. The media not only perpetuates information, sometimes charged information, on the vaccine debate, but it is also a forum for prominent people to choose sides and lead their followers into that opinion. Prominent people include celebrities, politicians, and wealthy members of society.

This section of the thesis will explore the politicization more fully, specifically Donald Trump's, as he is now the President of the United States. Politicians lead us in all issues. The majority of the country is not against vaccines or the current state mandate system, however the President is and he may make moves in collaboration with anti-vaccine advocate Robert Kennedy, Jr. to take down vaccines.

Chapter Three: The Parameters of Informed Consent and How They Are Not Fulfilled During the Physician-Patient Conversations on Vaccines

The third chapter will provide a landscape of the current discussions going on in pediatricians' offices between parents and providers. It will use articles in journals and in the news about the mindset in medicine to presume that parents are fine with vaccines.[17] The current conversation in pediatricians' offices is often one that is lacking information. Physicians assume that parents either understand vaccines and the vaccine schedule or are required to vaccinate their children by the state, so they do not need to be given any more details regarding the administration or the vaccine itself. Ultimately, this lack of discussion has led to mistrust and animosity between pediatricians and any parents who ask questions about vaccines.

To begin, this chapter will focus on the legal parameters of informed consent, the policy behind it, and why it is not fulfilled in vaccine discussions between providers and patients. It will also explore how and why physicians are able to provide minimal information regarding vaccines and fail typical informed consent standards without any action or repercussion.

[17] Neighmond, P. (2015, February 27). To Get Parents to Vaccinate Their Kids, Don't Ask. Just Tell. *NPR*.

This chapter moves focus from the information given to the public by outside sources, such as the media in chapter two, to the information given to the public by medical providers.[18] Doctors are "the most trusted communicators of information."[19] For medical providers to combat misconceptions of vaccines, the conversation in pediatrician's offices must include information on vaccines, rather than an assumption that parents will understand and are fine with whatever vaccines doctors choose to administer without asking.

To change this conversation, this thesis aims to bridge the gap between the "reasonable practitioner" and the "reasonable patient" standards.[20] These are both legal concepts on disclosure standards that attempt to explain what is a caregiver responsible for telling patients to enable autonomy in making a medical decision. The "reasonable practitioner" standard is that "doctor knows best" for the patient.[21]

While there are all types of relationships between sellers and consumers, the physician-patient relationship is unique, especially when it comes to negligence.[22] The fiduciary duty owed to patients requires that physicians put their patients before themselves and their own business profits.[23] In order to put a patient's concern before their own, providers must be willing to take a few extra minutes,

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[18] The terms "caregiver," "practitioner," "physician," and "provider" will be used interchangeably.
[19] http://www.npr.org/sections/health-shots/2015/06/01/411188093/training-doctors-to-talk-about-vaccines-fails-to-sway-parents
[20] Raab, E.L. (2004). The Parameters of Informed Consent, *Transactions of the American Opthalmalogical Society*. 102: 225-232.
[21] *Id.*
[22] The legal definition of "negligence" is "a failure to behave with the level of care that someone of ordinary prudence would have exercised under the same circumstances." Cornell University Law School: Legal Information Institute. *Negligence*. Retrieved from https://www.law.cornell.edu/wex/negligence
[23] Schuck, P.H. (1994). Rethinking Informed Consent, *Yale Law Journal Company, Inc*. 103(4): 899-959.

which is a daunting order in their daily work schedule, and speak with their patients more frankly about their situations and what they hope to get out of their health care.[24] This requires going beyond informed consent and liability.

Providers are taught about informed consent as a step in the process of caregiving. However, when it comes to procedures as ubiquitous as vaccines, informed consent conversations are shortened, perhaps because it is expected that everyone has heard of and thus understands vaccines. This thesis postulates that if providers adhere to the standard of informed consent more closely, rather than providing the bare minimum, it will help the process of neutralizing the conversation to one that is science-based, rather than opinion based.

Chapter Four: Caregivers' Responsibility to Empower Patients to Make Their Own Choices via Education

The fourth chapter aims to start a new conversation between physicians and patients that empowers patients to make their own immunization decisions. The purpose is to establish a clean slate for this conversation, leaving all preconceived notions about vaccines or about people who choose not to vaccinate their children, behind. If clinicians are able to revolutionize this conversation so that patients feel able to make the choice, rather than feeling forced, vaccine rates will increase again, securing the public health. To neutralize the topic, clinicians must begin by providing information that not only satisfies informed consent standards, but also allows patients to feel as though they are making an autonomous choice regarding their babies' health. This can be accomplished by starting the conversation early and

[24] *Id.*

having it often. This chapter will seek to find where the line is drawn between personal and public health goals.

This conversation will benefit if it begins in the Obstetrician's (Ob/Gyn) office with a soon-to-be mother. Ob/Gyn's, while focusing on women's health, do play a part in childhood health, specifically infant health. Ob/Gyn's vaccinate pregnant women in order to protect infants for the months before they are able to receive their own vaccines.[25] The American College of Obstetricians and Gynecologists made a formal recommendation to integrate immunizations into ob-gyn practice in April, 2016.[26]

This proposed conversation will use the informed consent doctrines from chapter three and the patient centered care concepts in chapter four. This chapter will include information tools doctors should use in their conversations with patients, such as Center for Disease Control statistics; realistic discussions about possible side effects of the vaccines that goes beyond immediate reactions, such as redness at the injection site; improved techniques for connecting with patients; and emphasizing that when discussing vaccines, it is important to spend more time with your patients than is typically reasonable of physicians.

Another issue that often comes up with new parents is that the vaccine schedule is too front loaded. There are too many immunizations when their babies

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[25](2016, March 23). Educate and Vaccinate: Ob-Gyns Play an Essential Role. *The American College of Obstetricans and Gynecologists.* Retrieved from http://www.acog.org/About-ACOG/News-Room/News-Releases/2016/Educate-and-Vaccinate-Ob-Gyns-Play-an-Essential-Role

[26] Integrating immunizations into practice. Committee Opinion No. 661. *American College of Obstetricians and Gynecologists*. 2016;127:e104–7. Retrieved from http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Integrating-Immunizations-Into-Practice

are very young and parents find that overwhelming.[27] Parents may ask about alternative schedules and some pediatricians oblige, but some do not. The practical implications of this is that pediatricians who refuse to provide alternative schedules will either force the full vaccine schedule or refuse to vaccinate.[28] This is an example of a common piece of the conversation that is currently dictated by paternalistic medical practices, but if changed to a more open and informative discussion, could empower parents. Physicians may be hesitant to relinquish control to parents because of the field's paternalistic nature, but by allowing parents to take control of their children's full vaccination schedule, those parents who are opting out may be more likely to opt in at a different pace.

In the name of public health safety, this thesis will explore how neutralizing the vaccine conversation can increase our nation's vaccine rates and bring us back to a time without outbreaks of diseases we thought were almost entirely removed from our communities. The ultimate proposition of this thesis is that if a new conversation can happen in pediatric offices that leaves behind what the media has said about "anti-vaxxers" or the benefits of vaccines, patients will feel more empowered to choose and will more often choose to have their children vaccinated.

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[27] Boghani, P. (2015, March 23). Dr. Robert W. Sears. Why Partial Vaccinations May be an Answer. *Frontline PBS.* Retrieved from http://www.pbs.org/wgbh/frontline/article/robert-w-sears-why-partial-vaccinations-may-be-an-answer/

[28] This is anecdotal from people I spoke to in the Vaccine Court during the summer of 2015 and from an MSL student in the law school. I have not been able to find many articles on similar situations, but I am going to find out what I can use from my summer in the Vaccine Court.

CHAPTER ONE: LAW & POLICY

SECTION I: STATE VACCINE MANDATES

A. Public Health and Safety

States have mandated vaccine administration since the early 20th century. One of the first challenges to mandatory vaccines came from Massachusetts in the case *Jacobson v. Massachusetts*. In 1905, the Supreme Court ruled that in order to protect the public health and safety, the scope of states' police powers[29] includes the ability to enact reasonable regulations to achieve that protection.[30, 31] Mandatory vaccines were found to be such a reasonable regulation.

This case arose when smallpox was a threat. The Commonwealth of Massachusetts' statute, Chapter 75 § 137 (referred to as "§ 137"), provided that

> The board of health of a city or town if, in its opinion, it is necessary for the public health or safety, shall require and enforce the vaccination and revaccination of all the inhabitants thereof, and shall provide them with the means of vaccination. Whoever, being over twenty-one years of age and not under guardianship, refuses or neglects to comply with such requirement shall forfeit $5.[32]

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[29] Police powers come from the Tenth Amendment of the Constitution. This Amendment states that the Federal Government's powers are only those enumerated by the Constitution, giving states the rights and powers "not delegated to the United States." As such, States are granted the power to establish and enforce laws protecting the general welfare, safety, and health of the public. (Chemerinsky, E. (2011). *Constitutional Law*. 319. New York. Wolters Kluwer: Fourth Edition.) Vaccines are categorized under the health of the public, giving States the sole right to create any laws regarding vaccine administration. While it cannot create its own mandates regarding public immunization requirements, the federal government does regulate vaccine production and can provide financial compensation to States and to individuals, under the National Childhood Vaccine Injury Act. The federal government's role with the National Childhood Vaccine Injury Act will be discussed more in Section II of this Chapter.

[30] *Jacobson v. Commonwealth of Massachusetts,* 197 U.S. 11 (1905).

[31] The specific issue in *Jacobson* was whether in order to protect public health and safety, does the scope of the state's police power include the authority to enact reasonable regulations to do so? To which the Court answered, yes.

[32] 197 U.S. at 12.

The statute also provided an exception for any children who could show that they were medically unfit for vaccination by a certificate signed by a registered physician. Due to the rise of smallpox threatening the Commonwealth's population, Massachusetts enforced this statute by demanding any inhabitant who had not been vaccinated since March 1, 1897, be vaccinated at no cost. Jacobson refused to comply with the required vaccination. Jacobson claimed § 137: (1) violated the rights secured to citizens by the Preamble to the United States Constitution; and, (2) violated the rights secured to citizens by the 14th Amendment of the Constitution.

1. The Massachusetts Statutory Mandate Requiring Everyone Receive the Smallpox Vaccine Did Not Violate the Preamble of the United States Constitution.

In regards to Jacobson's first argument, the Court stated that

> Although that preamble indicates the general purposes for which the people ordained and established the Constitution, it has never been regarded as the source of any substantive power conferred on the government of the United States, or on any of its departments. Such powers embrace only those expressly granted in the body of the Constitution, and such may be implied from those granted.[33]

The Court rejected Jacobson's argument that § 137 violated the rights of citizens provided by the Preamble of the Constitution because the Preamble does not function as law. Rather, it is the roadmap outlining the Constitution's intentions.

[33] *Id.* at 25.

2. The Massachusetts Statutory Mandate Requiring Everyone Receive the Smallpox Vaccine Did Not Violate the 14th Amendment.

In regards to Jacobson's argument that § 137 violated the 14th Amendment, the Court stated that all states have the authority to enact reasonable regulations established to protect the public health and the safety.[34]

Jacobson argued that § 137 violated the 14th Amendment, especially:

> The clauses of that amendment providing that no state shall make or enforce any law abridging the privileges or immunities of citizens of the United States, nor deprive any person of life, liberty, or property without due process of law, nor deny to any person within its jurisdiction the equal protection of the laws.[35]

In his 14th Amendment claim, Jacobson argued that § 137 violated the Privileges or Immunities Clause, the Due Process Clause, and the Equal Protection Clause.

The Privileges or Immunities Clause of the 14th Amendment states that, "no state shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States."[36] The Privileges or Immunities Clause is vague and thus rarely used. It conflicts with or is redundant of other parts of the Constitution, thus is often overlooked in favor of those clearer articles.[37] What is clear about the 14th Amendment Privileges or Immunities Clause is that it allows citizens to sue state governments in federal courts. While Jacobson did have standing to sue Massachusetts in Federal Court; he did not show any violation of the 14th Amendment Privileges or Immunities Clause.

The purpose of the 14th Amendment Due Process Clause is to ensure that the American government operates within the law and provides fair procedures for its

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[34] *Id.*
[35] *Id.* at 13.
[36] Chemerinsky, E. (2011). *Constitutional Law*. 479. New York. Wolters Kluwer: Fourth Edition.
[37] *Id.* at 510.

citizens.[38] There are two types of due process: procedural and substantive. Procedural due process "refers to the procedures that the government must follow before it deprives a person of life, liberty, or property."[39] Substantive due process, on the other hand, asks whether the government has an adequate reason to deprive the claimant.[40] Substantive due process is analyzed by three levels of scrutiny created by the United States Supreme Court: low-level rational basis scrutiny, intermediate scrutiny, and high-level strict scrutiny. The issue in *Jacobson* is a substantive due process issue and deals with a fundamental right recognized by the Court, the right to refuse medical treatment. For a deprivation of substantive due process in regards to a fundamental right, the individual challenging the law has the burden to prove that the government interference is not necessary to achieve a compelling government interest. This is a strict scrutiny standard.

When analyzing if a statute violates due process, three questions are posed:

1. Does the statute deprive individuals of a fundamental right or interfere with the free exercise thereof?
2. Is the statute intended to achieve a compelling government interest?
3. Is there any less restrictive means for achieving the purpose?[41]

In *Jacobson,* the Massachusetts statute did deprive individuals of the fundamental right to refuse medical treatment by requiring individuals to get vaccinated or face a

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[38] *Due Process.* Cornell School of Law: In Legal Information Institute. Retrieved from https://www.law.cornell.edu/wex/due_process

[39] *Supra* 63 at 557.

[40] *Id*. at 558.

[41] Strict Scrutiny Analysis of Substantive Due Process. Retrieved from https://www.google.com/imgres?imgurl=https://nationalparalegal.edu/conLawCrimProc_Public/DueProcess/images/SubstantiveFundamentalRights1.gif&imgrefurl=https://nationalparalegal.edu/conLawCrimProc_Public/DueProcess/SubstantiveFundamentalRights.asp&h=477&w=573&tbnid=B9gm9enWyEIBuM:&vet=1&tbnh=160&tbnw=192&docid=56RnV8JeyviJVM&usg=__T9mRmRHQn-uhUR4A8gAjEV3dE_k=&sa=X&ved=0ahUKEwi9ptWjobjQAhUC7YMKHbXjBMwQ9QEIHjAA

penalty. The Massachusetts statute intended to achieve a compelling government interest, the public health and safety of the state, which are recognized police powers of the states. Finally, there was not a less restrictive means for achieving the public health and safety of the state. To ensure smallpox did not decimate the population of Massachusetts, the state had to ensure herd immunity[42] via vaccination.

The 14th Amendment's Equal Protection Clause provides that a state must treat an individual the same as others in similar conditions and circumstances. Massachusetts did treat Jacobson as other people in the same condition and circumstance. The state provided Jacobson, like all other citizens of the Commonwealth, the option to get the smallpox vaccine or pay a small penalty for opting not to receive the vaccine. Every equal protection clause issue can be analyzed for validity by asking three questions:

1. What classification does a government action create?
2. What level of scrutiny should be applied to this classification?
3. Does this particular government action meet that level of scrutiny?[43]

With respect to Question 1, the classifications the Commonwealth of Massachusetts makes are between people who get vaccinated and people who do not. Jacobson is a person in the second category, one choosing not to get vaccinated. By having to pay $5, he is treated differently from those in the first category, people who do get the state-mandated vaccine.

To answer Question 2, Jacobson is not a member of a protected class as determined by the Supreme Court; therefore, the standard applied to his claim is low-level rational

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[42] Herd immunity (or "community immunity") requires that a certain majority of the population be vaccinated in order to protect the entire population from disease. [Community Immunity ("Herd Immunity"). (2016, June 23). U.S. Department of Health & Human Services. Retrieved from https://www.vaccines.gov/basics/protection/.

[43] *Equal Protection.* Cornell School of Law: Legal Information Institute. Retrieved from https://www.law.cornell.edu/wex/equal_protection

basis. The Supreme Court determines protected classes. For example, race is the most protected class. Gender is also a protected class, but it is not protected to the same extent that race is protected. If Jacobson were forced to pay $5 because of his race or gender, then the level of scrutiny would be higher (strict or intermediate scrutiny, respectively) based on those factors. Under rational basis review, the individual challenging the law bears the burden of proof that the classification is not reasonably related to some rational purpose of the state.[44] This test is extremely deferential to the government. Jacobson, as a person choosing not to follow Massachusetts's statutory mandate for vaccination, failed to prove that the law had no rational purpose.

As to Question 3, the Court evaluates whether the means of the government action (Massachusetts's statutory vaccine mandate) justify its end (the public health of Massachusetts and a society free of smallpox). For a rational basis level of scrutiny, the law must have a legitimate purpose. In evaluating the relationship between the means of the law and the end, the Supreme Court focuses on the degree to which a law is under-inclusive, over-inclusive, or some combination of the two.[45] A law is under-inclusive if it does not apply to people who are similar to those whom the law does apply. For example, "a law that excludes those under age 16 from having drivers' licenses is somewhat under-inclusive because some young drivers undoubtedly have the physical ability and the emotional maturity to be effective drivers."[46] A law is over-inclusive if it unnecessarily applies to a group of people.[47] In Jacobson's case, the law was neither under- nor over-inclusive. It was not under-inclusive because it applied to everyone living in

[44] *Supra* 63 at 688.
[45] *Id.* at 689.
[46] *Id.* at 690.
[47] *Id.*

Massachusetts. It was not over-inclusive because it did not apply to a group of people to whom it did not need to apply. For the public welfare of the State, each person needed to be vaccinated against smallpox, or bear the penalty if they declined vaccination. Thus, § 137 did not violate the Equal Protection Clause of the 14th Amendment, as the government's action used reasonable or rational means to achieve a legitimate end. The means was the state statute, § 137, requiring everyone receive the smallpox vaccine or pay $5 if they opt out of the vaccine. The end was public health and safety.

The Court continued that the Constitution does not "import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint."[48] The Court explained "persons and property are subjected to all kinds of restraints and burdens in order to secure the general comfort, health, and prosperity of the state."[49] It concluded "upon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members."[50]

The takeaway from *Jacobson* is that the states' police powers take priority over an individual's fundamental rights when it comes to the public health and safety of the states' citizens. This is especially true considering the penalty for not complying with the state vaccine mandate was a fee of $5. This penalty is equivalent to $121.54 inflation-adjusted 2016 dollars.[51]

Each state, and the District of Columbia, has its own laws regarding vaccine requirements. The purpose of these laws is to ensure that enough children who enter

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[48] *Supra* 59 at 26.
[49] *Id.*
[50] *Id at 27.*
[51] Inflation Calculator. Retrieved from http://www.in2013dollars.com/1910-dollars-in-2016?amount=5

public arenas are not spreading communicable diseases. State "vaccination requirements for daycare and school entry are important tools for maintaining high vaccination coverage rates, and in turn, lower rates of vaccine-preventable diseases (VPDs)."[52] State laws also have exemptions to these requirements, which will be discussed further below. These laws require children entering school to provide documentation that they have met the state's immunization requirements.[53] The Supreme Court case *Zucht v. King* upheld a local ordinance requiring schoolchildren to be vaccinated.[54] In addition to this precedent, North Carolina's vaccine requirement states that,

> Every child present in this state shall be immunized against diphtheria, tetanus, whooping cough, poliomyelitis, red measles (rubeola), and rubella. In addition, every child present in this State shall be immunized against any other disease upon a determination by the Commission that the immunization is in the interest of the public health. Every parent, guardian...or agency…with legal custody of a child shall have the responsibility to ensure that the child has received the required immunization at the age required by the Commission. If a child has not received the required immunizations by the specified age, the responsible person shall obtain the required immunization for the child as soon as possible after the lack of the required immunization is determined.[55]

All states have laws requiring vaccination; school is simply the typical way to measure a child's vaccine record. Another example is Alabama's law, which requires that

> [I]n the absence of an epidemic or immediate threat thereof, the child shall be exempt from immunization requirements if the parent or guardian of the child objects in writing on grounds that such immunization conflicts

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[52] (2016, January 29). *State Vaccination Requirements*. Centers for Disease Control and Prevention. Retrieved from http://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html
[53] Cole, J.P. & Swendiman, K.S. (2014). *Mandatory Vaccinations: Precedent and Current Laws*. (CRS Report No. RS21414). Retrieved from Congressional Research Service. https://fas.org/sgp/crs/misc/RS21414.pdf
[54] *Id.; Zucht v. King, et. al.* 260 U.S. 174
[55] N.C.G.S.A § 130A-152.

> with his religious tenets and practices. Medical exemptions are also allowed.[56]

This law requires that all children be vaccinated unless their parents file a religious or medical exemption. In the case of an epidemic or threat of an epidemic, exemptions do not apply and all children must be vaccinated if the state deems it necessary.[57] This statute does not specifically state that schools require vaccination. In addition to the statute, however, Alabama case law states, "vaccination of all children may be required as a condition precedent to the right to attend schools."[58] All state laws are written to apply to public schools and often apply to private and parochial schools. Homeschooling is a bit more complicated because each home does not have to have a vaccine policy to protect other students. However, some states treat homeschools as though they are private schools.[59, 60] Other states have similar laws that require vaccination against this group of diseases. New York's vaccine law includes exceptions for religion and an instance when a physician determines the vaccine would be detrimental to the health of the child.[61]

Like New York, many state vaccine laws have exemptions. The three types of exemptions are: medical, religious, or philosophical. All 50 states allow medical exemptions, 48 allow religious (West Virginia and Mississippi do not), and 18 allow

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[56] (2016, August 11). *Alabama State Vaccine Requirements*. National Vaccine Information Center. Retrieved from http://www.nvic.org/Vaccine-Laws/state-vaccine-requirements/alabama.aspx

[57] *Id.*; Ala. Code 1975 § 11-47-132.

[58] *Herbert v. Demopolis School Bd. Dept. of Educ.,* 197 Ala. 617 (1916).

[59] *Homeschool Immunization Requirements.* The Coalition for Responsible Home Schooling. Retrieved from https://www.responsiblehomeschooling.org/policy-issues/current-policy/homeschool-immunization-requirements/

[60] Four states require homeschool parents to submit proof of immunization (MN, ND, PA, TN). 11 states require homeschooled students to be immunized but do not require homeschool parents to submit proof of immunization (CO, IL, IN, KS, KY, MT, NM, NC, TX, VA,WY). Nine states have multiple homeschool options with conflicting requirements (AK, FL, IA, LA, ME, MD, MI, NE, WA). 26 states do not require homeschoolers to be immunized (AL, AZ, AR, CA, CT, DE, GA, HI, ID, MA, MI, MO, NH, NJ, NY, OH, OK, OR, RI, SC, SD, UT, VT, WV, WI).; *Id.*

[61] McKinney's Public Health Law § 2805-h. Immunizations.

exemptions under philosophical objections.[62] The difference between the religious and philosophical exemptions is that religious exemption "indicates that there is a provision in the statute that allows parents to exempt their children from vaccination if it contradicts their sincere religious beliefs."[63] Philosophical exemption, however, "indicates that the statutory language does not restrict the exemption to purely religious or spiritual beliefs."[64]

Medical exemptions are straightforward and outlined by the Center for Disease Control. Generally, a child may be medically exempt if he or she has a weakened immune system or if the child has an allergy to any of the ingredients used in the production of the vaccine.[65] Anti-vaccination groups claim that acquiring medical vaccination has becoming increasingly difficult.

> Since 1986 the U.S. Centers for Disease Control and Prevention (CDC) and American Association of Pediatrics (AAP) have eliminated most officially recognized medical reasons for withholding vaccination so that almost no medical condition qualifies for a medical exemption to vaccination. In most states, a medical exemption to vaccination written by a medical doctor can be denied if the medical reason given does not strictly conform to CDC and AAP contraindication guidelines.[66]

This is only demonstrated on a case-by-case basis. While it may be that medical exemptions are strictly held to CDC and AAP standards, these standards have been developed with the direct purpose of protecting children from vaccine-related harms. If a child's medical condition does not exempt her from vaccines based on these guidelines, it

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[62] *Id*.
[63] States with Religious and Philosophical Exemptions From School Immunization Requirements. (2012). National Vaccine Information Center. Retrieved from http://www.nvic.org/vaccine-laws.aspx#
[64] *Id*.
[65] Kleifgen B, Silpe J. (2010). Vaccination Requirements and Exemptions. *VaccineEthics.org.*
[66] Mercola. (2011). *How to Legally Get a Vaccine Exemption*. Retrieved from http://articles.mercola.com/sites/articles/archive/2011/12/27/legal-vaccine-exemptions.aspx

is because there is no need for that child to be medically exempt. However, if an individual does not receive an exemption, gets vaccinated, and experiences a rare, detrimental side effect, there is the National Vaccine Injury Compensation Program, discussed in the next section of this chapter.

Each state with a religious exemption has different guidelines for proving the need for such exemption. Generally, belonging to an organized house of worship does not prove beliefs, but rather that beliefs are demonstrated by one's personal spiritual beliefs being honestly held, defined clearly, and one's willingness to attest to his or her beliefs in court if necessary.[67] If these measures are taken, one can file for vaccine exemption. When states offer religious exemptions, those exempted cannot be limited to members of "recognized religious organizations." Courts have struck down such provisions because they violate the Establishment and Free Exercise Clauses of the Constitution.[68] The state also cannot "inquire into the sincerity of a parents' religious obligations."[69] However, if a parent's objection seems personal rather than religious, the courts have upheld denials of these exemptions.[70]

Philosophical exemptions are often related to parents citing their right to "determine the medical care of their children without government involvement."[71] This group is not necessarily anti-vaccine, but opposes vaccine requirements. In California, for

[67] *Id.*
[68] Ala. Code 1975 § 11-47-132.
[69] *Id.*
[70] *Id.*
[71] *Supra* 97.

example, proving a philosophical need in order to be exempt does not require anything beyond parents simply stating they do not want their children to be vaccinated.[72]

While there is no direct financial penalty for not being vaccinated, as there was during the smallpox outbreak in *Jacobson v. Massachusetts*, there are daily consequences, such as being denied from all public schools, and most private schools. For example in New York, statutory law dictates, "Where a father who does not believe in vaccination sends his child to school unvaccinated, but the school authorities refuse to allow the child to attend school, and thereafter the father does not cause the child to attend up instruction as provided in [Education Law], he is subject to the penalty provided by said law."[73] Courts will uphold such consequences, such as being denied entry to public schools, as a reasonable repercussion to a citizen who refuses to have his or her child vaccinated.

State laws also include provisions for public health emergencies. These laws provide for mandatory vaccinations and quarantines for those who are unwilling or unable to vaccinate during the public health emergency.[74] In addition to state statutes, there is the Model State Emergency Health Powers Act (Model Act).[75] The Model Act seeks to "grant public health powers to state and local public health authorities to ensure strong, effective, and timely planning, prevention, and response mechanisms to public

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[72] Garey S. (2013, August 22). Opting-Out of Vaccines; Dipping Below Herd Immunity, wbur's Common Health Reform and Reality. *WBUR*. Retrieved from http://commonhealth.legacy.wbur.org/2013/08/low-state-vaccine-rates

[73] McKinney's Pubic Health Law § 2164. Definitions; immunization against poliomyelitis, mumps, measles, diphtheria, rubella, varicella, Haemophilus influenza tybe b (Hib), pertussis, tetanus, pneumococcal disease, meningococcal disease, and hepatitis B. October 26, 2015.

[74] *Supra* 97.

[75] The Model Act has not been passed in most states, but serves as a draft of model legislation that would increase state powers. States then draft their own legislation based on The Model Act. (2017). Model State Emergency Health Powers. *American Civil Liberties Union*. Retrieved from https://www.aclu.org/other/model-state-emergency-health-powers-act.

health emergencies (including bioterrorism) while also respecting individual rights."[76, 77] The Model Act, like many state laws, provides that during a public health emergency, public health authorities are authorized to "vaccinate persons as protection against infections disease and to prevent the spread of contagious or possibly contagious diseases."[78] The Model Act also provides that those who are unwilling or unable to be vaccinated for medical, religious, or "conscience"[79] reasons may be subject to quarantine to prevent the spread of a disease.[80]

B. Paying for Vaccines

The federal government pays for 95% of all publicly funded vaccines.[81] This practice began in 1963 with the Vaccine Assistance Act.[82] Some of these funds come from the Vaccines for Children Program (VFC), which covers vaccines for children who are uninsured, Medicaid-eligible, underinsured, or Native American or Alaska

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[76] (2010, January 27). The Model State Emergency Health Powers Act (MSEHPA). *The Centers for Law & The Public's Health: A collaborative at Johns Hopkins and Georgetown Universities.* Retrieved from http://www.publichealthlaw.net/ModelLaws/MSEHPA.php

[77] The MSEHPA has been "introduced in whole or in part through 171 bills or resolutions in forty-four (44) states, the District of Columbia, and the Northern Mariannas Islands. Thirty-eight (38**)** states [AL, AK, AZ, CA, CT, DE, FL, GA, HI, ID, IL, IN, IA, LA, ME, MD, MN, MO, MT, NV, NH, NJ, NM, NC, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WI, and WY] and DC have passed a total of 66 bills or resolutions that include provisions from or closely related to the Act." *Id.*

[78] *Id*.

[79] *Id*.

[80] *Id.* at Article VI, Sec. 604.

[81] Public programs cover about 34% of all childhood immunizations. 50% of vaccines are paid for by private insurance. The remaining 14% of children are underinsured. (2003). Financing Vaccines in the 21st Century: Assuring Access and Affordability. Institute of Medicine (US) Committee on the Evaluation of Vaccine Purchase Financing in the United States. *National Academies Press*. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK221817/

[82] Hinman, A.R., Orenstein, W.A., and Rodewald, L. (2004). Financing Immunizations in The United States. *Clinical Infections Disease*, 38(1), 1440-1446. Retrieved from http://cid.oxfordjournals.org/content/38/10/1440.full.pdf+html

Native.[83] Underinsured children include those who do have health insurance coverage but their coverage does not cover certain or any vaccines. Underinsured children may also have coverage for vaccines up to a fixed dollar limit.[84] Not all physicians are VFC providers. If a pediatrician is not a VFC physician, children can receive vaccines at public health clinics, federally qualified health centers, and rural health clinics.[85]

The remaining 5% comes from Section 317 of the Public Health Services Act, which provides grants to states, territories, commonwealth trusts, and cities for vaccine purchase.[86] States supplement these funds in two ways. Fourteen states are some form of "universal purchase" states. Generally, these states purchase the recommended vaccines for all children, even those who are fully insured.[87] Alternatively, the Affordable Care Act also requires new health plans and insurance policies to "provide coverage without cost sharing, such as copayments or coinsurance, for certain preventative services."[88] Each state varies on which immunizations are covered.

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[83] (2015, January 12). *Immunizations Policy Issues Overview: Financing Childhood Immunizations.* National Conference of State Legislatures. Retrieved from http://www.ncsl.org/research/health/immunizations-policy-issues-overview.aspx
[84] (2014, December 17). *VFC Detailed Questions and Answers for Patients*. Centers for Disease Control and Prevention. Retrieved from http://www.cdc.gov/vaccines/programs/vfc/parents/qa-detailed.html
[85] *Id.*
[86] *Id.*
[87] *Id.*
[88] *Id.*

SECTION II: FEDERAL VACCINE LAW

A. National Childhood Vaccine Injury Act

The National Childhood Vaccine Injury Act (NCVIA) passed the United States Congress in 1986, creating the National Childhood Vaccine Injury Program (NCVIP).

The NCVIP was established to "achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines."[89] The NCVIA and NCVIP were a direct response to a vaccine shortage that occurred after a Diptheria Pertussis Tetanus (DPT) vaccine scare. The DPT vaccine supply caused side effects that resulted in claims before civil jury courts. The courts fairly awarded compensation to the public, to the detriment of manufacturers, causing production to slow to a halt.[90] Health officials still valued the vaccine's health benefits and feared the population could lose herd immunity.[91] The NCVIP was created to keep the public from losing faith in vaccines.[92] Congress recognized the advantages of vaccines due to their ability to prevent "catastrophic epidemics" and thus their cost-effectiveness.[93] Congress specifically said that vaccines are necessary to prevent disease and that access to vaccines was the responsibility of the government.[94] Because of this, it

[89] 42 U.S.C. § 300aa-1. Establishment.
[90] Sugarman S.D. (2007). Cases in vaccine court—legal battles over vaccines and autism. *New England Journal of Medicine* 357(13): 1257-7. Retrieved from http://content.nejm.org/cgi/content/full/357/13/1275
[91] Herd immunity is the concept that if the majority of people are vaccinated, the "herd" is protected from the illness. The more people vaccinated, the stronger the immunity of the group.
[92] Sugarman S.D. (2007). Cases in vaccine court—legal battles over vaccines and autism. *New England Journal of Medicine* 357(13): 1257-7. Retrieved from http://content.nejm.org/cgi/content/full/357/13/1275
[93] Binski, L. (2011). *Balancing Policy Tensions of the Vaccine Act in Light of the Omnibus Autism Proceeding: Are Petitioners Getting A fair Shot at Compensation?* 39 Hofstra L. Rev. 683, 705.
[94] *Id.*

was noted that "the [f]ederal government has an interest in the development, distribution, and use of vaccines."[95]

The NCVIP was created on October 1, 1988,[96] to ensure "an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines."[97, 98] The NCVIP is the joint responsibility of the U.S. Department of Health and Human Service (HHS), the U.S. Department of Justice, and the U.S. Court of Federal Claims. The Court houses the Office of Special Masters (OSM) also known as the Vaccine Court.[99]

The Vaccine Rules govern "all proceedings before the United States Court of Federal Claims pursuant to the National Childhood Vaccine Injury Act, as amended, 42. U.S.C. §§300aa1- to -34 (Vaccine Act)."[100] The Vaccine Act allows the Special Master[101] to govern many aspects of the court to their discretion, so long as it is "consistent with these rules and with the purpose of the Vaccine Act" and she decides "the case promptly and efficiently."[102] This allows immense flexibility between cases and between Special Masters' chambers.

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[95] *Id.*
[96] *National Vaccine Injury Compensation Program* (2015). U.S. Department of Health and Human Services. Retrieved from http://www.hrsa.gov/vaccinecompensation/index.html
[97] *Id.*
[98] The NCVIP's forum for individuals injured by vaccines was created as part of the federal government's attempt to inspire confidence in immunization. Because individual states do not have the resources to ensure safe vaccine manufacturing, an adequate vaccine supply, or a forum for those individuals and families hurt by vaccines, the federal government took on this role. This allows the federal government to exercise its interest in a healthy nation via vaccine administration, while not violating the Tenth Amendment by interfering with the states' police powers. The federal government may not make affirmative mandates to the states, but it may create other avenues to obtain its objectives.
[99] *Id.*
[100] Vaccine Rule 1(a), 2005.
[101] A special master is similar to a judge. They are technically subordinate because they are appointed by a judge under Rule 53 of the Federal Rules of Civil Procedure.
[102] Vaccine Rule 1(b), 2005.

B. The "Vaccine Court"

When an individual or a child is injured after receiving a vaccine that is recommended by the Centers for Disease Control, that individual or family files a claim as a "petitioner" in the Vaccine Court. The Vaccine Court looks at all the evidence presented, any expert witness testimony, and any medical literature provided as support of the petitioner's claim to determine whether the petitioner is entitled to compensation based on the injury. If it is determined that the petitioner is entitled to compensation, the Vaccine Injury Compensation Trust Fund compensates them.[103] This fund is created by a 75-cent tax on vaccines that are recommended by the CDC for the vaccines routinely administered to children.

The Vaccine Court determines whether a petitioner is entitled to compensation. On the one hand, the government does not want people to be afraid of vaccinating their children, as herd immunity is a valued part of public health. On the other, the government does not want those who are injured by the government-required vaccines to personally suffer financial damages due to a government requirement. There are two types of claims that determine entitlement to compensation: on-Table and off-Table. The existing Vaccine Injury Table assesses on-table claims. The Vaccine Injury Table (42 U.S.C. § 100.3) lists and explains injuries that "are presumed to be caused by or exacerbated by" vaccinations.[104] Additionally, it lists time periods in which the first symptom of the vaccine injury would manifest. If the presumed injury occurs within the listed time period after the vaccination is administered, the petitioner will likely be compensated without

[103] *Id.*
[104] 42 U.S.C. §100.3.

much further complication.[105] For example, if a petitioner files a claim for entitlement because his or her child experienced symptoms of encephalopathy 48 hours after receiving the Diptheria-Tetanus-Pertussis (DTaP) vaccine, that petitioner will likely be compensated. DTaP is associated with encephalopathy and the time period between administration of the vaccine and the onset of symptoms is 72 hours.[106] The petitioners can file this claim with medical records showing when the DTaP vaccine was administered, when the onset of symptoms began, and that the symptoms were diagnosed as encephalopathy.

If a petitioner claims an injury that is not on the Table or that does not occur within the time period listed on the Table, this is an "off-Table," or causation-in-fact, injury. Entitlement for these claims is determined by the three-prong *Althen* test.

Althen v. Secretary of Health & Human Services created the standard of proof for off-Table claims.[107] The Federal Circuit affirmed the previous rulings of the lower court, requiring petitioners to present "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury."[108] If petitioner is able to satisfy all three prongs, the burden of proof shifts to the government. The government must show that, by a preponderance of evidence, there is an alternative cause to the injury.[109] If the case is too

[105] 42. U.S.C. §100.3.
[106] *Id.*
[107] *Althen v. Sec'y of HHS,* 418 F.3d 1274, *1278* (2005).
[108] *Id.*
[109] *Id*

close to call, the evidence presented must be viewed by the OSM in the light most favorable to the petitioner.[110]

In determining whether a petitioner has satisfied *Althen*, the petitioner must provide evidence from the medical record, just as with on-Table injury claims, and the opinions on causation from treating physicians.[111] As with on-Table claims, providing medical literature in support of the petitioner's off-Table claim (or if the burden of proof has shifted to the government, the government's claim) is also useful.

The regulations mandating vaccine administration and incentivizing immunization are different from other medical treatments because vaccines are a public health measure. The purpose of vaccines is to prevent individuals from contracting infectious disease. Achieving this protection of each individual is accomplished by requiring the entire community to subject themselves to an immunization. In order for vaccines to be effective, physicians must administer vaccines to each member of the public masses,[112] rather than tailoring the treatment on an individual basis. While the law's intention in this aspect is clear, most members of society are not proficient in the law behind state vaccine mandates. An introductory education on state and federal case law and the NCVIA is part of the ongoing conversation between patient parents and caregivers that this thesis encourages.

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[110] *Id*. at 1280
[111] Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).
[112] An explanation of vaccines and herd immunity will be covered in Chapter Two, Section I, Part C.

CHAPTER TWO: MEDIA PORTRAYALS OF THE AUTISM SCARE & THE POLITICIZATION OF VACCINES

"Physicians in general no longer have the unquestioned public trust and esteem they enjoyed a generation ago. The image of the doctor as omniscient and beneficent has been tarnished by a spate of stories in the media about incompetent, venal, and unethical physicians and by a growing suspicion of all authority."[113]

SECTION I: BACKGROUND ON VACCINES: RATES AND HOW VACCINES WORK

A. Development of Vaccines

Immunization practices began in the West in 1717 England.[114] Each attempt at immunization was to prevent against smallpox, the most dreaded disease. At the time, the procedure was called "ingrafting," which consisted of taking pus from the pock of a mildly-infected individual and spreading it over the open wound of an uninfected person. It was risky and not entirely harmless, as the uninfected person still became sick, but that was the point of the procedure. The idea was that a small, purposeful case of smallpox was the only way to ensure lifelong immunity against an unanticipated, unprotected, and thus harsher dose of it later.[115] This crude yet effective form of immunization was a desperate attempt to protect the population against the ravages of smallpox. Ingrafting became more sophisticated and evolved into inoculation when instead of taking pus from a smallpox-infected person, Edward Jenner, an English doctor, took pus from cowpox lesions and spread it onto the arms of a young boy. Six weeks later, Jenner attempted to infect the boy with smallpox, but he was unaffected and never fell ill. After repeating this

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[113] Relman, A. (1989). Medical Professional Liability and the Relations Between Doctors and Their Patients. *Medical Professional Liability and the Delivery of Obstetrical Care: Volume II: An Interdisciplinary Review*. Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK218649/

[114] Experts predict that inoculation practices actually began in the Far East over 2,000 years ago. Mnookin, S. (2011) *The Panic Virus*. New York, New York: Simon & Schuster Paperbacks.

[115] *Id.* at 24

experiment many times, Jenner asserted, "the cow-pox protects the human constitution from the infection of small pox."[116]

Since the 1700s, the science of immunizations has improved dramatically, making the immunizations more effective, safer, and far less disgusting. Vaccines more like those we know today first appeared in the mid 20th century.[117] Vaccines against diphtheria and pertussis were developed in the 1940s. The polio vaccine, discovered during the devastating polio epidemic, was developed in the 1950s. More vaccines preventing childhood diseases, such as measles, mumps, and rubella, were developed in the 1960s. The ability to grow viruses in laboratory settings allowed for rapidly evolving innovations.[118]

B. Vaccination Rate Trends

The first effective polio vaccine was developed in 1952. When the vaccine was developed, parents readily accepted it. At this point in time, young children all over the world, including America, were dying from polio. According to Robert Chen, the former head of immunization safety at the CDC, there is a natural four-phase progression of public opinion that each vaccine goes through. The first phase is ready acceptance. Parents rush to get the newly available vaccine because everyone knows someone who has been affected by the disease. For example, parents readily accepted the polio vaccine in the 1950s because everyone knew someone that had been paralyzed or killed by polio. The country was in an epidemic. In the 1960s, parents readily accepted the measles,

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[116] Stern, A.M. & Marker, H. (2005). The History of Vaccines and Immunization: Familiar Patterns, New Challenges. *HealthAffairs,* 24(3). pp. 3. Retrieved from http://content.healthaffairs.org/content/24/3/611.full

[117] *The History of Vaccines*. (2016). The College of Physicians of Philadelphia. Retrieved from http://www.historyofvaccines.org/timeline.

[118] *Id.*

mumps, and rubella vaccines because they were all too familiar with the devastation caused by these childhood diseases.[119]

The second phase is vaccines become a victim of their own success. Parents start to focus on the side effects, which are often far less devastating than the disease being prevented, and immunization rates plateau.[120] The new vaccine is no longer the hot product that every child needs.

The third phase, the phase the United States currently finds itself in, is the rising fear of vaccines. This leads to immunization rates falling and preventable diseases increasing.[121] The fourth and final phase is a bleak prospect. The final phase is that immunization rates rise again, but only because the number of preventable deaths from preventable diseases becomes so high that parents "again seek solace in vaccines."[122] This final phase is what is on the horizon unless immunization rates rise before the number of vaccine preventable deaths rises.

C. Herd Immunity

Herd immunity is the term used to explain how vaccinating a certain percentage of the population helps to prevent the spread of an infectious disease through that group.

> The resistance to an infectious agent of an entire group or community (and, in particular, protection of susceptible persons) as a result of a substantial proportion of the population being immune to the agent. Herd immunity is based on having a substantial number of immune persons, thereby reducing the likelihood that an infected person will come in contact with a susceptible one among human populations, also called 'community immunity.'[123]

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[119] Offit, P.A. (2011). *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All.*New York, New York: Basic Books.
[120] *Id.* at 192
[121] *Id.*
[122] *Id.*
[123] (2006). *Glossary of Epidemiology Terms.* Centers for Disease Control and Prevention. Retrieved from http://www.cdc.gov/excite/library/glossary.htm#immunityherd

The threshold number, or the percentage number of people needing to be immunized for herd immunity to be effective, is calculated differently for each infectious disease. This is because each disease has a different basic reproduction number, known as the R_0. The basic reproduction number is the number of people one infected person can infect. For example, an individual infected with smallpox can infect five to seven other people, while someone with pertussis can infect 12 to 17 others (Refer to Figure 1).[124] If the number of individuals immunized falls below the threshold number of a particular disease, the population will be in danger should that disease be introduced. This happens when people choose to opt out of immunizing their children. Schools are very common places for diseases to spread and this has an effect on not just those students in the school, but the larger population. For example, San Diego had a measles outbreak in 2008. It was found that the outbreak started with a seven year old boy whose parents opted out of vaccinating him. The young boy had recently come back from Switzerland where he had been unknowingly infected with measles. An estimated 839 people were exposed and there were 11 cases of the measles. The reason only 11 out of 839 showed signs of the infection was that the vaccination rate in San Diego was very high. However, this example shows that 11 more people were infected after only one boy brought the infection to California from Switzerland.[125] Since then, in 2014, the United States had a

[124] History and Epidemiology of Global Smallpox Eradication. Smallpox: Disease, Prevention, and Intervention Course. Retrieved from http://www.bt.cdc.gov/agent/smallpox/training/overview/pdf/eradicationhistory.pdf

[125] Garey S. (2013, August 22). Opting-Out of Vaccines; Dipping Below Herd Immunity, wbur's Common Health Reform and Reality. *WBUR*. Retrieved from http://commonhealth.legacy.wbur.org/2013/08/low-state-vaccine-rates; Sugerman, D.E., Barskey, A.E., Delea, M.G., Ortega-Sanchez, I.R., Bi, D., Ralston, K.J., Rota, P., Waters-Montijo, K., LeBaron, C.W. (2010). *Measles Outbreak in a Highly Vaccinated Population, San Diego, 2008:*

record number of measles cases, 667 reported from 27 states. This is the highest number of cases since measles was eliminated from the United States in 2000.[126,127] While the number of reported cases has gone down in the United States since 2014 (188 people from 24 states and the District of Columbia in 2015 and 70 people from 16 states in 2016), the fact that measles has returned to the U.S. after being eliminated entirely shows the importance of continuing immunization within the population. Even with the number of cases declining in 2015, 84 people in 14 states (59 of which were in California)[128] reported having the measles in the month of January alone.[129] These cases were linked to a single incident where at least 40 people who visited or worked at Disneyland theme park in Orange County, California, contracted the disease.[130]

An example that shows long-term global benefits of vaccines is smallpox. In 1966 the World Health Organization (WHO) began the Smallpox Eradication Program.[131] The WHO used a targeted herd immunity process called Ring Theory in West and Central

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Role of the Intentionally Undervaccinated. Pediatrics. Retrieved from http://pediatrics.aappublications.org/content/early/2010/03/22/peds.2009-1653.

[126] (2017, March 6). *Measles Cases and Outbreaks.* The Centers for Disease Control. Retrieved from https://www.cdc.gov/measles/cases-outbreaks.html

[127] Another article claims that this number is the highest not only since Measles was eradicated in America, but in 20 years. Lam, B. (2015, February 10). Vaccines are Profitable, So What? *The Atlantic*. Retrieved from https://www.theatlantic.com/business/archive/2015/02/vaccines-are-profitable-so-what/385214/

[128] Nagourney, A & Goodnough, A. (2015, January 21). Measles Cases Linked to Disneyland Rise, and Debate Over Vaccinations Intensifies. *The New York Times*. Retrieved from https://www.nytimes.com/2015/01/22/us/measles-cases-linked-to-disneyland-rise-and-debate-over-vaccinations-intensifies.html?_r=0

[129] Another article claims that this number is the highest not only since Measles was eradicated in America, but in 20 years. *Supra* 127.

[130] (2016, December 23). *Measles*. California Department of Public Health. Retrieved from http://www.cdph.ca.gov/HealthInfo/discond/Pages/Measles.aspx.

[131] Lane J.M. (2006). Mass Vaccination and Surveillance/Containment in the Eradication of Smallpox. *Current Topics in Microbiology and Immunology*. *304*:17-29.

Africa in 1975 to reduce smallpox in the region.[132] Ring theory is "the vaccination of all susceptible individuals in a prescribed area around an outbreak of an infectious disease (Figure 2)."[133] This immunity method reduced the number of smallpox cases from 800 to 30 when vaccine rates tripled from 20% to 80%.[134]

Another example that is pertinent not only around the world but also to American history is the polio vaccine. Interest in the nation's polio epidemic was spurred on by the discovery that President Franklin Delano Roosevelt was debilitated and eventually killed by the disease. The President once said in regards to the difficulty of living with the disease, "Once you've spent two years trying to wiggle one toe, everything is in proportion."[135] Polio rates did not merely decrease through vaccination, it was eradicated in the United States.[136]

The WHO aims towards global immunization. The WHO puts out a progress report on reaching the immunization goal that measures each vaccine's progress by country. The polio vaccine's eradication progress shows that nations with widespread access to the polio vaccine are certified polio-free nations. The United States, Canada, and the Netherlands have been polio free since 1988.[137] A more recent report, released in 2012, shows that most of the world is now certified polio-free. If the regions are not certified polio-free, such as parts of Africa and Southeastern Asia, most are not

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[132] Kaplan E.H. & Wein L.M. *Smallpox Eradication in West and Central Africa: Surveillance-Containment or Herd Immunity*. Retrieved from http://ih.stanford.edu/foege/resources/Ring%20Vaccination%20Doesn't%20Work.pdf
[133] (2013, November 10). *Medical Definition of Ring Vaccination*. MedicineNet.com. Retrieved from http://www.medterms.com/script/main/art.asp?articlekey=23979
[134] *Supra* 132.
[135] (2012). *Whatever Happened to Polio?* Smithsonian National Museum of American History. Retrieved from http://amhistory.si.edu/polio/howpolio/fdr.htm
[136] (2012). *Progress Towards Global Immunization Goals*. World Health Organization.
[137] *Id*.

endemic.[138] Between 1988 and 2012, the WHO reported that the number of polio endemic countries has gone from 125 to three, which are Nigeria, Pakistan, and Afghanistan.[139] The Global Polio Eradication Initiative reports that the number of cases reduced from 350,000 to 2,000 in 2009, which is a 99% reduction around the world.[140]

Two more benefits of a vaccinated population are that vaccines reduce the need for antibiotics and also increase life expectancy. For example, a pneumococcal vaccine that was introduced to American infants in 2000 caused a 57% decline in disease caused by penicillin-resistant strains and a 59% decline in strains resistant to multiple antibiotics.[141] Similar numbers have also been seen with typhoid vaccines. As such, the development of new vaccines helps stymie the problem of increasing antibiotic resistance.

In stark contrast to the positive effects of immunization are the damaging infections by those who choose not to be immunized. An example of the damaging effects a population can suffer when it does not achieve the threshold number necessary for herd immunity was seen in California and Texas. In 2010, 9,120 Californians were infected with whooping cough, also known as pertussis.[142] Ten of these were babies who were too young to be vaccinated and died after being exposed to pertussis. The suspected reason for the dramatic increase in infected patients is the number of parents opting out of getting their children vaccinated. Areas with high rates of personal belief exemptions are

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[138] *Global Polio Eradication Initiative*. Retrieved from http://www.polioeradication.org/Aboutus/Progress.aspx
[139] *Supra* 136.
[140] *Supra* 138.
[141] Andre F.E., Booy R., Bock H.L., Clemens J., Datta S.K., John T.J., Lee B.W., Lolekha S., Peltola H., Ruff T.A., Santosham, Schmitt H.J. (2013). *Vaccination greatly reduces diseases, disability, death and inequity worldwide.* The World Health Organization.
[142] Shute N. (2013, September 30). Vaccine Refusals Fueled California's Whooping Cough Epidemic: Shots. *National Public Radio*.

2.5 times more likely to have a high number of pertussis cases.[143] Pertussis has a threshold of 95%.[144] In 2010, 91% of Californian kindergartners were immunized, falling just short of the threshold number.[145] The extra 4% of people who opted out of immunization put the rest of the population at risk. This 4% needed to get immunized to maintain threshold because the last 5% were potentially unable to receive vaccines. According to the Texas Department of State Health, Texas was under a "Pertussis Health Alert" in 2013, with 3,985 cases reported. This department urged parents to ensure that they and their children are up to date on their vaccines, rather than choosing to opt out.[146] The U.S. reported 20 pertussis-related deaths in 2012. That year had the highest number of cases reported, with 48,277 cases.[147] The year 2012 is seen as a "peak year"[148] and reporting declined after with a total of 28,639 cases of Pertussis in 2013, and 32,971 in 2014.[149]

These examples show the detriment of acting as a vaccine "free rider." A free rider is an individual in the population who relies on herd immunity to protect them while

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[143] *Id*.
[144] *History and Epidemiology of Global Smallpox Eradication*. Smallpox: Disease, Prevention, and Intervention Course. Retrieved from http://www.bt.cdc.gov/agent/smallpox/training/overview/pdf/eradicationhistory.pdf
[145] *Supra* 142.
[146] (2013). *Pertussis*. Texas Department of State Health Services. Retrieved from http://www.dshs.state.tx.us/idcu/disease/pertussis/
[147] (2015, September 8). *Pertussis Outbreak Trends*. The Centers for Disease Control and Prevention. Retrieved from https://www.cdc.gov/pertussis/outbreaks/trends.html
[148] A "peak year" occurs every three to five years. The last two peak years for Pertussis in the United States were 2012 and 2010, which had more than 27,000 cases reported. Reported cases of pertussis vary from year to year and tend to peak every three to five, but the United States has experienced two peak years between the five-year span 2010 and 2015. (2017, January 10). *Pertussis (Whooping Cough) Questions and Answers*. The Centers for Disease Control and Prevention. Retrieved from https://www.cdc.gov/pertussis/outbreaks/faqs.html
[149] *Supra* 147.

not getting vaccinated themselves, and thus not contributing to group immunization.[150] This is detrimental because there are those who genuinely need to be exempt from vaccines, which is why the threshold target number is in place. For example, someone who has an allergy to an ingredient in vaccines cannot receive certain types of vaccines. Another example is someone who received a vaccine that gave them Guillain-Barré[151] cannot receive any similar type of vaccine for fear of recurrence or exacerbating the syndrome. If the threshold number is achieved, the herd will protect those who need medical exemptions from vaccines. This makes it the responsibility of those who are physically capable to receive vaccines to be immunized.

There are arguments against vaccination, though I do not believe they are stronger than the arguments in favor of vaccination. However, there are also those individuals who just do not feel pressured to get their children vaccinated because America is generally not overrun by these types of devastating diseases. However, if there are a small number of people who are not immunized and one of them is infected, then those around them are put in danger as well. Vaccines are not 100% effective, thus if those who are not immunized are infected, it is more likely that those are immunized will get infected as well, causing an epidemic. Putting oneself as well as the larger population in danger when one are able to prevent this danger with relatively low burden is seen by those who are not anti-vaccine[152] as irresponsible and unethical. Maintaining threshold immunities

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[150] Fine P., Eames K., Heymann D.L. "Herd Immunity": A Rough Guide. *Oxford Journals*. 2013;57(11): 911-916.

[151] Guillain-Barré syndrome "is a rare disorder in which your body's immune system attacks your nerves." Guillain-barré can range in severity and the amount of time symptoms last. (2016, June 1). *Guillain-Barre Syndrome*. Mayo Clinic. Retrieved from http://www.mayoclinic.org/diseases-conditions/guillain-barre-syndrome/basics/definition/con-20025832.

[152] This includes CDC and government officials, pediatricians and other government officials, and parents who do vaccinate their children. This will be addressed further in chapter 3, section III.

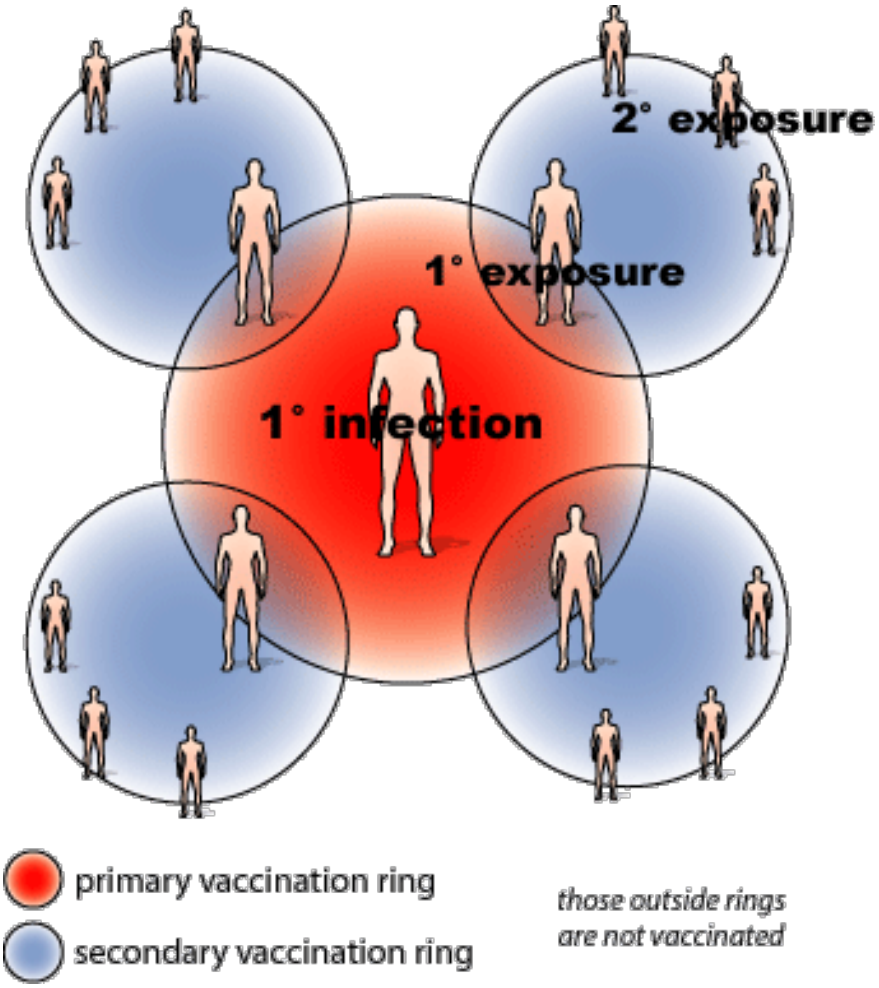
by having the majority of the population immunized is vital to keeping our society safe from disease.

Figure 1: Basic Reproduction Numbers[153] of Common Diseases

Disease	Reproduction #
Influenza	2-3
Measles	12-18
Pertussis	12-17
Rubella	5-7
Diphtheria	6-7
Smallpox	5-7
SARS	2-5

[153] "In epidemiology, the basic reproduction number…of an infection can be thought of as the number of cases on case generates on average over the course of its infections period, in an otherwise uninfected population." Fraser, C. Donnelly, C.A., Cauchemez, S., Hanage, W.P., Van Kerkhove, M.D., H.D. (2009, June 19). *Pandemic Potential of a Strain of Influenza A (H1N1): Early Findings.* Science. 324 (5934): 1557-1561. Retrieved from http://science.sciencemag.org/content/324/5934/1557.full?sid=642959de-2968-4d85-8006-31053edd9dff

Figure 2: Ring Theory[154]



SECTION II: THE SPARK

Andrew Wakefield was a gastroenterologist specializing in an inflammatory bowel disease called Crohn's disease. This chronic, potentially debilitating disease, is rare, incurable, difficult to treat, and has no known cause.[155] During his career, Wakefield proposed that the medical field's understanding of Crohn's disease as an autoimmune disorder that causes the body to attack food as foreign invaders was wrong. Wakefield proposed that Crohn's was not an immune disorder, but rather the result of a gut with

[154] Hickey T. (2013). Smallpox: Then and Now. *The Science Creative Quarterly. 8*.
[155] (2014, August 14). *Crohn's Disease*. Mayo Clinic. Retrieved from http://www.mayoclinic.org/diseases-conditions/crohns-disease/basics/definition/con-20032061

clogged blood vessels. This proposal would drastically change how Crohn's was treated, but unfortunately, Wakefield's colleagues never felt comfortable following his idea because there was no evidence supporting it. Refusing to be discouraged, Wakefield built on his study of Crohn's disease, targeting measles as the cause.

Wakefield was the lead scientist on a paper that was published in 1998 in the British medical journal, *The Lancet*. The paper claimed to have found a link between vaccines and the autism surge in the 1990s. The link followed that the Measles-Mumps-Rubella (MMR) vaccine could cause chronic measles infection in some children. This infection caused a gastrointestinal condition called "leaky gut syndrome" that allowed toxins to enter the bloodstream rather than be broken down in the gut. By way of the bloodstream, these toxins would make their way to the child's brain and cause neurological and developmental damage, such as the kind that might result in autism.[156] Wakefield's recommendation was to start administering monovalent vaccines.[157]

The results of Wakefield's study were initially released in a press conference held by his employer, the Royal Free Hospital School of Medicine. Presenting the findings were Wakefield and five experts who agreed that further research was needed before any definitive conclusions about the link between the MMR vaccine and destruction of the gastrointestinal system could be drawn, any advice given to patients, and any drastic changes to patient care made. However, Wakefield presented his findings as definitive proof that children's systems were overloaded and could not handle the MMR vaccine and would be better off receiving the M, M, and R vaccines separately.[158,159,160] He stated,

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[156] Novella S. (2007). The Anti-Vaccination Movement. *The Lancet.*
[157] *Supra* 115 at 107-108.
[158] *Id.* at 108

> With the debate over MMR that has started[161]…I cannot support the continued use of the three vaccines given together. We need to know what the role of gut inflammation is in autism…My concerns are that one more case of this is too many and that we put children at no greater risk if we dissociated those vaccines into three, but we may be averting the possibility of this problem.[162]

Immediately following Wakefield's statement, the Dean of Royal Free Hospital School of Medicine took the lectern and stated, "if this were to precipitate a scare that reduced the rate of immunization children will start dying from measles"[163] in an effort to begin immediate damage control. The Dean was right.

The Dean of the Royal Free Hospital School of Medicine was not the only person in the medical community concerned about Wakefield's rumor. *The Lancet*'s editor reprinted the study and demanded that it clearly state the paper was an early report that was only speculative, not definitive.[164] The editor also asked two CDC vaccine specialists to evaluate the paper. Both agreed that *The Lancet* should not have printed the paper. Not because its results were scary or because it contradicted the government public health officials' vaccine agenda, but because "there really didn't seem to be that much there."[165] The criticism continued when 37 physicians of various specialties, including pediatricians, psychiatrists, epidemiologists, gastroenterologists, immunologists, and virologists, reviewed the paper and deemed the research incomplete and the theory itself

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[159] Separate vaccines such as separate measles, mumps, and rubella vaccines are known as monovalent vaccines.
[160] In his self-made movie, *Vaxxed*, Wakefield also claims that perhaps the MMR should be given to children when they are older and their guts are better able to handle the combined vaccine. This proposed solution leaves the young children, who are most vulnerable, vulnerable to these diseases for longer periods of time.
[161] Note, that this debate that started was started by Wakefield himself at that very press conference.
[162] *Supra* 157.
[163] *Id.* at 108.
[164] *Id.*
[165] *Id.*

to be "biologically implausible."[166] Another group of 10 co-signers criticized *The Lancet* for publishing a paper that provided no scientific evidence. Three other members of the Barnsley Health Authority's Department of Public Health Medicine suggested that journals such as *The Lancet* carry warnings explaining scientific studies and the evidence used in them such that the public outside the medical community can understand the value, or lack thereof.[167] Finally, the WHO released the following statement in regards to Wakefield's study: "Given our view, the claims made by Dr. Wakefield and his colleagues lack scientific credibility; and this present study does not meet the requirements of establishing a causal relationship."[168]

Subsequent studies were repeated in an attempt to learn more about the ostensible link. The studies began to doubt the alleged link and after a number of these studies were published, it became clear that no link could be found between vaccines and autism.[169]

> For example, a study in the British Medical Journal found that autism rates continued to climb in areas where MMR vaccination rates were not increasing. Another study found no association with MMR and autism or GI (gastrointestinal) disorders….Other studies showed no difference in the diagnosis rate of autism either before or after the MMR vaccine was administered, or between vaccinated and unvaccinated children. Most recently, a study found that there was no decrease in autism rates following removal of the MMR vaccine in Japan.[170]

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[166] *Id.* at 114.
[167] *Id.*
[168] *Supra* 122 at 34.
[169] During this time, autism diagnoses had risen dramatically, from four in 10,000 children in the 1960s to 1 in 88 in the 2010s. While Wakefield and others attributed this rising rates of autism to vaccines finally showing side effects, the rise in diagnoses is actually attributed to an expanded criteria in the definition of autism being published in the DSM-V. Heasley, S. (2012, June 29). Autism Surge Due to Diagnostic Changes, Analysis Finds. *DisabilityScoop.* Retrieved from https://www.disabilityscoop.com/2012/06/29/autism-surge-analysis/15957/; (2015, January 6). Can Rise in Autism Be Explained By Broadened Diagnosis? *Autism Speaks*. Retrieved from https://www.autismspeaks.org/science/science-news/can-rise-autism-be-explained-broadened-diagnosis.
[170] *Supra* 156.

In addition to multiple studies repeatedly finding that combined vaccines do not overload children's gastrointestinal systems and lead to autism, it turned out the original study claiming the link between MMR and autism was done by a scientist conducting research on behalf of parents who were suing for damages from the MMR vaccine.[171] Wakefield was paid £50,000 by the law firm[172] representing the parents who were planning to sue pharmaceutical manufacturers to collect data for the suit. The attorney leading the case against the MMR vaccine referred about half of the only twelve children who took part in the study to Wakefield.[173] Ultimately, Wakefield was paid £435,643 for his help in the lawsuit against GlaxoSmithKline, Aventis Pasteur, and Merck. The publicly funded lawsuit filed by the parents was unsuccessful.[174] This relationship with the lawsuit was purposefully never revealed by Wakefield, discussed at the press conference, or disclosed in his paper. An investigative journalist for the London *Sunday Times* collected and revealed this information to the editor of *The Lancet* in 2004, five years after the paper was published.[175] This obvious conflict of interest brought to light the motivations of this study and the invested interest in its unsupported results. Ultimately, Britain's General Medical Council banned Dr. Wakefield from practicing medicine in Britain.[176]

Besides the fact that his paper was conducted for personal financial reasons, rather than for the advancement of science; had no evidence supporting its results and in fact many other studies have refuted Wakefield's hypothesis; and that it was based on the

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[171] *Id.*
[172] Dawbarns was the law firm. The personal injury attorney leading the case was Richard Barr.
[173] *Supra* 166 at 116.
[174] *Id.*
[175] *Supra* 168 at 36.
[176] Whelan, A.M. (2016). Lowering the Age of Consent: Pushing Back against the Anti-Vaccine Movement. *The Journal of Law, Medicine, & Ethics, 44*: 462-473. 463.

observance of only twelve (particularly selected) children, there is good reason to ignore Wakefield's advice not to stop administering vaccines, but rather to administer monovalent vaccines only. Receiving one MMR vaccine rather than the monovalent vaccines results in fewer shots. Receiving fewer shots is helpful if only for the comfort of the child. Additionally, his statement that disassociating the vaccines into three does not put children at greater risk is incorrect. Receiving all of the vaccines at once decreases the chance of delays in protection from measles, mumps, and rubella.[177] After all, if Wakefield recommends monovalent vaccines because children's digestive systems cannot handle that many vaccines at once, resulting in an overflow of the measles virus in the bowel, it is not as though he recommends a child take three monovalent vaccines in one day. In fact, he recommended a year's break between each in his press conference.[178] That would be a two-year delay in protection from the childhood disease rubella. For those two years, children would be vulnerable to this disease, which is easily spread by coughing and sneezing. Rubella, once contracted, is not curable, has no identified treatment, and can be lethal.[179] Because this risk is so high with monovalent vaccines, and because vaccines are very costly to manufacture, Merck stopped making monovalent vaccines in 2009.[180]

Unlike Wakefield's study with a sample size of only twelve, a study that concluded there was "no signal to suggest a relationship between MMR and the

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[177] (2009, October 26). *Monovalent Vaccines—ATTENUVAX® (measles vaccine), MUMPSVAX® (mumps vaccine) and MERUVAX® (rubella vaccine).* Centers for Disease Control and Protection. Retrieved from https://www.cdc.gov/vaccines/hcp/clinical-resources/mmr-faq-12-17-08.html
[178] *Supra* 173 at 108.
[179] *(2017*). *Rubella*. World Health Organization. Retrieved from http://www.who.int/mediacentre/factsheets/fs367/en/.
[180] *Mumpsvax no longer available from Merck*. LondonMMR Clinic. Retrieved from http://www.londonmmr.co.uk/faq.php.

development of autism in children," was conducted with a sample of 95,000 children.[181] U.S. government institutions rather than an interested party in a lawsuit funded this study.[182] A follow up found that of all the children in the study, 994, or .0104%, of them had been diagnosed with autism later in life. Of these 994 children, 6.9% of them had an older sibling diagnosed with autism, but whether or not they had been given the MMR vaccine did not affect their diagnosis.[183]

SECTION III: MEDIA AND THE POLITICIZATION OF VACCINES

As with the public, vaccines became a political issue in the early 2000s after the 1998 Wakefield study. This paper posits that the reasons vaccines became a political issue at all was because the media blew the vaccine stories out of proportion. The media did this for views and profits. After all, uncovering a major scandal is attention grabbing, while reporting day-to-day political business as usual is essentially no news at all. This section will discuss how the media's initial quick jump to conclusions based on Wakefield's one article and, later, slow movement to correct or retract the articles and broadcasts after more information came out regarding Wakefield's hypothesis affected the public's perceptions of vaccines and contributed to the politicization. The media

[181] Boseley, S. (2015, April 21). No link between MMR and autism, major study concludes. *The Guardian*. Retrieved from https://www.theguardian.com/society/2015/apr/21/no-link-between-mmr-and-autism-major-study-concludes; Jain, A., Marshal, J., Buikema, A., et al. (2015). Autism Occurrence by MMR Vaccine Status Among US Children With Older Siblings With and Without Autism. *JAMA, 313*(15):1534-1540. Retrieved from http://jamanetwork.com/journals/jama/fullarticle/2275444

[182] Conspiracy theorists may argue that funding by the U.S. government is not impartial either.

[183] *Supra* 181.

perpetuated anxiety and "even generalized social anxiety prepares the ground for the growth of distrust."[184]

A. Previous Doubts in Public Health Measures

Being a major part of health care and preventative medicine, this is certainly not the first time that vaccines, and the government promoting vaccines, have come under fire. A very early example took place in 1803, when the safety of the cowpox vaccine discussed in Section I was called into question.[185] Initially, the vaccine was readily accepted, just as Chen's first of four phases described, because the public was desperate to be protected from smallpox. As time went on and the disease was less of a threat, fewer people got vaccinated. In order to maintain population protection, places such as the United Kingdom and United States passed laws making the vaccine mandatory. These government vaccine mandates made people even more resistant to get vaccinated. No one likes being told what to do. Groups of people who were anti-vaccination formed and preyed on the public's anxiety about a power hungry government exploiting its dependent citizens. These anti-vaccination groups buoyed confidence in the public by sharing anecdotes based on their personal experience of how the government had let them down, rather than any scientific evidence of the shortcomings of the cowpox vaccine.[186]

Another more modern example in American history when vaccines and the concurrent government administration fell out of favor was in 1976, during Gerald Ford's presidency. On February 4, 1976, an Army Private fell ill with the flu in his barracks. He was hospitalized, along with four others, and he died 24 hours later. The strain of flu was

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[184] Heller, J. (2016). Trust in Institutions, Science and Self—the Case of Vaccines. *Narrative Inquiry in Bioethics, 6*(3): 199-203, pp. 199. Retrieved from https://muse-jhu-edu.go.libproxy.wakehealth.edu/article/646342/pdf.
[185] *Supra* 173 at 32.
[186] *Id.* at 32-33.

found to be similar to the strain that caused the 1918 pandemic, which killed 5% of the world's population (estimates range from 20 million to 50 million people).[187] This strain of flu is known as the swine flu. The CDC realized that hundreds of other soldiers at the base were also infected. President Ford had to decide whether he should push for a mass vaccine campaign in the country. Ford feared that if he did not encourage the nation to vaccinate, thousands of citizens could die. However, if he did campaign and it turned out the decision to do so was rushed into out of fear based on a small population in close quarters at an army base, he risks creating a panic and coercing Americans into unnecessary medical treatment. Ultimately, Ford decided to go through with the mass vaccination campaign after meeting with Jonas Salk, the founder of the inactivated polio vaccine, and Albert Sabin, the creator of the oral polio vaccine.[188] The two endorsed the campaign along with the CDC director who stated in a memo that "The Administration can tolerate unnecessary health expenditures better than unnecessary death and illness."[189] In a good faith attempt to protect his citizens, Ford went ahead with the vaccine campaign. He manufactured the vaccine and the CDC tested it for safety using truncated testing measures in an effort to get the vaccine to the public as soon as possible. It turned out that his fears were correct. Ford's decision to lead the massive government campaign was rushed. The vaccine turned out to be unnecessary, as only the Army base,

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[187] *Id.* at 62.

[188] There has been some controversy around the oral polio vaccine ("OPV"). The OPV came into commercial use in 1961 after being created by Albert Sabin. The OPV contains active poliovirus. This is unlike Salk's 1955 inactivated polio vaccine ("IPV"), which is considered completely safe. Salk's IPV has led to 90% or more of individuals developing protective antibodies to the three types of poliovirus. OPV's side effects, including neurological infection and paralysis, are very rare but devastating; Robertson, S. (1993). *"Module 6: Poliomyelitis" (PDF). The Immunological Basis for Immunization Series*. World Health Organization (Geneva, Switzerland).

[189] *Supra* 187 at 63.

not the country, was threatened by a possible swine flu epidemic. The vaccination campaign was also detrimental as two months after administration began, the quickly-tested vaccine caused 500 cases of Guillain-Barré. The unnecessary vaccine prevented against a non-existent threat and caused a terrible syndrome. Ford's failure to "vaccinate everyone in the country against a threat that never materialized was widely viewed as one more example of the federal government's incompetence, its engagement in nefarious conspiracies, or both."[190] Ford's failure, though it came from honorable intentions, only added to the public's distrust in the government's motivations to push vaccination.

The MMR vaccine has also been called into question before, leading to resentment of the government health officials associated with the vaccine. In 1992, British health officials responsibly recalled two widely used brands of the MMR vaccine because the second M, the mumps portion, had caused mild meningitis in some of the recipients. This decision on the part of the British public health officials fueled distrust in the government and resulted in English parents filing suit against the government under claims that their children had been damaged. The meningitis symptoms caused by this MMR vaccine were fairly benign and mostly consisted of lethargy and vomiting. There were no deaths or permanent damage. Additionally, the population was effectively protected from mumps.[191]

Another example of the government's relationship with vaccines causing distrust among the public is when the government moved to remove thimerosal from vaccines from 1999-2000. The last batch of childhood vaccines with thimerosal was used in 2003.

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[190] *Id.* at 66.
[191] *Supra* 167 at 99.

Thimerosal, an ethylmercury compound, started being used in vaccines in the early 1930s as a preserving agent. In the late 1950s, it was discovered that a different compound, methylmercury, was poisonous to humans. With concerns around mercury products rising, the FDA Modernization Act of 1997 called for a federal report on all foods and drugs containing mercury.[192] This included vaccines, as a drug containing a mercury compound. Upon review of vaccines, health officials admitted that while there had never been any cause for concern, there were no studies about the long-term affects of thimerosal. With little concrete knowledge of the long-term affects of thimerosal, the government decided it was best to remove the mercury-based preserve from childhood vaccines. In 2001, the Institute of Medicine[193,194] reviewed all of the MMR-autism data available to date and concluded that there was no association.[195] Despite the lack of evidence for any safety concern, thimerosal was removed from childhood vaccines, and by 2002 no new childhood vaccines with thimerosal were being sold in the U.S.[196] By 2003, no child received a vaccine with thimerosal in it.[197] Again, while there had been no

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[192] *Id.* at 123.

[193] It should be noted that the Institute of Medicine, now known as the National Academy of Medicine, is an independent nonprofit organization that provides advice on issues relating to biomedical science, medicine, and health, and serves as an adviser to the nation to improve health aims and provide unbiased, evidence-based, and authoritative information concerning health and science policy to policy-makers, professionals, and the public. Their only goal is to improve the health and well being of all people. (2017). Vision and Mission. *The National Academies of Sciences, Engineering, Medicine*. Retrieved from http://www.nationalacademies.org/hmd/Activities/PublicHealth/HealthLiteracy/Vision_Mission.aspx

[194] The scientists who serve on Institute of Medicine Committees all work on a volunteer basis; *Supra* 192 at 144 & 149.

[195] If the National Academy of Medicine found no association between vaccines and autism, the study was either an honest assessment or it was a lie in an attempt to conspire against Andrew Wakefield.

[196] *Supra* 171.

[197] (2015, August 28). *Timeline: Thimerosal in Vaccines (1999-2010)*. The Centers for Disease Control and Prevention. Retrieved from https://www.cdc.gov/vaccinesafety/concerns/thimerosal/timeline.html.

reason to suspect anything harmful in thimerosal, the consensus was better safe than sorry. This move brought the entire vaccine program into doubt.[198] What was being pumped into our nation's children and why had it not been tested for safety earlier? After all, in 2000 many devastating childhood diseases had already been all but eradicated from the United States. Why was the government still pumping potentially toxic mercury into babies? Deciding to remove thimerosal from childhood vaccines at this time was especially suspicious following Wakefield's study, further fanning the flames of doubt in the government's motives.

There have been many instances of the public losing faith in the government because of the part it plays in vaccines. However, the current situation is a bit different. For one reason, it has been nearly 20 years since Andrew Wakefield's study was presented to the public. The anti-vaccination groups who are suspicious of government health officials, physicians, and those who do choose to vaccinate their children has not waned over this significant period of time. Finally, autism is an incurable, lifelong disease. Those who are concerned about vaccines' effect on childhood development have no opportunity to forget or lose focus on the role vaccines ostensibly played in their lives.

B. Media Creates Us versus Them

It is not just the government's public health officials that have been called into question. Physicians are also seen with animosity. Generally, physicians "no longer have the unquestioned public trust and esteem they enjoyed a generation ago. The image of the doctor as omniscient and beneficent has been tarnished by a spate of stories in the media

[198] *Supra* 194 at 165.

about incompetent, venal, and unethical physicians."[199] The vaccine-autism scare started by Andrew Wakefield created an us-versus-them culture in our society. Wakefield claims that this divide came from the "medical establishment" and their determination to discredit him because "he threatened their hegemony by taking parents' concerns seriously."[200] The drama of this assertion that those medical caregivers opposed to Wakefield were the "establishment," also known as "The Man," created a sense among Wakefield's supporters that they were part of an underdog resistance group. It was "anti-vaxxers" versus the world. This was prime material for the media, who quickly took up Wakefield's claims, despite his overwhelming lack of proof. News stories poured out about government conspiracy theory and the "maverick doctor…trying to protect innocent children from corrupt politicians and a rapacious pharmaceutical industry."[201]

The terms used when talking about vaccines and autism are different depending on what side of the issue you fall. For example, when discussing whether vaccines cause autism, those who reject the idea use the word "vaccines," whereas those who support the link call vaccines "environmental factors."[202] Another major example that divides people who support the theoretical link between vaccines and autism and people who do not support the theory, is "anti-vaxxers." The term, in the first place, is somewhat of a misnomer. Many people labeled "anti-vaxxers" are actually not anti-vaccine. For example, Andrew Wakefield. He is not anti-vaccine, but he is anti vaccines that are not

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[199] Relman, A. (1989). Medical Professional Liability and the Relations Between Doctors and Their Patients. *Medical Professional Liability and the Delivery of Obstetrical Care: Volume II: An Interdisciplinary Review*. Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK218649/
[200] *Supra* 198 at 5
[201] *Id.*
[202] *Id.*at 229.

monovalent. Another example is Robert F. Kennedy, Jr.,[203] who was appointed by President Donald Trump to lead a new commission on vaccine safety and scientific integrity. Upon his appointment, Kennedy stated that he and the President are "in favor of vaccines," but that the commission is to investigate some doubts as to the science of vaccine's effectiveness and safety.[204] This statement shows that those who support the theoretical link between vaccines and autism reject being called "anti." Rather, they wish to be advocates for choice. Andrew Wakefield wishes for parents to have a choice between the MMR combination vaccine and its three monovalent counterparts. An advocate for patient choice is not inherently contrary to medical care and what the majority of the "medical establishment" wants for the practice of medicine. Legally required practices such as informed consent exist to ensure that patients have a choice in their medical care. However, the fact that vaccines are a public health measure (that requires individual participation) limits personal choice in the matter.

While stating that he is not anti-vaccine in his press release, Wakefield continued his crusade against the popular combination vaccines and the vaccine schedule. Andrew Wakefield appeared on *60 Minutes* in 2000 and discussed vaccines and his own children. Wakefield has four children who had all been vaccinated, but when asked if he would give them the MMR vaccine "knowing what [he knows] now," Wakefield responded definitively: "No, I wouldn't. I would most certainly vaccinate them. I would give them

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[203] Robert F. Kennedy, Jr. is the nephew of John F. Kennedy, Jr, the 35th U.S. President. He is also the son of the late Massachusetts Senator Robert F. Kennedy.

[204] Memoli, M.A. (2017, Jaunary 10). Trump wants Robert F. Kennedy, who warned of disproved link between immunization and autism, to lead a panel on vaccines. *Los Angeles Times*. Retrieved from http://www.latimes.com/nation/politics/trailguide/la-na-trailguide-updates-robert-f-kennedy-sees-link-between-1484079298-htmlstory.html

[separate shots of] measles, mumps, and rubella vaccines."[205] Unfortunately, because pharmaceutical companies no longer make monovalent vaccines and the CDC's recommendation to not delay vaccine because it delays protection, refusing the MMR for nonexistent monovalent vaccines is essentially refusing vaccination period. Wakefield's statement on *60 Minutes* spread through other news agencies around the world, resulting in Japan's Ministry of Health suspending its recommendation to use the MMR vaccine. More than 10,000 American parents opted out of giving the vaccine to their kids.[206] The effect of this statement is a clear example of Wakefield's vaccine-autism scare resulting in the drop in immunization rates in America and around the world, leading to todays return of Measles and increased infection rates.

The media's purpose is to inform the public on things that affect society but the public would have no access to the information or to understand the information otherwise. The media's spreading of Wakefield's exotic rumor, rather than any fact-based reporting on vaccines, led to celebrities and politicians picking up on the topic and choosing sides in order to gain public favor. The celebrity perhaps most famously associated with the anti-vaccine agenda is Jenny McCarthy.

Jenny McCarthy used her celebrity status to push support for the vaccine-autism link with no scientific evidence to back up her assertions, but rather her "mommy instinct."[207] In 2007, years after Wakefield's study had been debunked and many studies were unable to find a connection between vaccines and autism, McCarthy appeared on the *Oprah Winfrey Show* ("*Oprah*") to advertise her book, *Louder than Words: A*

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[205] Offit, P.A. (2008) *Autism's False Prophets*. New York, New York: Columbia University Press.
[206] *Id.* at 36.
[207] *Supra* 202 at 255.

Mother's Journey in Healing Autism. McCarthy's book focused on her son, Evan, who was born in 2002 and was diagnosed with autism in 2005. McCarthy's book talks about her journey from Evan's diagnosis, to feeling mistreated by doctors, to finding a cure for autism through her own personal research. McCarthy's story begins with having a bad feeling about the MMR vaccine. She reportedly said to her son's doctor: "I have a very bad feeling about this shot. This is the autism shot, isn't it?" According to McCarthy, her physician dismissed her fears by saying, "No, that's ridiculous."[208] McCarthy tracks her son's struggles back to this moment, saying "And not soon thereafter, I noticed that change in the pictures: Boom! Soul, gone from his eyes."[209] McCarthy's retelling of this event emphasizes her belief that the doctor dismissed the instincts she had around the MMR vaccine. Her relationship with her son's physicians never much improved. McCarthy felt physicians were condescending and claims that one pediatrician "had become so incensed by her insistent questioning that he shouted at her to 'leave the hospital—now!'"[210] This event allegedly took place after Evan suffered a series of life-threatening seizures.

McCarthy claims to have cured her son's autism with behavioral therapy (the standard treatment, not cure, for children with autism and other developmental disorders)[211] and a wheat- and dairy-free detox diet.[212] McCarthy took her book to *Oprah*

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[208] *Id.* at 255.
[209] *Id.*
[210] *Id.* at 253.
[211] *Applied Behavior Analysis (ABA).* Autism Speaks. Retrieved from https://www.autismspeaks.org/what-autism/treatment/applied-behavior-analysis-aba.; Wood, J.J., Drahota, A., Sze, K., Har, K., Chiu, A., Langer, D.A. (2009, March). Cognitive behavioral therapy for anxiety in children with autism spectrum disorders: a randomized, controlled trial. *Journal of Child Psychology and Psychiatry, 50*(3) 224-234.
[212] McCarthy, J. (2008) *Louder Than Words: A Mother's Journey in Healing*. Retrieved from https://www.amazon.com/Louder-Than-Words-Mothers-Journey/dp/0452289807

to advocate for "anti-vaxxers." Winfrey praised McCarthy's book and also read a statement from the CDC that stated "the vast majority of science to date does not support an association between thimerosal in vaccines and autism."[213] To this short statement, McCarthy responded, "My science is named Evan, and he's at home. That's my science."[214]

McCarthy's book and *Oprah* interview are an important show of the lack of information and support McCarthy felt her physician was providing her and Evan. McCarthy expressed her appreciation for Google on *Oprah* because that is where she looked for information when multiple pediatricians ostensibly dismissed her requests for help.[215] Whether these pediatricians did in fact dismiss McCarthy may be irrelevant.[216] McCarthy is far from the only patient parent of a child with autism who feels disconnected from physicians.[217] These statements are an important illustration of a physician-patient relationship and how poor physician communication can lead to feeling alienated during patient visits and ultimately to misguided actions, such as not vaccinating children.[218] Perhaps McCarthy felt that her physicians were creating an us-versus-them environment, with her being a part of the them. McCarthy said on *Oprah* that her doctors' condescension would send her into a rage. She claimed that one pediatrician become so irritated by her questions about her son that he yelled at her to get

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[213] *Supra* 210 at 255.
[214] *Id.*
[215] *Id.* at 253.
[216] If McCarthy, or anyone else, was in fact dismissed by physicians this could possibly be relevant to a legal claim, depending on the facts of each particular situation. However, in this particular situation, it is not relevant whether the physicians did dismiss McCarthy's requests, but rather that that McCarthy sought solace in Google because she felt dismissed by her pediatricians.
[217] Chapter Three will discuss relationships between physicians and patients and examples of improved communication.
[218] The topic of physician-patient communication will be discussed in Chapter Three.

out of the hospital.[219] McCarthy even claimed that once Evan was diagnosed as autistic, no pediatrician guided her about next steps.[220] However, McCarthy's stated evidence for choosing to ignore the medical community's assertion that vaccines do not cause autism are not science or fact-based. Her reasons for becoming anti-vaccination appear to be that she felt burned by her physician, starting from the point when she had a bad feeling about the MMR vaccine, and so she acted out by crusading against medicine as a whole. If parents feel their physicians are treating them as "them," it is understandable that they would want to join a community of parents in similar situations so that she could be part of an "us." Evan's unfortunate diagnosis and McCarthy's belief that his autism was healed by diet changes have no scientific support, nor does the concept of mommy instinct being able to replace medical diagnoses. If Evan is indeed cured of autism, hopefully his case will be studied further. But, one person's experience is not science. It is hard to blame McCarthy, however, for wanting to spread the word about what she believes saved her son from autism. The *Oprah* show is an excellent medium to advertise. Winfrey's attempt at balancing McCarthy's story with a short CDC statement does not provide a balanced point of view.[221] It instead showcases one side of a story. The inflammatory side, which is far more exciting than the side that essentially says there is no news to report.

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[219] *Supra* 215.
[220] *Id.*
[221] The CDC has a specific page dedicated to refuting the theoretical link between vaccines and autism. The page is titled "Vaccines Do Not Cause Autism" and contains two subheadings: "There is no link between vaccines and autism" and "Vaccine ingredients do not cause autism." The page also includes more information about Autism Spectrum Disorders; thimerosal, mercury, and vaccine safety; and frequently asked questions. As of March 29, there are six related scientific articles posted on the page that can provide more information to those seeking it. (2015, November 23). *Vaccines Do Not Cause Autism.* Centers for Disease Control and Prevention. Retrieved from http://www.cdc.gov/vaccinesafety/concerns/autism.html

It is important to note that not everyone who has a child with autism or is associated with an autism organization is an "anti-vaxxer." Alison Singer, the president of the Autism Science Foundation, stated that Seth Mnookin, the author of the pro-vaccine book, *Panic Virus*, is

> An accomplished journalist, Seth Mnookin takes an objective look at both sides of the vaccine/autism controversy and lands squarely on the side of science. With humor and wit, *The Panic Virus* examines the often bizarre events that led some families to become distrustful of science and erroneously conclude that vaccines might cause autism. This book will leave you scratching your head in pure amazement that this issue could get so out of hand when the science is so clear.[222]

In addition to the Autism Science Foundation, Autism Speaks is a major organization that has never expressed support for the theoretical link between vaccines and autism. Autism Speaks is the largest autism advocacy group in the United States. The organization was started by the grandparents[223] of a young boy, Christian, with autism. When Christian's mother, and the daughter of the founders of Autism Speaks, publicly stated that she believed "environmental factors" caused her son's autism, the founders issued a statement to clarify the organization's stance on the increasingly divisive and polarizing issue. The statement boldly said that the founders of Autism Speaks disagreed with their daughter. The organization does not believe that vaccines cause autism and they do not believe that their grandson had autism because he received the MMR vaccine. The founders also stated that the organization is committed to the scientific mission of discovering what does cause autism.[224] Autism Speaks's statement was important for those with a child with autism and to support the vital cause to find what actually causes

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[222] Alison Singer, President, Autism Science Foundation quoted in Mnookin, S. (2011) *The Panic Virus*. New York, New York: Simon & Schuster Paperbacks.
[223] These particular grandparents were the former chairman of NBC Universal and his wife.
[224] *Supra* 220 at 247.

autism and if anything can be done to effectively treat or cure the disorder. Unfortunately, a consequence is, yet again, falling into the us-versus-them dynamic that the vaccine-autism scare created. The founders of Autism Speaks became part of the us-versus-them dynamic not only with much of the autism community, but also with their own daughter. Their statement specifically disagreed with their daughter's very publicly stated opinion. Additionally, the statement expressed their love for their daughter, but immediately pointed out that she "is not a spokesperson for Autism Speaks."[225] This disavowal of her association with the foundation implies that because of their differing beliefs about what causes autism, she ought to be distanced from the organization.

Part of the us-versus-them mentality came from the idea that the government had colluded with pharmaceutical companies to profit off of innocent children without any regard for the lives of the children. A proponent of that conspiracy is Robert Kennedy, Jr. Kennedy wrote an article for *Rolling Stone* in June 2005 called "Deadly Immunity."[226] The article was co-published by *Salon.* This inflammatory article began with a description of the Simpsonwood Conference.[227]

The Simpsonwood Conference took place in 2000 and was held by the CDC. The main event was a presentation on data from the Vaccine Safety Datalink, the CDC program that studies vaccine adverse events. The Datalink had examined the possible link between thimerosal and autism.[228] Attendees to the conference included autism experts, vaccine experts, pediatricians, toxicologists, epidemiologists, pharmaceutical companies, public health organizations, a statistician, consultants to the CDC, and someone to report

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[225] *Id.*
[226] This article is now archived on *Rolling Stone*'s website and a subscription to *Rolling Stone* is required to access it.
[227] *Supra* 206 at 94-95.
[228] *Id.* at 95.

on the proceedings.[229] The goal of the meeting was to determine if any research is warranted to determine possible side effects from the vaccines that had been distributed over the previous decade. The data was meant to be kept from the public because the group felt that the complex science could be easily misinterpreted by a general audience.[230] The media spreading the rumor of the vaccine-autism link was an example of why the scientists were justifiably wary of a general audience getting hold of this information. Wakefield presented his complex study at a press conference and made a definitive recommendation based on that one, yet to be replicated, study to the media, and it was taken as groundbreaking proof of the theoretical link. It seemed that data in the hands of an audience uneducated in the intricacies of scientific method would inevitably misinterpret data by taking preliminary results as definitive and misunderstanding the significance of sample sizes.[231] Just the fact that these scientists wanted to look into the claimed link in an effort to be cautious and informed could be twisted by the media into an admission that the theoretical link was proven and the government and pharmaceutical industries had either been hiding it for years or had negligently never looked into it.

The main presentation described a study that was done to study the compound ethyl-mercury. But because so little was known about the compound, the researcher himself stated that the group was interpreting "crude results."[232] He admitted that the crude results might show that link between thimerosal and developmental disorders could

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[229] (2000, June 7-8). *Scientific Review of Vaccine Safety Datalink Information.* [Meeting transcript]. Retreat Center: Norcross, Georgia. Retrieved from http://thinktwice.com/simpsonwood.pdf
[230] *Supra* 225 at 149.
[231] *Id.*
[232] *Id.* at 152.

be plausible. This plausibility was far from proving anything, but certainly warranted further research.

Barbara Loe Fisher, Sallie Bernard, and Lyn Redwood are three women who are major advocates for the "anti-vaxxer" movement. These three women were invited to the conference, even though they were members of the general public, because they were the leading advocates for the anti-vaccination group and could provide a broader context to the proceedings. Between the three of them, two organizations have been founded, the National Vaccine Information Center, which believes in patient autonomy when choosing vaccines,[233] and SafeMinds, an organization that was founded to fight mercury-induced neurological disorders.[234,235] When the presentation was complete and these women heard

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[233] The organization states that they are "an independent clearinghouse for information on diseases and vaccines, NVIC does not advocate for or against the use of vaccines. We support the availability of all preventive health care options, including vaccines, and the right of consumers to make educated, voluntary health care choices." However, the information on their website is heavily on the side of fear mongering. Some headlines currently listed on their homepage are "Know the Risks for You and Your Child," "Forced Vaccination: The Tragic Legacy of *Jacobson v. Massachusetts*," and "Protect Life: Witness a Vaccine Reaction by Video." Retrieved from www.nvic.org.

[234] The current mission stated on their website is "to end the autism epidemic by promoting environmental research and effective treatments." As stated earlier in this chapter, the word "environmental" in the context of autism research is a euphemism for vaccines. Retrieved from https://www.safeminds.org.

[235] Newsweek reported on a study funded by autism advocacy organization, SafeMinds (The National Autism Association Also Contributed to this study). The study funded by SafeMinds took place between 2003-2013 at Texas Southwestern School of Medicine, the University of Washington, the Johnson Center for Child Health & Development, and other research institutions. SafeMinds contributed roughly $250,000 "to conduct a long-term investigation evaluating behavior and brain changes of baby rhesus macaques (a type of primate) that were administered a standard course of childhood vaccines." The paper concluded that, "vaccines did not cause any behavior changes in the primates." SafeMinds representatives say the findings contradict an earlier pilot study and the progress reports the organization received throughout the study. The earlier pilot study, conducted at the University of Pittsburgh, did show differences in the development of the amygdala region of the monkeys' brains that received the complete childhood vaccine schedule. However, the Autism Science Foundation points out that this finding does not necessarily indicate anything about autism. The chief science officer of the Autism Science Foundation said, "There are likely many biological effects that occur in an organism after a vaccine administration, but that doesn't always mean it will cause autism." Firger, J. (2015, October 2). Anti-Vaxxers Accidentally Fund A Study Showing NO Link Between Autism and

the word "plausible" uttered from the lead researcher, Lyn Redwood left convinced that her "worst fears were true….[W]e're not so crazy after all."[236]

Kennedy's 2005 article claimed that the Simpsonwood conference was held in secrecy. This is obviously false because three people in attendance were top leaders in the anti-vaccination movement. Kennedy's article was widely circulated, reported on by TV news such as *The Daily Show*, and led to calls for him to run for public office by MSNBC's Joe Scarborough.[237] However, Kennedy was quickly criticized heavily for inaccuracies in his article. Kennedy made at least eight major mistakes[238] in the article and blatantly quoted things out of context.[239] *Salon* eventually retracted the article over the inaccuracies, but it took six years.[240] The retraction stated,

> the piece was co-published with *Rolling Stone* magazine—they fact checked it and published it in print; we posted it online. In the days after running "Deadly Immunity," we amended the story with five corrections that went far in undermining Kennedy's exposé. At the time, we felt that correcting the piece—and keeping it on the site, in the spirit of transparency—was the best way to operate. But subsequent critics, including most recently, Seth Mnookin in his book "The Panic Virus," grown to believe the best reader service is to delete the piece entirely. I regret that we didn't move on this more quickly, as evidence continued to emerge debunking the vaccines and autism link. But continued revelations of flaws and even fraud tainting the science behind the connection make taking down the story the right thing to do.[241]

Vaccines. *Newsweek*. Retrieved from http://www.newsweek.com/anti-vaxxers-accidentally-fund-study-showing-theres-no-link-between-autism-and-379245?piano_t=1

[236] *Supra* 232 at 153.

[237] Kloor, K. (2014, July 18). Robert Kennedy Jr.'s belief in autism-vaccine connection, and its political peril. *The Washington Post*. Retrieved from https://www.washingtonpost.com/lifestyle/magazine/robert-kennedy-jrs-belief-in-autism-vaccine-connection-and-its-political-peril/2014/07/16/f21c01ee-f70b-11e3-a606-946fd632f9f1_story.html?utm_term=.b979e2b38ddd.

[238] *Supra* 228 at 94-95.

[239] *Supra* 237.

[240] Lauerman, K. (2011, July 16). Correcting our record. *Salon*. Retrieved from http://www.salon.com/2011/01/16/dangerous_immunity/

[241] *Id.*

When Kennedy started facing this backlash, he pushed further and more aggressively. He had previously called thimerosal "the most potent brain killer imaginable."[242] He changed his assertions from whether thimerosal causes autism to whether it is a potential contributor in neurodevelopmental disorders.[243] He said that the only way he would stop his crusade is "if someone shows me I'm wrong on the science," which many have shown multiple times over the years. Instead of submitting to the evidence against his claim, proving that he is in fact wrong on the science, he claims that the federal government, specifically the CDC, commissioned fraudulent studies to exculpate thimerosal so that the public's confidence in the vaccine program would not be undermined.[244] Instead of submitting to evidence against his claim, he has stated that scientists who support vaccines are in on the government conspiracy and "should be in jail, and the key should be thrown away."[245] Kennedy's declarations of personal strength and integrity are not evidence of his honesty or accuracy. Kennedy's baseless accusations against other government figures and scientists support the contrary. The final straw of his outlandish statements was when he likened the U.S. vaccine program to a holocaust. When apologizing to the public for using the incendiary term, he said he "employed the term…as I struggled to find an expression to convey the catastrophic tragedy of autism,

[242] Helmuth, L. (2014, July 20). Don't Feel Sorry for Robert F. Kennedy Jr. *Slate*. Retrieved from http://www.slate.com/articles/health_and_science/science/2014/07/robert_f_kennedy_jr_profile_in_the_washington_post_anti_vaccine_theory_and.html
[243] *Supra* 239.
[244] *Id.*
[245] *Supra* 242.

which as now destroyed the lives of over 20 million children and shattered their families."[246]

Setting aside the fact that every major scientific and medical organization in the country has concluded that thimerosal was safe after conducting studies since 2000 and that the science of vaccines is entirely settled scientifically,[247, 248] consider why the government would want to take part in a huge conspiracy that damages and potentially kills its constituents. Perhaps because doctors and pharmaceutical companies could stand to profit from selling vaccines that are mandatory for everyone in the country, guaranteeing that their supply would be purchased at any cost. Setting aside the fact that vaccines are extremely costly to make and the federal government pays for a considerable number of the vaccines being administered through the VFC,[249] consider how much money is actually made from vaccines. As far as pharmaceutical companies, they used to lose money on vaccine manufacturing until very recently. In the past,

> vaccines were so unprofitable that some companies stopped making them altogether. In 1967, there were 26 vaccine manufactures. That number dropped to 17 by 1980. Ten years ago, the financial incentives to produce vaccines were so weak that there was growing concern that

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[246] McGreevy, P. (2015, April 13). Robert Kennedy Jr. apologizes for likening vaccine effects to 'holocaust.' *The Washington Post*. Retrieved from http://www.latimes.com/local/political/la-me-pc-robert-kennedy-jr-apologizes-for-likening-vaccine-impacts-to-holocaust-20150413-story.html

[247] *Supra* 245.

[248] In doing further research, it has been found that while thimerosal has been taken out of vaccines administered to babies, studies have shown that thimerosal has no connection to autism-like behavior or neuropathy. Gadad, B.S., Wenhao, L., Yazdani, U., Grady, S., Johnson, T., Hammond, J., Gunn, H., Curtis, B., English, J., Yutuc, V., Ferrier, C., Sacket, G.P., Marti, C.N., Young, K., Hewitson, L., German, D.C. (2015, October 6). Administration of thimerosal-containing vaccines to infant rhesus macaques does not result in autism-like behavior or neuropathology. *PNAS, 112*(40): 12498-12503. Retrieved from http://www.pnas.org/content/early/2015/09/24/1500968112.full.pdf

[249] The percentage of vaccines paid for by VFC is at least 34% of all childhood immunizations. This is addressed in Chapter 1, footnote 51. *The Atlantic* stated that the VFC purchases vaccines for "about 50% of children in the U.S."; Lam, B. (2015, February 10). Vaccines are Profitable, So What? *The Atlantic*. Retrieved from https://www.theatlantic.com/business/archive/2015/02/vaccines-are-profitable-so-what/385214/

> pharmaceutical companies were abandoning the vaccine business for selling more-profitable daily drug treatments. Compared with drugs that require daily doses, vaccines are only administered once a year or a lifetime. The pharmaceutical company Wyeth (which has since been acquired by Pfizer) reported that they stopped making the flu vaccine because the margins were so low.[250]

Vaccines are so expensive to make because the science behind manufacturing them is very particular and contains many moving parts. It requires significant research for each batch made. Vaccines are biologics, meaning a pharmaceutical drug or device that is made from (or using) a biological source. It is impossible to identically replicate biologics because of the material they come from.[251] Vaccines have high production costs, low market costs, and are heavily regulated.[252] The game has changed for pharmaceutical companies. The introduction of new vaccines, such as human papillomavirus (HPV), has increased the value of the vaccine manufacturing industry to $24 billion. Pharmaceutical companies found that you can sustain high prices for those vaccines that can be administered as monovalent single dose vaccines.[253] Regardless of the fact that pharmaceutical companies can make money off of some vaccines, those vaccines are not typically the ones being given to small children under the age of 18 months. Those vaccines given to small children are heavily funded by the federal government's VFC program. For example, the current CDC pediatric-contract price for MMR is $19.91 while the private sector pediatric price is $59.91. The federally

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[250] Lam, B. (2015, February 10). Vaccines are Profitable, So What? *The Atlantic*. Retrieved from https://www.theatlantic.com/business/archive/2015/02/vaccines-are-profitable-so-what/385214/

[251] So, A.D. & Katz, S.L. (2010, March 7). Biologics Boondoggle. *The New York Times.* Retrieved at http://www.nytimes.com/2010/03/08/opinion/08so.html?_r=0

[252] *Supra* 250.

[253] This chapter already discussed why childhood vaccines such as MMR and DPT cannot be given as monovalent single-dose vaccines.

subsidized vaccine is far more affordable.[254] Merck, the only company licensed to offer the measles vaccine in the U.S. released their 2014 earning report, which showed that three of their vaccines (ProdQuad for measles, mumps, rubella, and varicella), MMR II, and Varivax for chicken pox together brought in $1.4 billion. The company totaled $42.2 billion in global sales.[255] Those three vaccines brought in 3.3% of Merck's total sales. Even Merck's top selling vaccine is the HPV vaccine, Gardasil, only brought in $1.7 billion. As for physicians, pediatricians tend to lose money on vaccine administration. Vaccines are more expensive now so doctors spend a lot of money stocking them.[256]

Even with the increased costs of vaccines, consider that because of the number of diseases they prevent, so much value is actually saved because the cost of treating those diseases is spared. Bill Gates said that immunization

> [I[]s the cheapest thing ever done in health. This general thing where organisations come out and say, 'hey, why don't vaccines cost zero?' – all that does is that you have some pharma companies that choose never to do medicines for poor countries because they know that this always just becomes a source of criticism. So they don't do any R&D [research and development] on any product that would help poor countries. Then they're not criticised at all because they don't have anything that these people are saying they should price at zero.[257]

He went on to praise pharmaceutical companies willing to invest in vaccines because they are not good moneymakers.[258] A study released in 2013 estimated that fully

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[254] *Supra* 252.
[255] *Id.*
[256] *Id.*
[257] Bosley, S. (2015, Janurary 27). Bill Gates dismisses criticism of high prices for vaccines. *The Guardian*. Retrieved from https://www.theguardian.com/global-development/2015/jan/27/bill-gates-dismisses-criticism-of-high-prices-for-vaccines.
[258] *Id.*

immunizing babies resulted in $10 saved for every dollar spent. The total estimate was $69 billion.[259] Vaccines are "the most cost-effective interventions we have."[260]

Everyone has a right to speak freely. Anyone can write a blog expressing his or her opinion on any topic. Anyone can write his or her opinion in his or her Facebook status. However, journalists have a responsibility to report balanced, unbiased, and accurate information to the public.[261] Journalists have a responsibility to take specialized information like issues in law, politics, and medicine, analyze it and synthesize it, and report it in a simpler form to the masses. The major tenet of journalism is to fact check.[262] Perhaps Oprah should have asked Jenny McCarthy more questions about her scientific method. The fact that *Salon* repeatedly corrected Kennedy's "Deadly Immunity" immediately after it was posted and eventually retracted Kennedy's "Deadly Immunity" shows that they did not fact check in the first place. Many of the major mistakes made in "Deadly Immunity" could have been fact checked before publishing or being profiled on *The Daily Show* or nominated for office by MSNBC. For example, Kennedy claimed, "by the age of six months [children] were being injected with levels of mercury one hundred eighty seven times greater than the EPA's limit for daily exposure." When in fact, levels exceeded the Environmental Protection Agency (EPA) limit twofold and even then, that

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[259] *Supra* 256.
[260] *Id.*
[261] Heuvel, K.V. (2014, July 15). The distorting reality of 'false balance' in the media. *The Washington Post*. Retrieved from https://www.washingtonpost.com/opinions/katrina-vanden-heuvel-the-distorting-reality-of-false-balance-in-the-media/2014/07/14/6def5706-0b81-11e4-b8e5-d0de80767fc2_story.html?utm_term=.5972d17f8eeb; *Never deliberately distort facts or context, including visual information. Clearly label illustrations and reenactments*. Society of Professional Journalists. Retrieved from http://blogs.spjnetwork.org/ethicscode/?p=155.
[262] *Provide context. Take special care not to misrepresent or oversimplify in promoting, previewing or summarizing the story*. Society of Professional Journalists. Retrieved from http://blogs.spjnetwork.org/ethicscode/?p=10

EPA limit was made for methylmercury not ethylmercury (thimerosal).[263] Another false claim in Kennedy's article that could have easily been fact checked before the piece was every published is his claim that "[f]our of the eight CDC advisors who approved guidelines for a rotavirus vaccine laced with thimerosal had financial ties to the pharmaceutical companies developing different versions of the vaccine." No rotavirus vaccine has ever had thimerosal.[264] In addition to this information being blatantly incorrect and easily checkable, the inflammatory language used by Kennedy that the vaccine was "laced" with thimerosal, as though it was a drink at a bar laced with rohypnol, indicates that the vaccine was illegally drugged. Other issues with "Deadly Immunity," such as the science behind the theoretical link between vaccines and autism took more time for CDC scientists (and others) to dig into deeper, which *Salon* claims as the reason for waiting so many years to retract the article entirely.

C. Looking Ahead: The Threat of Robert F. Kennedy Jr.

The politicization of vaccines, not only through the us-versus-them language used in the argument and the media's spreading rumors of a government conspiracy, has been seen through the cause being taken up by politicians themselves. Besides Kennedy's political associations, many Republican politicians have come forward as anti-vaccination. Five of the 13 GOP candidates for the 2016 presidential election believed that vaccines should, at the very least, be left to the parents' discretion.[265] President Donald Trump, the winner of the 2016 presidential election and the 45th President of the United States, is considering creating a commission to study vaccines, to be led by

[263] *Supra* 238 at 95.
[264] *Id.*
[265] This was discussed in the Introduction.

Kennedy. Kennedy said that Trump has doubts about vaccine policies.[266] It is unclear what exactly he doubts. Kennedy's thimerosal link has been refuted time and again, and he has even backed off his claims once he was appointed by Trump stating "everybody ought to be able to be assured that the vaccines that we have…[are] as safe as they possibly can be."[267]A far cry from being like the "holocaust" or the "most potent brain killer imaginable." The most known at this time is that Trump wants to explore "smaller doses over a longer period of time,"[268] which is not related to thimerosal, but closer to Wakefield's claim. Trump has also told a story multiple times, including during one of the republican primary debates, about a child of one of his employees who suffers from autism. According to Trump, the child got a vaccine and "A week later [the child] got a tremendous fever, got very, very sick, now is autistic."[269] Trump's desire to explore and change the way vaccines are administered is of grave concern to pediatricians because a major component of their job is giving vaccines to "safeguard" the welfare of patients and protect them against diseases that could "seriously sicken or kill them."[270] A pediatrician writing his opinion for *The Washington Post* wrote,

> [T]he idea of creating a commission to study one of the most settled subjects in medicine confirms a gnawing fear I've had since the earliest days of Trump's presidential campaign. Drowned out by the noise of his outrageous statements and intemperate tweets is the fact that Trump

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[266] Memoli, M.A. (2017, January 10). Trump wants Robert F. Kennedy, who warned of disproved link between immunization and autism, to lead a panel on vaccines. *Los Angeles Times*. Retrieved from http://www.latimes.com/nation/politics/trailguide/la-na-trailguide-updates-robert-f-kennedy-sees-link-between-1484079298-htmlstory.html

[267] *Id.*

[268] *Id.*

[269] Marcotte, A. (2015, September 16). Donald Trump Uses GOP Debate to Push Anti-Vaccination Myths. *Slate*. [Video File]. Retrieved from http://www.slate.com/blogs/xx_factor/2015/09/16/donald_trump_suggested_vaccines_cause_autism_during_the_cnn_gop_debate_he.html; *Trump on Vaccines*

[270] Summers, D. (2017, January 11). Donald Trump and Robert F. Kennedy Jr. just made pediatricians' jobs a lot harder. *The Washington Post.*

> believes vaccines cause autism. He has loudly proclaimed that misinformed belief for years….He is unambiguously wrong about this. In the words of my colleagues at the American Academy of Pediatrics in a statement released shortly after Trump's meeting with Kennedy, 'Vaccines are safe. Vaccines are effective. Vaccines save lives.'[271]

Another, a pediatrician at Baylor College of Medicine and the Director of the Texas Children's Hospital Center for Vaccine Development, also wrote,

> Today, parents in Texas have to live in fear that something as simple as a trip to the mall or the library could expose their babies to measles and that a broader outbreak could occur. Perpetuating phony theories about vaccines and autism isn't going to help them—and it's not going to help children on the autism spectrum, either.[272]

These statements by pediatrician, backed by the American Academy of Pediatrics (AAP), are not that far from how many feel about Trump. He, like Kennedy, champions his own ability while making baseless claims that are not based on the evidence or facts before him. The fact that the commission on vaccine safety may be created by Trump and led by Kennedy not only keeps vaccines alive as an unnecessary political distraction, but also may have dire consequences on the public health of our nation if their goal to spread vaccines out over time is achieved. During such times of controversy and with the ability to easily spread misinformation, it is important to "look at the evidence rather than the sensational rhetoric" shouted repeatedly by high-profile members of the media and politics.[273]

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[271] Summers, D. (2017, January 11). Donald Trump and Robert F. Kennedy Jr. just made pediatricians' jobs a lot harder. *The Washington Post.*
[272] Hotez, P.J. (2017, February 8). How the Anti-Vaxxers Are Winning. *The New York Times.*
[273] Whelan, A.M. (2016). Lowering the Age of Consent: Pushing Back against the Anti-Vaccine Movement. *The Journal of Law, Medicine, & Ethics, 44*: 462-473. 463.

CHAPTER THREE: THE PARAMETERS OF INFORMED CONSENT AND HOW THEY ARE NOT FULFILLED IN PHYSICIAN-PATIENT CONVERSATIONS ON VACCINES

This chapter will discuss the origins of informed consent, its purpose in patient-centered care, and why it does not apply to the vaccine conversation. This chapter will also discuss the physician-patient relationship and the part informed consent plays in the connection and building of trust between these two parties.

SECTION I: INFORMED CONSENT

Informed consent was born from the tort of battery.[274,275] Battery is the "unpermitted, unprivileged, intentional contact with another's person. The contact need not result in bodily harm; the intended contact itself is the harm."[276] There are four elements packed into the definition of battery. The first element (1) is the physical contact requirement. This physical contact could be direct or indirect between the defendant and plaintiff.[277] For example, indirect contact may be if someone keeps poking another person with a stick. In the medical context, this may be an exam using medical instruments, such as an ultrasound machine, or a treatment or preventative administered via injection. The second element (2) is harmful or offensive contact. The contact, "need not cause actual physical injury to the plaintiff…offensive but not harmful contact is sufficient."[278] However, determining what constitutes "offensive" is situational. For

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[274] Raab, E.L. (2004). The Parameters of Informed Consent, *Transactions of the American Opthalmalogical Society*. 102: 225-232.
[275] Battery is a violation of both criminal and tort law. The definition for criminal battery is "a physical act that results in harmful or offensive contact with another's person without that person's consent." *Battery Definition*. Cornell School of Law: Legal Information Institute. Retrieved from https://www.law.cornell.edu/wex/battery.
[276] *Id.*
[277] Abraham, K.S. *The Forms and Functions of Tort Law*, Fourth Edition. (2007) Thomson Reuters: New York, New York.
[278] *Id.* at 25.

example, an unwanted kiss on the cheek from an acquaintance may be uncomfortable, but not offensive. A polite kiss is not contact that "intentionally interferes with a reasonable sense of personal dignity."[279] However, a kiss on the cheek from a work colleague who repeatedly flirts with the person being kissed may be offensive contact. This type of unwanted kiss may be an invasion of "bodily autonomy—a touching without consent—[that] may be offensive even if it is not physically harmful." The goal of the tort is to protect not only physical security, but also "personal autonomy and dignity."[280] The third element (3) is intent. The intent required is not necessarily an intent to harm, but an intent to contact. Additionally, the intent is not required to be of a malicious nature or even for the defendant to understand that the contact is wrongful.[281] The fourth element (4) is the doctrine of transferred intent. This means that the "individual who actually suffers the contact need not be the person whom the defendant intended to harm or offend," but the contact is "so blameworthy that it would be inappropriate to allow [defendant] to escape liability on the ground that [defendant] did not harm or offend the particular person [defendant] intended to harm or offend."[282]

Looking at the four elements of battery, it is easy to see how each could be fulfilled in a doctor's visit if the patient did not consent to each part of an examination or treatment. Depending on the type of medicine, most physicians have to touch their patients often. This is why, in the medical context, everyone of a sufficient age and mental capacity has the right to consent to any examination or treatment that involves

[279] *Id.*
[280] *Id.*
[281] *Id.* at 26.
[282] *Id.* at 29.

direct or indirect touching.[283] This right is respected by obtaining informed consent before any touching occurs. Informed consent aims to reduce the power differential between patient and physician and maintain patient dignity.[284,285] The power differential is so great between physicians and patients because of the amount of technical knowledge possessed by the physician and the patient's vulnerable nature of putting one's life in another's hands. The doctrine was created to increase patient trust, protect patient's legal right to autonomy over his or her body, and foster rational decision-making in medical contexts.[286] Practically, informed consent has become a doctrine that serves to protect physicians from liability. As Justice Ginsberg said on the relationship between physician and patient:

> At a time when the patient is in need of treatment, the patient is most reliant on the knowledge and skill of the physician. The patient needs the physician's services and the physician knows it. The physician has all of the medical, scientific, and technical information about the necessary treatment or procedure and the patient knows it. There is no balance of power in this relationship.[287]

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[283] As Justice Benjamin Cardozo said in 1914, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body." Coughlin, C.N., King, N.M.P., & Kemper, K. (2010). When Doctors Become "Patients": Advocating A Patient-Centered Approach For Health Care Workers In the Context of Mandatory Influenza Vaccinations and Informed Consent. *Wake Forest Law Review, 45*(5), pp. 1558.

[284] Coughlin, C.N. (2015). E-Consent: Can Informed Consent Be Just a Click Away? *Wake Forest Law Review, 50*(2), pp. 384.

[285] While the goal of informed consent is to level the power disparity between physician and patient, the purpose of informed consent is more cynical. Informed consent is used in medical offices to document the conversation between doctor and patient and "to be exculpatory in the event of any later disputes over whether relevant information was adequately conveyed." *Id.* at 389.

[286] *Supra* 283.

[287] Marc D. Ginsberg. *Informed Consent: No Longer Just What the Doctor Ordered? The "Contributions" of Medical Associations and Courts to a More Patient Friendly Doctrine,* 15 MICH. ST. J. MED. & L. 18, 19 (2010) quoted in Coughlin, C.N. (2015). E-Consent: Can Informed Consent Be Just a Click Away*? Wake Forest Law Review, 50*(2), pp. 384.

As a legal doctrine, informed consent generally consists of five elements.[288,289] These elements put the burden on the physician to ensure that the patient is able to consent. The five elements are to inform patients of (1) nature of the decision or procedure; (2) any reasonable alternatives to the proposed intervention; (3) the relevant risks, benefits, and uncertainties related to each alternative; (4) an assessment of the patient's understanding; and (5) the patient's acceptance of the intervention.

> A proper informed consent dialogue requires that the patient receive the information in ordinary terms and in his or her customary language, translated if necessary. There must be the opportunity to decide free of duress, although this does not prevent the physician from offering a recommendation based on expertise and judgment. Disclosure should always include the possibility of no treatment at all and the anticipated consequences of that course. Any undisclosed treatment alternatives, or withholding the option to do nothing, can be construed as an imposition of the physician's choices upon the patient's power to decide.[290]

Like with any legal doctrine, there are exceptions to a required informed consent. These exceptions vary by jurisdiction, but one common one is "the procedure is simple and the danger remote and commonly appreciated to be remote," otherwise called a "known risk."[291] Vaccines fit this description, as the procedures are a quick and simple small injection in the arm or other fatty part of a baby, the risks of vaccines are very unlikely to occur, and most people are thought to understand that the risks are unusual. As this paper has posited, this final idea that most understand that the risks associated with vaccines are

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[288] The elements of informed consent varies slightly be states. The elements discussed in this paper are a general explanation of the elements.
[289] As of 2015, at least 23 states have a general informed consent statute, or a statute that addresses informed consent in health-care settings. In those states that do not have a statute addressing the topic, the common law of the state determines the informed consent law for that state. *Supra* 284 at 388-89.
[290] *Supra* 274.
[291] Schuck, P.H. (1994, January). Rethinking Informed Consent. *The Yale Law Journal*, *103*(4). pp. 899-959.

rare and unusual is no longer true because of the autism scare and claims regarding thimerosal.

A patient would have a claim against a physician for not providing informed consent if the patient can show that (1) the physician did not present the risks and benefits of a proposed treatment and of alternative treatments; (2) if the physician did provide full information, the patient would have declined the treatment; and (3) the treatment, even if appropriately prescribed and skillfully carried out, substantially contributed to the patient's injuries.[292,293]

A patient may also feel coerced, even if provided informed consent. Certain types of physicians can be aggressive in their recommendations. Coercion "occurs if one party intentionally and successfully influences another by presenting a credible threat of unwanted and avoidable harm so severe that the person is unable to resist acting to avoid it.'"[294] Situational coercion[295] occurs when patients face health problems and undergo medical treatment because patients feel powerless and vulnerable.[296] While babies receiving vaccines are not necessarily facing health problems when undergoing medical treatment, some parents may feel coerced into receiving vaccinations. Parents feel vulnerable about the strength of their babies and the power dynamic in the physician-patient relationship can make parents feel inferior, if not powerless. It is reasonable to

[292] *Supra* 290 at 226-227.
[293] If a patient does bring a claim against a physician that informed consent was not provided, the physician may defend his or her case by providing expert testimony establishing that the patient received the appropriate information. *Supra* 292 at 227.
[294] *Supra* 283 at 1559.
[295] It should be noted that situational coercion is not the same as true coercion. Coercion requires that one party has the capacity to threaten the other. This paper focuses on situational coercion.
[296] *Supra* 294.

think this feeling of coercion[297] may be a result of the fact that some pediatricians[298] are often unwilling to treat babies who are not vaccinated. Pediatricians make this choice because they are afraid of their other patients developing illnesses because of exposure in their own offices when parents refuse to vaccinate. It may not be the situation where a parent refuses to vaccinate, but rather they are curious about alternate schedules or simply have questions regarding vaccines. Because vaccines are considered common knowledge and the subject has become so politicized, some pediatricians feel irritated when parents ask any questions at all. This makes parents uncomfortable during their visit and they may feel situational coercion into vaccinating. The coercion likely does not become an issue, however, unless the baby has a side effect or develops an illness, which may or may not even be related to the vaccine administration.

Vaccines are state mandated in the sense that physicians are not required to vaccinate a child, but public schools are required to reject un-immunized children (who do not meet state exemption standards). Physicians feel an obligation to vaccinate because vaccines protect our communities, which are the communities in which these physicians have patients they feel obligated to protect from preventable illness. Vaccines are not consented to in the typical way a procedure is consented to, where a diagnosis is identified, a chosen treatment is determined to be the most efficient and the least

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[297] Two of three definitions of "coerce" is "to compel to an act or choice," or, "to achieve by force or threat." *Definitions of Coerce.* Merriam-Webster. Retrieved from https://www.merriam-webster.com/dictionary/coerce. This paper uses variations of the word to describe the feeling patients may have when they face losing their doctors if they choose not to vaccinate. As noted in FN 22, this paper is only referring to situational coercion.

[298] This paper in no way means to imply that all pediatricians or physicians immediately refuse patients, or refuse patients at all, who refuse vaccination. Refusing patients who refuse vaccination is a trend that has been seen anecdotally and for the reason given above, which is to protect other patients in the office from exposure. Examples of physicians who refuse or do not refuse unvaccinated patients will be explored further in Chapter Four, Section I, Part B.

detrimental to the patient, and the patient can agree to that treatment or search for other options. Vaccines on the other hand are offered, even assumed, and parents do not have the option to actively say, "yes, I choose" to vaccinate, but rather can only actively say "no." If a parent chooses to say no, the parent must file an exemption with the state if they intend their child to attend public school.[299] More and more states allow personal[300] or religious[301] exemptions. One of the explanations for the return of measles is that the rate of personal belief exemptions has increased.[302] A 2006 study reported that in the states allowing personal belief exemptions, exemption rates rose 6% per year between 1991 and 2004.[303] This increase in personal exemptions is more incentive for the communication between physicians and patients to improve, especially in regards to accurate vaccine information. More education may improve parent morale.[304]

Because vaccines are state mandated, and can only be purposefully opted out of rather than purposefully chosen, perhaps instead of calling the current conversation consent, the conversation on vaccines between physician and parents would be labeled more accurately if considered an acknowledgement.[305] Physicians owe a fiduciary duty to their patients, which includes the obligation to "act exclusively in the patient's interests

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[299] Most private schools also require students to be vaccinated. footnote 60 explains that certain states require homeschool children to also be vaccinated.
[300] Personal exemptions, also referred to as philosophical exemptions, are sought by those who object to immunizations because of personal, moral, or other beliefs. Currently 18 states allow personal exemptions. (2016, August 23). States With Religious and Philosophical Exemptions From School Immunization Requirements. *National Conference of State Legislatures.* Retrieved from http://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx
[301] 48 out of 50 states allow religious exemptions. Hinman A, et al. (2002). Childhood immunization: Laws that work. *J Law Med Ethics, 30*:124.
[302] Hinman, A.R., Orenstein, W.A., & Schuchat, A. (2011, October 7). *Morbidity and Mortality Weekly Report (MMWR): Vaccine-Prevntable Diseases, Immunizations, and MMWR---1961—2011.* Centers for Disease Control and Prevention. Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/su6004a9.htm
[303] *Supra* 273 at 464.
[304] *Supra* 296 at 1561.
[305] *Id.* at 1560.

and to disclose all information material to those interests."[306] Vaccines only work if everyone uses them. Administration to one patient does not protect that patient or the larger public. Vaccines ultimate service is to public health, which is made up of individuals.[307]

SECTION II: PHYSICIAN-PATIENT RELATIONSHIP

The physician-patient relationship is a special one because, while physicians are paid based on the number of patients they see or number of treatments they prescribe, this is not a typical commercial buyer and seller relationship.[308] Physicians get to know patients in an intimate way that other sellers do not. It is not typically a single transaction between the two parties, but rather a long-term relationship.[309]

A. Informed Consent Standards

Informed consent, with the intention of protecting patients from battery and educating them to make evidence-based decisions, is difficult to apply in real life situations. A physician may be able to spout a fountain of knowledge about a diagnosis or treatment, conforming to the general requirements of informed consent, but he or she may not be able to provide a detail that is relevant to the particular patient. The patient, on the other hand, may not know what questions to ask. Medical jargon is confusing and the patient is already in a vulnerable position because he or she is ailing. The patient does not know if he or she has all the information that would apply specifically to the patient. Rather, the patient is given general information that the doctor can check off a checklist.

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[306] *Supra* 291.
[307] This is why patient-centered care in the vaccine discussion matters.
[308] *Supra* 306.
[309] *Id.*

Existing empirical studies on the implementation of informed consent, of which there are not many, show three difficulties to implementing informed consent:

> (1) most physician-patient discussions appear to be rather perfunctory and reinforce physician control; (2) the treatment context discourages patients from exploiting the information that physicians do provide; and (3) the nature of the tort system makes it difficult for patients to establish an effective legal claim.[310]

Meaningful dialogue is necessary to change all three of these impediments to informed consent. More physicians need to consider what the patients need to hear, not just to avoid liability, but rather to educate. Many patients say they would prefer more discussion with their physicians.[311] Again, because of the existing power disparity in the relationship, patients often feel overwhelmed to ask questions or do not know what to ask questions about or what facts to provide that may affect the information they are being given.

Informed consent is scrutinized for accuracy under two different standards, depending on the jurisdiction: reasonable practitioner standard and reasonable patient standard.[312] Ideally, these two standards could meet in the middle of both parties' values, resulting in both parties feeling comfortable with the information shared.

The reasonable practitioner is the ruling standard because it is more objective. The reasonable practitioner standard,[313] also known as the reasonable physician standard, considers what a reasonable doctor would consider important information to relay to the

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[310] This paper will not get into the details of tort law. The importance of this third factor is that it is difficult for patients to establish a legal claim. Schuck, P.H. (1994, January). Rethinking Informed Consent. *The Yale Law Journal*, *103*(4). pp. 899-959.
[311] *Supra* 309.
[312] Supra 292 at 227.
[313] Any "reasonable" standard is an objective standard. Meaning, the standard considers the action of the parties in question and decides whether a typical person in that situation might make that same decision.

patient so as to inform the patient's decision. The standard is more objective because there is such a thing as an average and reasonable physician. A typical physician would know what the side effects are, what the alternative treatments are, and an estimate of whether the treatment will be beneficial. The physician, being in the position of power, is expected to cover anything pertinent without being expected to guess any obscure preferences a patient may have. The assessment is simply asking whether one physician provided the same amount and type of information other physicians would. This standard is essentially the paternalistic idea that "doctor knows best." While doctors do know best as far as the science behind a diagnosis or treatment, doctors do not necessarily know what is best for individual patients, because the doctor may not know the patient's personal preferences or priorities. "Doctor knows best" ignores the individualism of patients and thus, disregards their autonomy.[314]

The reasonable patient standard, also known as the prudent patient standard, considers whether a doctor has disclosed what a typical patient would want to know in order to make a thoughtful decision. The reasonable patient standard developed because it became easy for physicians to prove through expert testimony that the information they provided was reasonable, even if the information was lacking. Perhaps the experts testified that the information was sufficient because the small amount of information conveyed became standard.[315] This standard emphasizes the rights of the patient.[316] The criticism of the reasonable patient standard is that there is no typical patient, so it is difficult to estimate "what factors might control in the mind of a hypothetical 'reasonable

[314] *Supra* 312.
[315] *Id.*
[316] *Id.*

patient."[317] A typical physician exists because physicians become physicians by going to medical school and learning how to approach patients, how to break down information, and what information is pertinent. Physicians develop a sense of talking to patients throughout their day-to-day practice. Patients, on the other hand, have no medical training and many patients are not experienced with being ill until later in life. One patient may not want to hear what another patient does, but there is no way for the patient or the physician to recognize the distinction. The reasonable patient's objective standard ignores the desires of the individual patient at issue.

The Subjective standard is a third standard used by states, however it is used less frequently.[318] As can be noted from the title, this standard is different from the reasonable patient and physician standards because it is not objective. Under this standard, the patient would receive information that satisfies that individual patient. This responds to the criticism of the reasonable patient standard. The patient needs to be given enough information such that he or she can make a personal, confident and knowledgeable decision in regards to treatment.[319]

B. Paternalism

"Paternalism advocates the idea that the doctor knows best. Under a paternalistic model of health-care delivery, doctors only participate in basic disclosure of information to patients. Today, paternalism is largely considered unacceptable as a guiding principle in the practice of medicine."[320]

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[317] *Id.*
[318] *Supra* 289 at 388.
[319] *Id.*
[320] *Id. at* 385.

There are four general categories in which physicians fall: the autocratic doctor, paternalistic doctor, agent, and doctors who hold autonomy yielded by the patient.[321] The four different types of doctors each have very different relationships with their patients. Depending on the type of patient, each doctor has his or her value and can foster excellent relationships with their patients. However, just as easily, a patient can end up working with the wrong type of doctor and the relationship is a negative experience. With the complications of choosing a physician (depending on what area a patient lives in, what type of insurance a patient has, whether or not a patient needs a specialized physician, and many other reasons), choices are limited.

The autocratic doctor "has little regard for the opinions of the patient."[322] The physician sees himself as the expert and all knowing when in consult with the patient. When a patient comes in with a problem, the autocratic doctor diagnosis the patient, tells him or her what to do, and the appointment ends there. Questions are an annoyance and practically rude to the autocratic doctor as they "signify a lack of recognition of the…practitioner's abilities."[323] If a patient chooses not to follow the autocratic doctor's recommended treatment, it is at the patient's loss, and the doctor does not feel the need to recommend another treatment or another physician. The autocratic doctor does not work for the patient, but rather for the advancement of the field of medicine.[324]

The paternalistic doctor "genuinely wants the best for the patient, but believes that patients often need to be guided firmly through the decision making process as they

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[321] Mckinstry, B. (1992). Paternalism and the doctor—patient relationship in general practice. *British Journal of General Practice, 42*:340-342, pp. 340-41.
[322] *Id.* at 340.
[323] *Id.*
[324] *Id.*

do not always know what is best for them."[325] The paternalistic doctor, unlike the autocratic doctor, listens to the patient's concerns, answers questions, and will even take small suggestions.[326] However, the paternalistic doctor feels comfortable convincing, pushing, and even coercing patients to follow what the paternalistic doctor's recommendations. The paternalistic doctor, though more polite than the autocratic doctor, still sees him or herself as superior to the patient, always right, and at liberty to ignore the patient's wishes when he or she feels it is appropriate.[327]

The doctor as the patient's agent is very different from both the autocratic and paternalistic doctor. The agent is still in charge as the medical professional, but works for the patient. The operation of the agent is to "explain to the patient the likely results of different treatment options and why one treatment is preferred to another. However, the doctor does not believe that it is necessary to explain every decision made, assuming the patient's consent for what the doctor considers to be minor decisions."[328] The agent does not pressure or coerce the patient. Instead, any influence that the agent exerts over the patient comes from the agent's ability to accurately communicate, his or her knowledge of the patient and experience with the patient, the patient's own personality, the nature of the problem being discussed, and the amount of time the physician has to discuss with the patient.[329] If the patient disagreed with the physician-agent, the physician would explain why the recommended treatment is believed to be the best course. If the patient still disagreed, the physician would submit and prescribe another option or offer the option for

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[325] *Id.*
[326] *Id.*
[327] *Id.*
[328] *Id.* at 341.
[329] *Id.*

the patient to seek another opinion.[330] The physician-agent, as much as he or she tries to serve the desires of the patient, does not provide every detail of every possible option, but rather determines how detailed an explanation is best for the particular patient.[331]

The final type of doctor may be the type that is most cooperative with patients, while at the same time being in the best position of power. The doctors who allow the patient to yield their autonomy entirely to them are put in a position of power by the patient. Many patients do not feel emotionally or intellectually qualified to understand medical decisions. As such, they ask the doctor to take control over their healthcare. While this may be an issue for liability concerns, to deny the patient the choice to put the physician in this position of power is considered paternalistic.[332]

It is important that doctors recognize that while they have superior technical knowledge of medicine, their ethical or moral beliefs cannot be considered better than those of their patients.[333] The main issue with paternalism in medicine is whether doctors are "justified in making decisions about patients' treatment to which they know the patients would object if they were properly informed."[334] Today, most say no, doctors are not justified in making these types of decisions for patients. Depriving patients of this choice essentially says that patients are unable to make their own decisions and therefore worth less than physicians in this relationship. Paternalism dehumanizes patients.[335] With increased prioritization of autonomy, paternalism in medicine is generally thought to no

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[330] *Id.*
[331] *Id.*
[332] *Id.*
[333] *Id.* at 342.
[334] *Supra* 332.
[335] *Id.*

longer be an appropriate standard in medical practice.[336] Medicine has been moving towards standards that encourage patient-centered care.[337] Standards of professional practice in medicine, like the reasonable physician standard in some states and the fading practice of paternalism, focus on the agency of the clinician rather than the best methods of approaching a patient.[338] This is sensible. Professional standards and ethics codes dictate the practices and behaviors of those working in the profession. However, professional standards dictate these practices in behaviors such that those being served by the profession receive fair, responsible, and safe services. Patients ought to be considered in medical ethics.

Medical ethics, or bioethics, is often structured on four pillars: autonomy, beneficence, nonmaleficence, and justice.[339] Patient autonomy (in this case, parents are the practitioners of patient autonomy because the patients are small children) is born of the idea that patients want "to be an active member in making decisions about their care; they want…doubled-agency. In that partnership, they count on clear professional recommendations."[340] Doubled-agency describes "two actors, retaining separate identities, working toward a common goal."[341] While patients and patient families want to be part of the decision making process, they are not often equipped to be when they walk into a medical consultation. To become part of the process requires caregivers to be

[336] Pollard, B.J. (1993, December). Autonomy and paternalism in medicine. *Medical Journal Australia, 159*: 797-802.
[337] Churchill, L.R., Fanning, J.B., and Schenck, D. (2013). *What Patients Teach: The Everyday Ethics of Health Care*. Oxford University Press: New York, New York.
[338] *Id.* at 135.
[339] *Id.* at 136.
[340] *Id.* at 138.
[341] *Id.*

supportive, trustworthy, communicative, and considerate of each patient's situation.[342] Essentially, medical caregivers need to create a small community where the patient feels welcome. Vaccines complicate autonomy. It is true that "few if any choices are more private and intimate than those that concern the use made of one's own body."[343] However, mandatory immunizations are a recognized example of an exception to autonomy because of their effect in protecting the health of society.[344] What parents want, in regards to immunology and autonomy, is not to disregard protecting their children from infections disease, they want this protection but also want to be in control by being informed about what is being injected into their babies' bodies.[345]

Beneficence is the concept that the patient's well being is the primary objective of the physician-patient relationship. Again, beneficence is also relevant in doubled-agency.[346] The common goal is the patient's well being. Someone like the autocratic doctor may not prioritize beneficence. Autocratic doctors prioritize medicine via treating patients, rather than prioritizing patients via medical treatments. However, each of the other three types of doctors likely does prioritize beneficence as part of their professional standards.

Nonmaleficence is the principle that caregivers must avoid doing harm to their patients.[347] Not all bioethicists consider this separate from beneficence, as with the prioritization of beneficence, a physician prioritizes not harming patients. However, nonmaleficence ought to be considered separately because certain treatments,

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[342] *Id.*
[343] *Supra* 330.
[344] *Id.*
[345] *Supra* 236 at 17.
[346] *Supra* 341 at 138.
[347] *Id.* at 140.

chemotherapy for example, could provide harm to patients in tandem with life saving treatments. While chemotherapy is given in prioritizing saving the patient's life, it does also harm their immune systems and has potentially lasting damaging effects. Thus, beneficence and maleficence are separate concepts, not two sides of a single concept.

Finally, justice is a pillar of bioethics and professional standards. Justice in this context simply means fair access to care and remedies. For example, an injustice in health care can be a lack of access to care because the only doctor's office in town is overloaded and a patient can get an appointment for many months. Another example can be as simple as a lack of access because a physician refuses to answer a patient's questions during a consultation.[348]

Consider how a physician may attempt to foster a good relationship with a patient and what sort of gestures could be done to create a trusting environment and improve communication. How does a physician ensure that he or she is not acting paternalistically, but rather employing autonomy, beneficence, maleficence, and justice in day-to-day practice? There are small things that can help in a typical interaction between physicians and patients, such as the physician introducing not just him or herself to the patient, but also the members of the practice that will be working with the patient. This includes any physician assistants, nurses, technicians, and administrators. The physician can greet everyone in the room in addition to the patient. Cordial, yet warm social niceties can improve the relationship between physicians and patients, such as smiling, sitting down next to the patient, making eye contact while talking, and limiting

[348] *Id.* at 141.

distractions.[349] Physicians should also listen to patients' complaints, rather than interrupting the patient's explanation of his or her experience with his or her ailment. Physicians tend to want to interrupt patients. Perhaps this is because the physician hears a key detail. However, it appears as though the physician is trying to hurry the interaction.[350] Just "hearing patients' reasons for seeking help, even if it yields nothing in addition to what can be discerned through diagnostic tests, can be an essential part of healing."[351] Physicians tend to be pressed for time and it shows in their patient consultations. They are often distracted by nurses walking into office rooms, trying to take notes in medical records, and the fact that they are running behind schedule to see all of their patients. The average time a physician spends with their patients can be as little as eight minutes.[352] The longest average amount of time reported in studies in 13-16 minutes.[353] If the physician can use these precious minutes to not just inform patients, but also to make a connection with them, patients would feel more comfortable in these interactions. All of these recommendations may seem obvious, but each helps bridge the gap between physician and patient and reduces the disparity of power in the relationship. The idea is that if two parties can feel a connection, the feelings associated with the relationship are more positive.[354] The catch is that the physician cannot simply go

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[349] Schenck, D & Churchill, L.R. (2012). *Healers: Extraordinary Clinicians at Work*. Oxford University Press: New York, New York.
[350] *Id.* at 12.
[351] *Id.* at 18.
[352] Chen, P.W. (2013, May 30). For New Doctors, 8 Minutes Per Patient. *New York Times.* Retrieved from https://well.blogs.nytimes.com/2013/05/30/for-new-doctors-8-minutes-per-patient/?_r=0
[353] Peckham, C. (2016, April 1). *Medscape Physician Compensation Report 2016*. Medscape.. Retrieved from http://www.medscape.com/features/slideshow/compensation/2016/public/overview?src=wnl_physrep_160401_mscpedit&uac=232148CZ&impID=1045700&faf=1
[354] *Supra* 351 at 8.

through the motions of introductions, smiles, and eye contact. He or she must be authentic in their interactions, which can be difficult to muster because of the aforementioned time constraints. The authenticity makes the time quality, even if it is lacking in quantity.[355]

In addition to relating to patients, it helps if patients feel as though they can relate to physicians. To develop this sort of rapport, it is encouraged for physicians to appear human, rather than heroes. In describing how one physician tries to relate to patients, he said,[356] "I like to have them understand that I am a human being, that I am not a god. I am a physician." It is easy for both the physician and the patient to get caught up in the power disparity, as many patients believe physicians to have god complexes. To avoid this image of superiority, it is important for both parties to reveal and recognize the humanity in each other. It is appropriate for a physician to admit when he or she does not know the answer to a question, but will instead do some research to provide the best and most up-to-date information. It is alright if the physician appears vulnerable or empathetic. It is especially important that the physician not communicate in a strictly clinical language or manner.[357]

SECTION III: VACCINES AND INFORMED CONSENT

As noted above, the vaccine conversation is exempt from the informed consent conversations. The idea of informed consent, as a protective measure created for patients, encourages patient-centered care standards in medical care via the autonomy and beneficence pillars of bioethics. Vaccines, on the other hand, are not about the typical

[355] *Id.* at 10.
[356] *Id.* at 16.
[357] *Id.* at 11.

idea of patient-centered care.[358,359] Vaccines focus on public health, not the individual patient receiving the immunization. "Patient-centered care is arguably distinguishable…from public health. Nonetheless, just as public-health concerns and individual medical choices have come together in some health care decision-making contexts…contemporary questions…involve[ing] legal and ethical principles underlying the patient-centered movement, most notably that of informed consent"[360] can come together to in the vaccine conversation.

The amount of incorrect information circulating about vaccines between the media, conspiracy theorist politicians, and concerned parents who are not medically trained can be overwhelming to a parent deciding whether to opt out of childhood vaccines. Due to this enormous amount of misinformation and scary stories, parents can have a sort of cognitive dissonance[361] between the truth about vaccines and what they perceive from the media and horror stories they hear on online forums. Breaking this cognitive dissonance down with multiple, honest, clear conversations with physicians

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358 The Institute of Medicine defines patient-centered care as "providing care that is respectful of, and responsive to, individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions." (2001). Institute of Medicine Committee on Quality of Health Care in America. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academy Press. quoted in Clay, A.M., Parsh, B. (2016). Patient- and Family-Centered Care: It's Not Just for Pediatrics Anymore. *AMA: Journal of Ethics*, *18*(1):40-44.

359 The eight points of patient-centered care are (1) access to care, (2) continuity and transition, (3) involvement of family and friends, (4) emotional support, (5) physical comfort, (6) information and education, (7) coordination and integration of care, and (8) respect for patients' preferences. (2015, May 15). The Eight Principles of Patient-Centered Care. *Oneview Blog*. Retrieved from http://www.oneviewhealthcare.com/the-eight-principles-of-patient-centered-care/. This paper focuses on concepts (2), (6), and (7) when attempting to apply patient-centered care to a public health initiative.

360 *Supra* 305 at 1552.

361 Cognitive dissonance is "the state of having inconsistent thoughts, beliefs, or attitudes, especially as relating to behavioral decisions and attitude change." *Cognitive Dissonance*. Oxford Dictionaries. Retrieved from https://en.oxforddictionaries.com/definition/us/cognitive_dissonance.

brings parents up to date on accurate information and fully acquaints them with the realities of vaccines.

For example, as previously mentioned, the measles had been effectively eliminated in the United States, up until recently. When confronted with this information by scientific correspondent, Jeffrey Kluger, during her *Time* magazine interview, McCarthy responded "If you ask a parent of autistic child if they want the measles or the autism, we will stand in line for the...measles."[362] While autism can be a terrible disease for the patient and the patient's family, the measles can be lethal. McCarthy's emotionally devastating personal experience separates her from a larger reality. Someone like McCarthy, who has access to the best physicians who can provide her with the best and most recent information regarding vaccines or autism, is unlikely to be swayed by these conversations. However, other parents who are not anti-vaccination, but simply have questions based on bad information, need to have these conversations with physicians to understand why the measles needs to be prevented. It is certainly better than these parents getting information from celebrities McCarthy, who has no medical qualifications and at best simply has a single instance of personal experience backing up the medical information she gives out in interviews, her blogs, and her books. If parents want an accurate understanding of vaccines, it is best if they are able to get the information from the source by talking to medical professionals with whom they feel comfortable. McCarthy's experience with her son's doctors bred her distrust in medicine. Another high profile mother, the daughter of the founders of Autism Speaks, also said that she was frustrated when "one high-paid doctor after another," specialists in four or

[362] *Supra* 122 at 152.

five different states, refused to even consider autism as her son's diagnosis.[363] The dismissal these mothers felt made it easy to choose the point in time when they felt hurt by physicians, when they questioned the safety of vaccines, as the cause of their tragedy, making their physicians the ones to blame.

Additionally, Jim Carrey, who became an anti-vaccine activist along with McCarthy during their relationship, urges parents to be informed regarding vaccines and medical decisions for children. However, he also says that, "people that are charged with the public health [no] longer have our best interests at heart all the time."[364] It is unclear where Carrey expects parents to become educated on medical decisions if not from medical professionals.

For starters, physicians ought to have more thorough conversations with parents. Ideas for improving and expanding this conversation will be discussed in Chapter Four. The information should include basic statistics, such as the fact that there have been no confirmed deaths caused by vaccines. Public schools (and most other schools) require student to be vaccinated and anyone who tries to homeschool their child to get around this should check the laws of their state, as explained in Chapter One, footnote 60. Additionally, studies continue to suggest that the benefits of vaccines far outweigh the risks.[365] The risks are few and far between and often, though not always, minor compared to the effects of the diseases they protect.

Another important point that needs to be understood by parents is that vaccines are a preventative measure. They cannot treat an existing infection, but they can prevent the infection from occurring if administered before potential exposure. For example, the

[363] *Supra* 345 at 231.
[364] *Supra* 362 at 163-164.
[365] *Supra* 303 at 464.

HPV vaccine will not stop an HPV infection if the infection has already been acquired. However, receiving HPV during childhood. before a person is sexually active, will prevent an HPV infection once sexual activity begins.[366]

These concepts, which may be obvious to physicians and perhaps were obvious to parents in the past when the devastation caused by diseases was more common and thus more common knowledge, need to be discussed. Facts and statistics provide a basic understanding of what vaccines do and how they work while refuting some of the stories that have been sensationalized or misreported by the news and anecdotal evidence that is passed around.

Even if it is not the state's legal standard for assessing informed consent delivery, the reasonable patient standard needs a place in the doctor's office. The danger of not considering what a reasonable patient might want to hear may contribute to the feeling of "other" that patients feel. If the patient's point of view is not considered, he or she may feel patronized, alienated, and confused. Many patients just want to be active in their care.[367] Studies show "that participating in the decision-making process can enhance a patient's physical and psychological well-being."[368]

There is a disconnect between medicine and the reality of a patient's everyday life. A physician may get frustrated when he or she feels as though a parent is concerned over every cough, but parents who are not in the practice of medicine do not know what a cough for a vulnerable baby might mean. Patients feel they are treated as if they "don't

[366] *Id.*
[367] *Supra* 348 at 138.
[368] Supra 318 at 385.

know what they're talking about" when it comes to the health of their baby.[369] It may be true that parents do not know the science behind why their baby is coughing, but they do know their baby better than any doctor could. Reasonably, they are protective of that relationship to their child. When a child is diagnosed with autism and they are frustrated, scared, and looking for someone or something to blame, it is easier for them to target the physician who they feel patronized or dismissed by and with whom they do not feel a connection. "We live in an increasingly litigious society in which there is a growing tendency to assign personal responsibility for almost every misfortune."[370] Patients are much less likely to sue a physician if they know each other well and have developed a trusting relationship. This trusting relationship comes from physicians taking the time to answer patient questions and admitting to any past mis-diagnoses or failed treatments. [371] While there are no statistics available on the topic, many parents provide testimony that they feel their questions are going unanswered by their children's physicians.[372] This mistrust and animosity between physicians and any parent who appears anti-vaccine, even if by simply asking questions, is a danger to immunization rates.

In defense of physicians, pediatricians feel as though they are stuck between a rock and a hard place. Doctors who choose to refuse care for unimmunized children are sending a message with this harsh standard. These pediatricians are saying that vaccination is so important, they cannot be asked to withhold them and that unvaccinated

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[369] W. A. J. (Director). (2016). *Vaxxed: From Cover-Up to Catastrophe* [Motion picture on ITunes]. United States of America: Cinema Libre Studios.
[370] Relman, A. (1989). Medical Professional Liability and the Relations Between Doctors and Their Patients. *Medical Professional Liability and the Delivery of Obstetrical Care: Volume II: An Interdisciplinary Review.* Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK218649/
[371] *Id.*
[372] W, A. J. (Director). (2016). *Vaxxed: From Cover-Up to Catastrophe*[Motion picture on ITunes]. United States of America: Cinema Libre Studios; Mnookin, S. (2011) *The Panic Virus*. New York, New York: Simon & Schuster Paperbacks.

children are putting other patients in the office and the community in danger.[373] Pediatricians need to care for all of the patients coming through their waiting room. When unvaccinated children endanger the other children with easily preventable diseases, pediatricians prioritize the vaccinated children because they are at danger, not endangering. However, refusing to treat the unvaccinated children further harms them and society by leaving them unvaccinated. This keeps them in danger of contracting these preventable diseases and without access to care should these children contract any illness. If pediatricians accept all patients, including those who are refusing immunization, pediatricians feel as though they are sending a message to parents that their decision was ok, while the pediatricians themselves disagree strongly with the choice.[374] Plenty of pediatricians have children themselves. Walter Orenstein, the former director of the National Immunization Program said, "we're human, we have children. And we use the same vaccines in our own children as we recommend for anybody else."[375] Another physician, Dr. Robert Sears, who uses an alternative vaccine schedule that he created himself without any studies done to test for efficacy (this will be discussed in Chapter 4), did say that his goal in interacting with parents is to find "how can I, as a doctor, work with you? I don't want to just kick you out of my office like most doctors do. If parents question the system, they often get kicked out of doctors' offices, and that doesn't help

[373] Vaccines are also required for health care workers. For those who refuse to get a vaccine, most commonly the flu vaccine, there are extensive repercussions. They could be quarantined, forced to stay home during flu season, and even fired from their jobs. While the vaccine is mandatory for health care workers, each is still required to consent. This is admittedly different from children being sent away from pediatricians' offices or school because children require doctors and an education, while health care workers choose to work in health care. For children who are not vaccinated and are sent away from school, there is the option of homeschooling. Refer to chapter 1, footnote 60 for a list of states that do not require homeschooled children to be vaccinated.
[374] *Supra* 175 at 197.
[375] *Id.* at 200.

anybody."[376] This attempt to connect with parents and assure them is what changing the vaccine conversation will hopefully to provide.

Parents, on the other hand, feel as though pediatricians devalue their own children when pediatricians value all of their patients as a group. As one mother whose child could be vaccinated but she declined, said she distrusts vaccines and it is exactly because she loves her child so much that she will not vaccinate. She went on, "the fact that his vaccination status is putting other children at risk is not my problem….I don't appreciate being told your kids are more important than mine." [377] Based on her statement, it seems clear that this mother would feel differently if other kids were putting her child at risk. A professor at the School of Law at the University of California Berkeley said about those who are staunchly anti-vaccine, "there are a lot of people who strongly believe in this connection and no amount of science is going to dissuade them….They have congressmen and celebrities on their side. And they have a group of lawyers who have now made thimerosal litigation their specialty."[378] This cognitive dissonance is what more thorough conversations with physicians needs to change. The idea that so many people are unable to face the results of studies is an inability to face reality. This is not a judgment on these people's intelligence or mental state, as it would be absurd to judge each of these individuals who make up an ever-growing population. Rather, it is recognition that some people do not follow what they think in their head, but instead follow what the "know with their heart."[379] Deeper connections with physicians and open conversations may push this population to not ignore what they study in favor

[376] Boghani, P. (2015, March 23). Dr. Robert W. Sears: Why Partial Vaccinations May be An Answer. *PBS*. Retrieved from http://www.pbs.org/wgbh/frontline/person/priyanka-boghani/.
[377] *Supra* 365 at 467.
[378] *Supra* 205 at 246.
[379] *Supra* 363 at 9.

of what their heart is telling them caused a child's illness. This conversation could lead to the end of statements such as, "we don't care about the science because we know in our hearts that our child got autism from vaccines."[380]

These conversations can bridge the gap between physicians and patients, even if the state's legal standard is not to provide information that would be suitable from the patient's perspective. These conversations can build trust because

> Physicians in general no longer have the unquestioned public trust and esteem they enjoyed a generation ago. The image of the doctor as omniscient and beneficent has been tarnished by a spate of stories in the media incompetent, venal, and unethical physicians and by a growing suspicion of all authority.[381]

Hospitals and health care are seen as a business, rather than as your dependable family doctor. Perhaps this leads to the conspiracy theories that grew out of media stories claiming that doctors were in on a government conspiracy run by pharmaceutical companies "When the Samaritan ethic was more in evidence and patients believed that their doctors were more interested in their welfare than in economic gain, liability actions were unlikely, even when things went very wrong."[382]

Changing the informed consent discussion on vaccines allows parents to participate, learn, and feel in control of their child's care. Parents "must consent to immunizations, even if they are required for public school attendance or day care."[383] Walter Orenstein, said, "there should be a procedure whereby people have to read information, understand information, and sign that they understand the risks they are putting that child through. Right now, in some places, it's a hell of a lot easier to get an

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[380] *Id.* at 248.
[381] *Supra* 370.
[382] *Id.*
[383] *Supra* 377 at 465.

exemption than to get your child vaccinated."[384] By this, perhaps Orenstein is saying that there should be a more structured process requiring parents to read the literature and the physicians to engage in a discussion to ensure that parents read and understood the literature around vaccines prior to an administration. Supporting the informed consent process for vaccines is crucial in creating a trusting environment for parents to feel as though by opting into vaccines they are participating in the care of the child and have a modicum of control, as opposed to only actively participating by choosing to opt out.

[384] *Supra* 375 at 196.

CHAPTER FOUR: THE RESPONSIBILITY OF CAREGIVERS TO EMPOWER PATIENTS BY EDUCATING THEM SO THEY CAN MAKE THE RIGHT CHOICE

SECTION I: APPLYING INFORMED CONSENT DOCTRINE TO REFUTE RUMORS

A. Using Informed Consent Doctrine to Address Cognitive Dissonance

Approximately 4,320,000 people die of vaccine preventable diseases around the world each year.[385] This includes underdeveloped countries that do not have the same access to vaccination that most Americans are privileged to have.[386]

Preparing medical caregivers to openly explain vaccines, medical consequences, benefits, statistical probabilities of injury, and personal and public health benefits to those being vaccinated is not simply a matter of a training session, but rather a complete overhaul in how medical caregivers approach the topic of vaccines. To begin with, there needs to be recognition by providers that vaccines and the illnesses they prevent are no longer common knowledge to the general public. The amount of misinformation (or accurate information that is not easily understood by non-scientists) reported in the media and spread through social media has warped the understanding of vaccines. What may be considered a common belief to some, such as that vaccines cause autism, is completely contradictory to the common knowledge of others; such as that vaccines prevent potentially fatal illnesses. This situation requires patience among caregivers when interacting with patients. For example, a patient asking about mercury (in the form of

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[385] Crislip, M. (2011, October 21). *Alternative Vaccine Schedule*. Retrieved from https://sciencebasedmedicine.org/alternative-vaccination-schedules/

[386] On the other hand, approximately 2.5 million lives are saved from 85% of the world's children receiving the tuberculosis, polio, diphtheria, tetanus, pertussis, and measles vaccines. (2014, December 1). *Global Immunization: Worldwide Disease Incidence.* Children's Hospital of Philadelphia. Retrieved from http://www.chop.edu/centers-programs/vaccine-education-center/global-immunization/diseases-and-vaccines-world-view

thimerosal) in vaccines should be met with patience when caregivers explain that thimerosal has not been in childhood vaccines since 2003. The patient is asking because they do not know that what they heard about thimerosal in vaccines is false.

In addition to recognizing that vaccines are not common knowledge, medical providers need to recognize that some patients may experience cognitive dissonance based on their personal experience with illness or vaccines. The reason people are so willing to believe stories that have no scientific backing about how a diet can cure Jenny McCarthy's son's autism or that vaccines caused the autism in the first place is because they are searching for answers to their situation. Parents of autistic children often attest to feeling helpless, guilty, resentful, bitter, and angry.[387] To resolve these overwhelming feelings, parents need someone or something to blame for the tragedy that has befallen them. Without someone or something to blame, each pair of parents feels isolated.[388] Coming together into a community that has a cause, to fight against the government's vaccine conspiracy, they no longer feel as though their family is an island. From here, the belief becomes prevalent. Stories spread on the media, celebrities and politicians take on the cause, and other parents, who do not have children diagnosed with autism, develop fears based on this faulty information.

Not only do patients want answers to explain why they are ailing, but patients also want to be heard. Patients want to ensure that their physician understands what is hurting them or if any of their symptoms are strange, because to the patient all of the symptoms are abnormal. Parents of children who have autism are no exception. Many of the stories discussed in this paper, such as that of Jenny McCarthy's, have in common that no one

[387] *Supra* 380 at 12.
[388] *Id.*

has really talked to parents about the side effects of vaccines and why the vaccine-autism link is so improbable. It is unsurprising that these parents feel alone and even alienated and search for a community of understanding and acceptance. One parent describing her experience in the anti-vaccine community said "You can't go to a doctor or leave your home---so yeah, it was so great for me, for sure…to find [other parents] in all parts of the country it was so helpful."[389]

Andrew Wakefield, though his theory has been debunked many times over, offered a possible answer when parents felt other physicians were not. Wakefield's dubious study, rife with conflicts of interest and dangers to the 12 participating children, presented Wakefield as a martyr to these parents. To the "anti-vaxxer," Wakefield was willing to sacrifice his reputation to serve the parents of children with autism and the children themselves, and his believers saw him as such.

The threats of not getting vaccinated seem so hypothetical.[390] There is no immediate reward for getting vaccinated; it is not like taking an antibiotic when ill and feeling better over the next few days. The possibility of a child contracting diseases that have become so rare in our country, like the measles or pertussis, seems so unlikely.[391] The needle, on the other hand, is immediate, visible, and scary. The fact that a child may cry from the needle prick makes the vaccine seem like a punishment. The child may even feel sick for a few hours immediately after. This explains the visceral discomfort over vaccines. Parents "who delayed or refused some vaccines were less likely to believe that

[389] *Supra* 236 at 234.
[390] *Id.* at 18.
[391] Of course, as this paper has discussed, contracting the measles or pertussis is now not such a far off threat.

vaccines are necessary to protect children's health, that their child might get a disease while unvaccinated or that vaccines are safe."[392]

One mother said that she "'felt safe in making the choice to vaccinate selectively' because she lives in a 'relatively health first world country' with a well-functioning health care system. 'Looking at the diseases mumps, measles, and rubella in a country like the US…it doesn't tend to be a problem,' she said. 'Children will do fine with these diseases in a developed country that has good nutrition. And because I live in a country where the norm is vaccine, I can delay my vaccine.'"[393] This statement recognizes the importance of vaccines. The mother recognizes that because the norm is to vaccinate in America, her child will benefit from herd immunity. While it appears she understands the purpose of vaccines, this mother's logic is flawed. She expects other mothers to shoulder the responsibility of vaccinating their children, which excusing herself from the same responsibility. This mother is directly removing herself and her child from the community by acting as though she is special and can vaccinate her child differently or not at all. This mother is a free rider.[394] As these diseases become more and more of a memory, people find them less and less risky.[395] This mother, instead of fearing a potentially fatal illness that is easily contractible in a world without vaccines, suffers from cognitive dissonance. Her expectation of other parents' behaviors and what she expects of herself are inconsistent. Instead of fearing the reality of disease, which she expects other parents to bear the burden of preventing, she fears that her child will be that

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[392] Haelle, T. (2014, June 2). Delaying Vaccines Increases Risks—with No Added Benefits. *Scientific American.* Retrieved from http://www.scientificamerican.com/article/delaying-vaccines-increases-risks-with-no-added-benefits/

[393] *Supra* 390 at 19.

[394] Free riders are discussed in Chapter Two, Section I, Part C.

[395] Remember the concept of the four-phase progression of public opinion discussed in Chapter Two, Section I, Part B.

one rare case of a child who suffers a vaccine related injury, excusing her from bearing the same burden. Rather than "amassing evidence to prove a conjecture, [she] used the conjecture itself as evidence."[396]

B. Examples of How Physicians Have Handled (or Not Handled) Parents

There is a wide-range of how physicians handle the vaccine question when it comes up, yet a "right way" has not been advanced. Among the possibilities, plenty of wrong options have appeared. A mother asked her doctor about mercury in vaccines in April 2006. At this point, vaccines no longer contained the ethyl-mercury compound Thimerosal. The last batch, as stated in Chapter two, was administered in 2003. This mother was asking about mercury because her chiropractor advised her to "make [her son's] pediatrician prove to her that the vaccines [her son] was scheduled to receive were one hundred percent safe."[397] When the mother asked for a label to prove that there was no mercury in the vaccine, the pediatrician said no and the mother said she felt as if the "pediatrician was hiding something."[398] "I don't think I heard anything else she might have said, quite honestly. At that point I had lost faith."[399] After this non-discussion between the mother and her child's pediatrician, this mother decided not to vaccinate her child further. Her child later contracted Haemophilus influenza type b, or Hib, which could have been prevented by a vaccine that her child had not been administered. After severe swelling in his throat, to the point the young boy could not breath, he was put into a medically induced coma.

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[396] *Supra* 393 at 144-145.
[397] *Id.* at 2.
[398] *Id.* at 2-3.
[399] *Id.* at 3.

Whether the physician actually did not provide information regarding mercury, or lack thereof, in vaccines only becomes an issue if a case is brought. Physicians often answer questions and provide informed consent for the purpose of avoiding a case of malpractice. Based on this story, it is unknown whether the physician actually did not answer or whether the mother felt the answer was unsatisfactory. What is clear from the mother's reaction in the anecdote is that she felt dismissed when she asked the question, which is the fault of the physician regardless of whether her question was actually answered. One cannot know what was truly said between the mother and physician, but suppose if after answering the mother's question, the physician asked the mother whether she could explain what the physician told her to another if asked. If the mother felt she could not, the physician could continue the explanation.

It is important to note that nothing can be proven to be 100% safe. There is always a chance (no matter how small) something could go wrong. In this situation, there is overwhelming evidence that the benefits of vaccines outweigh any potential consequences. The consequences are rare and are often less severe than the diseases being prevented. This is not always the case. Vaccines can have severe side effects as well.[400] For example, seizures caused by encephalopathy are listed as a side effect of vaccines on the vaccine injury table.[401] The seizures will often be temporary and not have long lasting effects, but they are still upsetting for the child suffering and the parents. Unfortunately, it has been some parents' experience that when their baby suffers a seizure after a vaccine, their caregivers do not pay much attention, because seizures are a recognized side effect. Some parents are simply told that it was an "extreme but within

[400] *Supra* 348 at 110.
[401] 42 U.S.C. 300aa-14:Vaccine Injury Table

the normal reactions."[402] Consider an example where a baby suffers a seizure after a vaccine and the family is told that seizures are an unfortunate side effect, but not abnormal. Consider then that the baby grows up to have neurological problems. This could be coincidental and have nothing to do with the vaccine, but it would not be surprising or unreasonable for a parent with no medical background to associate the issues with the one seizure their baby suffered after a vaccine. If instead the caregivers are more compassionate, patient, and willing to listen to the parents say that they got their baby vaccinated and soon after the baby had a seizure (making an association), parents might feel more confident in the physicians reassurances that the seizure is indeed a side effect.

In contrast, vaccines can have severe side effects because their manufacture was faulty. This is unlikely, but far from unheard of. For example, in 1998 the FDA licensed rotavirus vaccine was recommended for all infants but turned out to cause an intestinal blockage called intussusception. Babies with this blockage can have bacteria from their intestine enter the bloodstream, which can cause death. The blockage can also cause damage to the blood vessels in the intestine, which can cause massive bleeding, which can in turn be fatal to the babies. In 1998, one million babies received the CDC recommended rotavirus vaccine, 100 suffered from intussusception, and one did die.[403] In such a situation, parents may file a claim in the Vaccine Court to recuperate medical costs that may have been incurred and for reparations. While this avenue is available, no amount of reparations can suffice when a child dies, even in an attempt to promote the public health and safety of other children.

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[402] *Supra* 399 at 263.
[403] *Supra* 400.

David Weldon, physician and congressman from Florida has stated "It is past time that individuals are persecuted for asking questions about vaccine safety."[404] David Weldon is a conspiracy theorist who believes that when any scientists found results showing vaccines to be unsafe, they suspiciously lost their grants, no one would publish their findings, and they lost clinical privileges. Instead of believing that this is bad science, Weldon believes that this is the CDC silencing anyone who threatens the CDC's stance. While there is no evidence supporting Weldon's claim that these scientists were driven out of business by the government, Weldon makes a good point about people being persecuted for simply asking questions. The questions that parents ask should be met with welcome at their interest in their child's health, rather than intimidation. Recognizing that vaccines are not common knowledge may help achieve this change in mindset for providers. Questions show curiosity and a desire to be educated on a topic, which should not be met with derision for lack of knowledge. Physicians do not have to see these questions as a challenge of their authority, but rather the parents respecting the fact that the physicians have knowledge in this situation that the parents do not.

1. Poor Examples of Physicians Handling (or not Handling) the Anti-Vaccine Conversation

Not having a good conversation runs the risk of the opposite happening—having no conversation at all. There is evidence that "simply educating parents about the safety and efficacy of vaccines doesn't increase the likelihood that they will get their children vaccinated."[405] As a result, there are groups of physicians who do not see the point in

[404] *Id.* at 101.
[405] Alferis, L. (2015, June 1). Training Doctors to Talk About Vaccines Fails to Sway Parents. *KQED National Public Radio*. Retrieved from http://www.npr.org/sections/health-shots/2015/06/01/411188093/training-doctors-to-talk-about-vaccines-fails-to-sway-parents

even talking about vaccines with parents.[406] Most vaccines on the CDC schedule are state mandated and perhaps physicians do not feel the need to get parent permission when vaccines are so pervasive and supported by the state. In Australia, vaccines are not a legal requirement but if a child is not vaccinated, the parents are not eligible for childcare rebates. This is similar to the United States. Vaccines are state mandated so that children can attend public school and attending school is a requirement. If attending school was not a requirement, theoretically a child could go unvaccinated and there would be no violation. Three Australian states—Queensland, New South Wales, and Victoria—require children to be immunized before enrolling in childcare. Prime Minister Malcolm Turnbull is now calling for similar nationwide legislation. This push has come after an Australian Child Health Poll survey of almost 2,000 parents showed 5% of Australian children were not fully vaccinated, enough to not have herd immunity for many preventable diseases, and a baby died from whooping cough. PM Turnbull said, "'This is not a theoretical exercise—this is life and death,' Mr. Turnbull said. 'If a parent says, "I'm not going to vaccinate my child," they are not simply putting their child at risk, the are putting everybody else's children at risk too.'"[407] This push to convince parents from the head of state in Australia is heartening.

A study was done by Dr. Doug Opel, a pediatrician at Seattle's Children's Hospital and a researcher at the University of Washington. The study enrolled 111 parents, some of whom were hesitant about vaccines and some not. The study consisted of videotaping the parents talking with their doctors on the day of their child's routine

[406] Neighmond, P. (2015, February 7). To Get Parents to Vaccinate Their Kids, Don't Ask. Just Tell. *National Public Radio WAMU 88.5*. Retrieved from http://www.npr.org/sections/health-shots/2015/02/06/384322665/to-get-parents-to-vaccinate-their-kids-dont-ask-just-tell

[407] (2017, March 13). Australia considers childcare ban on unvaccinated children. *BBC News*. Retrieved from http://www.bbc.com/news/world-australia-39251585

well-child visit. One group of doctors was "presumptive," meaning they just gave the child injections without asking. The other group was more flexible, meaning they invited patient input and questions regarding vaccines. 70% of the parents who met with presumptive doctors had their children vaccinated.[408] When the physicians were more flexible with parents and invited discussion, 83% of the parents decided against vaccination. This is an unfortunate finding because the number of those parents who want to refuse vaccinations after doctors showed flexibility on the topic is high.[409]

The Group Health Research Institute created an intervention "designed to involve parents and respect where they were coming from, respect that they wanted what was best for their child and the provider wanted that, too."[410] The intervention failed, but that is just an indication that this method can be changed or improved. The study participants required the participating physicians and health care providers receive a special 45-minute training session.[411] The participating parents received no such training.

No minds were fully changed. However, the results did show that the parents were less hesitant by the end of the study. This is a positive move forward. Some things that were recommended were a longer training session for health care providers or to help providers make time for parents who have more questions.[412]

The study recognized a very important concept: that attitudes toward vaccines are a on a continuum, not an all-or-nothing proposition, which is how many caregivers treat the topic. Patient parents do not fall into two groups, pro-vaccination and anti-

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[408] It is unclear whether these parents said anything to the doctor later about the doctor just injecting their child. It is also unclear whether the patients continued with these pediatricians or showed any other signs of a distrusting relationship.
[409] *Supra* 406.
[410] *Supra* 405.
[411] *Id.*
[412] *Id.*

vaccination. As noted in chapter two, there are many different types of "anti-vaxxers." There are those who are completely anti-vaccine, those who ignore the vaccination schedule but still vaccinate their children, those who pick and choose immunizations, and many other kinds of parents who question the CDC schedule and all of its many recommended vaccines.

While the goal of this intervention is noble and very similar to the one this paper discusses, the major difference is that this paper advocates for more than a 45-minute training on how to talk to patient parents, something more akin to a revolution in the relationship physicians and parents have. Rather, this paper advocates for prioritizing patient-centered care, even in public health measures and when the patient does not agree with the prescribed care method. This paper advocates for an overhaul of the informed consent doctrine in respect to childhood vaccination. With regards to Dr. Opel's study, this paper advocates both longer training sessions for health care providers and helping providers make time for patients who have more questions by training more doctors on the topic and starting the conversation with patients early and often. Finally, this paper advocates not for physicians and health care providers to learn how to say the right thing to patients, but rather to participate in a thorough on-going conversation where caregivers do not go through the motions of acting as though they are listening to parents, but genuinely listen and treat parents as concerned individuals, rather than as the opposition.

A positive move forward, and in the similar wheelhouse of the 45-minute training sessions, was a talk held by Dr. Paul Offit in 2014. During this talk, Dr. Offit asked the audience of doctors questions that replicate the "pushback doctors have come to expect in

affluent parts of Los Angeles and California."[413] Dr. Offit kicked off the talk by asking, "I know you doctors keep telling me that vaccines don't cause autism. If that's true, then why is it on this package insert?" To which one of the doctors eventually replied that they are a legal requirement and that she did not know the answer. This example is typical of what happens in doctor's offices around the country. Doctors do not actually know the answer to all questions, even those that seem related to medicine. In fact, these inserts are legal documents, not medical documents. Dr. Offit explained, "Drug companies must list any condition known to have occurred within six weeks of a vaccination, whether the medication caused the condition or not, and even if it occurs at the same level as with a placebo."[414] He then said that the chicken pox vaccine inserts used to include warnings for a broken leg for this reason.

One of the doctors in the audience stated that she has "stock answers for all of the questions."[415] While her preparedness is admirable and definitely a step forward in changing the conversation, stock answers may not make a parent feel confident and does not foster a trusting connection on an individual level. One of this doctor's answers included, "your kid is going to travel. You're going to take your child to Africa. You can't take an unvaccinated child to Africa."[416] True this may be, but it is preaching and demanding. It is an offensive to a perceived attack, rather than considering the parent's reason for asking questions. This is not patient-centered care because it does not consider the present patient.

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[413] Brown, E. (2014, October 31). Doctors learn to push back, gently, against anti-vaccination movement. *The Los Angeles Times.* http://www.latimes.com/local/california/la-me-pediatricians-vaccines-20141031-story.html
[414] *Id.*
[415] *Id.*
[416] *Id.*

Trying to open the conversation trusts that it will make parents feel a certain way—namely, this paper argues, empowered and secure in choosing to vaccinate. Unfortunately, this has not proven true. Dr. Offit warned that "if you say: 'OK, we're going to make this decision together'—which is to say that they're going to be a major fore in the decision—then you have to be willing to watch them make a bad one and stand back."[417] While this may be the case now, hopefully a complete change in how our society approaches the vaccine question will change this outcome. The burden is on physicians and medical caregivers to change how our society does approach the vaccine question.

Another study, led by Dr. Brendan Nyhan, found that none of the four studied interventions "increased parental intent to vaccinate a future child."[418] The four interventions, given to four different groups of the 1759 parents, were

> (1) Information explaining the lack of evidence that MMR causes autism from the [CDC]; (2) textual information about the dangers o the diseases prevented by MMR from the Vaccine Information Statement; (3) images of children who have diseases prevented by the MMR vaccine; (4) a dramatic narrative about an infant who almost died of measles from a [CDC] fact sheet; or to a control group.[419]

The results showed that refuting the MMR/autism link successfully reduced misperceptions that vaccines cause autism but had no effect on parents' decisions to vaccinate, especially among those parents who "had the least favorable vaccine attitudes."[420] A potentially surprising finding was that images of sick children suffering from diseases such as the mumps actually increased belief in a vaccine-autism link. On a

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[417] *Id.*
[418] Nyhan, B., Reifler, J., Richey, S., Freed, G.L. (2014). Effective Messages in Vaccine Promotion: A Randomized Trial. *Pediatrics, 133*(4):1-8.
[419] *Id.*
[420] *Id.*

similar note, a narrative about an infant in danger increased the self-reported belief in the serious side effects of vaccines.[421]

2. Good Examples of Physicians Handling the Anti-Vaccine Conversation

The Pediatric Association of NYC ("PANYC") has a vaccine policy that explains their position in the anti-vaccine debate:

> PANYC strongly believes in the importance of vaccinating your child and does not accept families who are unwilling to vaccinate their children. This is against our philosophy of high quality, preventive medicine. The immunization of children against a multitude of infectious agents is the most important health interventions of the 20th century. Weighing the pros and cons of immunizations and based on current medical evidence, we fully support the current complete immunization schedule. Feel free to discuss immunization questions with your physician.[422]

This is the entirety of the policy. While encouraging questions, this is so bare bones that patient parents may not even know what questions to ask. Perhaps physicians bringing up the topic of vaccines in the office would create a more supportive forum. This is not to indicate that physicians should bring it up by asking parents whether the physician should vaccinate the child, but rather the physician could bring up the benefits of vaccines or start by explaining the vaccine schedule and then ask if the parents have any questions or hesitations that the physician can address.

Another example is the KidsFirst Pediatrics page.[423] Kids First Pediatrics is a practice in Raleigh, NC. The page includes a chart of all the recommended immunizations; the time periods in which they are recommended by the CDC; any flexibility within that schedule; information on how the CDC schedule was created; and a

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[421] *Id.*
[422] *Office Policy & Procedures*. Pediatric Associates of New York City, PC. Retrieved from http://www.pediatricassociatesnyc.com/docs/Policy%20Procedures.pdf
[423] Recommended Immunizations. KidsFirst Pediatrics. Retrieved from http://www.kidsfirstraleigh.com/pediatric-services/immunizations/

table of vaccine-preventable diseases with the vaccines that prevent the disease, symptoms of the disease, how the disease is spread, and complications that arise from the disease. The KidsFirst practice is a good start, because the information is comprehensive and accessible. This webpage also must be discussed in person in the office.[424] This webpage could be used as a guide in the office. The information on this site is well organized, approachable, and fairly comprehensive. The website consistently uses the word "recommended," which implies that there is a choice and no one is bound. This is also true of the CDC. The vaccine schedule is the recommended schedule. While this paper encourages everyone to vaccinate in accordance with the CDC schedule, it is important that there is a sense of choice and autonomy, as discussed in chapter three, section III.

Dr. Robert Sears[425] is a pediatrician who has taken it upon himself to create a new vaccine schedule for his patients when parents are concerned about the existing CDC schedule. While it is irresponsible that Sears would create, without any help from the CDC or other outside evidence, and subject children to what he has decided is a fair schedule, Sears has made advances in the discussion he has with parents. Sears said that the impetus for changing the way he handles the vaccine topic was that he

> wanted to put something together that parents can read, that gave them a fair look and an educated look about vaccines so they could understand what the possible reactions are. Fortunately they're very rare. But parents also need to understand what the risks of the diseases is so that parents can weigh both sides of the story so they're understanding what's going on and they can make a decision for their child.[426]

[424] For more information, visit http://www.kidsfirstraleigh.com/pediatric-services/immunizations/
[425] Dr. Sears was also mentioned in chapter three, Section III.
[426] *Supra* 376.

Dr. Sears also wanted parents to know that, "Illnesses that are very rare right now, that most parents don't have to fear, could escalate and could start killing babies left and right if fewer and fewer parents are vaccinating."[427] While it is irresponsible that Sears is creating an alternative schedule based on nothing, at least Sears is ensuring that his patients are being vaccinated at some point.

Below is a sort of manifesto that was placed in the waiting room of a pediatrician's office.

Emphasis has been added in the form of underlined text.

[427] *Id.*

Figure 3: Pediatrician's Office Manifesto[428]

We firmly believe in the effectiveness of vaccines to prevent serious illnesses and save lives.

We firmly believe in the safety of vaccines.

We firmly believe that all children and young adults should receive all of the recommended vaccines according to the schedule published by the Centers for Disease Control and Prevention and the American Academy of Pediatrics.

We firmly believe based on all available literature, evidence, and current studies that vaccines do not cause autism or other developmental disabilities.

Furthermore, by not vaccinating your child you are taking selfish advantage of thousands of others who do vaccinate their children, which decreases the likelihood that your child will contract one of these diseases. We feel such an attitude to be self-centered and unacceptable.

We are making you aware of these facts not to scare you or coerce you, but to emphasize the importance of vaccinating your child. We recognize that the choice may be an emotional one for some parents. We will do everything we can to convince you that vaccinating according to the schedule is the right thing to do. Please be advised, however, that delaying or "breaking up the vaccine" to give one or two at a time over two or more visits goes against expert recommendations and can put your child at risk for serious illness (or even death) and goes against our medical advice.

Finally, if you should absolutely refuse to vaccinate your child despite all our efforts, we will ask you to find another healthcare provider who shares your views. We do not keep a list of such providers nor would we recommend any such physicians.

[428] *Supra* 384 at 198.

This manifesto is used as a good example of how to handle the conversation because it is upfront and clear from the moment the patient steps into the waiting room. It also explains why the practice will not stray from the vaccine schedule, the reason being for the protection of their office and all of the office's patients. The failure of this manifesto is that it immediately and purposefully separates those choosing not to vaccinate from those who will not stray from the recommended schedule. It does not attempt to start the conversation with those thinking of not following the schedule, but rather shuts it down from the get-go. By saying "we will do everything we can to convince you that vaccinating according to the schedule is the right thing to do," the practice may come across as closed off to anyone else's opinion when the intention seems to be that the practice is willing to answer any questions in the hopes that parents will choose to vaccinate according to the schedule and stay with the practice. Recalling chapter three, section II, part B, the physicians of this office appear to be paternalistic. These physicians clearly express that they want the best for their patient. It is also clear that the practice believes they know what is best for the patient and that parents need to be guided through the decision making process around vaccines.

Some of the practice's parents have said "thank you for saying that. We feel much better about it."[429] This is evidence that there was indeed a discussion surrounding the topic, even if that discussion was simply that the parents noted the manifesto and appreciated it. Trying to have these prolonged discussions is better than taking patient autonomy away all together, which has been suggested after studies found that these conversations did not make a significant difference. Again, this gets back to the concept that patients just want to be heard.

[429] *Id.* at 199.

C. The Liability Form Parents Ask Physicians to Sign Assuring Them That Vaccines Are Safe

The liability form is a form that some parents have asked physicians to sign to assume liability in the event of an adverse reaction to a vaccine.[430] The form provides four questions to ask a pediatrician before accepting any vaccines. These four questions are:

1. Do you know if any of the chemicals or preservatives inside the vaccine will accumulate in my child's body?
2. I read that thimerosal and mercury derivatives were banned 15 years ago by the [Food and Drug Administration]. Are they no longer in the current influenza vaccines? Was there ever any conclusive evidence that thimerosal caused any harm?
3. Aren't researches now finding that vaccines have actually caused many more diseases than they have prevented?
4. Has there ever been an INDEPENDENT scientific study which was randomized, double-blind and placebo-controlled which showed the long-term (20+ years of infant to adulthood) safety and effectiveness of vaccines?[431]

The questions can indeed by answered by physicians, but the answers will probably not be satisfactory to the patients who would ask such questions. As with the mother discussed in Part A of this section, these questions do not amass evidence to prove a conjecture, but used the conjecture itself, rather than using other scientific evidence. No theory can be proven 100%. There is always the possibility that science cannot yet see how the preservatives build up inside a child's body. However, at the moment there is no such evidence. A lack of evidence supports the current information that vaccines benefit, rather than hurt, children.

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[430] Philips, A. (2012, June 27). Why NOT to give your doctor an anti-vaccine liability form. *Natural News.* Retrieved from http://www.naturalnews.com/036307_vaccinations_liability_form_doctor.html

[431] (2012, April 2). If Your Doctor Cannot Answer These 4 Questions, Don't Vaccinate! *Preventdisease.com.* Retrieved from http://preventdisease.com/news/12/040212_If-Your-Doctor-Cannot-Answer-These-4-Questions-Dont-Vaccinate.shtml

Those advocating the form be signed argue that anyone who willingly vaccinates their child is blindly following doctor's orders, doctors who are ignorant to the dangers of the vaccines themselves. Advocates of the form have said that doctors are "likely unfamiliar with the toxic ingredients contained in vaccines which can immediately begin to degrade both short- and long-term health. If your doctor insists that vaccines are safe, then they should have absolutely no problem in signing this form" so that parents and patients may have the attestation for their own records in the event of an adverse reaction.[432] Ultimately, the goal of the form is that the ignorant doctor will be faced with the pressure of responsibility and opt to not administer the immunization at all.[433]

Advocates of the form also insist that modern medicine is essentially irrelevant to the improved health of the population.[434] Dr. Dave Mihalovic, leading this crusade, believes that all medical students are "brainwashed" to believe that vaccines immunize, rather than natural immunity wiping out diseases such as polio or almost eliminating diseases such as the mumps.[435]

Though this paper and much scientific evidence from around the world disagree with Dr. Mihalovic, the doctor does make a point. Physicians should be able to answer the questions parents have. Not answering or giving a standard perfunctory answer may appear to parents as though the physician either does not know the true answer or that the physician is uninterested in connecting with the parent. If a question is particularly outlandish, physicians should be able to explain why the question is irrelevant.

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[432] Mihalovic,D. (2012, May 2). If Your Doctor Insists That Vaccines Are Safe, Then Have Them Sign This Form—Dr. Dave Mihalovic. *The Refusers*. Retrieved from https://therefusers.com/if-your-doctor-insists-that-vaccines-are-safe-then-have-them-sign-this-form-dr-dave-mihalovic/#.V0ICiKMrJbU

[433] *Supra* 430.

[434] *Supra* 432.

[435] *Id.*

Additionally, physicians should explain why vaccines, while the benefits far outweigh the risks, can never be considered 100% safe. Not because the vaccines are not safe, but because of how medical research and scientific method works.

The form is illogical for at least three reasons. First, there is no other situation in which patients require their own separate contract signed by their physician. For example, when a patient takes an antibiotic, they do not bring in their own contract for the physician to sign that says they will have no adverse reaction to the antibiotic. Second, the form is ineffective in the case of an adverse event because the NCVIA and the Vaccine Court run this procedure, which does not include a patient's personal contract as evidence.[436] The physician, even if he or she did sign the form, would not be held responsible.

Third, regardless of whether a physician signs the form or opts out of administering the immunization because this form has convinced them that vaccines are a danger to health, the vaccines are still mandated.[437] The parent is still liable to either get their child vaccinated or to file an exemption, which may be very easy depending on the state in which the exemption is being sought. Having this signed form does not excuse a parent's legal obligation. A vaccine or an exemption is always required. Additionally, though many parents feel the relationship they have with their child's pediatrician lacks a positive connection, which is part of what this conversation aims to change, asking the doctor to sign this form is not signaling a positive relationship to the physician.

[436] The NCVICP "is a no-fault alternative to the traditional legal system" to resolve petitions filed after a vaccine injury. (2017, March). *National Vaccine Injury Compensation Program.* HRSA. Retrieved from https://www.hrsa.gov/vaccinecompensation/
[437] *Supra* 430.

SECTION II: WHAT CAN PHYSICIANS DO

A. Starting in the Obstetrician's Office

Obstetrician-gynecologists ("Ob/Gyns") are "uniquely positioned as a source of information and recommendations on immunizations."[438] Studies show that recommendations from physicians are one of the "best influences on patient acceptance." As such, Ob/Gyns are recommended to highlight the benefits of immunization and address the risks of not immunizing when a woman is expecting a family. During pregnancy, women are themselves advised to be vaccinated against certain diseases like influenza and pertussis so that their infants can reap the benefits of vaccination before they are old enough to be vaccinated themselves.[439] When immunizing the expecting mother, this could be the ideal time to talk about the importance of immunizing the expected baby, why babies ought to be vaccinated at such a young age, why the CDC schedule exists, and the dangers of not vaccinating or vaccinating contrary to the CDC schedule.

Much of the advocacy around Ob/Gyns making immunizations a more central part of their practice has to do with the fact that Ob/Gyns immunize women of all ages, including pregnant women. This is because women tend to use Ob/Gyns as primary care physicians (PCP).[440] Ob/Gyns fill this role because they are the physicians women see

[438] (2016, March 23). *Educate and Vaccinate: Ob-Gyns Play an Essential Role.* The American College of Obstetricians and Gynecologists. Retrieved from http://www.acog.org/About-ACOG/News-Room/News-Releases/2016/Educate-and-Vaccinate-Ob-Gyns-Play-an-Essential-Role

[439] *Id.*

[440] Walker, M. (2016, March 24). ACOG: Vaccines Should be Part of Routine Practice. *Medpage Today.* Retrieved from http://www.medpagetoday.com/obgyn/generalobgyn/56905

most regularly, especially if the woman is pregnant.[441] The push for immunizations in the Ob/Gyn practice is not specifically about baby vaccination, but vaccinating pregnant women is relevant to baby immunization, as the vaccinated pregnant woman protects the newborn baby before he or she can be vaccinated. Thus, the advocacy around prioritizing immunization in the Ob/Gyn practice is an ideal place to start the conversation about vaccinating one's babies and start it early.

The American College of Obstetricians and Gynecologists began the Immunization for Women Campaign,[442] which addresses such concerns. The goal of this campaign is "to provide Ob/Gyns and their patients with a central, trusted source of up-to-date information on seasonal flu and other vaccine-preventable diseases, including immunization facts and safety, immunization schedules, clinical and practice management guidelines, and links to other reliable immunization resources."[443] This resource addresses vaccinating pregnant women, rather than babies, but again, a way to start the conversation early regarding the immunization of babies via the immunization of pregnant women. Consider that "if a woman begins to see the value of immunizations for herself and her child during pregnancy, than they may be more apt to take the same take steps to protect their child after birth."[444] Just recognizing this during the pregnancy phase with one's obstetrician is a start to considering the importance of immunization protection for one's child. It seems like the next logical step could be that if obstetricians actually started the conversation and discussed the importance of immunization beyond

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[441] Vara, C. (2011, April 19). *OB-GYNs Have Critical Role in Immunizations for Women*. Retrieved from https://shotofprevention.com/2011/04/19/ob-gyns-have-critical-role-in-immunizations-for-women/
[442] Immunization for Women website retrieved from http://www.immunizationforwomen.org/.
[443] *Supra* 441.
[444] *Id.*

this recognition would give the mother-to-be time to consider immunizations and the protections they provide.

Considering that pregnancy can also be an overwhelming time where the expecting mother is thinking about her own changing body and health, the health of her womb, her family's changing lifestyle, and a plethora of other things, the detail of vaccination is probably not on pregnant woman's radar until her pediatrician tells her to get her baby vaccinated. As one mother said,

> [N]ot one [Ob/Gyn] ever offered, or even discussed, immunizations with me. Not one over the course of five pregnancies. As a result, I never knew about protections I could have taken. Additionally, I didn't begin considering the importance of protecting my children with recommended vaccines until after they were born.[445]

The American College of Obstetrics and Gynecology (ACOG) agrees that Ob/Gyns can play a major role in increasing awareness around immunization in their capacity as primary care physicians and in their contact during pregnancy. The ACOG released a list of seven recommendations to Ob/Gyns on how to take on this responsibility in April 2016.[446] These recommendations include such things as, "talk with each patient directly and strongly recommend indicated immunizations. Many studies have shown that a recommendation from an obstetrician-gynecologist or other health care provider for an immunization is one of the strongest influences on patient acceptance."[447] Another tip is that Ob/Gyns should "counsel their pregnant patients about vaccination in an evidence-based manner that allows patients to make an informed decision about its

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[445] *Id.*
[446] Eckert, L.O., Beigi, R. Tucker, M. Minkoff, H. Integrating immunizations into practice. Committee Opinion No. 661. *American College of Obstetricians and Gynecologists.* 2016;127:e104–7. Retrieved from http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Integrating-Immunizations-Into-Practice
[447] *Id.*

use."[448] These recommendations also include that the Ob/Gyn should make patients aware of the National Childhood Vaccine Injury Act of 1986, the National Vaccine Injury Compensation Program, and the vaccine information statement (VIS).[449] The VIS is produced by the CDC and explains the risks and benefits of vaccines.[450]

The ACOG recommendations include the ethical obligation of clinicians to decrease vaccine-preventable diseases for health care providers and staff. Health care providers have an ethical obligation to lead their patients by example by themselves being vaccinated and being able to answer questions about vaccines. The ACOG recommends that the office develop an immunization culture in the office by educating everyone on the staff and by designating an immunization coordinator to organize the logistics of immunizations, such as ordering, storing, and knowing who to contact in the local, regional, or national government level about questions such as funding and mandates.[451]

There is an expectation among the population that people know what vaccines are and understand how they work and why they are implemented. This is why vaccines are exempt from the full informed consent conversation as known risks. This expectation is detrimental because it assumes that patients and patient parents are knowledgeable about a topic, which stops a conversation and unintentionally keeps patients and parents uninformed. There is so much misinformation out there via news stories and what

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[448] *Id.*
[449] The complete list of recommendations can be found at www.immunizationforwomen.org or here: *Eckert, L.O., Beigi, R. Tucker, M. Minkoff, H. Integrating immunizations into practice. Committee Opinion No. 661. American College of Obstetricians and Gynecologists. 2016;127:e104–7. Retrieved from http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Integrating-Immunizations-Into-Practice*
[450] *Vaccine Information Statement.* Department of Health and Human Resources. Retrieved from https://www.vaccines.gov/more_info/vis/
[451] *Supra* 448.

celebrities and politicians say about vaccines. Whether that information be false or simply confusing because the logic is self-contradicting.

The science behind vaccines, which this thesis did not really touch on, is extremely complicated. Like other terms entrenched in medical jargon, vaccines have a general meaning to the public and a more specific meaning within the medical community itself. Ob/Gyns can play a major role in breaking this communication barrier and starting the education process for new or expecting parents.

A survey collected data on vaccine-related knowledge, perceptions, intentions, and information-seeking behavior between June to September 2014 from 200 first time mothers in their second trimester.[452] This study had many indications, including that these first time mothers generally had a positive outlook towards vaccines and the vaccine schedule.[453] However, the study also highlighted where expectant mothers are lacking information and where they may be misinformed.

This study did show that 75% of the mothers planned to have their child receive all of the vaccinations recommended on the recommended schedule. However, 10.5% planned to have their child receive vaccines but on an alternative schedule. Of the group, 4% planned to have their child receive some vaccines, but not all. There were no respondents who indicated that they planned on giving their child none of the recommended vaccines.[454]

This study looked at not only the intention of mothers in regards to vaccines, but also their intention in choosing physicians:

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[452] Weiner, J.L., Fisher, A.M., Nowak, G.J., Basker, M.N., Gellin, B.G. (2015, November 17). *Childhood Immunizations*. Vaccine Supplement 4. D92-D98. Retrieved from http://www.sciencedirect.com/science/article/pii/S0264410X15013134

[453] *Id.*

[454] *Id.*

> When asked how important a doctor's willingness to be flexible regarding which vaccines their child receives was or would be a factor in selecting a pediatrician or a family doctor for their child, over half indicated that it would be important (23%) or very important (36.5%).[455]

Similar responses were given when the mothers were asked "how important a doctor's willingness to be flexible regarding the vaccine schedule" would be in choosing a doctor.[456]

Most of the mothers characterized their knowledge of vaccines as good (33.7%) or fair (35.7%), but 14.6% reported it as poor.[457] 7% of mothers did not know there was a recommended vaccine schedule and only 29.5% reported themselves as very familiar (8%) or familiar (21.5%).[458] Of the 200 women, only 73 reported having received vaccine information from their Ob/Gyn or midwife (consider that because this includes midwives, even less than 73 had received information from their Ob/Gyn). Two-thirds of the mothers "indicated that they had not received any information on childhood vaccines from their [Ob/Gyn] or midwife."[459] In fact, the most commonly reported source of information reported by these expectant mothers was the internet, not primary care physicians or Ob/Gyns.

The write-up of the study concluded with a few recommendations for Ob/Gyns. Healthcare providers should recognize that the high interest in vaccines does not indicate high familiarity or understanding of vaccines. It also does not necessarily indicate that respondents are actively seeking information either. Only 7% stated that they had sought

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[455] *Id.*
[456] *Id.*
[457] *Id.*
[458] *Id.*
[459] *Id.*

information on vaccines, while about half indicated that they were very interested in vaccines.[460]

The study showed that there is need for improvement in vaccine-related knowledge. Mothers lacked specific knowledge, such as being aware that some vaccine preventable diseases are still common in the U.S. Some mothers were unfamiliar with the schedule and the details surrounding it, which created indecision in how they planned to vaccinate their children.[461]

There needs to be an expanded effort to provide vaccine-related information to expectant mothers. So few women were receiving information from their Ob/Gyns.

> Even though infant immunizations are outside an Ob/Gyn or midwife's scope of practice, results here suggest finding or creating ways to assist Ob/Gyns and midwives in directing expectant mothers to vaccine and receiving immunization information from other reliable and trusted sources could help strengthen vaccine education efforts and promote immunization. Although expectant mothers may use many sources, most may place a higher value on sources recommended by their Ob/Gyn.[462]

It is important that people understand what vaccines are, how they work, and why they are administered. They are important to safety of all babies, including those who should not get vaccinated. Not who choose not to get vaccinated, but should not be.[463] Understanding that there are in fact some people who should not be vaccinated may help those who choose not to vaccinate understand the context of their choice.

A practice of Ob/Gyns provided a short list of methods to decrease a child's discomfort with immunizations. This list was broken down by age group; starting at

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[460] *Id.*
[461] *Id.*
[462] *Id.*
[463] Please refer to this link from the Vaccine Education Center at the Children's Hospital of Pennsylvania for more information on how vaccine dosage works and when someone should not be vaccinated. http://www.chop.edu/centers-programs/vaccine-education-center/vaccine-schedule/other-schedule-issues#.V5-ZM6OAOko

newborn to 12 months, and continuing to ten through 18 years old. This page includes tips such as, " your baby is less likely to be uncomfortable or upset after immunization if he or she is not hungry or tired. See that your baby has a good nap 2 to 4 hours before the immunization is given. Feed your baby 1 to 2 hours before the immunization is to be given."[464] A physician simply providing advice as to how to make a baby more comfortable can make parents more comfortable. Having this discussion brings the parent and physician closer; it indicates to the parent that the physician is looking out for the baby's well-being, not just administering the vaccine because it is part of the physician's job; and if the baby shows fewer signs of distress during the vaccination, the parent might be more comfortable with the baby getting more vaccines.

Another way in which Obstetricians have an advantage when discussing vaccines with expectant mothers is that they can explain what sorts of behaviors to look out for to catch signs of autism. When having the vaccine discussion with expectant mothers, Obstetricians can tell mothers that signs of autism begin to appear between 12 to 18 months,[465] coincidentally around when babies are getting many vaccines. If expectant mothers know what to look for, they may recognize the signs before their babies receive many vaccines, which would help them to recognize that vaccines and autism are unrelated.

B. The Part Other Physicians Play

As has been noted previously, the only physicians that typically come into contact with the vaccine discussion are pediatricians and PCPS. Section I of this chapter showed

[464] More tips can be found here: Swainston, D., Martin, J.V., Reynolds, T.R., Zeluff, J. (2016, February 9). Helping Children During Immunizations. *Women's Health*. Retrieved from http://www.theobgynspecialists.net/womens-health/hw-view.php?DOCHWID=tj4676

[465] Frequently Asked Questions. Autism Speaks. Retrieved from https://www.autismspeaks.org/what-autism/faq

a few examples of how physicians have handled the vaccine topic. Some of those examples, such as the manifesto or the PANYC's briefly yet clearly stated policy, are an attempt to not only make the practice's stance on vaccines clear to patients before a physician-patient relationship begins and a child starts forming a connection, but also to save time within the visit itself. As was mentioned in chapter three, the average time a physician spends with a patient can be as little as eight minutes. Physicians need to be able to provide the best care to each of their patients, which means that the average patient does not get a lot of time. If Ob/Gyns begin the conversation in their offices, pediatricians and PCPs may feel that the task of having the conversation with parents is less daunting. Starting the conversation in the OB/Gyn's office means that once the conversation gets to pediatricians and PCPs, it can be had within the well-child visit without drastically adding to the amount of time a physician spends with each patient. This may keep the physicians from any extra stress, allowing them to continuously add small pieces of the conversation over multiple visits, beginning with the obstetrician and ending with pediatricians and or PCPs. Not only does this keep from overburdening each physician, but creates a continuous conversation that provides a reason for the patient and physician to discuss and connect. Additionally, the topic will never stray from the parents' minds, because it will be an ingrained part of each visit and they will hear it often.

Allowing for a continuous conversation, starting before the baby is born, also creates a space for physicians to discuss the idea of an alternative schedule with parents without shutting it down completely and immediately. This open discussion may lead to parents better understanding the purpose behind the CDC schedule. The value of an

alternative schedule is that it still provides that each child will be vaccinated. The downside, as has been discussed, is that children will be left vulnerable to the diseases whose vaccinations have been delayed for longer, providing more time for these diseases to be contracted.

An estimated 40% of parents in the United States are delaying or refusing some vaccines for their children in the hopes of avoiding rare reactions while, perhaps unintentionally, inviting common diseases.[466] Some delay vaccines because they have heard that vaccines overload their child's system, eventually leading to developmental delays and neurological disorders (essentially, the Wakefield theory). Others, while not having a more specific reason, simply say, "it just feels like a lot for a developing immune system to deal with."[467] This statement runs counter to empirical evidence or deductive reasoning. These parents, like those discussed in chapter three, section III who knew "with their hearts," refuse the CDC schedule even though there is no evidence supporting spreading out vaccines. In fact, evidence shows not only are their children left vulnerable to disease the long they are left unvaccinated, but that severe side effects such as seizures are more likely to occur the older the child receiving the vaccine is. For the parents who believe in Andrew Wakefield, their grounds for delay have some semblance of logic, even if that logic was debunked not only as poor science but as a result of poor ethical choices.

Even those parents who follow the CDC schedule and vaccinate on time, believe that delaying would be safer than following the CDC schedule. Where these beliefs come

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[466] Haelle, T. (2014, June 2). Delaying Vaccines Increases Risks—with No Added Benefits. *Scientific American.* Retrieved from http://www.scientificamerican.com/article/delaying-vaccines-increases-risks-with-no-added-benefits/

[467] *Supra* 402 at 10.

from is the flood of misinformation spread. Paul Offit, director of the Vaccine Education Center at The Children's Hospital of Philadelphia, clarified

> No vaccine can be put onto the schedule unless there is data showing it doesn't interfere with the other vaccines' [effectiveness] or safety…When you choose to spread out the vaccines, you're making something up that hasn't been tested. You don't know how well that schedule will work whereas the CDC schedule is well tested.[468]

This is something that Dr. Sears should make note of in conversations with patients when he so willingly gives vaccines on an alternative schedule that he freely admits has never been tested.

The delay in vaccination, contrary to what the autism-vaccine link believers push, does not affect behavioral or cognitive assessments in children as they grow to seven or 10 years old.[469] Considering that there is no improvement on cognitive or behavioral growth and the risks of the already rare side effects are not mitigated, but rather increase, there is no benefit to delaying vaccines. There is only the perceived benefit that parents have when they see their child get up to five needles poked into them at once. This perception needs to be challenged by thorough conversations, where questions are allowed, between physician and patient parents.

How a physician treats a parent who comes in asking about the alternative schedule can be revealing into what type of physician they are: autocratic, paternalistic, agent, or those who hold autonomy yielded to them by patients. Ideally and depending on the type of patient, a physician would be an agent or one who holds autonomy that has been yielded to them by patients. In the case of an agent, the physician might approach the alternative schedule question by explaining the results of vaccinating now versus

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[468] *Supra* 466.
[469] *Id.*

vaccinating later. The agent could cite statistics about the dangers of not vaccinating all at once, such as that "A study reported that the 2009 routine childhood immunization schedule, published by the Advisory Committee on Immunization Practices (ACIP) will prevent approximately 42,000 early deaths and 20 million cases of disease among" those born in 2009. These preventions produce "a net savings of $13.5 billion in direct costs and $68.8 billion in in total societal costs."[470] The agent can also explain that delaying vaccines is actually correlated with an increase in the risk of seizure after vaccination, in addition to leaving children at risk to preventable diseases longer. [471] For example, delaying the MMR shot later than the CDC schedule recommends,

> Doubles the child's risk of developing a fever-caused, or febrile, seizure as a reaction to the vaccine. The risk of a febrile seizure following the MMR is approximately one case in 3,000 doses for children aged 12 to 15 months but one case in 1,500 doses for children aged 16 to 23 months.[472,473]

The agent could also explain that in addition to this increased risk and the extended vulnerability, spreading out the vaccines requires more doctors' visits, which is a hindrance to parents and upsetting to children who associate each doctor's visit with pain and a needle stick. This creates a relationship of fear between the physician and patient, rather than one of trust. [474]

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[470] *Supra* 374 at 463.
[471] *Supra 469.*
[472] *Id.*
[473] According to the same study, the reason for the increase in febrile seizures when vaccines are administered at this time is not exactly known. However, febrile seizures caused by viruses do naturally peak between 16 to 18 months because this is when the immune system is maturing Because vaccines "rev up" the immune system to "mount a better immune response," introducing vaccines this late is more dangerous than introducing them earlier. This is not to say that a child will definitely have febrile seizures during these months anyway, so the shot may as well be administered later. Rather, it means that the child is more susceptible to febrile seizures at this age.
[474] *Supra* 472.

An agent would not pressure or coerce the patient when the patient states that regardless, they choose to vaccinate later. Instead, the agent could document the patient's choice in front of the patient. If the agent is concerned for the other patients in the practice, the agent should express this concern. Perhaps the agent could see the child as the first patient of the day, before others come in, or as the last patient after other patients leave. This would ensure that the physician-patient relationship still exists, demonstrate the physician's interest in the health of his patients, and keep parents from feeling ostracized for vaccinating on a delayed schedule. If a parent feels ostracized by choosing to vaccinate on an alternative schedule, it may discourage vaccination all together. Seeing the unvaccinated patient when no other patients are in the office will also express the severity of the parent's choice.

If the physician is one who has been given autonomy yielded to them by the patient, the physician will be able to vaccinate according to the CDC schedule without the specific consent of the patient's parents because the physician has been given this discretion.

What can a physician do when confronted by a parent who is asking questions in line with the anti-vaccine movement? Firstly, not turn the parent and patient away. A study by the AAP found that between 2006 and 2013, pediatricians reported increased vaccine refusal and consequently began dismissing those refusing.[475] The study found that "6.1

[475] Hough-Telford, C., Kimberlin, D.W., Aban, I., Hitchcock, W.P., Almquist, J. Kratz, R., O'Connor, K.G. (2016, August). Vaccine Delays, Refusals, and Patient Dismissals: A Survey of Pediatricians. *The American Academy of Pediatrics.* Retrieved from http://pediatrics.aappublications.org/content/early/2016/08/25/peds.2016-2127?sso=1&sso_redirect_count=3&nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3A%20No%20local%20token&nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token

percent of pediatricians in 2006 reported that they 'always' asked intransigently anti-vaccine families to take their families elsewhere; that number had nearly doubled to 11.7 percent, by the time the 2013 survey was taken."[476] While this number may have to do with the fact that more "anti-vaxxers" are coming into contact with pediatricians (87% of pediatricians say they deal with vaccine refusals while in 2006 it was reportedly 75% of pediatricians),[477] this still shows that more children are being turned away because of their parents' beliefs.

The stance of the AAP is not to turn away such families, but rather to "continue to engage with vaccine-hesitant parents, provide other health care services to their children, and attempt to modify their opposition to vaccines."[478,479] In regards to this advice, the study found that 94% of the 2013 respondents said they attempted to educate anti-vaccine parents. Among them, one-third reported the conversation to be successful.[480] This is hugely motivating.

It is important for all parties to remember that changing someone's mind is very difficult. In fact, it has been repeatedly found that "once informed, impressions are remarkably perseverant."[481]Even when a belief has been refuted, like those following

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[476] Caplan-Bricker, N. (2016, September 7). Pediatricians are Increasingly Dismissing Anti-Vaxxer Patients. *Slate*. Retrieved from http://www.slate.com/blogs/xx_factor/2016/09/07/new_pediatrics_study_says_doctors_are_dismissing_anti_vaxxer_patients.html

[477] *Id.*

[478] *Id.*

[479] This AAP page provides pointers talking with vaccine hesitant parents, the vaccine information statements, and for caregivers to counsel those refusing vaccines. (2017). *Communicating with Families.* American Academy of Pediatrics. Retrieved from https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/communicating-parents.aspx

[480] *Id.*

[481] Kolbert, E. (2017, February 27). Why Facts Don't Change Our Minds. *The New Yorker.* Retrieved from http://www.newyorker.com/magazine/2017/02/27/why-facts-dont-change-our-minds?mbid=social_facebook

Andrew Wakefield, "people fail to make appropriate revisions in those beliefs."[482] The phenomenon known as "confirmation bias" is that people tend to seek out and embrace information that supports their preconceived beliefs. They also reject information that contradicts their beliefs. Confirmation bias is prevalent among those in the anti-vaccine community.[483] For example, those parents who say that bundled vaccines just seem like too much for their babies' systems, they find the scientific studies that show this to be true and reject the overwhelming evidence that refutes the theory.

Cognitive dissonance, preconceived impressions, and confirmation bias will all make the conversation this paper proposes difficult, frustrating, and potentially fruitless in many cases. However, the evidence that patients trust recommendations from physicians and that patient-centered care bolstered by a trusting relationship indicates that trying to open a more tolerant conversation around the vaccine topic may, over time, change the way our society perceives them, resulting in a renewed increase in vaccination rates. It is important that physicians cease to turn away patients, as this will only result in more and more children not being vaccinated. Once turned away, parents are not necessarily encouraged to vaccinate for fear of losing their doctor, but rather lose trust in their doctor. This not only increases the rate of unvaccinated children, it is a refusal of a physician to perform his or her ethical duty to one patient by citing all of his or her other patients as an excuse. While the misinformation around vaccines is indeed frustrating to debunk with each parent that walks into a physician's office, it is the duty of medical caregivers to educate parents about the reality. This duty to educate is inherent to providing care in the form of vaccines. If this burden is shared between Ob/Gyns, pediatricians, and primary

[482] *Id.*
[483] *Id.*

care physicians, perhaps it will be less overwhelming to each of the physicians and parents alike.

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