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Vaccines

Personal Connection to Vaccines

Have you ever had a vaccine? I have. Some haven't. I remember when I was a kid, maybe around six, sitting on the paper-covered exam table in my doctor's office. The room was sterile and cold, and a nurse was approaching me with the needle. Like most children, I was absolutely petrified. The fear of the unknown, of the pain, of a foreign metal penetrating my body...completely out of control and unaware of what it was supposed to protect me from...only aware of the fear. I cried. I tried to get away. They had to hold my arm down to keep me from pulling away. My mom couldn't watch and had to leave the room because she felt so guilty watching me sob in fear, with no way to comfort me. It stung when the needle pierced my skin. And then again and again. Five times. At least they didn't do a finger prick that day too. Those scared me the most.

When I was 13, I was pulled out of school early one afternoon to get my tetanus vaccine. They told me most people's arms were sore for a week. I took this one like a champ. I couldn't watch and I was still terrified, but I didn't cry and it was over quickly. I wasn't sore at all after. That was the last shot I remember receiving.

Now, as an adult, I've questioned whether vaccines are the best option. The idea of unknown chemicals and particles of diseases being injected into my body makes me a bit queasy, and I wonder if it truly is safe. I've purposely avoided the flu shot as an adult. I've heard stories of people getting really sick after it and then still getting the flu later in the year. Now, in the

midst of the COVID-19 pandemic, doctors are racing to discover a vaccine to prevent a potential global catastrophe. Since December 2019, over 178,000 people have died worldwide (Coronavirus Death Toll)¹. A vaccine would be designed to prevent further loss of life. However, I'm wrestling with the idea of whether I would want to receive it myself and if there could be any possible side effects I should be aware of.

Intro to Vaccines

Infectious diseases were the biggest killers of mankind until the start of the twentieth century (Calandrillo, 362). In fact, the U.S. Center of Disease Control and Prevention (CDC) has listed the use of vaccines as one of the Ten Greatest Public Health Achievements both in the U.S. and worldwide (What is Public Health). In 1920 alone, 469,924 cases of measles were reported in the United States, and 7,575 deaths occurred. In the same year, out of 147,991 diphtheria cases reported, 13,170 people died (Achievements). Between 1964 and 1965, an epidemic of rubella infected 12.5 million Americans, which led to 2,000 infant mortalities and 11,000 miscarriages (What Would Happen). However in 1998, after the introduction of each related vaccine, there were only 89 cases of measles and no measles-associated deaths in the U.S. (Achievements). Between 2004 and 2014, only two cases of diphtheria were reported to the CDC (What Would Happen). Since 2012, just 15 cases of rubella have been documented in the U.S. (What Would Happen), and The World Health Organization (WHO) now estimates that vaccines prevent between 2 million and 3 million deaths a year (Hodson).

Vaccination, also known as immunization or inoculation, is when a non-exposed individual is injected with an agent similar to a virus, such as a weakened form or a fragment of

¹ This statistic was up-to-date as of April 22, 2020 at 4:12 GMT.

the disease, so that an immune response is stimulated and the body learns to produce antibodies required for defense against the pathogen (Mikulic; Savage). Some vaccines are administered "along with adjuvants — substances such as aluminum salts, lipids and RNA that strengthen the immune response" (Savage). Thus, immunity is created "by artificial means-thereby protecting the individual against the underlying disease without forcing her to endure the daunting task of surviving it first" (Calandrillo 363).

The first vaccine was introduced in 1796 by Edward Jenner, an English doctor, to combat smallpox. Before the vaccine, an estimated 400,000 Europeans died of smallpox each year (Greenspan). Three out of every 10 people who contracted the disease died ("Clinical Disease"). After a decade, Jenner's smallpox vaccine was widely accepted and replaced earlier, less successful methods of inoculation, eventually leading to the eradication of smallpox in 1980 (History of Smallpox; Greenspan).

Herd Immunity

What is Herd Immunity?

The term herd immunity refers to the "immunization of large portions of the population to protect the unvaccinated...reducing the number of susceptible hosts to a level less than the threshold needed for transmission" (Reiss). When the majority of a population is immune to a disease, indirect protection, or herd immunity, is provided to those who cannot be vaccinated, such as newborn babies, the elderly, and the immunocompromised (such as cancer patients) (D'Souza and Dowdy). Depending on how contagious a virus is, 70% to 95% of people need immunity to prevent community spread and to protect the vulnerable members of the population (D'Souza and Dowdy; Drew). For example, the vaccination of over 80% "of the global

population against [the] smallpox virus reduced transmission rates to uninfected subjects to a point low enough to achieve eradication of the virus" (Reiss).

Measles, on the other hand, is a highly contagious disease and requires a community to be 95% immune to prevent its spread. This means that 19 out of every 20 people to be vaccinated ("Herd Immunity"). Under these conditions, if a measles patient is surrounded by individuals who have been vaccinated, it is difficult for the disease to be passed to anyone else ("Herd Immunity"). However, when immunization rates fall, herd immunity is not guaranteed. This can lead to an increase of new cases and potential outbreaks ("What is Herd Immunity"). Recent measles outbreaks throughout the West have been attributed to a decline in herd immunity (Cunningham; "Measles Cases Hit Record High").

Arguments Against Herd Immunity

However, some believe due to "imperfect vaccine technology and geographical and agestratified vaccination mandates" that true "herd immunity... is not attainable" (Holland and Zachary 47). Additionally, there have been numerous instances of disease outbreaks in communities with a high percentage of vaccination. One study concluded that "outbreaks of measles can occur in secondary schools, even when more than 99% of the students have been vaccinated and more than 95% are immune" (Gustafson et al.). Another study regarding a 1989 measles outbreak in Quebec, Canada concluded that "vaccination coverage for the total population was 99%. Incomplete vaccination coverage is not a valid explanation for the Quebec City measles outbreak" (Boulianne et al.). A 2001 chickenpox outbreak in an Oregon elementary school occurred where "97% of [attending] students without a prior history of chickenpox were vaccinated" (Tugwell et al.). In 2014, an influenza outbreak occurred on a Naval vessel where.

"at the time of the outbreak, 99% of the crew had received an influenza vaccine" ("Influenza Outbreak"). In 2019, a whooping cough outbreak infected 30 students at a private high school. Only 1% of those attending the school were unvaccinated due to medical reasons ("LA Countywide Outbreak").

Can Vaccinated Individuals Still Contract Diseases

In 2019, the CDC stated that the recommended two doses of the mumps, measles, and rubella (MMR) vaccine is only 97% effective at preventing measles ("Vaccines for Measles"). Yet, the United Kingdom National Health Service stated in 2020 that the MMR vaccine protects 99% of people against measles and rubella and 88% against mumps ("MMR Vaccine"). Recently, "the startling occurrence of measles in vaccinated individuals has many people wondering if they're fully protected against the virus" (Ries). In 2011, one such vaccinated individual contracted the measles and was later proven to be the "ground zero" of an outbreak in New York which affected 88 people. This led Jennifer Rosen, the director of Epidemiology and Surveillance at the New York City Bureau of Immunization, to conclude that "the actual duration [of immunity] following infection or vaccination is unclear" (Akpan).

A study on the growing number of mumps outbreaks throughout the U.S. surveyed "twenty-three outbreaks with 20-485 cases per outbreak" from the year 2010 to 2015 (Clemmons et al). It was found that "multiple mumps outbreaks among highly vaccinated populations in close-contact settings occurred. Most cases occurred among vaccinated young adults" (Clemmons et al.). One such outbreak occurred in 2014, when 13 students at a New York college campus contracted the mumps ("Fordham University"). All 13 had been previously vaccinated with the MMR vaccine.

Vaccine Hesitancy

Vaccine hesitancy denotes an uncertainty regarding vaccination that often results in a delay in or the lack of immunization in an individual or their children. It is most commonly driven by concerns over vaccine safety. In 2018, a survey of over 140,000 people, from over 140 countries, was conducted regarding the "public attitudes to science and health on a global scale" ("Summary of Key Findings").

It found that:

In high-income regions, there is less certainty about the safety of vaccines, with 72% of people in Northern America and 73% in Northern Europe agreeing that vaccines are safe. In Western Europe, this figure is even lower, at 59%, and in Eastern Europe it stands at only 40%. In low-income regions, the proportion of people who agree 'strongly' or 'somewhat' that vaccines are safe tends to be much higher at 80% or above, with highs of 95% of people in South Asia and 92% in Eastern Africa. In France, one in three people disagree that vaccines are safe, the highest percentage for any country worldwide. ("Chapter 5")

Specifically in America, Daniel Salmon, the director of the Johns Hopkins Institute for Vaccine Safety, has estimated that "up to one-third of Americans have concerns about vaccines" (Drew). One survey of American parents who expressed concerns about vaccines found that "26% worried about the development of autism or other potential learning difficulties after receiving vaccines, 13.5% expressed concern that vaccines could lead to chronic illnesses, and 13.2% stated that vaccines were not tested enough for safety prior to their use" (Dudley et al, v). Others believe that vaccine hesitancy is a product of vaccine success. In a Supreme Court case opinion,

Justice Antonin Scalia wrote that vaccines have "been so effective in preventing infectious diseases that the public [has become] much less alarmed at the threat of those diseases, and much more concerned with the risk of injury from the vaccines themselves" (Bruesewitz v. Wyeth).

A increasing number of celebrities have taken public stances against vaccinations, including actress Jenny McCarthy, actress Jessica Biel, world No. 1 tennis star Novac Djokovic, and Robert F. Kennedy Jr., attorney, author, and nephew to former president John F. Kennedy. The conversation around the safety of vaccines seems to be growing rather than diminishing. In 2019, the WHO listed vaccine hesitancy as one of the top ten threats to global health ("Ten Threats").

Accordingly, many scientists and legislatures are searching for solutions to vaccine hesitancy. Two commonly employed solutions are education on the benefits and safety of vaccination and legislative restrictions for individuals who have not been vaccinated. A less common solution is to have an open conversation with those questioning vaccines. The scientific journal, *Nature*, stated that "people are anxious. Parents need a space where they can have a conversation that makes them feel more confident and helps them to make the right decision. Doctors, nurses and vaccinators are usually too busy to do that" (El-Showk).

Another solution may be to remind people of the world before vaccines where "33 of every 100,000 people" who recovered from the measles "ended up with mental retardation or central nervous system damage" (Conniff). An outbreak of rubella could result in "20,000 children being born with brain damage, including autism, and other congenital abnormalities," while smallpox survivors were often left "blind, maimed, or brain damaged" (Conniff). Sarah Atanasoff, a physician at the National Vaccine Injury Compensation Program in Rockville,

Maryland, stated that "one injury from vaccines is one too many, but it is also important to keep perspective...The U.S. case fatality rate from tetanus...is 13.2%... [the vaccine] causes a life-threatening allergic reaction in at most 0.0006% of people who get the shot...The benefits of vaccination to the individual, the local community, and the nation as a whole far outweigh the risks" (Wadman).

Benefits of Vaccines

Vaccines have dramatically reduced morbidity and mortality rates of some of the worst diseases in history by preventing them on the front end. The benefits have been remarkable: millions of deaths have been prevented, millions more lives markedly improved, and billions of dollars of societal resources have been saved for use in countless other valuable endeavors. (Calandrillo 369)

Decrease in Diseases and Disease Related Death

There has been a dramatic decrease in diseased such as "smallpox, measles, mumps, rubella, diphtheria, tetanus, pertussis (whooping cough), polio, hepatitis A and B, some forms of influenza, pneumococcal disease, Haemophilus influenzae type b, and varicella (chicken pox)" since the introduction of vaccines (Calandrillo 369). A 92% decline in cases and a 99% decline in deaths related to vaccine preventable diseases has been shown for "diphtheria, mumps, pertussis, and tetanus" (Roush et al.). Since 1980, the decline of both disease and death for hepatitis A, acute hepatitis B, Hib, and varicella was at least 80% (Roush et al.). This amounts to a dramatic sparing of lives.

Between the years 1953 and 1963, before the MMR vaccine, an estimated "four million cases of the measles occurred annually in the U.S., with an average of 450 deaths per year"

(Calandrillo 372). By 1983, only 1,500 cases were reported in the U.S., while in 2004 only 37 cases were documented (373). Those numbers represent a "reduction of more than 99.99% from pre- to post-vaccine years" (373). However, it is important to note that in 2019, there were 1,282 documented cases of measles in the U.S, indicating a significant increase from the 375 reported cases in 2018 and an even greater increase from the 37 cases in 2004 ("Measles Cases and Outbreaks").

Before the DTaP vaccine, diphtheria was a major killer of people throughout the world. Specifically in the U.S., 14,000 people died annually throughout the 1920s. In Massachusetts in the 1800s, 79 per every 100,000 people died of diphtheria every year (Calandrillo 370). After the introduction of the vaccine, 41 cases were documented from 1980 to 1995 in America, two deaths were reported in 2000, and only two cases were reported between 2004 and 20017 (Calandrillo 370; "Diphtheria").

Decrease in Medical Costs

Another benefit to vaccination is the decrease in overall medical costs. Vaccines are significantly cheaper than treating a patient with a vaccine-preventable illnesses. For every \$1 spent on the MMR vaccine, it is believed that between \$7 and \$14 is saved, while for every \$1 spent on the DTaP vaccine, \$27 is saved (Calandrillo 380). Additionally, it has been estimated for each flu vaccine administered, \$117 in healthcare costs is averted (376). Thus, it is likely that billions of dollars have been saved simply by the introduction of the measles vaccine in 1964 (Calandrillo 373).

Benefit to Large Pharmaceutical Companies

Worldwide, vaccines are expected to generate \$59.2 billion by the end of 2020. That is nearly double the \$32.2 billion produced in 2014 (Doughman). The U.S. is the largest national market for vaccines (Elfein). Its total market size will reach \$18 billion by the end of 2020. One U.S. based pharmaceutical company, Merck & Co., one of the largest in the world, generated over \$6.5 billion in vaccine revenues just in 2017 (Elfein).

Are Vaccine Studies Reliable?²

In a 2009 study on scientific misconduct, "2% of scientists [admitted] to have falsified research at least once and up to 34% [admitted] other questionable research practices," such as cooking data, mining data, concealing conflicts of interest, and selectively publishing studies that supported their predetermined expectations (Fanelli). When asked about the behavior of colleagues, scientists "admission rates were 14% for falsification, and up to 72% for other questionable research practices." The study concluded that "the actual frequencies of misconduct could be higher than" what scientists had self-reported (Fanelli). Additionally, a study published in 2014 found that the "rate at which scientists [admitted to] having committed...fabrication, falsification and plagiarism in surveys has declined over time" (Pupovac and Fanelli). It seems logical to conclude that scientists would not be entirely truthful regarding the frequency of their own misconduct as it could result in their disgraceful fall from the scientific community.

² Studies concluding that vaccines may or may not cause harm are often explained away by opponents due to questions regarding funding, personal biases of scientists, manipulation of data, etc. These concerns runs on both sides of the vaccine debate. To the best of my abilities, I checked the sponsors of the studies in this paper to ensure their reliability and have excluded studies that have clear affiliations that may have influenced the study's outcome and clearly note when ties to a potentially biased organization exist.

In August of 2016, a group of 12 anonymous scientists employed at the CDC, calling themselves CDC Scientists Preserving Integrity, Diligence and Ethics in Research (or SPIDER), filed a complaint letter to the CDC Chief of Staff, Carmen Villar. The letter has been described as an "ethics complaint alleging the federal agency is being influenced by corporate and political interests" (Gillam). The letter states:

It appears that our mission is being influenced and shaped by outside parties and rogue interests...Congressional intent for our agency is being circumvented by some of our leaders...it is becoming the norm and not the rare exception...It occurs at all levels and in all of our respective units. These questionable and unethical practices threaten to undermine our credibility and reputation as a trusted leader in public health. (U.S. Right to Know)

The complaint included allegations that "definitions were changed and data 'cooked' to make the results look better than they were" (U.S. Right to Know). It revealed that the findings of an internal review were "suppressed so media and/or Congressional staff would not become aware of the problems." It also detailed two scientists "irregular (if not questionable) relationships with CocaCola and ILSI representatives" (U.S. Right to Know). They concluded the letter by stating, "the lack of respect for science and scientists that support CDC's legacy is astonishing" (U.S. Right to Know).

In another recent scandal, William Thompson, a CDC scientist, alleged the CDC in a cover-up involving an MMR vaccine study.³ The allegations involve "a cover-up of data pointing to high rates of autism in African-American boys after they were vaccinated with

³ Study can be viewed here: https://pediatrics.aappublications.org/content/113/2/259

MMR" (Solomon). Thompson stated in a statement to CNN by his lawyer, that he regretted "that my co-authors and I omitted statistically significant information in our 2004 article" (Edwards). However, Dr. Frank DeStefano, the CDC's Director of Immunization Safety and lead author of the study, said that he and his colleagues stand by their findings and that all authors, including Thompson, had agreed upon the analysis and interpretation of the study's data before it was published (Edwards). DeStefano does plan to review his notes from the study and may run another analysis on the data if necessary (Edwards).

Brian Hooker, a biochemical engineer, took the raw data from the aforementioned study and analyzed it himself. He found that "African-American boys who were given the measles, mumps and rubella vaccine, known as MMR, before age 24 months were more likely to be diagnosed with autism" (Edwards). However, his study was redacted from the scientific journal it was published in due to "undeclared competing interests on the part of the author...[and] concerns about the validity of the methods and statistical analysis" (Hooker).

Another major study, which has proven allegations of scientific misconduct and fraud, was the Wakefield study, published in 1998. It was the first study to link the MMR vaccine with autism and received worldwide attention. However, 10 years later, after evidence of falsification and manipulation of the data was proven, the study was redacted, and its primary author, Andrew Wakefield, had his medical license revoked (Grignolio 64-65).

Do Vaccines Cause Autism?

The Increase in Autism Over the Past 20 Years

There has been a noticeable increase in documented cases of autism over the past 20 years. Some have commented that the speed of this growth is at an alarming rate ("Autism").

Autism spectrum disorder, or ASD, is a "developmental disability that can cause significant social, communication and behavioral challenges" ("What is Autism Spectrum Disorder").

People with ASD typically "communicate, interact, behave, and learn in ways that are different from most other people," though there is often nothing distinctive about their appearance from individuals without the disorder ("What is Autism Spectrum Disorder"). A diagnosis of ASD includes four separate disorders: autistic disorder, childhood disintegrative disorder, pervasive developmental disorder-not otherwise specified (PDD-NOS), and Asperger syndrome ("What is Autism"). The cause of ASD is still unknown.

In the 1970s and 1980s, one in 2,000 children were diagnosed with ASD ("Autism"). In 2000, the rate was one in 150 children, while in 2008, it was one in 88 (Wright). In the CDC's most recent study completed in 2016, one out of every 54 children were identified with ASD ("Community Report" 6). That is 1.85% of eight-year-olds in the U.S. Additionally, the rate of autism was significantly higher in boys. "For every one girl identified with ASD, four boys were identified" ("Community Report" 10). In the state of New Jersey, the rate of autism in four-year-olds was one in 35 as of 2014, a 43% increase since 2010 (Rutgers University). Since the CDC began monitoring autism rates in 2000, its methods used to "estimate prevalence have stayed the same" according to a statement from Coleen Boyle, the director of the CDC's National Center on Birth Defects and Developmental Disabilities (Willingham).

Many scientists denote this rise in autism numbers to increased screening, a broader definition for what constitutes autism — which now includes four disorders, instead of one, — and biological factors such as having an older parent, especially an older father (Wright). Dr. Max Wiznitzer, a pediatric neurologist at the University Hospitals Rainbow Babies and

Children's Hospital, said that, "We're getting better at identifying under-unidentified populations, so it's not as if the numbers are rising. It's more that everyone is going to the number that it should be" (Mammoser).

A different and highly controversial reason for the increase in autism cases is the correlating increase in the number of vaccine doses recommended before a child's second birthday. In 1980, children were vaccinated against seven diseases by the age of two, receiving five shots total. In 2014, children were vaccinated against fourteen diseases by two years of age, receiving between 18 and 26 shots ("Too Many"). One scientific study published in the *Journal of Toxicology and Environmental Health* found a relationship between the rise in autism cases and recommended doses of vaccines.⁴ The study concluded that "the higher the proportion of children receiving recommended vaccinations, the higher...the prevalence of [autism] or [speech or language impairment]. A 1% increase in vaccination was associated with an additional 680 children having [autism] or [speech or language impairment]...Further study into the relationship between vaccines and autism is warranted" (DeLong). On the other hand, an unknown author at Discover Magazine, who refers to himself/herself as "Neuroskeptic," looked at the study's data and concluded that it "shows no evidence of any association" (Neuroskeptic).

⁴ The study explicitly states that the author, Gayle DeLong, a distinguished professor at Baruch College/City University of New York, has "two children with pervasive development disorder" and "has filed a petition in the U.S. Court of Federal Claims under the National Vaccine Injury Compensation Program for one of her children." The author is also "on the board of directors and research committee of Sensible Action for Ending Mercury-Induced Neurological Disorders (SafeMinds)" (DeLong).

The Wakefield Study

In 1998, a U.K. study,⁵ published by Andrew Wakefield and 12 other scientists, suggested a link between the MMR vaccine and autism in children. Wakefield observed 12 children between the ages of three and 10, 11 of which were boys. After receiving the MMR vaccine, the parents of eight of the 12 children reported an "onset of behavioral symptoms," and all 12 children developed "intestinal abnormalities, ranging from lymphoid nodular hyperplasia to aphthoid ulceration" (Wakefield et al. 637). The study received great notoriety and caused "a significant change in opinion, not just in the UK but across the west" (Grignolio 65). MMR vaccination rates began to drop shortly after, due to parental concern of autism risks (Rao).

However, in 2004, Wakefield's study came under public scrutiny when a journalist from *The Sunday Times* reported the fraudulent nature of the work, and "10 out of the 12 co-authors" of the study publicly stated they were retracting their conclusions (Grignolio 64-65). In the coming years, it was revealed that the studies' 12 children had been deliberately chosen "to prove the harmfulness of the vaccine" and had been purposefully recruited from "anti-vaccination families," rather than by random selection (64). It was proven that Wakefield had "falsified the clinical records and manipulated the data: some of the children had shown characteristics of autism before being given the vaccine" (64). The study had also "failed to disclose financial interests (e.g., Wakefield had been funded by lawyers who had been engaged by parents in lawsuits against vaccine-producing companies)" (Rao). In February 2010, the study was retracted, and the scientists of Wakefield et al. were "held guilty of ethical violations...scientific

⁵ Study can be viewed here: https://www.sciencedirect.com/science/article/pii/80140673697110960

misrepresentation...deliberate fraud" (Rao). Wakefield was considered "dishonest, immoral, and insensitive" and was removed from the U.K.'s medical register in May 2010 (Grignolio 65).

Studies Disproving Vaccine Causation of Autism

In the aftermath of Wakefield's study, scientists have been fighting to show nervous parents that vaccines do not cause autism. Numerous studies have been done to prove the lack of causation between vaccines, specifically the supposed link between the MMR vaccine and an increase in autism. In a CDC sponsored report published in 2004, the Immunization Safety Review Committee found that "the body of epidemiological evidence favors rejection of a causal relationship between the MMR vaccine and autism" (Institute of Medicine). A study of 95,727 U.S. children over the years of 2001-2012 found that, "receipt of the MMR vaccine was not associated with [an] increased risk of ASD, regardless of whether older siblings had ASD. These findings indicate no harmful association between MMR vaccine receipt and ASD even among children already at higher risk for ASD" (Jain).

In the largest study of its kind, all individuals born in Denmark of Danish-born mothers from 1999 to 2010, 657,461 children in total, were studied to determine whether "the MMR vaccine increases the risk for autism in children, subgroups of children, or time periods after vaccination" (Hviid et al.). The study found no evidence to support a link between the MMR vaccine and autism. In fact, it "strongly supports" that the "MMR vaccination does not increase the risk for autism, does not trigger autism in susceptible children, and is not associated with clustering of autism cases after vaccination" (Hviid et al.).

Studies Showing Vaccine Causation of Autism

However, there have also been numerous studies since 1998 showing a connection between vaccines and autism. The primary route has been to study the connection between aluminum (the most commonly used vaccine adjuvant and known neurotoxin), ASD, and vaccines (Tomljenovic and Shaw). One study found that "individuals with a diagnosis of ASD [had] extraordinarily high levels of aluminum" in their brains (Mold et al.). The samples studied accounted for "some of the highest values for aluminum in human brain tissue yet recorded," including that of a 15 year old boy (Mold et al.). However, the study was limited to five samples, the only available at the time.

Another study correlated the "increase in exposure to aluminum" present in vaccines with "the increase in ASD prevalence in the United States observed over the last two decades" (Tomljenovic and Shaw). It stated that aluminum-adjuvanted "vaccines may be a significant etiological factor in the rising prevalence of ASD in the Western world" (Tomljenovic and Shaw). The study concluded by stating, "given that the scientific evidence appears to indicate that vaccine safety is not as firmly established as often believed, it would seem ill advised to exclude pediatric vaccinations as a possible cause of adverse long-term neurodevelopmental outcomes, including those associated with autism" (Tomljenovic and Shaw).

A previously mentioned study showed evidence supporting the conclusion that a "1% increase in vaccination was associated with an additional 680 children having [autism] or [speech or language impairment]" (DeLong). This study went on to state:

Aluminum, which is found in at least 20 U.S. childhood vaccines ("Vaccine Excipient Summary," as cited in DeLong), is not only a neurotoxin, but also an immunosuppressant that may allow measles-containing vaccines to create cytokines that damage the brain. Enhanced exposure to aluminum via vaccines may be associated with an increase in the prevalence of neurological disorders such as autism, especially if an aluminum-containing vaccine is administered along with a measles-containing vaccine. (DeLong)

The National Vaccine Injury Compensation Program (NVICP), which is detailed in the follow section, awarded the first vaccine-autism claim in 2008 through settlement (Attkisson).
CBS News reported that Hannah Poling's family received \$1.5 million for her life care, lost earnings, and pain and suffering in an initial payment. Every year after, the family would receive \$500,000 to pay for Hannah's care. "Those familiar with the case believe the compensation could easily amount to \$20 million over the child's lifetime" (Attkisson). In a since removed article, Time Magazine stated that, "there's no denying that the court's decision to award damages to the Poling family puts a chink — a question mark — in what had been an unqualified defense of vaccine safety with regard to autism. If Hannah Poling had an underlying condition that made her vulnerable to being harmed by vaccines, it stands to reason that other children might also have such vulnerabilities" (Attkisson).

CBS News reported that Julie Gerberding, the director of the CDC at the time and the current president of Merck & Co., stated, "The government has made absolutely no statement indicating that vaccines are a cause of autism. This does not represent anything other than a very specific situation and a very sad situation as far as the family of the affected child" (Attkisson).

In this specific case, because compensation was rewarded as the result of a negotiated settlement, the review of the evidence of the alleged vaccine-caused injury had not been not concluded.

Thus, "being awarded compensation for a petition does not necessarily mean that the vaccine caused the alleged injury" ("National Vaccine Injury Compensation" 1).

One study showed that the NVICP awarded 83 families compensation for vaccine related injuries with symptoms of ASD (Holland et al.). Most of these injuries originated from either the DTaP vaccine or the MMR vaccine, and the awards ranged from \$80,000 to \$5.9 million (Lowes). Some doctors argue that these symptoms stemmed from a bad reaction to measles rather than to ASD. Dr. Paul Offit, a professor of vaccinology and pediatrics at the University of Pennsylvania School of Medicine, said that, "A child with measles encephalopathy...may have severe cognitive deficits that fall into the autism spectrum, but such symptoms themselves do not necessarily translate into a diagnosis of autism" (Lowes). However, in an interview which was later removed "in the interest of public health," directors of the Elizabeth Birth Center for Autism Law and Advocacy discussed the results of a study on the 83 cases with ASD-like symptoms. The study found that "in almost half of the 83 cases, [there was] confirmation of autism beyond parental report, including medical and education records and completed standard autism screening questionnaires which have a high degree of accuracy" (Kirby; Lowes).

The National Childhood Vaccine Injury Act of 1986 (§300AA)

Between 1978 and 1981, nine product liability suits were filed against manufacturers of the DTaP vaccine. However, by the mid-1980's, over 200 suits were filed each year (Bruesewitz

⁶ Message may be viewed here: <u>https://www.huffpost.com/static/editors-note-vaccine</u>

⁷ Study can be viewed here: https://digitalcommons.pace.edu/cgi/viewcontent.cgi? article=1681&context=pelr

v. Wyeth). The DTaP vaccine market was destabilized and two out of the three domestic DTaP manufacturers decided to halt production. The remaining manufacturer "estimated that its potential tort liability exceeded its annual sales by a factor of 200," and in 1984, due to production problems, vaccine shortages arose throughout the country (Bruesewitz v. Wyeth).

Noticing the problem, the U.S. government decided to intervene and created The National Childhood Vaccine Injury Act of 1986 (NCVIA). It was designed as "a no-fault compensation program to stabilize a vaccine market adversely affected by an increase in vaccine-related tort litigation" (Bruesewitz v. Wyeth). The law removed all liability from vaccine manufacturing companies for the production of vaccines. The result of which meant that U.S. citizens were no longer able to directly sue vaccine companies for injury or death.

The existence of tort liability often encourages companies to produce an ever improving product, and thus diminish their chances of a lawsuit. By completely removing liability from the vaccine manufacturing industry, a big reason to produce a safer product, often at cost to the vaccine companies themselves, was gone. Thus, the National Childhood Vaccine Injury Act also included a provision that the Health Resources and Services Administration (HRSA) would be tasked with "the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on the effective date of this part [effective Dec. 22, 1987] and promote the refinement of such vaccines" (§ 300aa-27a). The HRSA was instructed to submit bi-annual reports "describing the actions taken pursuant to subsection (a) during the

preceding 2-year period" (§300AA-27c). However, a recent Freedom of Information Act showed that the HCC has not produced a single such report over the past 30 years.8

National Vaccine Injury Compensation Program (NVICP)

The National Vaccine Injury Compensation Program (NVICP) was formed to compensate individuals through the Federal Court System for vaccine-related injuries or deaths (§ 300aa-10). It also established that the money for compensation would be provided for by the taxation of every dose of vaccine ("About the National Vaccine"). A table of vaccine injury was created in succession with the NVICP and is still in use today. It includes a list of scientifically supported vaccine related injuries and establishes a timeline in which each type of injury must present itself after vaccination for individuals to be entitled compensation. Not all vaccines are included in the table. Neither are all claimed injuries. To succeed in court, an individual, of any age, must first have an injury or death induced by a vaccination that is included in the Vaccine Injury Table. They must then prove that their injuries were in fact sustained from vaccinations and that their symptoms began in the time period allotted by the table.

Since the creation of the NVICP, thousands of petitions have been filed by the Court, many of which resulted in compensation. The HRSA stated that the "total compensation paid over the life of the program is approximately \$4.3 billion" ("National Vaccine Injury Compensation" 1). According to the CDC's records, between 2006 and 2018, "7,104 petitions were adjudicated by the Court, and of those 4,943 were compensated" ("National Vaccine Injury

⁸ FOIA report can be viewed here: http://www.icandecide.org/wp-content/uploads/2019/09/Stipulated-Order-copy-1.pdf

⁹ The Vaccine Injury Table can be viewed here: https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-table.pdf

Compensation" 1). In perspective, 3.4 billion doses of vaccines were distributed over the same period. That means that "for every 1 million doses of vaccines that were distributed, approximately 1 individual was compensated" ("National Vaccine Injury Compensation" 1).

COVID-19

Currently, there is a race across the globe to produce a vaccine for the novel coronavirus to halt the spread of the world's first global pandemic. Millions of dollars are being spent in the aim of this goal (Brewster). The U.K. has stated they will throw "everything we've got" towards development of a vaccine and began human trials on April 23, 2020 (Keown). Matt Hancock, the U.K's Secretary of State for Health and Social Care stated that it would typically "take years" to reach this stage under a normal health climate (Keown). The National Institutes of Health began the world's first clinical trial of a vaccine candidate on March 16 ("NIH Clinical Trial"), skipping animal research and going straight to human trials (Gallagher). The study enrolled 45 Seattle-based volunteers who will receive two doses of the vaccine 28 days apart ("NIH Clinical Trial").

China has also approved two vaccine possibilities for human trials (Liu and Lee), and the U.S. army has begun the testing of three possible vaccines on small animals, such as mice, and hopes to begin human trials in September (Maven). Worldwide, there are over 60 vaccine candidates currently in development (Lanese). The hope is that a vaccine would be ready within 12 to 18 months (Bostock). However, many scientists find such a short timeline to be "ridiculously optimistic," including Paul Offit, the co-inventor of the rotavirus vaccine, a disease similar in nature to the novel coronavirus (Bostock).

Safety of a Coronavirus Vaccine

Many throughout the scientific community are calling into question the safety of a rushed coronavirus vaccine. A typical vaccine usually takes seven to 10 years to reach the public, but can sometimes take up to 20 (Oakes). As seen above, one study has completely forgone animal trials and skipped directly to human trials. This creates a potential issue regarding "immune enhancement," where a vaccine actually weakens a person's ability to fight a virus, which is typically caught through animal testing (Bostock). Scientists around the world are urging vaccine developers not to rush and to rigorously test vaccines for safety (Bostock; Jiang). Some are asking questions such as, "If a vaccine does prove to be effective, would it be effective for long?" citing earlier studies on similar virus strains where immunity was short-lived (Haseltine). The dean of the National School of Tropical Medicine at Baylor College of Medicine stated, "I understand the importance of accelerating timelines for vaccines in general, but from everything I know, this is not the vaccine to be doing it with... There is a risk of immune enhancement" (Steenhuysen).

Alternative Treatments

Another solution to COVID-19 is discovering an effective treatment or cure. There are currently studies being done on hospitalized individuals attempting to find ways to reduce the duration and intensity of the disease. This is seen as safer than rushed vaccine testing as it uses drugs which are already FDA approved. Additionally, the testing is being done on patients who are potentially dying without a cure, rather than on healthy members of the general population.

Two leading drugs in the search for a cure are chloroquine and hydroxychloroquine, two related drugs already in use to treat malaria, lupus, and rheumatoid arthritis. They are both cheap,

already available, and are relatively free of side effects ("Treatments"). A small study conducted in southern France "compared 26 patients who received hydroxychloroquine to 16 who did not: after six days, the virus was gone from the body in 70% of those given the treatment, compared to only 12.5% of those who weren't. The drug appeared to be as effective in the sickest patients as in the least sick" but was inconclusive due to the small size of the study ("Treatments"). The FDA issued an Emergency Use Authorization to allow the use of these two drugs for "treatment of hospitalized adults and adolescents (weight ≥50 kg) with COVID-19" ("Therapeutic Options"). Clinical tests throughout the U.S. are being done in regards to the effectiveness of these drugs. The results of one such study involving 386 patients were decidedly negative, stating that death was more likely for those taking hydroxychloroquine. However, the study has yet to be peer reviewed or published in a medical journal, nor has it been reviewed by other scientists (Cohen). All in all, it is too early to tell whether these two drugs are an effective treatment of COVID-19 or could potentially do further damage to a patient.

Coronavirus patients in the ICU of New York's largest hospital system have been given high doses of vitamin C intravenously (Mongelli and Golding). According to Dr. Andrew G. Weber, a pulmonologist and critical-care specialist residing over two New York hospitals, "The patients who received vitamin C did significantly better than those who did not get vitamin C...It helps a tremendous amount, but it is not highlighted because it's not a sexy drug." (Mongelli and Golding). Current scientific studies on the matter are ongoing.

China has also encouraged its citizens to take herbal remedies to combat the Coronavirus.

In fact, a study by China's National Health Commission reported that during the month of

March, 90% of Chinese citizens infected with the virus took some form of herbal medicine

(Givetash). The secretary of the State Administration of Traditional Chinese Medicine stated that these traditional remedies "alleviated symptoms, reduced the severity of the virus, improved recovery rates and reduced mortality rate" (Givetash). Other scientists have doubted such method's efficacy (Givetash).

Will COVID-19 Vaccination be Mandatory?

There has been talk of a COVID-19 vaccination being mandatory for re-entry into certain societal norms such as schools, sports, and jobs. Former world No. 1 tennis star Amelie Mauresmo recently tweeted that "No vaccine = no tennis" (@AmeMauresmo). American businessman and #1 New York Times bestselling author, Robert Kiyosaki, made a prediction on April 8, 2020: "FUTURE: Everyone must be vaccinated. If not, cannot drive, travel, go to school, attend sporting events, go out to dinner" (@theRealKiyosaki). Others state that any vaccination would likely be voluntary (Martin). Still others predict that life cannot get back to "normal" until herd immunity is achieved through the wide distribution of a vaccine, yet make no mention of whether that distribution will be compulsory or voluntary (D'Souza and Dowdy).

In the past, the United States Supreme Court has held the constitutionality of requiring mandatory vaccination during an outbreak (Jacobson v. Massachusetts). In 1905, during a smallpox outbreak in Massachusetts, the Court held that "individual rights cannot themselves intrude upon other people's rights. Thus, despite passionate resistance, the Court made clear that when the health concerns of the larger community are at stake, the state may indeed infringe upon individual rights" (Calandillo 384). Ultimately, it is impossible to know how state governments, schools, businesses, and sports leagues will respond to the production of a coronavirus vaccine. Any theories are simply speculative at this point.

Personal Perspective Post-Research

I came into this paper with an open mind to anti-vaccination ideas and am leaving over 20 hours of collective research relatively unchanged in my perspective. The amount of directly contradicting studies and proof of fraud on both sides surprised me and makes me wary to trust the message of vaccination supporters and opposers. Additionally, I ran into frequent censorship of articles, studies, interviews, etc. that opposed vaccinations. The idea of hindering access to this information bothers me and makes me question if there is a reason that data is being covered up. Also, reading through the Vaccine Injury Table and discovering the amount of scientifically provable, albeit rare, side effects vaccines may cause definitely gives me cause for concern. Thus, I would currently label myself as vaccine hesitant.

When pondering whether I would take a COVID-19 vaccine, I don't think I would at the moment. At least not when it is initially released. The speed at which the vaccine process is progressing makes me question the safety of any marketed vaccine in the future. I would therefore want to wait until many others had been vaccinated to ensure that there were not adverse side effects before considering vaccination myself.

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